CORRESPONDENCE

Digital Health Support in Treatment for Tuberculosis

TO THE EDITOR: Improving support for patients with tuberculosis is a major priority for governments and development agencies.[1] Digital health interventions have the potential to address shortfalls in the current standard of care.[2] Although access to the Internet, smartphones, and other forms of technology is still limited in areas with a high tuberculosis burden, mobile "feature" phones (i.e., phones that lack the advanced functionality of smartphones but can be used to make calls, send text messages, and access some simple Internet features through a text-based interface) are ubiquitous.[3] We therefore developed a digital health platform that was compatible with feature phones to provide support for patients with tuberculosis.

Each day, patients received a text message asking them to verify adherence to treatment. Such interactive messaging approaches have shown more promise for promoting adherence than one-way reminders.[4] If the patient did not verify adherence, two additional messages were sent to the patient at 1-hour intervals, followed by messages and then phone calls from study team members who had personal experience of successful completion of treatment for tuberculosis; if there was still no response, a notification was sent to the clinic. This approach ensured that nonadherence was addressed in a timely fashion and presented patients with a resource for overcoming barriers such as challenges in accessing care, stigma in the community, and lack of information, motivation, or support. It also made patients feel accountable to others for their adherence or nonadherence; social science research suggests that such accountability motivates cooperative behavior.[5]

The digital health platform also provided information about tuberculosis. Weekly motivational messages such as "Taking your pills will help you get better and keep you from infecting family and friends" were sent by text message, and patients participated in an "adherence contest" in which they could compare their reported adherence with that of others and could qualify for a "winner's circle" if their adherence was 90% or higher. These features further enhanced accountability, helped to establish a norm of adherence, and emphasized the benefits of adherence in the community — all of which motivated patients to cooperate.[5] All platform content was developed in conjunction with local study team members to ensure that it would be comprehended by and appropriate for the study population.

To determine whether this platform would result in a better frequency of treatment success when it was combined with the standard of care, we collaborated with 17 clinics in Nairobi to perform an individual-level, parallel, randomized, controlled trial (Tables S1 through S3 in the Supplementary Appendix, available with the full text of this letter at NEJM.org). The primary trial outcome was an unsuccessful treatment outcome, which was defined as a composite of death during treatment for tuberculosis, treatment failure (i.e., the patient's sputum smear or culture was positive at month 5 or later), or loss

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to follow-up (i.e., the patient interrupted treatment for ≥2 consecutive months).

The trial was approved by the institutional review board of Kenyatta National Hospital and the University of Nairobi. Trial patients or their parents or guardians provided written informed consent. Details about the methods are provided in the Supplementary Appendix and the protocol and statistical analysis plan, available at NEJM.org; ClinicalTrials.gov number, NCT03135366.

After exclusion of patients who had received a misdiagnosis or were transferred out of their clinic, 1104 patients remained: 535 in the control group and 569 in the intervention group. Of these patients, unsuccessful treatment outcomes occurred in 70 patients (13.1%) in the control group and 24 patients (4.2%) in the intervention group (P<0.001) (Fig. 1). The results in the two groups were similarly large and significant when only loss to follow-up was considered, when only patients with bacteriologically confirmed infection were included, or after adjustment for individual characteristics (Tables S5 and S6 in the Supplementary Appendix). Our results suggest that interventions delivered with feature phones can help to address shortfalls in the current standard of care for patients with tuberculosis.

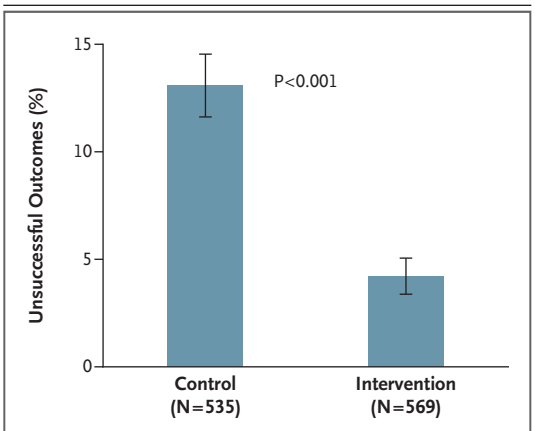

Figure 1. Unsuccessful Treatment Outcomes, According to Trial Group.

