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Treatment outcomes of patients with drug-sensitive tuberculosis under community-based versus facility-based directly observed treatment, short course strategy in Southwest Ethiopia: a prospective cohort study

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ABSTRACT

Objective To compare tuberculosis (TB) treatment outcomes and associated factors among patients attending community-based versus facility-based directly observed treatment, short course (DOTS).

Design A prospective cohort study.

Setting The study was conducted in Southwest Ethiopia. There were seven hospitals (five primary, one general and one specialised), 120 health centres and 494 health posts.

Participants A total of 1161 individuals consented to participate in the study (387 patients under community-based DOTS (CB-DOTS) and 774 patients under facility-based DOTS (FB-DOTS)). Individuals who could not respond to the questions, mentally or critically ill patients, and those less than 15 years old, were excluded from the study.

Primary outcome measure TB treatment outcomes were compared among patients under CB-DOTS versus FB-DOTS. Risk ratio (RR), risk difference (RD) and confidence interval (CI) were calculated among the study groups. In addition, χ^2 or Fisher's exact tests were used to compare group differences, with a p value of <0.05 considered statistically significant.

Results Patients who opted for CB-DOTS were more likely to be cured by 12% than those who opted for FB-DOTS (RR=1.12, 95% CI=0.96 to 1.30). Patients under CB-DOTS had a lesser risk of death (RR=0.93, 95% CI=0.49 to 1.77) and a lower risk of treatment failure (RR=0.86, 95% CI=0.22 to 3.30) than those under FB-DOTS. Furthermore, patients who opted for CB-DOTS were less likely to have a positive sputum smear result at the end of the treatment period (p=0.042) compared with their counterparts.

Conclusion The study showed that CB-DOTS is more effective than FB-DOTS in terms of improving cure rate and sputum conversion rate, as well as lowering treatment failure rate. Our findings show the need for scaling up and a further decentralisation of CB-DOTS approach to improve access to TB treatment service for the rural community.

Strengths and limitations of this study

- This study applied a relatively large sample size of patients with drug-sensitive tuberculosis under facility-based directly observed treatment, short course (DOTS), and those under community-based DOTS for comparison.
- The strongest observational study design (prospective cohort study design) was used.
- Relative risk and risk difference were applied to interpret the findings.
- The findings could be prone to selection bias due to the patients' preference to be under community-based or facility-based DOTS and the observed unknown outcomes of transferred out and not recorded cases.

INTRODUCTION

Tuberculosis (TB) is still a common cause of illness and death in low-income and middle-income countries. Globally, there were an estimated 10 million cases of TB in 2018. Moreover, there were an estimated 1.2 million among HIV negative and 251 000 (among HIV positive) deaths due to TB.[1] The 30 high TB burden countries shared 86.8% of the global TB incidence, with 24% of all cases found in Africa. Ethiopia is one of the 30 highest TB burden countries, and one of the 10 highest for TB, TB/HIV and multidrug-resistant (MDR) burden countries.[1 2] Based on the 2018 Global TB report, 117 705 TB cases were reported in Ethiopia. The report showed a 68% treatment coverage for drug-sensitive TB in the country.[3]

Ethiopia started implementing the enhanced form of the directly observed treatment, short course (DOTS) and the

WHO Stop TB strategy in 2006.[4 5] The expansion and enhancement of a high-quality DOTS is one of the focuses of this strategy. The strategy is an effective patient-centred strategy with the aim of reaching all patients and improving case findings.[6] While reinforcing the Stop TB strategy, the WHO has recently launched the End TB strategy for the period from 2016 to 2035, with a target of a 90% reduction in TB mortality and an 80% reduction in TB incidence by 2030, compared with what was achieved in 2015.[2] In order to achieve these targets, the scaling up of TB diagnostic and treatment services to the community is crucial.

