Effects of conditional cash transfers and pre-test and post-test tuberculosis counselling on patient outcomes and loss to follow-up across the continuum of care in South Africa: a randomised controlled trial

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Summary

Background Economic and behavioural factors lead to poor outcomes in patients with tuberculosis. We investigated the effects of a package of interventions consisting of pre-test and post-test tuberculosis counselling with conditional cash transfers on patient outcomes in adults undergoing investigation for pulmonary tuberculosis.

Methods This pragmatic, open-label, individual randomised controlled trial was done in nine clinics in Johannesburg, South Africa. Participants (aged ≥18 years) undergoing investigation for tuberculosis were randomly assigned (1:1) to the intervention group or control group (standard of care) via permuted block randomisation, stratified by clinic; group assignment was concealed using opaque envelopes. The intervention group received pre-test and post-test tuberculosis counselling, and for participants diagnosed with rifampicin-susceptible tuberculosis, a digital payment (R150; approximately US$10) at treatment initiation and each monthly treatment visit. Payments were contingent on timely attendance: 14 days from initial sputum sample collection and within 7 days on either side of their scheduled monthly appointment. The primary endpoint was successful patient outcome (patients who were cured or completed treatment) or unsuccessful patient outcome (pretreatment loss-to-follow-up, on-treatment loss-to-follow-up, development of rifampicin-resistant tuberculosis while on treatment, treatment failure [ie, smear or culture positive at 5 months or later after commencing treatment], or death). The primary outcome was analysed in the modified intention-to-treat population, defined as all randomly assigned participants with rifampicin-susceptible tuberculosis confirmed before the commencement of tuberculosis treatment. Weighted outcome prevalence, relative risks (RRs), and risk differences were calculated using a multivariable Poisson model with robust standard errors. This trial is registered with the Pan African Clinical Trials Registry (PACTR202410708311054) and is completed.

Findings Between Oct 25, 2018, and Dec 9, 2019, 4110 participants were enrolled and randomly assigned, 2059 to the intervention group and 2051 to the control group. 381 (9·3%) participants had microbiologically confirmed rifampicin-susceptible pulmonary tuberculosis (195 [9·5%] of 2059 in the intervention group *vs* 186 [9·1%] of 2051 in the control group; median age 37 years [IQR 30 to 45], 257 [67·5%] male, 124 [32·5%] female). At study closure, primary outcome data were available for 128 (65·6%) of 195 participants in the intervention group and 139 (74·7%) of 186 participants in the control group. 105 (82·0%) of 128 participants in the intervention group and 93 (66·9%) of 139 participants in the control group had a successful patient outcome; 23 (18·0%) of 128 participants in the intervention group and 46 (33·1%) of 139 participants in the control group had an unsuccessful patient outcome. The weighted regression analysis showed a substantial reduction in the risk of unsuccessful patient outcomes in the intervention group compared with the control group (weighted prevalence 15·9% *vs* 28·6%; RR in weighted population 0·52, 95% CI 0·33 to 0·82; risk difference in weighted population –14·1 percentage points, 95% CI –23·3 to –4·8). Pretreatment loss to follow-up was lower in the intervention group than in the control group (unweighted population: five [3·9%] of 128 participants *vs* 22 [15·8%] of 139 participants; risk difference in weighted population –9·6 percentage points, 95% CI –14·9 to –4·2).

Interpretation The package of interventions consisting of pre-test and post-test tuberculosis counselling with conditional cash transfers significantly reduced the risk of unsuccessful tuberculosis patient outcomes, bringing one of the 90–90–90 targets within reach (ie, achieving 90% tuberculosis treatment success). Furthermore, reduction in pretreatment loss to follow-up is expected to reduce transmission and lower incidence of the disease over time.

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Research in context

Evidence before this study

We searched PubMed for original research presenting results on "tuberculosis", "conditional cash transfers", "counselling", and "outcomes", published in English up to Sept 30, 2024, with no restriction on the start date. Using these four terms, no studies were identified. We widened the search by excluding the term "counselling". Seven studies were identified that covered use of conditional cash transfers in tuberculosis care and the effect on outcomes. Four of these studies did not estimate the effect but highlighted the limitations of the current studies using such an intervention. One of these studies was a systematic review that assessed use of cash transfers and material goods. The investigators noted that the evidence was too weak and the interventions variable, precluding any robust conclusions. One mixed-method study assessing use of cash transfers in India was unable to make firm conclusions, noting the challenges with routinely collected data. Another mixed-method study from Peru assessed the effect of a mixture of interventions, including conditional cash transfers, on tuberculosis prevention and treatment adherence. Again, this study highlighted the notable issues related to challenges with how the cash transfers were done and the reliability of their delivery. The fourth study was a retrospective study that focused on interventions other than conditional cash transfers. The remaining three studies were directly relevant. One was an ecological multiple-group time-trend study using a large routine dataset from Brazil. It showed a significant reduction in tuberculosis incidence in municipalities with a high-coverage conditional cash transfer programme compared with those with low and intermediate coverage (in a model adjusted for time, incidence rate ratio 0·96, 95% CI 0·93 to 0·99). However, ecological studies have inherent limitations that prevent drawing firm conclusions. The second study was done in south India using routine data, and assessed the effect of the Nikshay cash transfer system in patients with HIV and tuberculosis attending antiretroviral treatment initiation centres. The study did not find a strong association between patients receiving the payment and unsuccessful treatment outcomes (adjusted relative risk –1·1, 95% CI –0·9 to 1·3). However, only 16% of patients received payment in the first month of treatment, and only 78·5% of patients received at least one payment, although all patients were intended to receive monthly payments, highlighting weaknesses in the fidelity of the intervention. The final study was a prospective cohort of disadvantaged individuals in Argentina. Higher success rates (82% *vs* 69%; odds ratio [OR] 2·9, 95% CI 2·0 to 4·3, p<0·001) and lower loss to follow-up rates (11% *vs* 20%; OR 0·36, 0·23 to 0·57, p<0·001) were reported in individuals registered to receive conditional cash transfers versus those not registered to receive cash transfers. The investigators of the study noted the observational nature of the study with no randomisation as an important limitation. In addition to these studies, a pragmatic cluster-randomised controlled study in South Africa provided monthly vouchers to people with tuberculosis upon collection of their medication. Fidelity to the intervention was low, with 36% of eligible participants not receiving a single monthly voucher, and a further 32% only receiving between one and three vouchers. As a result, the study showed little improvement in the proportion of participants with treatment success (76·2% in the intervention group *vs* 70·7% in the control group; risk difference 5·6%, 95% CI –1·2 to 12·3). However, there was evidence of a dose response in participants from the intervention clinics, with successful treatment outcomes increasing from 68% in those who received no vouchers to more than 90% in those who received five or more vouchers.