An unsuccessful outcome of treatment for tuberculosis was defined as any of the following: death during treatment, treatment failure (the patient's sputum smear or culture was positive at month 5 or later), or loss to follow-up (the patient did not start treatment or interrupted treatment for ≥2 consecutive months). A total of 535 patients in the control group received the standard of care, whereas 569 patients in the intervention group received treatment support through a digital health platform. A total of 13.1% of patients in the control group (70 patients) had unsuccessful treatment outcomes, as compared with 4.2% of patients in the intervention group (24 patients) (P<0.001). I bars indicate standard errors.

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Disclosure forms provided by the authors are available with the full text of this letter at NEJM.org.

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Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Yoeli E, Rathauser J, Bhanot SP, et al. Digital health support in treatment for tuberculosis. N Engl J Med 2019;381:986-7. DOI: 10.1056/NEJMc1806550

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A Setting

Our study was conducted in Nairobi, Kenya. Nairobi reported 14,649 cases of tuberculosis in 2013 and 13,917 in 2014, a population case notification rate of roughly 400 out of 100,000[1]. Nairobi's rate of unsuccessful treatment outcomes was 11% in 2014 and 2015[2,3]. Mobile phone penetration in Kenya is over 90%[4–6].

B Study Population

Our RCT was conducted in Nairobi, Kenya between February 2016 and May 2017 in partnership with 17 health clinics that were selected by the Kenya Ministry of Health (Fig. S2). Individuals receiving treatment for TB at these clinics were eligible for the study if they: (1) had been clinically diagnosed or bacteriologically confirmed to have TB; (2) were not diagnosed with a drug-resistant strain of TB; (3) could communicate in either Kiswahili or English; (4) owned or had access to a mobile phone on the Safaricom network, the dominant network operator in Kenya; and (5) had at least two months of TB treatment remaining.

C Study Oversight and Procedures

Individuals were randomly assigned to either receive the standard of care plus access to our mobile phone platform (intervention group) or the standard of care alone (control group). We employed block randomization within each of the 17 clinics, so that half the individuals in each clinic were assigned to each group (Tbl. S2). Participant flow is reported in Fig. S1.

The standard of care in Nairobi is as follows. On the day of diagnosis, individuals engage in a group training session with a clinician, in which the clinician explains how to take the medication, describes some behaviors to minimize the risk of infecting others, and emphasizes the benefits of adherence for both the individual's health and the health of those around her. For the duration of treatment, patients return to the clinic regularly–weekly at first, then biweekly in months three onwards–to pick up the following week's supply of medication. Often, visits include a discussion with a clinician. The duration of treatment is usually six months for drug-sensitive, pulmonary TB, and 12 months or more for extra-pulmonary TB.

We hired six study team members from Nairobi who had either successfully completed TB treatment themselves, or aided a family member in successfully completing treatment. In December 2015-January 2016, we trained the study team on ethical conduct of research, including confidentiality and how to obtain informed consent. We also trained the study team on the selection of behavior change strategies from the social sciences discussed below. We then developed the platform's content in conjunction with the study team. Subsequently, the study team was responsible for consenting and enrolling individuals, following up with individuals who failed to verify, and providing support for individuals who requested it through the platform.

Subject recruitment was performed by a study team member at the clinic, at the conclusion of the individuals' visit to the clinic. For all individuals, study team members described the platform, checked if individuals were eligible for the trial, obtained written consent, and entered individuals' mobile phone num-

bers into the mobile platform system for random assignment to intervention.

D Interventions

D.1 Intervention Group

Individuals assigned to the intervention condition were offered a wristband inscribed with a motivational message emphasizing the communal benefits of good health in English and Kiswahili. They received a series of welcome messages introducing them to the platform's features. For the duration of treatment, individuals in the intervention retained access to the platform.