Ethiopia has been implementing the DOTS strategy since 1997.[7] DOTS is currently being implemented using two approaches: facility-based DOTS (FB-DOTS) (provided by a trained health worker at health facility level) and community-based DOTS (CB-DOTS) (provided by a health extension worker (HEW) or a trained TB treatment supporter at health post, patient's home or patient's workplace). The health facilities (hospitals and health centres) provided TB diagnostic and treatment services, whereas the health posts rendered the TB treatment services, identification and referrals of TB suspects to the nearest health facilities for confirmatory testing using an acid-fast bacilli smear microscopy test (diagnosis).[5 8] In the Jimma Zone (the study area), the DOTS was initiated in 1998.

The Health Sector Transformation Plan 2015/2016–2019/2020 of Ethiopia includes the need for a scaling up of community-based TB care which is provided at health post or community level to all health posts or kebeles (the lowest administrative level in Ethiopia).[9]

Studies in Ethiopia revealed that a long distance from TB clinics, a lack of money for transport, direct and indirect costs associated with the illness and the daily treatment, a loss of employment, a poor quality of health services and a lack of social support are the primary reasons for failing to fully comply with TB treatments.[10 11] A recent study conducted in the Jimma Zone, Ethiopia, showed that of all the MDR TB cases, two-thirds had a history of previous TB treatment, 37% had a history of treatment failures and 27% had a relapse history.[12]

The optimal implementation of FB-DOTS and CB-DOTS is crucial to achieve high TB case notification and cure rates.[13] Previous studies in different countries have shown that CB-DOTS is more effective than the FB-DOTS approach.[14–20] In the Jimma Zone, where this study was conducted, only 23% of the health posts provided TB treatment at the community level during the study period. To the best of our knowledge, a comparative study on CB-DOTS versus FB-DOTS delivery approaches has not been conducted in Southwest Ethiopia. Therefore, this study aimed at comparing TB treatment outcomes and associated factors among drug-sensitive patients attending CB-DOTS versus FB-DOTS at public health facilities and health posts in Jimma Zone, Ethiopia.

Findings from this study may contribute to the improvement of the TB control programme performance by providing evidence-based recommendations for decision-makers about CB-DOTS versus FB-DOTS in particular in the study area, and in Ethiopia at large.

METHODS

Study setting

The study was conducted in the Jimma Zone, Southwest Ethiopia, which is one of the zones in the Oromia Regional State of Ethiopia. It is located 354 km from Addis Ababa, the capital city of Ethiopia, with a total area of 199 316.18 km^2 (Jimma Zone health office, 2016; Jimma town health office, 2016). In 2016, the Jimma Zone had a total of 17 districts and two town administrations. There were seven hospitals, of which five were primary, one general and one specialised, as well as 120 health centres and 494 health posts during the study period. In addition, non-governmental health facilities, such as the Catholic mission and some private clinics, also provided TB diagnostic and treatment services. The Ethiopian government and global health agencies, such as The Global Fund and the US Center for Disease Control (CDC), have been the sources for funding and other resources, such as drugs and laboratory reagents for the implementation of the TB control programme (Jimma Zone health office, 2016; Jimma town health office, 2016). Based on a projection of the 2007 population census, the Jimma Zone had an estimated population of 3 261 371, of which 49.9% were women in the year 2017.[21]

Study design, study population and sampling

The study followed a prospective cohort study design.[22] The target population was all patients with drug-sensitive TB who were initiated on first-line anti-TB DOTS regimens at all public health facilities and health posts of Jimma Zone during the study period. Patients with drug-sensitive TB who started the first-line anti-TB DOTS regimens at sampled districts' and a town administration's public health facilities and health posts were consecutively enrolled in the study. Patients who could not respond to the questions, mentally or critically ill patients, as well as those less than 15 years old, were excluded from the study.

Eight districts and 1 town administration were randomly selected from 17 districts and 2 town administrations by using a simple random sampling (lottery method).[23 24] Afterwards, all DOTS sites in the sampled districts and a town administration were included in the study. The sample size was determined using Epi Info software, V.7. We considered a CI of 95% and a power of 80%. The treatment success rate was selected as an outcome variable, whereas the percentage of outcome in unexposed groups (DOTS at health facilities) and exposed groups (DOTS at health posts or community) was estimated to be 83.1% and 89.3%, respectively. This result was taken from a previous study done in Southern Ethiopia,[25] with an unequal ratio being employed (unexposed:exposed of 2:1). Accordingly, the sample size was calculated to be 1161 (774 under FB-DOTS and 387 under CB-DOTS).

