Abstract

Background: One of the main strategies to control tuberculosis (TB) is to find and treat people with active disease. Unfortunately, the case detection rates remain low in many countries. Thus, we need interventions to find and treat sufficient number of patients to control TB. We investigated whether involving health extension workers (HEWs: trained community health workers) in TB control improved smear-positive case detection and treatment success rates in southern Ethiopia.

Methodology/Principal Finding: We carried out a community-randomized trial in southern Ethiopia from September 2006 to April 2008. Fifty-one kebeles (with a total population of 296, 811) were randomly allocated to intervention and control groups. We trained HEWs in the intervention kebeles on how to identify suspects, collect sputum, and provide directly observed treatment. The HEWs in the intervention kebeles advised people with productive cough of 2 weeks or more duration to attend the health posts. Two hundred and thirty smear-positive patients were identified from the intervention and 88 patients from the control kebeles. The mean case detection rate was higher in the intervention than in the control kebeles (122.2% vs 69.4%, p<0.001). In addition, more females patients were identified in the intervention kebeles (149.0 vs 91.6, p<0.001). The mean treatment success rate was higher in the intervention than in the control kebeles (89.3% vs 83.1%, p = 0.012) and more for females patients (89.8% vs 81.3%, p = 0.05).

Conclusions/Significance: The involvement of HEWs in sputum collection and treatment improved smear-positive case detection and treatment success rate, possibly because of an improved service access. This could be applied in settings with low health service coverage and a shortage of health workers.

Trial Registration: ClinicalTrials.gov NCT00803322

Introduction

Each year, more than nine million new cases of tuberculosis (TB) occur and about two million people die of TB. As a result of the interaction between TB and human immunodeficiency virus (HIV) infection, TB incidence is rising in sub-Saharan Africa. It has also led to an increase in drug resistance and poor treatment outcomes [1].

Information from South India shows that directly observed treatment, short-course (DOTS) reduces TB incidence [2]. However, in many other countries, the case detection rates are too low to reduce the incidence of TB. The main obstacles are low health service coverage, shortage of health workers and poor programme performance [3].

Epidemiological models show that active case finding might reduce TB incidence and avoid TB deaths. Although active case finding is effective in contact tracing on a small scale, high cost and poor treatment adherence limit its use [4,5]. We therefore need alternative methods to improve TB case finding.

In Ethiopia, the National TB and Leprosy Control Programme (NTLCP) started to implement DOTS in 1992. NTLCP is responsible for policy formulation, resource mobilisation, monitoring and evaluation. Under the NTLCP, three levels of function exist in the regions, zones and districts for coordinating TB control activities. TB control is also integrated into the general service at health facilities. The district TB programme coordinator is responsible for supervision of the general health workers involved in patient care in hospitals and health centres. However, community DOTS was not started.

Ethiopia has the seventh highest TB burden in the world. In 2006, the estimated number of new smear-positive cases was 168 per 105 for Ethiopia. Unfortunately, the case detection rate was 27%, far below the target [6]. In 2004, the government of Ethiopia launched a community-based initiative to provide essential health services to the community under a health extension programme
rifampicin/isoniazid for 4 months. Follow-up sputum smear
continuation phase, ethambutol/isoniazid was replaced by
months with ethambutol and isoniazid. For children, in the
pyrazinamide followed by continuation phase treatment for 6
phase treatment with ethambutol, rifampicin, isoniazid and
for new smear-positive cases consisted of two months intensive
treatment for eight consecutive weeks after receiving treatment for at least 4
weeks was reported as a defaulter. A patient who was transferred
to another district after receiving treatment for at least 4 weeks and
whose treatment outcome was not reported to the referring district
was reported as transferred out. A patient who died while on
treatment was reported as dead irrespective of the cause of death

Methods
The protocol for this trial and supporting CONSORT checklist
are available as supporting information; see Checklist S1 and
Protocol S1.

Study area and population
This study was conducted in Dale and Wonsho, rural districts of
Sidama zone in southern Ethiopia from September 2006 to April
2008. There were 51 kebeles (lowest administrative units) in the
two districts. Fifty-five per cent of the population live within two-hour
walking distance of health facilities. There were 21 health
posts (operational unit for HEWs), two health stations, two nucleus
health centres (health stations upgrading to health centres) and one
health centre. Three health facilities (one health centre and two
health stations) conducted sputum microscopy, and DOT was
provided in the health centre, nucleus health centres and health
stations. None of the health posts provide DOT.