Added value of this study

To our knowledge, our study is the first to combine conditional cash transfers with counselling in tuberculosis care. Furthermore, although previous studies have shown positive effects of conditional cash transfers, these were largely observational. By contrast, the study from India showed no effect and had issues with the fidelity of the intervention. The current study was a randomised controlled trial, with high fidelity to the intervention, and showed that pre-test and post-test tuberculosis counselling with conditional cash transfers reduced the risk of unsuccessful patient outcomes. The largest reduction was for pretreatment loss to follow-up. Our study implemented two interventions that health programmes can directly manage. We used a digital banking payment system, overcoming the challenge seen with other mixed-package interventions and provision of other material incentives. Additionally, the study included a robust data quality improvement programme before and during the study, overcoming shortcomings of previous efforts and the use of routine data.

Implications of all the available evidence

Our findings show that pre-test and post-test tuberculosis counselling with conditional cash transfers is a powerful intervention that could significantly improve patient outcomes and reduce losses along the tuberculosis cascade on the basis of robust randomised control trial evidence. Cost-effectiveness analysis is planned to inform policy making.

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Introduction

South Africa has one of the highest burdens of tuberculosis worldwide, and an estimated one in five people were not recorded as having started treatment in 2023.[1] The percentage of people with microbiologically confirmed pulmonary tuberculosis in South Africa who do not initiate tuberculosis treatment (ie, pretreatment loss to follow-up) and who are thus less likely to be notified in the tuberculosis register ranges from 11% to 25%.[2–5] Notifications in the tuberculosis register only include individuals started on treatment. Furthermore, in 2023, treatment success was achieved in

only 76% of individuals who were initiated on antituberculosis treatment, well below the 90% target specified in the Global Plan to End TB 2023–2030.[6] A transmission model concluded that a 50% reduction in pretreatment loss to follow-up (from 16% to 8%) could reduce incidence of tuberculosis by approximately 30% in South Africa over an 18-year period (from 2014 to 2032).[7]

Patient education and counselling are some of the adherence interventions that result in improved tuberculosis treatment outcomes.[8] Despite the centrality of patient education and counselling and the documented complexities that come with tuberculosis treatment (eg, long duration of treatment, medication side-effects, and stigma), formal pre-test counselling before investigation for tuberculosis has not been implemented,[9] unlike for HIV. There has also been no formal post-test counselling on receipt of test results. However, the latest South African National Strategic Plan for HIV, TB and STIs 2023–2028 has included pre-test counselling for individuals being investigated for tuberculosis.[10]

See Online for appendix

Apart from patient knowledge, cost is another crucial factor.[11] A survey of patient costs in South Africa showed that 56% of tuberculosis-affected households faced catastrophic costs, with 25% of that cost due to direct non-medical expenditure.[12] The WHO End TB Strategy mandates the implementation of economic support and social protection to combat the financial burden of tuberculosis. In South Africa, the direct and indirect costs to individuals and households of accessing care remain a crucial barrier to tuberculosis treatment initiation and completion, with lower-income households incurring greater costs.[13] Furthermore, 41% of total tuberculosis management costs in South Africa are incurred before starting antituberculosis drugs, predominantly due to loss of income in this period.[13] The costs of repeated clinic visits for tuberculosis diagnosis and treatment amount to 60% of monthly income, resulting in many patients not accessing appropriate medical care and treatment.[14]

For the **End TB Strategy** see https://www.who.int/teams/global-tuberculosis-programme/the-end-tb-strategy

A Cochrane review identified only two trials that assessed the effect of material incentives on long-term adherence and completion of tuberculosis treatment, with neither trial showing an effect.[15–17] The first trial had problems with the intervention's acceptability, while the second had problems with its fidelity, which could have affected the results. However, in an exploratory analysis of the second trial, patients receiving more vouchers were more likely to complete treatment.

Reducing loss to follow-up before treatment initiation and through to the end of care is important in effectively addressing tuberculosis. There is a paucity of studies on the use of conditional cash transfers and the inclusion of pre-test or post-test tuberculosis counselling, as a combined strategy. We sought to determine the effectiveness of a package of interventions consisting of pre-test and post-test counselling and conditional cash transfers in improving patient outcomes, including reducing loss to follow-up, in patients with tuberculosis.