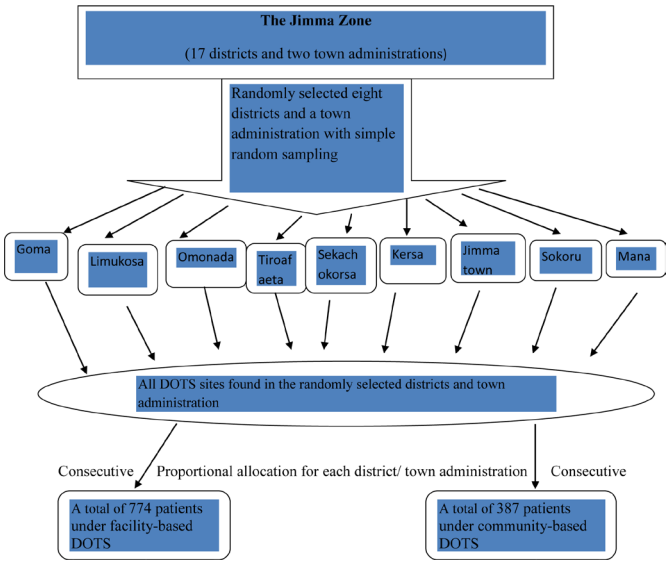

Figure 1 Schematic presentation of sampling procedure for a cohort study, Jimma Zone, 2017. DOTS, directly observed treatment, short course.

The sample size was proportionally allocated to the selected health facilities in the sampled districts, and the town administration based on a patient flow of the previous one year before the study's start. Subsequently, the study participants were consecutively enrolled until the required sample size was obtained (figure 1).

Data collection and analysis

A structured questionnaire was used to collect the data (sociodemographic characteristics and other independent variables) from the study participants. Clinical data including the treatment outcomes were collected with a checklist attached to the questionnaire from laboratory and unit TB registers. The data collection tool was prepared based on national and WHO's guidelines, as well as tools used in previous studies.[5 15 16 25–27] The questionnaire was translated to local language (Afan Oromo) by a University English teacher whose mother tongue is the local language. It was peer reviewed to check for any discrepancies between the forward translation and the original English version of the questions. The translated version of the questionnaire was translated back to English by another University English teacher who speaks and writes the local language fluently. Then, it was pretested in a district outside of the study area to check for the clarity and time needed to complete the questionnaire. Then, modifications like clarifying phrases were made based on the findings of the pretest. The overall process of data collection was organised and supervised by the principal investigator. Data collectors and supervisors were recruited and provided with the necessary training on the technique of data collection in the presence of the principal investigator. The enrolment of the study participants was done consecutively starting from September 2016 to October 2017. All patients were interviewed during the enrolment period. The patients were followed up from the first time of enrolment until their treatment outcomes were recorded (until June 2017). The second phase of data collection, including the treatment outcomes, was conducted from 1 October to 30 December 2018. Information from the laboratory and TB registers was gathered after obtaining permission from the head of the health facilities. The data on the treatment outcomes for the cohort were obtained from the unit TB register at the respective health facilities included in the study. The data were checked for completeness and consistency, then coded and entered into the EpiData entry client software, V.4.4.3.1, and exported to the Statistical Package for Social Sciences software (SPSS) V.21 for analysis. Additionally, WinPepi V.11.65 was used to calculate the risk ratio (RR) and risk difference (RD). Descriptive statistics were also computed. Groups were compared using the χ^2 or Fisher's exact tests when appropriate, with a p value of <0.05 considered statistically significant. The RR, RD and 95% CI were applied to interpret the groups' difference for the dependent and independent variables.

Definition of terms

Definitions used in this study are according to the National and WHO Tuberculosis guidelines.[5 28]

New case: The patient has never been treated for TB or has taken anti-TB drugs for less than 1 month.