The mobile platform could be accessed on both feature ('flip') and smartphones. The platform provided the following services. First, each day, at a time specified by the individual, in consultation with their doctor, the individual received a message reminding them to take their TB medication, and to log into the platform to verify adherence.

Aside from reminder messages, which were sent via SMS, all communication with the patient occurred on the platform, which employed the Unstructured Supplementary Service Data (USSD) protocol. USSD platforms are accessed using a code (ours was *384*000#), which initiates a real-time session with a cloud-based server. We chose this technology, rather than communicating purely via SMS, for a number of reasons. USSD platforms enhance security of health and other private data because no data is stored on the individual's device. USSD platforms obviate the need for the individuals purchase new hardware, or to install and maintain special software, and thus reduce barriers to adoption. Moreover, USSD platforms are ubiquitous in resource constrained regions like Kenya, where they are used for agricultural marketplaces, airtime top-ups, and mobile banking. So, the vast majority of individuals are already comfortable with the technology, which further reduces barriers to adoption. Finally, USSD is more affordable than SMS at scale: while network operators typically charge for each SMS, they only charge once for each USSD session.

Upon logging in to the platform, the individual had the option to verify, or to request a later reminder. If the individual failed to log in, or asked for a later reminder, the individual was sent a second reminder an hour later. If the individual again failed to verify, the individual was sent a third reminder an hour later. If the individual failed to verify yet again, the individual was marked as non-adherent, and the study team was alerted. Each day, study team members texted individuals who had been non-adherent for less than 24 hours, called individuals who had been non-adherent for between 24 and 48 hours, and notified clinics of individuals who had been non-adherent for more than 48 hours. This gives clinics the option of activating procedures for reaching the individual (e.g., via community health workers) earlier than might otherwise be possible if the clinic were to wait for the individual to miss their next visit(s).

The decision to employ a two-way system, rather than "one-way" SMS reminders, was partly motivated by previous research findings in which one-way SMS reminders have yielded modest and inconsistent results, whereas interactive approaches have shown promise for promoting adherence[7–9]. It also exemplifies our use of social science insights to maximize individuals' motivation to adhere and complete treatment. Two-way communication made it possible to monitor adherence, and thus increase accountability, which is known to motivate meaningful changes in behavior in contexts like ours, in which individuals decisions have

a large impact not only on themselves, but also on others[10]. The two-way system also eliminated plausible excuses for failing to adhere, like forgetting to reply, or not receiving a message[11]. For an overview of the social science tools we employed to develop the intervention, see Tbl. S1[10–20].

In addition to verifying adherence, individuals could log into the platform at any time to access three additional features: (1) a chat client that connected patients with the study team; (2) information about TB; and, (3) an 'adherence contest' that presented their adherence rank alongside that of other individuals, with identifying information obscured. The adherence contest was intended to be fun, while further enhancing feelings of accountability. Roughly once a week, the platform sent all individuals a motivational message, which helped to frame adherence in terms of its benefits to the community, and establish adherence as a norm[11].

D.2 Control Group

Individuals assigned to the control condition were sent a single SMS thanking them for consenting, and informing them they would not receive any further messages.

E Study Outcomes

Treatment outcomes were recorded by clinicians in the clinics' TB 'registers' according to World Health Organization guidelines. These outcomes include: cured (a bacteriologically confirmed individual whose sputum smear or culture was negative at month five or later), treatment completed (an individual who was not initially bacteriologically confirmed, but whose sputum smear or culture was negative at month five or later), misdiagnosed (an individual who was originally diagnosed but subsequently reported as not having TB), transferred out (an individual who transferred to another clinic), died (an individual died during TB treatment), failed (an individual whose sputum smear or culture was positive at month five or later), loss to follow-up (an individual who did not start treatment or interrupted treatment for two or more consecutive months; abbreviated as LTFU).

We define the binary variable 'unsuccessful treatment outcome', which indicates whether an individual's outcome was any of: died, failed, or LTFU. The primary study outcomes were unsuccessful treatment outcomes and LTFU.