Methods

Study design and participants

This pragmatic, multicentre, open-label, individual randomised controlled trial was done between Oct 25, 2018, and March 27, 2020 in nine clinics in Johannesburg, South Africa (appendix p 2). Initially, we selected 14 study clinics with a high tuberculosis caseload on the basis of data from the National Health Laboratory Service Corporate Data Warehouse. A data quality improvement project was done at all 14 facilities, of which nine were selected on the basis of operational study factors and established routine data quality practices.

To be eligible for inclusion in the study, participants had to be at least 18 years of age at the time of tuberculosis screening, undergoing smear or Xpert MTB/RIF Ultra (Xpert; Cepheid, Sunnyvale, CA, USA) sputum investigation for presumptive pulmonary tuberculosis, able and willing to provide written informed consent, and willing to undergo study procedures and visits at the study site. Exclusion criteria included individuals already diagnosed with pulmonary tuberculosis or on anti-tuberculosis treatment including those clinically diagnosed, and anticipated relocation to another province or facility to receive tuberculosis treatment.

Ethical approval was obtained from the Human Research Ethics Committee of the University of the Witwatersrand, Johannesburg, South Africa (M180453). Permission to conduct the trial was obtained from the Gauteng Department of Health (GP_2017RP1_806). This trial is registered with the Pan African Clinical Trials Registry (PACTR202410708311054). See appendix (pp 16–18) for the CONSORT checklist and appendix (pp 19–59) for the study protocol.

Randomisation and masking

Participants were randomly assigned (1:1) to either the intervention group or the control group using permuted block randomisation with varying block sizes stratified by clinic. In brief, random permuted blocks with block sizes of 4, 6, 8, and 10 were generated for each clinic. Sequentially numbered opaque sealed envelopes with carbonised paper, allocation slip, and an additional sheet of cardboard to ensure opacity were prepared by the central study team, excluding site coordinators, and delivered to each site. After eligibility was confirmed, informed consent signed, and baseline assessments completed, the participant study ID was written on the outside of the next sequential sealed envelope, which was then opened by the site coordinator in the presence of the participant. Given the nature of the intervention, it was not possible to mask participants or study staff to the allocation.

Procedures

As part of the routine services, all individuals with symptoms or signs suggestive of tuberculosis attending a facility were requested to provide an expectorated sputum specimen, which was tested using Xpert for detection of tuberculosis and rifampicin resistance. Individuals with a rifampicin-susceptible tuberculosis result were initiated on treatment and followed up monthly for 6 months while those with a rifampicin-resistant tuberculosis result were referred to a drug-resistant tuberculosis treatment initiation site. As such, patients with rifampicin-resistant tuberculosis results were not included in the analysis.

Participants allocated to the control group received the standard of care. Participants in the intervention group received pre-test and post-test tuberculosis counselling provided by study staff. The Human Sciences Research Council (Cape Town, South Africa) developed and piloted the counselling material before finalisation. Study counsellors were trained on the materials through role-play with repetitions to ensure counsellors' competence. Standardised materials, including visual displays and step-by-step guides and prompts, were used to guide the process. Refresher training sessions were held throughout the study period. A pamphlet was provided to each participant, which provided basic information on tuberculosis and key take-home messages (appendix p 5). The crucial elements of pre-test counselling included information on tuberculosis infection and disease, transmission risk, and the diagnostic and treatment processes. Pre-test counselling took approximately 10–15 min per patient. Post-test counselling was provided upon receiving the tuberculosis test results and included understanding the test results, treatment, and what to expect while on treatment.

In addition to the counselling package, participants randomly assigned to the intervention group who subsequently tested positive for tuberculosis were eligible to receive R150 conditional cash transfers (approximately US$10; $1:R14) at their tuberculosis treatment initiation visit and at each of their routine monthly clinic visits (months 1, 2, 3, 4, 5, and 6). The cash transfers were conditional on participants attending their appointments within the prespecified window period. The study's maximum value of the conditional cash transfers per individual was R1050 (approximately $75). This total potential value of the conditional cash transfer was selected on the basis of two considerations. First, Foster and colleagues[13] estimated the total direct pretreatment and treatment costs in South Africa to be equivalent to R1075 in 2013. After adjustment for the annual consumer price index, inflation equated to R1404 total direct costs in 2018 when the first patient was enrolled. Second, the recommended reimbursement for trial participants stipulated by the Medicines Control Council at initial conceptualisation was R150 per study visit, based on reasonable costs and not being an undue incentive.[18] Fidelity to the payment system was monitored by ascertaining the percentage of participants meeting the criteria to receive a payment at a specific time window with the digital bank record of a payment issued to those individuals.

ERS Biometrics, a fingerprint biometric data system used as a time and attendance tracking tool for businesses, was used to track participant visits. Its associated data recording tool was used to capture demographic information, contact details, the randomisation group, tuberculosis laboratory results, and study outcomes.

For more on **ERS Biometrics** see https://www.ersbio.co.za

Participants completed a structured questionnaire at enrolment and study exit to collect demographic, socioeconomic, and health information (appendix pp 6–15).

An electronic banking payment system (FNB eWallet) was used to make the conditional cash transfer payments. The site coordinators loaded payment requests which were then authorised on the online platform (computer or mobile phone) by a minimum of two study managers (this process occurred in real time during the study visit). This authorisation was required before the participant received an SMS with a personal identification number to access the payment voucher number and withdraw the cash at a local automated teller machine (ATM). The eWallet system did not require participants to have a bank account or bank card, thus making allowance for participants without bank accounts or bank cards. Participants without a mobile phone were provided with an eWallet voucher number.