Relapse: The patient has previously been treated for TB, was declared cured or treatment completed at the end of his/her most recent course of treatment, and was diagnosed with a repeated episode of TB.

Cured: A patient with bacteriologically confirmed pulmonary TB at the beginning of treatment, who was smear or culture negative at the end of treatment, and at least one previous time.

Treatment completed: A patient with TB who completed treatment without evidence of smear or culture negative at the end of treatment, and at least one previous time.

Treatment failure: A patient whose sputum smear or culture is positive at the fifth month or later in the course of treatment.

Lost to follow-up: A patient with TB who has been on treatment for at least 4 weeks and who interrupted the treatment for 8 or more consecutive weeks.

Died: A patient who dies from any cause during the course of TB treatment.

Transferred out: TB cases transferred to another treatment unit, and whose treatment outcome is not assigned.

Not recorded: Cases for which the treatment outcome is not recorded in the unit TB register.

Favourable treatment outcome: The sum of cured and treatment completed outcomes.

Unknown treatment outcome: The sum of transferred out and not recorded cases.

Unfavourable treatment outcome: The sum of deaths, treatment failures and lost to follow-up outcomes.

Facility-based DOTS: TB treatment provided at governmental health centres or hospitals by a trained health worker.

Community-based DOTS: TB treatment provided at a health post or patient's home by a HEW or a trained TB treatment supporter.

Not applicable: Sputum examination is not required either because the patient was not pulmonary TB positive or the outcome was known at this stage (died, transferred out).

Patient and public involvement

Representatives of the public, such as previous patients, were not involved in the development of the research question and the design of the study. The findings of this study will be disseminated to concerned stakeholders after being published in a peer-reviewed journal.

RESULTS

Characteristics of the study participants

A total of 1161 patients with drug-sensitive TB were enrolled (774 who opted for FB-DOTS and 387 who opted for CB-DOTS) in the study. The mean age of the total cohort was 33.2 years with an SD of ±14.4, and the range was from 15 to 90 years. The mean age for patients under FB-DOTS was 32.3 years with an SD of ±13.8, while for those under CB-DOTS, it was 35.1 years with an SD ±15.4. Most (47.7%) of the patients under FB-DOTS versus 45.2% of the patients under CB-DOTS had an age range of 24–44 years (tables 1 and 2).

The average money paid in relation to TB care was approximately 203 Ethiopian birr (ETB) for patients under FB-DOTS, and 101 ETB for patients under CB-DOTS (table 2).

Patient factors associated with choice of FB-DOTS versus CB-DOTS

Compared with patients who opted for FB-DOTS, patients who opted for CB-DOTS were more likely to be female (p=0.009) and illiterate (p<0.001) (table 1). HIV coinfected TB patients were less likely to opt for CB-DOTS (p<0.001). Patients under CB-DOTS were less likely to have a positive sputum smear result at the end of the treatment period compared with their counterparts (p=0.042). Patients under CB-DOTS were more likely to have a contact person registered with an address compared with patients under FB-DOTS (p<0.001). The majority (96.5%) of patients under FB-DOTS versus (97.2%) patients under CB-DOTS were new TB cases (table 3).

TB treatment outcomes among patients who opted for CB-DOTS versus those who opted for FB-DOTS

Patients who opted for CB-DOTS were more likely to be cured by 12% than those who opted for FB-DOTS (RR=1.12, 95% CI=0.96 to 1.30). Moreover, patients under CB-DOTS had a lesser risk of death (RR=0.93, 95% CI=0.49 to 1.77) and a lower risk of treatment failure (RR=0.86, 95% CI=0.22 to 3.30) than those under FB-DOTS. The treatment success rate for patients opting for CB-DOTS was 87.6%, whereas for those opting for FB-DOTS, it was 86.4% (tables 3 and 4).

In relation to absolute effect (risk difference), patients who were treated under CB-DOTS had approximately four additional cured cases per 100 patients compared with patients treated under FB-DOTS (RD=4.26%). There were approximately three less death cases per 1000 patients opting for CB-DOTS, compared with their counterparts. In general, there was approximately one excess favourable treatment outcome case per 100 patients who opted for CB-DOTS, compared with those who opted for FB-DOTS (RD=1.16%). However, the difference was not statistically significant, which means both patients under CB-DOTS and those under FB-DOTS had comparable favourable treatment outcomes (p=0.854) (tables 3 and 4).