Health service and HEP
The Government of Ethiopia has a four-tier health service, and
the lowest level is a primary health care unit (a health centre and
five satellite health posts). On average, a health post serves a kebele
with 5000 people. The health policy focuses on provision of
preventive and promotive health care to the population under the
HEP, which involves prevention and control of diseases, including
TB. The local health authorities in consultation with kebele
leaders select two female residents, who have completed tenth
grade, from each kebele. The women receive training for 1 year
and are placed as HEWs in their respective kebele. They receive a
salary from the government and they are accountable to the health
centre [7].

Participants
TB case finding and treatment outcome
Case finding. TB suspects, who had cough for two weeks or
more, were referred for further investigations. A smear-positive
pulmonary TB case was defined by two positive sputum smears or
one positive smear and x-ray findings consistent with active TB.

Treatment regimen and duration. The treatment regimen
for new smear-positive cases consisted of two months intensive
phase treatment with ethambutol, rifampicin, isoniazid and
pyrazinamide followed by continuation phase treatment for 6
months with ethambutol and isoniazid. For children, in the
continuation phase, ethambutol/isoniazid was replaced by
rifampicin/isoniazid for 4 months. Follow-up sputum smear
examination was done at the end of 2, 5 and 7 months treatment.

Treatment outcome. A patient with at least two negative
smears including that at 7 months was reported as cured. A patient
who finished the treatment but did not have the 7-month smear
result was reported as treatment completed. If a patient remained
or became smear-positive at the end of 5 months or later, he/she
was reported as treatment failure. A patient who missed treatment
for eight consecutive weeks after receiving treatment for at least 4
weeks was reported as a defaulter. A patient who was transferred
to another district after receiving treatment for at least 4 weeks and
whose treatment outcome was not reported to the referring district
was reported as transferred out. A patient who died while on

Ethics. We obtained ethical clearance from the Ethical
Review Committee of the Regional Health Bureau in southern
Ethiopia. We obtained permission from TB programme managers
and kebele leaders after discussing with them community-based
TB care. TB patients were enrolled after giving informed
consent after explaining the aim of the study and the right
to refuse or to withdraw from the study. HIV testing was not
offered to TB patients because of the unavailability of HIV testing
and treatment in the study area at the time the study was
conducted.

The intervention
Training on how to identify TB suspects and administer
DOT. We trained health workers, laboratory technicians and
HEWs for 2 days. The training focused on symptoms and
transmission of TB, how to identify TB suspects, how to collect,
label, store and transport sputum specimens, administer DOT,
and follow patients during treatment. The messages and the
content of our training were similar to the curriculum of training
HEWs. HEWs, in the intervention kebeles, received on job
training about how to collect sputum samples and support patients
to adhere to treatment. HEWs collected sputum specimens once a
month. An ice box was used to keep the sputum specimens in the
health post and during their transportation on foot to diagnostic
units. The intervention included sputum collection and providing
DOT.

During health education sessions at health posts, HEWs
informed people living in the kebele about TB and advised
them to come to a health post if they had productive cough of
2 weeks or more duration. TB suspects who came to the health
posts were told about community-based TB care. HEWs
collected spot-morning-spot sputum specimens, and labelled and
transported them to the diagnostic units every month for
examination for acid-fast bacilli by direct microscopy. Smear-
positive patients in the intervention kebeles received standard
DOTS under the direct observation of HEWs. TB patients visited
health posts daily during the intensive phase and once a month in
the continuation phase.

Control kebeles
Identifying TB suspects and DOT administration. HEWs
in the control kebeles did not receive on job training about
how to collect sputum samples and how to support patients to
adhere to treatment. However, they provided health services,
including health education about TB, to the people living in their
kebeles. TB suspects presented themselves to diagnostic units.
However, the health workers from health facilities were trained as
they provided the service to intervention and control kebeles.
Smear-positive patients in the control kebeles received standard
DOTS were treated under the direct observation of general health
workers at health centres. TB patients visited health centres and
health stations daily during the intensive phase and once a month in
the continuation phase.
Objective. The objective of the study was to investigate whether involving HEWs in TB control improves the case detection and treatment success rate in southern Ethiopia.

Outcome variables

Case detection rate. The number of new smear-positive cases detected divided by the estimated number of incident smear-positive cases, expressed as a percentage.

Treatment success rate. Cure or treatment completion rate was calculated as the number of patients cured or treatment completed divided by the total number of patients reported expressed as a percentage. Treatment success rate (TSR) was the sum of cure and treatment completion rate.