Participants in the intervention group who tested positive for tuberculosis were eligible for conditional cash transfers for the initial payment only if they returned to the clinic for results within 14 days of the sputum sample collection date. To receive subsequent payments during their treatment course, participants needed to attend their scheduled appointment within a window period of 7 days on either side of their scheduled appointment. If an individual did not meet the prespecified window period, no payment was made. However, the person was still eligible for subsequent payments if they attended the next visit on time. No effort was made by study staff to contact the person to return for care.

Apart from the interventions and processes described, routine clinic staff provided care, treatment, and support to all participants according to the South African national tuberculosis treatment guidelines.[19]

Outcomes

The primary endpoint was successful patient outcome or unsuccessful patient outcome. Successful patient outcome was defined as patients who were cured or completed treatment as per national tuberculosis control guidelines for South Africa[19] and ascertained by routine

clinic staff. Unsuccessful patient outcome was defined as one or more of the following: failure to initiate treatment within 14 days of the baseline sample being submitted (pretreatment loss to follow-up), loss to follow-up during tuberculosis treatment (defined as more than 56 days late for a scheduled appointment), development of rifampicin-resistant tuberculosis while on treatment, treatment failure (ie, smear or culture positive at 5 months or later after commencing treatment), and death from any cause. Note that loss to follow-up here refers to programmatic care rather than the trial per se. Prespecified secondary outcomes included the proportion of participants with microbiologically confirmed pulmonary tuberculosis who did not initiate treatment within 14 days of their first positive sputum sample collection date. The other prespecified secondary outcomes of time to tuberculosis treatment initiation, cure rates, and treatment completion rates will be reported elsewhere.

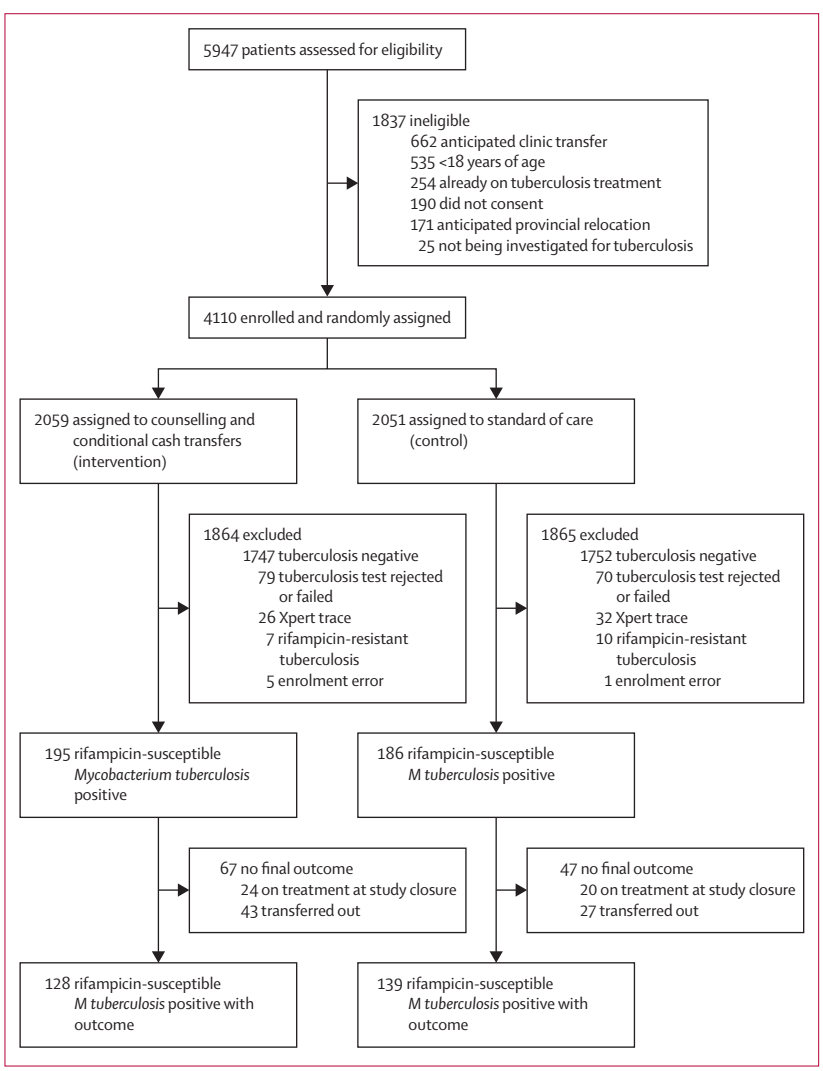

Figure: **Trial profile**

Statistical analysis

Baseline data collected in study clinics from Oct 1 to Dec 29, 2017, were used to estimate the proportion of people with presumptive tuberculosis with microbiologically confirmed pulmonary tuberculosis (9·8%), the proportion of participants with microbiologically confirmed pulmonary tuberculosis with unsuccessful patient outcomes (23·7%), and the proportion of patients with tuberculosis transferred to other facilities before completion of tuberculosis treatment (15·0%). Using these baseline data, a sample size of 9740 people with presumptive tuberculosis was determined to provide 80% power to detect a 35% relative reduction in unsuccessful patient outcomes and allowing for 15% of participants to exit the study without evaluable endpoints due to transfers. In total, the study sought to enrol 960 participants with microbiologically confirmed pulmonary tuberculosis. The study was halted because of the COVID-19 pandemic, and the ensuing hard lockdowns prevented achievement of the sample size envisioned at the outset.