DISCUSSION

The present study compares TB treatment outcomes and associated factors among a cohort of drug-sensitive patients attending CB-DOTS versus FB-DOTS in Southwest Ethiopia. Our finding shows that patients who were treated under CB-DOTS were more likely to be cured than those who were treated under FB-DOTS. This result is different from a previous study report in Ethiopia, whereby the cure rate was almost similar for both CB-DOTS and FB-DOTS performance (88.9% vs 88.2%).[19] The finding is also different from two other studies conducted in Tanzania, whereby the cure rate did not significantly differ between the two treatment approaches.[15 29] Conversely, the study result is comparable to a study reported from Mongolia, whereby patients who opted for CB-DOTS showed a higher cure rate than those who attended the FB-DOTS approach (89.9% vs 77.2%)[22] and a study in Namibia in which the cure rate was significantly increased with the implementation of CB-DOTS.[20] Our finding could be explained by the fact that the CB-DOTS option is more accessible to patients, as it is convenient and nearer to their home.[30] In addition, CB-DOTS is flexible in terms of time and place for patients to obtain DOTS service compared with the FB-DOTS approach. The discrepancies in the study findings may be related to differences in the study settings and study period, as well as study designs used in the respective studies.

Lower risk of death and treatment failure were observed for patients under CB-DOTS than those under FB-DOTS. These results are similar to findings from former studies in Ethiopia,[19] Nepal and Tanzania.[15 18] Some of the reasons for these findings could be related to a less severe TB disease among patients who chose CB-DOTS than those who chose FB-DOTS. It is common that most patients with TB comorbidities (TB/HIV or TB and diabetes or cardiovascular diseases) are treated at hospitals where FB-DOTS service is offered.[31 32] The risk of treatment failure and death among such patients is higher compared with patients attending CB-DOTS, who are often ambulatory cases with less severe TB disease.[33 34]

Table 1 Sociodemographic characteristics of the study participants under FB-DOTS and CB-DOTS

Variables		Total cohort (N=1161)	Patients under FB-DOTS (n=774) n (%)	Patients under CB-DOTS (n=387) n (%)	P value
Sex	Male	594	417 (53.9)	177 (45.7)	
	Female	567	357 (46.1)	210 (54.3)	0.009
Age in years	15–24	365	253 (32.7)	112 (28.9)	0.092
	25–44	544	369 (47.7)	175 (45.2)	
	45–64	202	120 (15.5)	82 (21.2)	
	>=65	50	32 (4.1)	18 (4.7)	
Marital status	Single	330	246 (31.8)	84 (21.7)	
	Married	765	476 (61.5)	291 (75.2)	<0.001
	Divorced	30	25 (3.2)	5 (1.3)	
	Widowed	34	27 (3.5)	7 (1.8)	
Educational level	Illiterate	459	268 (34.5)	191 (49.4)	
	Read and write only	98	61 (7.9)	37 (9.6)	<0.001
	Primary school	396	269 (34.8)	127 (32.8)	
	Secondary school	132	105 (13.6)	27 (6.9)	
	College/University	76	71 (9.2)	5 (1.3)	
Occupation	Farmer	739	430 (55.6)	309 (79.8)	
	Merchant	74	64 (8.3)	10 (2.6)	<0.001
	Government/non-government organisations employee	58	50 (6.5)	8 (2.1)	
	Daily labourer	88	81 (10.5)	7 (1.8)	
	Housewife	19	18 (2.3)	1	
	Student	142	102 (13.2)	40 (10.3)	
	Unemployed	41	29 (3.6)	12 (3.1)	
District/town administration	Goma	220	120 (15.5)	100 (25.8)	
	Jimma	157	157 (20.3)	0 (0.0)	<0.001
	Kersa	122	73 (9.4)	49 (12.7)	
	Limmu Kosa	144	90 (11.6)	54 (13.9)	
	Mana	97	64 (8.3)	33 (8.5)	
	Omo Nada	102	73 (9.4)	29 (7.5)	
	Seka Chekorsa	120	80 (10.3)	40 (10.3)	
	Sokoru	108	62 (8.1)	46 (11.9)	
	Tiro Afeta	91	55 (7.1)	36 (9.4)	

CB-DOTS, community-based directly observed treatment, short course; FB-DOTS, facility-based directly observed treatment, short course.