F Statistical Analysis

We conducted power calculations based on our prediction that the marginal effect of the intervention would be 7.5 percentage points on the primary outcome. We assumed unsuccessful treatment would be correlated within clinic, and that 80% of the variance in unsuccessful treatment would be at the clinic level. We therefore calculated that we needed 1200 individuals to have greater than 80% power at a significance level of 0.05. The protocol was prospectively filed with the appropriate oversight bodies prior to initiation. However it was registered late with clinicaltrials.gov when we became aware of the registration requirements for behavioral health studies.

Summary statistics of individuals' characteristics are presented in Tbl. S3 for the entire sample, and

for the control and intervention groups separately. A histogram of verification rates for individuals in the intervention group is presented in Fig. S3.

We omitted individuals who were misdiagnosed or who transferred out (Tbl. S4). For the primary outcome (unsuccessful treatment outcome), we performed a t-test by intervention group (Tbl. S5). We also fitted logistic regressions to estimate the marginal effect of the intervention (Tbl. S6). The unit of analysis was an individual. In some regression specifications, we included binary indicators for each clinic as a fixed effect and controls for individual characteristics. In some analyses, we restricted to bacteriologically-confirmed individuals.

Data analysis was performed by E.Y., S.B., and D.R..

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Table S1: Behavioral Insights Employed in the Design of the Keheala Intervention

Behavioral Intervention	How It Was Delivered	Examples and Reviews from Outside Public Health
Framed adherence as a contribution to public health	via automated messages and in interactions with support sponsors	Tversky and Kahneman (1981); Andreoni (1995)
Established a norm of adherence	via automated messages and in interactions with support sponsors	Goldstein et al. (2008); Allcott (2011); Kraft-Todd et al. (2015)
Asked individuals to make a public commitment	by wearing a wristband with a prosocial inscription	Cotterill et al. (2013)
Eliminated plausible deniability	by requiring that an individual either take their pill and verify, or explicitly lie about it	Dana et al (2007); Andreoni et al (2017); Rand et al. (2014)
Enhanced actual and perceived observability of individual's adherence	via monitoring and the inclusion of adherence scores	Gerber et al (2008); Yoeli et al. (2013); Kraft-Todd et al. (2015)

Behavioral interventions employed in the design of the Keheala intervention, how each was delivered, and examples or reviews.

Table S2: Number of individuals in each clinic, by intervention group

	Control	Intervention	Total
Baraka	64	62	126
Dandora	36	41	77
Embakasi	37	43	80
Kahawa West	20	18	38
Kamti Prison Public	16	18	34
Kangemi	27	30	57
Kasarani	42	42	84
Kayole 2 Sub District	36	41	77
Kibera DO	6	11	17
Kibera South MSF	31	31	62
Mathare North	14	14	28
Mukuru	36	38	74
Ngara	21	21	42
Rhodes	34	41	75
Riruta	57	57	114
St. Marys	46	51	97
Umoja Health Centre	12	10	22
Total	535	569	1104

Table S3: Individual and Disease Characteristics by Intervention Group

	Experimental Condition			
	Control (n=535)	Intervention (n=569)	All (n=1104)	(p-value)
Female (%)	42.62	40.42	41.49	0.46
Age (yrs.)	31.87	30.62	31.22	0.09
Child (%)	9.533	7.909	8.696	0.34
English Language Preference (%)	60.56	68.37	64.58	0.01
Slum Dweller (%)	45.57	40.74	43.08	0.11
Number of Household Members	2.098	1.968	2.031	0.22
Education (%):				
None	18.46	13.03	15.65	0.01
Primary	33.52	29.93	31.67	0.20
Secondary	36.16	40.14	38.22	0.18
Advanced	11.86	16.90	14.47	0.02
Employment (%):				
Unemployed	25.61	22.75	24.13	0.27
Casual Day Worker	28.81	23.81	26.23	0.06
Self-Employed	23.16	26.63	24.95	0.19
Multiple Jobs	0.565	0.353	0.455	0.60
Formal Employment	17.70	21.16	19.49	0.15
Student	4.143	5.291	4.736	0.37
Travel Time to Clinic (minutes)	28.30	27.90	28.09	0.78
Bacteriologically Confirmed (%)	55.85	61.13	58.56	0.09
Previously Treated (%)	65.85	68.43	67.18	0.36
HIV Coinfection (%)	32.82	28.37	30.53	0.11
Extrapulmonary (%)	23.22	23.20	23.21	0.99
Provided Nutrition Supplement (%)	92.18	90.44	91.28	0.31

Demographics by experimental condition. The p-values come from a single regression of treatment assignment on these demographics. An F test for joint significance rejects that the sample is balanced (F = 1.70, p = 0.03).