The modified intention-to-treat population, in which the primary and secondary outcomes were analysed, included all randomly assigned participants with rifampicin-susceptible tuberculosis. Participants with rifampicin-susceptible tuberculosis were defined as participants with a tuberculosis-positive rifampicin-susceptible or rifampicin-unsuccessful Xpert result before the commencement of tuberculosis treatment. Participants who started tuberculosis treatment on the basis of chest x-rays or clinical grounds before receipt of tuberculosis laboratory results were excluded. Patients with only semiquantitative trace positive results—ie, those without a definitive confirmatory result before tuberculosis treatment as per South African guidelines at the time—were excluded from the analysis even if they commenced tuberculosis treatment. Participants with rifampicin-resistant tuberculosis were excluded because these individuals were transferred to drug-resistant treatment initiation sites and duration of treatment was different.

Stata version 14.2 was used for data cleaning and analysis. Frequencies, proportions, medians, and IQRs were used to summarise the data. Some participants started treatment but transferred clinics before the primary outcome could be determined or were still on treatment at the study termination due to COVID-19. We weighted participants with observed primary outcomes to represent these censored individuals. Specifically, considering time from treatment initiation, for each censored participant we weighted the other participants still on treatment at that time to represent the censored participant (as well as themselves). The process was repeated across all censoring times from first to last until those who started treatment and had an observed outcome were weighted to represent all those who started treatment. The weights are calculated this way within

trial group and clinic separately except for participants at the clinic that closed, who are represented by weighting participants in the same group at other clinics. The weighting procedure assumed that trial closure is uninformative for trial outcomes, and clinic transfer is uninformative conditional on clinic and trial group. Weighted independence estimating equations using Poisson regression with robust error variance were then done for the primary analysis adjusted for facility to estimate relative risks (RRs).[20] A sensitivity analysis excluding the weights was done to assess the effect of the weighting. Adjusted risk difference for unsuccessful patient outcomes was estimated from the final weighted facility-adjusted model using contrasts of the average marginal predictions.

A data safety monitoring board was formed to monitor and evaluate potential social harm that might occur due to randomisation to either the control or intervention groups. Site coordinators were trained to document and report any instances of withdrawal of consent, verbal or physical aggression in response to randomisation to the control group, or intimidation or theft of conditional cash transfers experienced by participants in the intervention group. No social harms were detected during the study.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Participants were recruited from Oct 25, 2018, to Dec 9, 2019, from nine clinics in Gauteng. 5947 individuals were assessed for inclusion in the study (figure). 4110 participants were enrolled and randomly assigned, 2059 to the intervention group and 2051 to the control group. Six participants were enrolled in error. Two commenced treatment before enrolment and four initiated treatment on the basis of diagnostic methods other than Xpert (chest x-ray, n=3; clinical diagnosis, n=1).

One of the study clinics was closed in January, 2019, because of infrastructure problems that required renovation. Although study participants attending the closed clinic were offered the choice to transfer to another study site, all the participants with microbiologically confirmed pulmonary tuberculosis (n=12, six in each group) elected to exit the study because the locations of the other study sites were not convenient; these participants were classified as transferred out.

Baseline characteristics of all enrolled participants (n=4110) in the intervention and control groups are shown in the appendix (p 1). 381 (9·3%) of 4110 participants were diagnosed with microbiologically confirmed rifampicin-susceptible pulmonary tuberculosis (195 [9·5%] of 2059 participants in the intervention group *vs* 186 [9·1%] of 2051 participants in the control group; table 1). The distribution of trace positive results, rifampicin resistance, and failed tests was similar between the groups.

	Intervention (n=2059)	Control (n=2051)
Negative	1747 (84·8%)	1752 (85·4%)
Rejected or failed	79 (3·8%)	70 (3·4%)
Mycobacterium tuberculosis trace* detected	26 (1·3%)	32 (1·6%)
Rifampicin-susceptible *M tuberculosis* detected	195 (9·5%)	186 (9·1%)
Rifampicin-resistant *M tuberculosis* detected	7 (0·3%)	10 (0·5%)
Enrolled in error	5 (0·2%)	1 (0·1%)

*Trace is the lowest semiquantitative reporting category for Xpert MTB/RIF Ultra.

Table 1: **Tuberculosis test results for enrolled participants (n=4110)**

Overall, 257 (67·5%) of the 381 participants with microbiologically confirmed pulmonary tuberculosis were male, with a slightly higher proportion of male participants in the control group than in the intervention group (125 [64·1%] of 195 in the intervention group *vs* 132 [71·0%] of 186 in the control group). The percentage of participants with microbiologically confirmed pulmonary tuberculosis who were receiving social grants was lower in the intervention group than in the control group (44 [22·6%] in the intervention group *vs* 64 [34·4%] in the control group), whereas other characteristics, including age, previous tuberculosis history, HIV and antiretroviral therapy (ART) status, household income, employment level, and education level, were similar between the groups (table 2).

Of the 381 participants with microbiologically confirmed pulmonary tuberculosis, 267 (70·1%) had a final tuberculosis treatment outcome at the time of study closure (table 3). At study closure, 44 (11·5%) of 381 participants were still on treatment, 24 in the intervention group and 20 in the control group (figure). A further 70 (18·4%) participants had been transferred to another clinic before study closure. Of these, 12 attended the clinic site that was closed. A higher proportion of participants in the intervention group transferred out compared with the control group (43 [22·1%] of 195 participants in the intervention group *vs* 27 [14·5%] of 186 participants in the control group).