Furthermore, obtaining CB-DOTS services could be less stressful, more convenient and provide flexible time and the opportunity for negotiation between patients and HEWs or TB treatment supporters regarding a suitable time for getting the service by patients.[19 35] This type of flexibility could increase a patient's adherence to the treatment. On the contrary, attending FB-DOTS leads patients to travel long distances, which takes a lot of time. In addition, patients need to wait for some more time at health facilities to be seen by the attending clinician or health worker.[36] Thus, the long distance from a patient's home to a health facility, in combination with the time required for travel, might decrease patients' adherence to treatment.[30 35] CB-DOTS has the potential to solve problems related to the need for travelling every day to a health facility to receive DOTS services. Due to the long travel distance and waiting time at health facilities, the chance of skipping breakfast or lunch among patients is high.[29 36] Waiting for a long time on an empty stomach may expose patients to increased drug side effects, and thereby reduce their possibility to adhere to the treatment.[35] Furthermore, most patients under FB-DOTS are likely to have

Table 2 Community vs facility-based DOTS in relation to mean age and mean money paid

Variables		Mean	SD	SEM
Age in years	FB-DOTS (n=774)	32.28	13.84	0.50
	CB-DOTS (n=387)	35.10	15.37	0.78
Money paid in ETB	FB-DOTS	202.98	585.45	21.08
	CB-DOTS	100.91	359.22	18.26

CB-DOTS, community-based directly observed treatment, short course; ETB, Ethiopian birr; FB-DOTS, facility-based directly observed treatment, short course.

increased costs for transportation service, food and other expenses, than patients who chose CB-DOTS.[16] Based on former studies in Ethiopia, various healthcare providers were inspired by the effectiveness and acceptability of a community-based TB care approach for poor communities and households.[37 38] Compared with FB-DOTS, patients who opted for CB-DOTS were less likely to have a positive-sputum smear result at the end of the treatment period. This finding is different from a previous study report in Tanzania, which showed no significant difference in smear conversion rates between patients under CB-DOTS versus FB-DOTS (99.5% vs 99.5%).[15] Our findings may show an optimal implementation of CB-DOTS approach in the study area.

DOTS has been primarily undertaken in facility settings in many developing countries, including Ethiopia. FB-DOTS may lead to a high patient load in health facilities and require patients to travel daily to a health facility for their treatment. CB-DOTS could solve most of these problems. The findings from the present and previous studies conducted in Nigeria, Namibia, Mongolia, Tanzania and Ethiopia, where CB-DOTS was provided by community health workers,[39] community- based health workers,[20] community volunteers,[17] treatment supporters or family members,[15] and HEWs[27] proved that CB-DOTS was more or at least as effective as FB-DOTS. Such findings encourage the involvement of the community health workers or HEWs into TB treatment supervision. The CB-DOTS approach seems to be highly accepted by patients and has been shown to be cost-effective.[27 39]

Our findings suggest that HIV-infected patients with TB were less likely to be under CB-DOTS compared with their counterparts. This finding is similar to a previous study done in Ethiopia, in which patients with HIV positive who opted for FB-DOTS were higher than those who attended CB-DOTS.[19] However, the study result is different from a study reported from Nigeria, where the proportion of HIV-coinfected patients was similar in both DOTS approaches.[39] Our findings may be related to the observed high proportion of rural patients with TB who preferred CB-DOTS compared with the FB-DOTS approach.[19] In Ethiopia, the prevalence of HIV infection is lower in rural areas (0.4%) than urban areas (2.9%).[40]