Table S4: Individuals who were misdiagnosed or transferred out, by intervention group

	All Individuals (n=1189)			Bacteriologically Confirmed Individuals (n=620)		
	Misdiagnosed					
	Intervention (n=609)	Control (n=580)	p-value	Intervention (n=331)	Control (n=289)	p-value
Count	3	1		2	0	
Rate (%)	0.49	0.17	0.34	0.6	0.00	0.19
(Std. Error)	0.28	0.17		0.42	0.24	
	Transferred Out					
	Intervention (n=609)	Control (n=580)	p-value	Intervention (n=331)	Control (n=289)	p-value
Count	37	44		16	17	
Rate (%)	6.08	7.59	0.30	4.83	5.88	0.56
(Std. Error)	0.97	1.1		1.18	1.38	

Table S5: Treatment Outcomes

	All Individuals (n=1104)			Bacteriologically Confirmed Individuals (n=585)		
	Unsuccessful Outcome (Loss to Follow Up, Failed Treatment, Died)					
	Intervention (n=569)	**Control (n=535)**	**p-value**	**Intervention (n=313)**	**Control (n=272)**	**p-value**
Count	24	70		17	32	
Rate (%)	4.22	13.08	<0.001	5.43	11.76	0.006
(Std. Error)	0.84	1.46		1.28	1.95	
	Loss to Follow Up					
	Intervention (n=569)	**Control (n=535)**	**p-value**	**Intervention (n=313)**	**Control (n=272)**	**p-value**
Count	10	53		9	27	
Rate (%)	1.76	9.91	<0.001	2.88	9.93	<0.001
(Std. Error)	0.55	1.29		0.95	1.81	
	Failed Treatment					
	Intervention (n=569)	**Control (n=535)**	**p-value**	**Intervention (n=313)**	**Control (n=272)**	**p-value**
Count	4	1		4	1	
Rate (%)	0.70	0.19	0.20	1.28	0.37	0.23
(Std. Error)	0.35	0.19		0.64	0.37	
	Died					
	Intervention (n=569)	**Control (n=535)**	**p-value**	**Intervention (n=313)**	**Control (n=272)**	**p-value**
Count	9	15		3	3	
Rate (%)	1.58	2.80	0.16	0.96	1.10	0.86
(Std. Error)	0.52	0.71		0.55	0.63	
	Cured					
	Intervention (n=569)	**Control (n=535)**	**p-value**	**Intervention (n=313)**	**Control (n=272)**	**p-value**
Count	260	211		224	188	
Rate (%)	45.69	39.44	0.04	71.57	69.12	0.52
(Std. Error)	2.09	2.11		2.55	2.80	
	Treatment Completed					
	Intervention (n=569)	**Control (n=535)**	**p-value**	**Intervention (n=313)**	**Control (n=272)**	**p-value**
Count	285	254		72	52	
Rate (%)	50.09	47.48	0.39	23.00	19.12	0.25
(Std. Error)	2.10	2.16		2.38	2.38	