Of the 267 participants with final outcomes reported, 105 (82·0%) of 128 in the intervention group and 93 (66·9%) of 139 in the control group had a successful patient outcome; 23 (18·0%) of 128 in the intervention group and 46 (33·1%) of 139 in the control group had an unsuccessful patient outcome. The lower proportion of participants with unsuccessful patient outcome in the intervention group was mainly a result of a reduction in pretreatment loss to follow-up (five [3·9%] of 128 participants in the intervention group *vs* 22 [15·8%] of 139 participants in the control group) and on-treatment

	Intervention (n=195)	Control (n=186)
Sex		
Male	125 (64·1%)	132 (71·0%)
Female	70 (35·9%)	54 (29·0%)
Age, years	37 (30–45)	37 (31–45)
Born in South Africa		
No	33 (16·9%)	24 (12·9%)
Yes	162 (83·1%)	162 (87·1%)
Previous tuberculosis		
No	164 (84·1%)	161 (86·6%)
Yes	31 (15·9%)	25 (13·4%)
HIV status		
Negative	62 (31·8%)	63 (33·9%)
Positive	117 (60·0%)	110 (59·1%)
Unknown	16 (8·2%)	13 (7·0%)
ART in HIV-positive individuals (n=227)		
Not on ART	62 (53·0%)	56 (50·9%)
On ART	55 (47·0%)	54 (49·1%)
Receiving any social grant		
No	149 (76·4%)	122 (65·6%)
Yes	44 (22·6%)	64 (34·4%)
Unknown or missing	2 (1·0%)	0
Food security		
Insecure	72 (36·9%)	76 (40·9%)
Secure	115 (59·0%)	98 (52·7%)
Unknown	8 (4·1%)	12 (6·5%)
Monthly household income*		
≤R400 (≤US$29)	76 (39·0%)	66 (35·5%)
R401–800 ($30–57)	22 (11·3%)	31 (16·7%)
R801–1600 ($58–114)	30 (15·4%)	27 (14·5%)
R1601–3200 ($115–229)	27 (13·8%)	26 (14·0%)
≥R3201 (≥$230)	40 (20·5%)	36 (19·4%)
Employment		
Unemployed	89 (45·6%)	74 (39·8%)
Informal or part-time	34 (17·4%)	42 (22·6%)
Full-time	64 (32·8%)	60 (32·3%)
Student or pensioner	7 (3·6%)	10 (5·4%)
Unknown	1 (0·5%)	0
Highest education level		
None	21 (10·8%)	11 (5·9%)
Completed primary	6 (3·1%)	9 (4·8%)
Incomplete secondary	90 (46·2%)	102 (54·8%)
Completed secondary	68 (34·9%)	55 (29·6%)
Incomplete tertiary	10 (5·1%)	8 (4·3%)
Other	0	1 (0·5%)

Data are n (%) or median (IQR). ART=antiretroviral therapy. *US$ are approximate conversions.

Table 2: **Baseline characteristics of participants with microbiologically confirmed rifampicin-susceptible pulmonary tuberculosis**

	Intervention (n=128)	Control (n=139)
Successful patient outcomes	105 (82·0%)	93 (66·9%)
Cured	49 (38·3%)	36 (25·9%)
Completed treatment	56 (43·8%)	57 (41·0%)
Unsuccessful patient outcomes	23 (18·0%)	46 (33·1%)
Pretreatment loss to follow-up	5 (3·9%)	22 (15·8%)
Loss to follow-up on treatment	10 (7·8%)	16 (11·5%)
Developed rifampicin-restistant or multidrug-resistant tuberculosis	2 (1·6%)	1 (0·7%)
Treatment failure	1 (0·8%)	1 (0·7%)
Died	5 (3·9%)	6 (4·3%)

Data are n (%).

Table 3: **Observed, unweighted tuberculosis treatment outcomes in participants with rifampicin-susceptible tuberculosis and outcome data**

loss to follow-up (ten [7·8%] of 128 *vs* 16 [11·5%] of 139); proportions of participants who died, had treatment failure, or who developed rifampicin-resistant or multidrug-resistant tuberculosis were similar between groups (table 3).

The weighted outcome prevalence, RR, and 95% CIs for unsuccessful patient outcomes obtained from the Poisson model with robust standard errors included clinic as a variable to account for the stratified randomisation. The weighted regression analysis showed a substantial reduction in the risk of unsuccessful patient outcomes in the intervention group compared with the control group (RR 0·52, 95% CI 0·33 to 0·82; table 4, appendix p 3), or, in absolute terms, from a model-estimated 29·5% to 15·4% (risk difference in weighted population –14·1 percentage points, 95% CI –23·3 to –4·8). The weighted observed percentages for pretreatment loss to follow-up were 2·6% in the intervention group and 11·8% in the control group (risk difference in weighted population –9·6 percentage points, 95% CI –14·9 to –4·2). Full-time employment and food security were also associated with reduced risk of unsuccessful patient outcomes (RR 0·48 [95% CI 0·26 to 0·87] and RR 0·55 [0·36 to 0·87], respectively). Previous history of tuberculosis was associated with increased risk of unsuccessful outcome (RR 2·18 [95% CI 1·39 to 3·39]). Factors that did not increase the risk were age, sex, being born outside South Africa, HIV status, use of ART among HIV-positive individuals, income, and education level. The unweighted RRs for unsuccessful patient outcomes were very similar to the weighted RRs, with little discernible difference between the two approaches (appendix p 4).

Fidelity to the conditional cash transfer intervention was good. 919 routine clinic visits by participants in the intervention group met the window period criteria for receipt of a conditional cash transfer (appendix p 2). Of these, 862 (93·8%) conditional cash transfer payments were made to participants. In the small proportion of situations where payments could not be made digitally, these were because of network issues or a change in the participant's registered mobile phone number.