In this study, sociodemographic factors were found to be linked to patients' choice between the two DOTS approaches. Patients who opted to CB-DOTS were more likely to be illiterate than patients who chose FB-DOTS. The reason for this might be linked to access inequalities in terms of educational opportunity for urban and rural communities in Ethiopia. Based on the 2016 national report, the school enrolment rate for children in urban areas was 57.93%, while it was only 3.36% for rural children.[41] Because a majority of patients who live in rural areas preferred CB-DOTS, most of them may not have gotten the chance for education and may have become illiterate.[41] Our study also revealed that women were more likely to opt to CB-DOTS than men. This finding is in contrast to a study result reported in Ethiopia, whereby a gender difference did not show a statistically significant difference between the two DOTS approaches.[19] Nonetheless, the study result is in line with the findings reported in Tanzania and Mongolia.[15 17] Our findings could be linked to the fact that Ethiopian women are the main caretakers for their families and are occupied with daily home activities. Thus, they may perceive the CB-DOTS option as interfering less with their daily activities, as it is more accessible than FB-DOTS.[27]

According to the WHO and the national TB control programme of Ethiopia, an increasing cure rate and a reducing death rate are among the primary objectives of TB treatment. To help achieve these objectives, anti-TB chemotherapy needs to be provided correctly and regularly taken by patients for the recommended period of time. The proper monitoring of DOTS implementation is crucial to confirm that all patients are adhering to the treatment and attaining a successful treatment outcome.[5] Ensuring that those patients who have received a quality TB treatment with DOTS, and who are able to take the entire course of treatment consistently and completely without interruption, is one of the basic components of TB programmes.[5 42] Health facilities (hospitals and health centres) and health workers alone cannot do all of the TB programme activities. To reach the Global TB elimination goal, more people in the community and other organisations need to be involved in TB care. TB treatment requires taking several types of drugs regularly for the course of several months. This could cause challenges, such as developing drug side effects, lost to follow-up and the stigma of being patients with TB. Therefore, the involvement of HEWs and TB treatment supporters at the community level may help to solve these difficulties.[5 42] Furthermore, improving access to DOTS services is one of the objectives of community TB care, with community-based DOTS and treatment follow-up being one of its components.[5] Studies in Tanzania and Mongolia show that the TB treatment success rate was higher for patients under CB-DOTS than patients under FB-DOTS.[15 17 43] Based on the combined results of all cohort studies and randomised controlled trials,

Table 3 Association of type of TB, sputum smear conversion, HIV/TB coinfection and treatment outcome with type of DOTS approaches among the study participants

Variables		Total cohort (N=1161)	Patients under FB-DOTS (n=774) n (%)	Patients under CB-DOTS (n=387) n (%)	P value
TB classification	Smear-positive PTB	567	364 (47.0)	203 (52.5)	0.097
	Smear-negative PTB	251	166 (21.5)	85 (22.0)	
	Extrapulmonary TB	343	244 (31.5)	99 (25.5)	
TB treatment category	New	1123	747 (96.5)	376 (97.2)	0.560
	Retreatment	38	27 (3.5)	11 (2.8)	
HIV status	Reactive	38	31 (4.0)	7 (1.8)	<0.001
	Non-reactive	1040	669 (86.4)	371 (95.9)	
	Unknown	83	74 (9.6)	9 (2.3)	
Contact person registered with address	Yes	1104	722 (93.3)	382 (98.7)	<0.001
	No	57	52 (6.7)	5 (1.3)	
Sputum result at the end of second or third month	Negative	493	318 (41.1)	175 (45.2)	0.216*
	Positive	16	11 (1.4)	5 (1.3)	
	Not done	58	34 (4.4)	24 (6.2)	
	Not applicable	594	411 (53.1)	183 (47.3)	
Sputum result at the end fifth month	Negative	434	280 (36.2)	154 (39.8)	0.150*
	Positive	5	3 (0.4)	2 (0.6)	
	Not done	120	73 (9.4)	47 (12.1)	
	Not applicable	602	418 (54.0)	184 (47.5)	
Sputum result at the end the treatment	Negative	399	260 (33.6)	139 (35.9)	0.042*
	Positive	3	3 (0.4)	0 (0.00)	
	Not done	156	92 (11.9)	64 (16.5)	
	Not applicable	603	419 (54.1)	184 (47.6)	
TB treatment outcomes	Cured	435	279 (36.1)	156 (40.3)	0.756*
	Treatment completed	573	390 (50.4)	183 (47.3)	
	Died	41	28 (3.6)	13 (3.4)	
	Treatment failure	10	7 (0.8)	3 (0.7)	
	Lost to follow-up	15	10 (1.3)	5 (1.3)	
	Transferred out	34	26 (3.4)	8 (2.1)	
	Not recorded	53	34 (4.4)	19 (4.9)	
TB treatment outcome category	Favourable outcome	1008	669 (86.4)	339 (87.6)	0.854
	Unfavourable outcome	66	45 (5.8)	21 (5.4)	
	Unknown outcome	87	60 (7.8)	27 (7.0)	