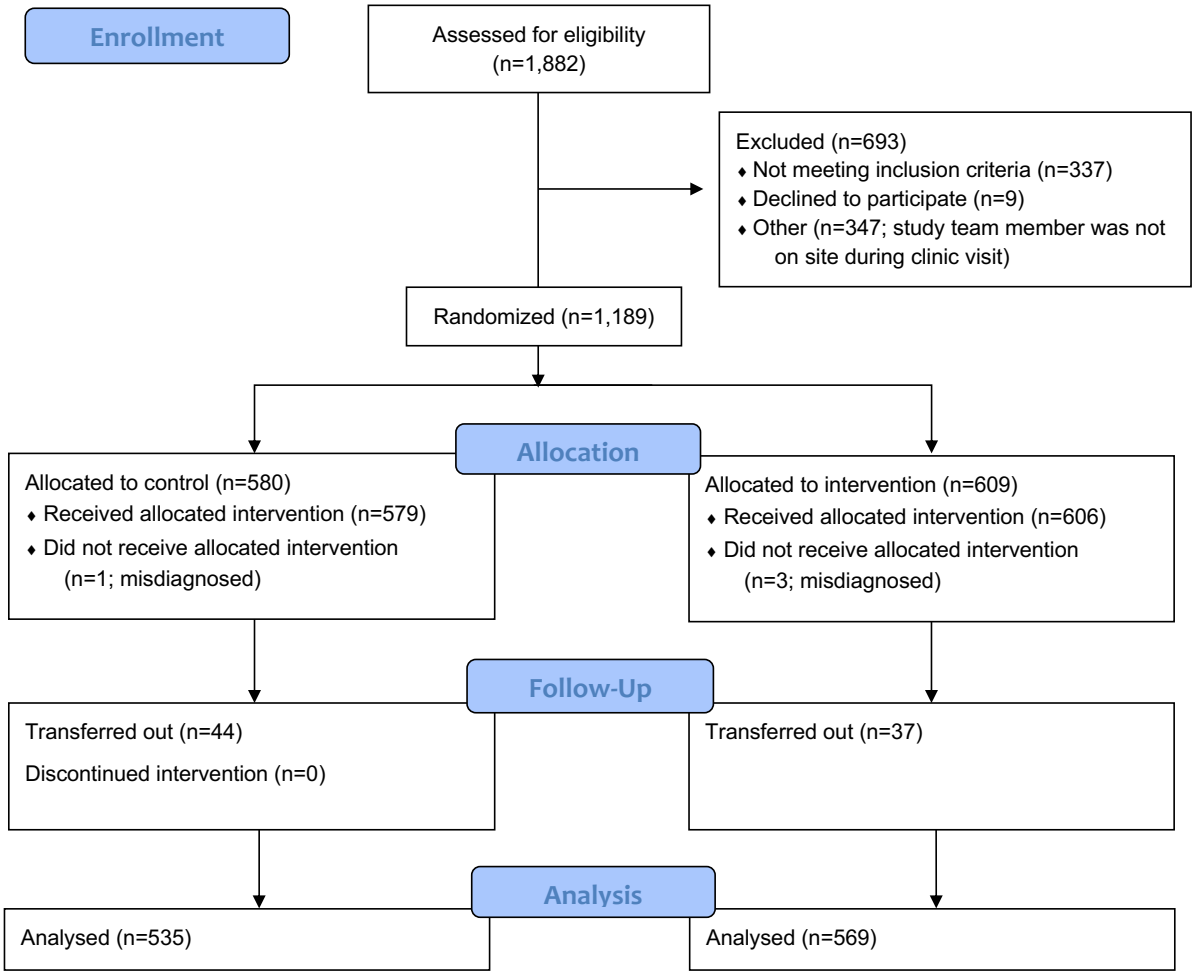
Treatment outcomes by experimental condition, presented separately for all individuals and bacteriologically-confirmed individuals only. We present the composite outcome of interest (treatment failure, death, or patient loss to follow up), which we call 'unsuccessful treatment outcomes'. We also present each individual treatment outcome separately. The p-values come from t-tests of the differences in rates of each outcome across experimental condition.