Discussion

Combining tuberculosis pre-test and post-test counselling with conditional cash transfers significantly reduced the risk of unsuccessful patient outcomes and improved the overall treatment success rate from 66·9% to 82·0%, bringing one of the 90–90–90 targets within reach. The achievement was primarily due to decreased pretreatment loss to follow-up (3·9% in the intervention group *vs* 15·8% in the control group). Reduction of pretreatment loss to follow-up is expected to reduce community transmission of tuberculosis, leading to lower incidence over time,[7] a key goal of the End TB strategy.

Our findings are based on randomised controlled trial evidence with good fidelity to the interventions, with 93·8% of eligible conditional cash transfers made. Furthermore, the results are internally consistent. Participants in full-time employment and with food security had lower risks of unsuccessful patient outcomes, providing additional evidence of the importance of socioeconomic interventions in improving tuberculosis treatment outcomes. Our findings are also consistent with other evidence on the value of counselling and incentives to improve adherence and treatment outcomes.[8] The counselling with conditional cash transfers intervention is a useful alternative to medication monitors which seek to achieve similar outcomes but do not directly address underlying factors related to patient education and costs.

Our findings differ from the previous two clinical trials, which did not show an effect of incentives on tuberculosis outcomes. In the first study, done in Timor-Leste, the incentive provided was a daily hot meal during the intensive tuberculosis treatment phase and food parcels during the continuation phase.[15] The incentive was generally unacceptable to the participants because attending the clinic daily to receive the hot meal was inconvenient. By contrast, our study provided incentives timed with routine clinic visits and a cash payment providing agency to individuals making life choices. Additionally, our study combined cash transfers with counselling. The high fidelity to the intervention and the effect on reducing loss to follow-up suggest that the intervention was acceptable. We did not evaluate the acceptability threshold or consider a dose–response relationship on the incentive amount.

The second study, a cluster-randomised controlled trial in South Africa, used conditional cash transfers with vouchers that could be used for purchases at specific stores in the area. There was very low fidelity to the intervention as a result of nursing staff rationing the vouchers and logistical problems.[16] This resulted in a third of participants in the intervention group not receiving a single voucher. The current study provided greater flexibility, because cash was provided in an eWallet that participants could withdraw at an ATM. Another cluster-randomised study from Uganda assessed a cash transfer intervention,[21] but the cash transfer was unconditional; the intervention positively affected completion of diagnostic testing. The number of patients who initiated tuberculosis treatment was higher in the

	Successful patient outcome	Unsuccessful patient outcome	Unsuccessful patient outcome RR* (95% CI)
Study group			
Control	71·4%	28·6%	1 (ref)
Intervention	84·2%	15·9%	0·52 (0·33–0·82)
Sex			
Female	77·4%	22·6%	1 (ref)
Male	79·2%	20·8%	1·17 (0·74–1·85)
Age, years†	36 (30–45)	36 (29–43)	1·0 (0·98–1·02)
Age, years			
<30	74·1%	25·9%	1 (ref)
30 to <50	80·1%	19·9%	0·80 (0·50–1·30)
≥50	74·9%	25·1%	0·90 (0·44–1·83)
Born outside South Africa			
No	77·0%	23·0%	1 (ref)
Yes	83·7%	16·3%	0·76 (0·37–1·55)
Previous tuberculosis			
No	80·4%	19·6%	1 (ref)
Yes	64·5%	35·6%	2·18 (1·39–3·39)
HIV status			
Negative	76·7%	23·3%	1 (ref)
Positive	83·8%	16·2%	1·45 (0·85–2·45)
ART in HIV-positive individuals			
Not on ART	75·0%	25·0%	1 (ref)
On ART	78·4%	21·6%	0·88 (0·51–1·54)
Receiving any social grant			
No	75·6%	24·4%	1 (ref)
Yes	82·5%	17·5%	0·64 (0·38–1·09)
Food security			
Insecure	73·8%	26·2%	1 (ref)
Secure	79·1%	20·9%	0·55 (0·36–0·87)
Employment			
Unemployed	74·8%	25·2%	1 (ref)
Informal or part-time	72·7%	27·3%	0·98 (0·60–1·61)
Full-time	86·8%	13·2%	0·48 (0·26–0·87)
Student or pensioner	64·4%	35·6%	0·88 (0·39–1·96)
Highest education level			
Incomplete secondary	75·7%	24·3%	1 (ref)
Complete secondary or higher	81·2%	18·8%	0·70 (0·44–1·12)
Monthly household income‡			
≤R400 (≤US$29)	74·7%	25·4%	1 (ref)
R401–800 ($30–57)	64·6%	35·4%	1·23 (0·70–2·13)
R801–1600 ($58–114)	83·4%	16·6%	0·54 (0·26–1·11)
R1601–3200 ($115–229)	86·2%	13·8%	0·52 (0·23–1·17)
≥R3201 (≥$230)	78·0%	22·1%	0·60 (0·32–1·16)

Data are percentage or median (IQR), unless otherwise stated. Absolute numbers are not shown because participants are weighted. ART=antiretroviral therapy. RR=relative risk. *Adjusted for study site. †RR for an increase of 1 year. ‡US$ are approximate conversions.

Table 4: **Successful and unsuccessful patient outcomes in weighted study population**

intervention period versus the pre-intervention period, but the difference was not significant.