*Fisher's exact test was applied.
CB-DOTS, community-based directly observed treatment, short course ; FB-DOTS, facility-based directly observed treatment, short course ; TB, tuberculosis.

systematic reviews and meta-analysis of studies conducted in all high, middle and low-income countries, CB-DOTS provides a successful TB treatment outcome compared with clinic-based DOTS for all pulmonary TB cases. This is because of the cost-effectiveness of CB-DOTS, especially for low-income countries, and its acceptance by most community members.[44] Thus, findings from the present study and previous studies indicated that CB-DOTS is an effective approach to decentralise TB treatment services for a majority of the community.

The present study has several strengths and some limitations. The strengths include use of the strongest observational study design (prospective cohort study design); the risk of recall bias is lower as the data were collected in a prospective manner. In addition, the study has a relatively large sample size and has applied a relative risk

Table 4 Comparison of TB treatment outcomes among patients who opted for CB-DOTS with those opted for FB-DOTS

TB treatment outcomes	CB-DOTS (%)	FB-DOTS (%)	Risk difference (%)	Risk ratio (RR)	95% CI of RR
Cured (1)	40.31	36.05	4.26	1.12	0.96 to 1.30
Treatment completed (2)	47.29	50.39	−3.10	0.94	0.83 to 1.06
Died (3)	3.36	3.62	−0.26	0.93	0.49 to 1.77
Treatment failure (4)	0.78	0.90	−0.13	0.86	0.22 to 3.30
Lost to follow-up (5)	1.29	1.29	0.00	1.00	0.34 to 2.91
Transferred out (6)	2.07	3.36	−1.29	0.62	0.28 to 1.35
Not recorded (7)	4.91	4.39	0.52	1.12	0.65 to 1.93
Favourable outcome (1+2)	87.60	86.43	1.16	1.01	0.97 to 1.06
Unfavourable outcome (3+4+5)	5.43	5.81	−0.39	0.93	0.56 to 1.54
Unknown outcome (6+7)	6.98	7.75	−0.78	0.90	0.58 to 1.39

CB-DOTS, community-based directly observed treatment, short course; FB-DOTS, facility-based directly observed treatment, short course; TB, tuberculosis.

and RD to interpret the findings. The limitation of the study is that our findings could be prone to selection bias because of the patients were not randomly assigned but opted to FB-DOTS and CB-DOTS. We have tried to minimise this by consecutive enrolment of patients in both groups. The selection bias could also happen due to the observed unknown outcomes of transferred out and not recorded (attrition) TB cases. However, since the number of such cases is very low, the effect of selection bias may not significantly affect the interpretation of our findings.

CONCLUSION

Compared with the FB-DOTS approach, the CB-DOTS approach showed a better performance in terms of improving cure rate, lowering the treatment failure rate and improving the sputum conversion rate. These attributes of CB-DOTS make it to be considered as an effective and alternative approach of implementing DOTS in our setting and other resource-limited settings. Our findings show the need for scaling up and a further decentralisation of CB-DOTS approach particularly in the study area generally in Ethiopia to help improve access to TB treatment service for the rural community.

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