Table S6: Estimated Treatment Effect with Controls

	Unsuccessful Outcomes			LTFU		
	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Intervention	-0.0933***	-0.0876***	-0.0868***	-0.0947***	-0.0912***	-0.0950***
	(0.0195)	(0.0202)	(0.0195)	(0.0203)	(0.0206)	(0.0201)
Observations	1104	970	970	1104	970	934
Demographic Controls	No	Yes	Yes	No	Yes	Yes
Clinic Fixed Effects	No	No	Yes	No	No	Yes

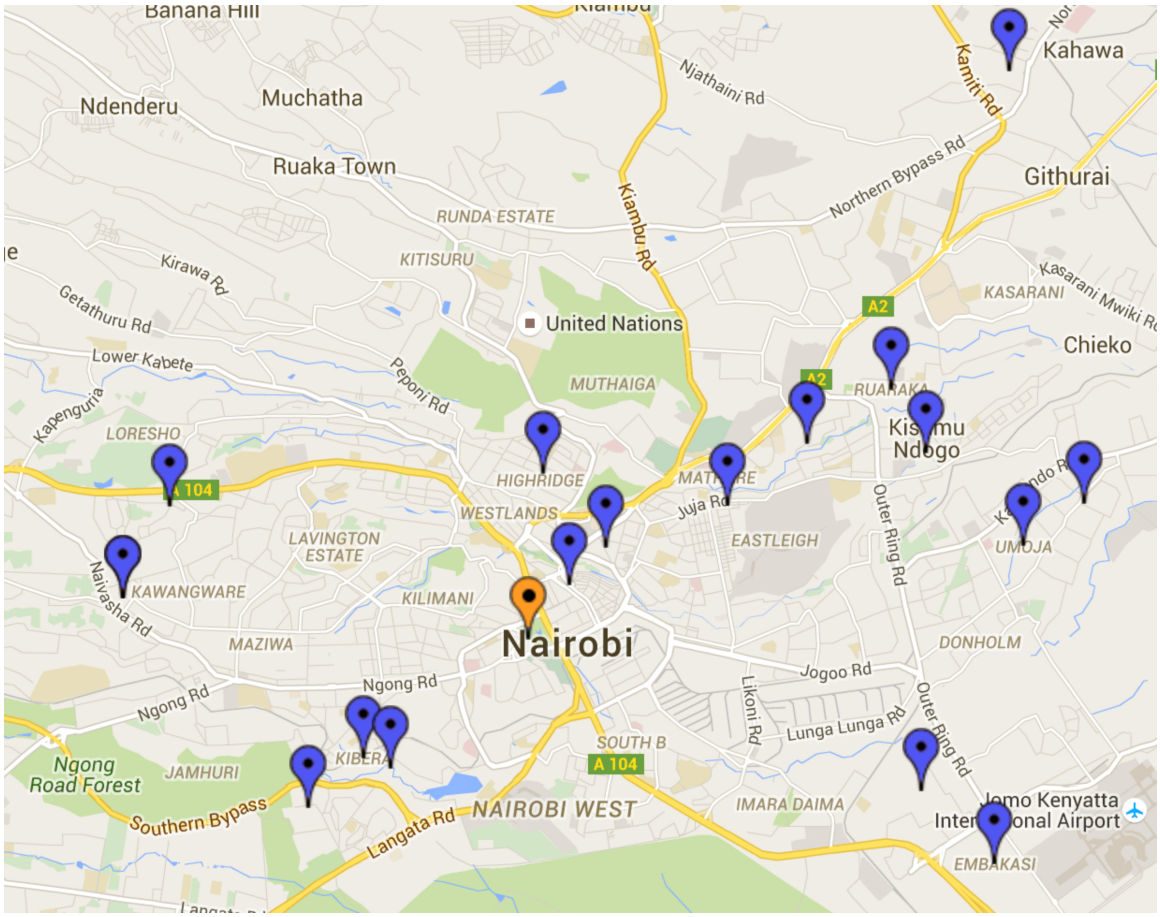
The estimated marginal treatment effect of the intervention, evaluated at covariates' means. *** indicates a coefficient is significant at the 1% level. The estimated marginal treatment effect remains roughly as large and statistically significant, even after adding controls for individual demographics and clinic fixed effects.