Sample size calculation

The sample size was calculated based on a difference in effect size of 30%, power of 80%, 95% significance level, and coefficient of variation of 0.25. Based on the average annual smear-positive case detection rate (CDR) of 41% (unpublished review of three years of DOTS in the study area; the national CDR was 29%), we calculated the number of clusters required per group with 30% contingency. Based on the principle of allocating an unequal number of clusters for randomization [9], we allocated 30 kebeles to the intervention and 21 kebeles to the control group.

Randomization: generation and implementation

Before starting the intervention, we explained the aim of the study to the programme coordinators of the districts and health facilities. After we obtained their consent, we used the list of kebeles in the two districts and randomly allocated them to intervention and control groups using a table of random numbers (Figure 1).

Blinding

Neither the general health workers nor TB programme managers were blinded to the allocation. Although we did not blind the laboratory technicians, they were not informed whether the sputum specimens were from the intervention or control kebeles.

Data collection

TB case finding and treatment outcome data were collected from TB registers at health facilities and districts. The information collected included date, age, sex, address, TB classification, smear results and treatment outcome using the official reporting system of the NTLCP.

Statistical analysis

We used Microsoft Excel and SPSS for Windows 14 (SPSS Inc, Chicago, USA) for data entry and analysis. We analysed the data on the basis that all TB patients in the intervention kebeles intended to use community-based case finding and treatment. We described the patients by age, sex, season and treatment outcome. We calculated summary values of case detection and treatment success rates for each kebele. We used independent sample t test, weighted by cluster size, to compare the mean CDR and TSR using kebele as a unit of analysis. This is robust for cluster level analysis of binary outcomes [9]. The intra-cluster correlation coefficient was calculated using one-way analysis of variance [10,11].

Figure 1. Map of the study area in Sidama zone in south Ethiopia. Shaded area - Intervention kebeles. White area with black box - Control kebeles. Red box - Health centers and health stations. doi:10.1371/journal.pone.0005443.g001
Results

Participants flow, recruitment and number analysed

In a year, the number of pulmonary TB suspects examined was 723 from intervention and 328 from control kebeles. Among these, 230 and 88 smear-positive patients were identified from the intervention and control kebeles, respectively. All the smear-positive patients were analyzed (figure 2).

Baseline data

Of the 51 kebeles included in the study, 30 were intervention kebeles with a population of 178,138 and mean kebele population of 5938 people, while 21 were control kebeles with a population of 118,673 and mean kebele population of 5651 people. 53.4% (123/230) of patients from intervention and 42% (37/88) from control kebeles were female (Table 1).

Outcomes and estimation

Patients from control kebeles were younger than those from intervention kebeles (26 vs 29 years, p = 0.011). The mean CDR was higher in intervention kebeles (122.2% vs 69.4%, p<0.001) and for female patients (149.0% vs 91.6%, p<0.001) (Table 2).

Among the 230 patients from the intervention kebeles, 172 (74.8%) were cured, 33 (14.3%) completed treatment, eight (3.5%) died, two (0.9%) had treatment failure, 15 (6.5%) defaulted and no patient was transferred out. Of the 88 patients in the control kebeles, 60 (68.2%) were cured, 14 (15.9%) completed treatment, two (2.3%) died, nine (10.2%) defaulted, three (3.4%) were transferred out, and none had treatment failure (Figure 2). The mean TSR was higher in the intervention than control kebeles (89.3% vs 83.1%, p = 0.012). Similarly, the mean TSR for females was higher in the intervention than control kebeles (89.8 vs 81.3%, p = 0.05) as shown in Table 3.

Discussion

Interpretation and overall evidences

We showed that involving HEWs in TB control improved the smear-positive CDR and TSR in the intervention kebeles. Both the CDR and TSR were higher for female patients in the intervention kebeles.

DOTS uses passive case finding to detect TB cases, through health education and tracing contacts of index cases [6]. However, decades after implementing the strategy, smear-positive CDR has remained far below the target. In particular, the trend in CDR was consistently low for women, to the extent that passive case finding seems to favour men [12,13,14,15]. The reasons are low health service coverage, shortage of trained health workers and poor health seeking behaviour [3,16,17]. Alternatively the advantage of active case finding in improving case detection is limited due to the associated high cost in resource-constrained settings [5,18]. Moreover, neither rapid community surveys [19,20] nor community DOT [21,22] seems to improve CDR.