Apart from the clinical trials, several observational studies have assessed the effect of material incentives on tuberculosis patient outcomes, including for drug-resistant tuberculosis.[22] Of these, the most well known are the large national programmes in Brazil and India, showing improvements in treatment success, cure, and incidence.[23–27] However, their findings carry the limitations of observational studies, whereas in the current study, the findings are from a randomised controlled trial, which overcomes many of these issues. A crucial review of the programme in India highlighted the lack of conditionality when providing incentives and banking access issues.[28]

To our knowledge, this was the first study to combine formal pre-test and post-test tuberculosis counselling and conditional cash transfers. Pre-test and post-test counselling is not new and has been widely used for HIV, confirming feasibility in low-income and middle-income countries; however, it is missing in tuberculosis care. The conditions for cash transfers were tied to health visits, and the amount allocated was sought to offset patient-sided costs in accessing care. The outcomes were improved because pretreatment and on-treatment loss to follow-up were reduced. The study used biometric systems to ensure that the correct person was attending and that payments could be reliably released, which worked well. The payment used an electronic payment system, which obviated the risk of dealing with cash, did not require participants to have a bank account, and assisted with having a digital log of payments. These technologies are increasingly used and available in many settings, making such approaches feasible and robust.

A cost-effectiveness analysis evaluating the medium to long-term impact of implementing such an intervention will be published separately.

As highlighted, counselling is certainly implementable at scale, as demonstrated in the HIV programme; the digital payment systems are available country-wide in South Africa, while large health programmes in India and Brazil already use such approaches. The challenge is scaling conditionality applied to an individual. It will require a major shift in public service delivery models. Such models are widely used in the private sector, with most banks and medical schemes in South Africa having reward programmes to change behaviour and impact outcomes. Implementing the package of counselling with conditional cash transfers would require collaboration between the public and private sectors, the value of which was exemplified during the COVID-19 pandemic.

One additional challenge is the ability to identify individuals uniquely. In this study, we used a biometric system obviating the need to carry an identity document, and the autogenerated time–date stamp was used to validate the conditionality. It is a preferred option but comes with complex operational, data, and privacy issues unless mandated as national policy. South Africa has legislated the implementation of a national health insurance system, and the implementation guide includes the use of biometrics as the format for registration on the system,[29] opening the door for counselling with conditional cash transfers to be implementable in the context of such a system. Beyond South Africa, countries contributing to the largest global burden of tuberculosis, such as Brazil, China, Indonesia, and the Philippines, share similar banking and information technology capabilities, and have universal health coverage systems implemented or in progress. Implementing the counselling and conditional cash transfer intervention in low-income countries would not be as easy. A staggered implementation beginning with counselling, followed by regional conditional cash transfers could be a reasonable approach.

We included a data quality improvement programme that reduced the baseline proportion of missing people with tuberculosis who were not captured but on treatment (data not shown) before the start of the trial, ensuring that the standard of care reporting was robust. Such quality monitoring practices are expected to be in place on the basis of WHO guidance for tuberculosis surveillance and reporting, although they are not always consistently applied.

Our study had several limitations, and results should be interpreted in this context. First, the study used a combination of interventions—counselling and cash transfers—preventing the effects of the individual components to be assessed. Nonetheless, we firmly believe that while financial drivers are essential, patient education is crucial and inseparable. Second, we did not include participants with Xpert trace positive results in the analysis because there was uncertainty about interpretation of these results and management of such patients in routine practice with inconsistent application, meaning that some patients would be further investigated before starting treatment, while others would be treated on the basis of the trace result alone. Similarly, individuals who were diagnosed with rifampicin-resistant tuberculosis were excluded because they would be managed at a more centralised non-study facility and treatment would be different; therefore, the effect on this population is unknown. Third, the study was stopped before the sample size was reached because of logistical factors. A futility analysis was done in 2019 to inform future planning without foreseeing the impending pandemic. The analysis showed a positive signal for the study to continue. However, with the start of the COVID-19 pandemic and lockdown, we had no choice but to suspend the study. Although the sample size was not reached, the effect size was greater than anticipated, mitigating the shortened period. The halting of the trial did not affect the quality of the data obtained except that the primary outcome could not yet be determined for some individuals at the trial close—ie, they were

censored—which we addressed through weighting. Financial incentives are known to positively impact behaviour, although, for chronic health issues such as smoking, they can be less effective.[30] We also note that the same quantum of money given to a person with low income is worth more than to a person with high income, and small incentives are more likely to be effective in low-income groups. This assumption supports the larger effect we observed in our study compared with the initial conservative estimation during the planning of the trial. Additionally, weights were used to account for the censoring of some participants before the primary outcome could be observed.

Our study provides robust evidence that pre-test and post-test tuberculosis counselling with conditional cash transfers of R150 (approximately $10) per visit at treatment initiation and monthly follow-up visits for the 6-month period reduced the risk of unsuccessful outcomes. The combined intervention can effectively contribute to the End TB Strategy goals of improving successful outcomes, reducing disease incidence, and offsetting catastrophic patient costs.

Contributors

NI, SVO, HM, SAM, AC, and IA were involved in the conception and design of the study. NI, SVO, HM, JM-K, SM, DS, FI, and LG were involved in the implementation of the study. HM, JM-K, and AC did the data collation and analysis. JM-K and HM accessed and verified all the data. NI, HM, and SVO wrote the first draft. NI, SVO, HM, SAM, AC, IA, JM-K, SM, DS, FI, AI and LG interpreted the data and provided intellectual input, including editing and reviewing the final draft. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

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Data sharing

Summary results will be provided as per WHO requirements. De-identified data that include key variables described in the peer-reviewed publication will be made available upon a reasonable request after the publication of the peer-reviewed article. The access criteria for sharing are a well defined protocol that aligns with the research focus of the current work, the protocol has received institutional review board approval, and a data requestor that seeks to collaborate when using the data.

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