Figure S1: CONSORT Diagram



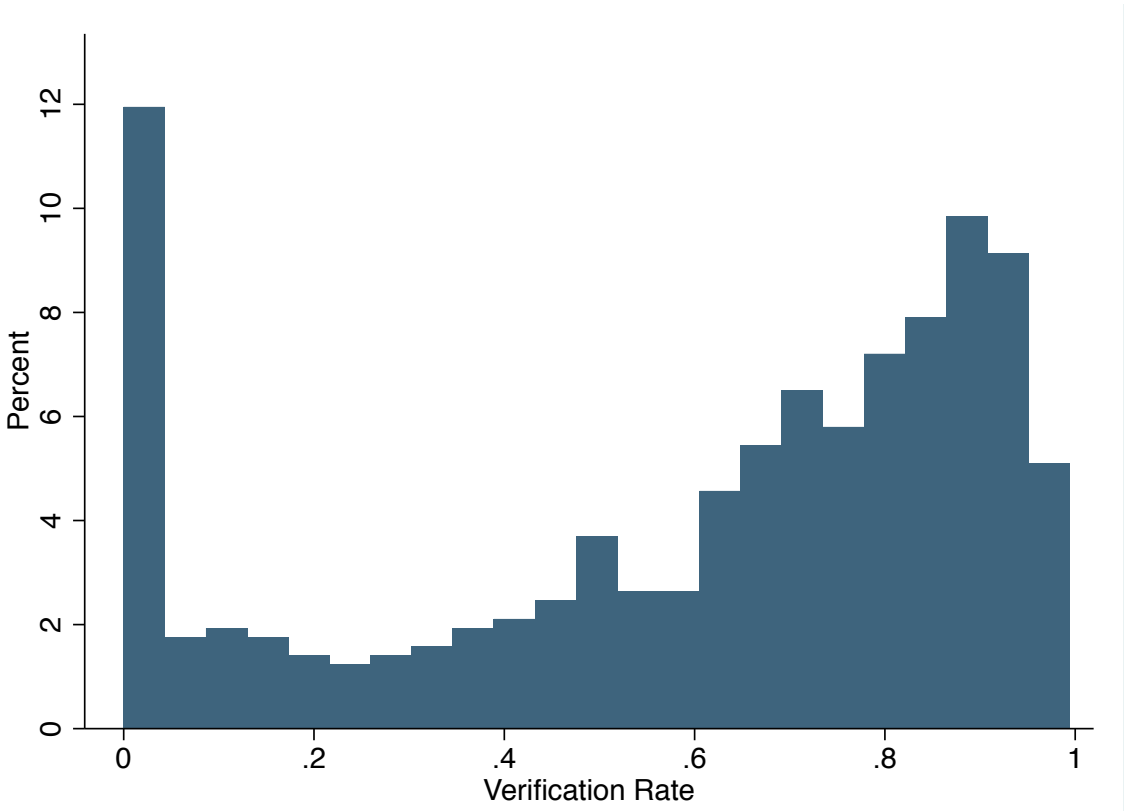
The number of individuals assessed for eligibility was identified using Kenya's "TIBU" digital TB registry. It is the number of TB patients with at least two months of treatment remaining at the 17 partner clinics, during the period in which we were collaborating with the clinics. The number of individuals randomized and their allocations were identified by counting the number of mobile phone numbers entered into our digital health platform by study team members. The number of individuals excluded is just the number assessed for eligibility minus the number randomized. It was not always possible for study team members to identify the reasons an individual did not participate; the number of individuals excluded for not meeting the inclusion criteria, for declining to participate, and because a study team member was not on site during the individual's visit is thus estimated based on study team members' notes. The number of individuals who were misdiagnosed and transferred out was identified from clinics' TB registers.

Figure S2: Map of Partner Clinics



Each clinic is identified by a blue pin. The orange pin represents the headquarters of Kenya's National TB Program. The list of partner clinics and the number of patients at each clinic is presented in Tbl. S2.

Figure S3: Histogram of Verification Rates



Verification rates–defined as the proportion of days on which a user in the intervention group self-verified–are represented along the X-axis. The height of each bars represents the percent of individuals who verified a particular proportion of the time. The mean verification rate was 60%; 94% of individuals verified at least once.