In our study, community-based case finding significantly improved the CDR for all age groups more for women than for men. The increase in CDR was lower for children compared to those aged 15 years and above. This could be explained by an inability to produce sputum specimens, low disease burden, or the low number of children enrolled in the study [23]. Patients from the intervention kebeles were older than those from control kebeles for both sexes. This may have been caused by poor access,
poverty, and low health seeking behaviour that might have hindered them from coming to the health facilities.

Routine surveillance reports have repeatedly shown higher CDRs for men than women [24]. However, in our study, the CDR was higher for females in the intervention group. This could be explained by the improved geographic and socioeconomic access to the service as sputum collection was done in the intervention kebeles. As expected, the number of TB cases detected was greater than that estimated. This may have resulted from underestimation of TB incidence as reported from Myanmar [8], the backlog of TB cases that were not reached by the health service [19,24], or underestimation of the population in the study area. Further study is required to determine the magnitude of TB in the community.

Studies have shown that using different treatment supervisors for DOT has improved the TSR for passively detected TB cases [25,26,27]. However, poor treatment adherence remains a challenge for patients identified by active and enhanced case finding [28]. In our study, decentralisation of the treatment to the kebele improved the TSR for TB patients detected by enhanced case finding. Similar to CDR, the TSR was higher for women aged above 14 years because of improved access created by DOT provision in the kebele.

Our findings suggest seasonal variation in CDR and TSR. In the intervention kebeles, the rates peaked in spring (September–November) and winter (December–February) possibly as a result of the economic gain from the harvest in spring. However, in the intervention and control kebeles, the rates were low in autumn (March–May) when farmers prepare for the farming season, and this was followed by another peak in early summer (June–August). Previous studies have suggested that overcrowding and staying indoors during the rainy season favour transmission of TB, which results in greater seasonal variation in children [29,30,31]. In our setting, further study is required to establish more about the seasonal variation and its associated factors.

Although cluster randomized controlled trials are considered valid studies, their methodological limitations should be addressed. The baseline demographic and clinical characteristics were similar in the two groups. We kept potential for bias to a minimum by comparing and analysing information from complementary

### Table 1. The baseline characteristics of the study area and smear-positive tuberculosis cases of southern Ethiopia 2006/07.

| Variable | Intervention | Control |
|----------|--------------|---------|
| Communities | | |
| Number of clusters | 30 | 21 |
| Study population | 178,138 | 118,673 |
| Male | 91,206 | 63,464 |
| Female | 86,932 | 55,209 |
| Mean kebele population | 5938 | 5651 |
| Male | 3040 | 3022 |
| Female | 2898 | 2629 |

Smeared-positive TB patients

| Variable | Intervention | Control |
|----------|--------------|---------|
| Mean age (SD) | 29 (13) | 26 (11) |
| Male | 29 (13) | 26 (13) |
| Female | 29 (13) | 24 (8) |
| Number (%) of TB cases by sex | | |
| Male | 107 (46.6) | 51 (58) |
| Female | 123 (53.4) | 37 (42) |
| Number (%) of TB cases by age (in years) | | |
| ≤14 | 23 (10.0) | 9 (10.3) |
| 15–24 | 63 (27.4) | 34 (39.1) |
| 25–34 | 72 (31.3) | 28 (32.2) |
| 35–44 | 58 (25.2) | 13 (14.9) |
| 45–54 | 14 (6.1) | 3 (3.4) |
| Number (%) of TB cases by season | | |
| Spring | 55 (23.9) | 29 (33.0) |
| Winter | 69 (30.0) | 18 (20.4) |
| Autumn | 45 (19.6) | 22 (25.0) |
| Summer | 61 (26.5) | 19 (21.6) |

DOI:10.1371/journal.pone.0005443.t001

### Table 2. Case detection rates of smear-positive tuberculosis cases in southern Ethiopia, 2006/07.

| Variable | Intervention | Control | Mean difference (95%CI) | P - value | ICC * |
|----------|--------------|---------|-------------------------|----------|-------|
| CDR (%) | 122.2 | 69.4 | 52.8 (39.8–65.4) | <0.001 | 0.00052 |
| Male | 112.6 | 86.0 | 26.6 (7.4–46.0) | 0.008 | 0.00039 |
| Female | 149.0 | 91.6 | 57.4 (31.9–82.9) | <0.001 | 0.00073 |
| For ≤14 years (%) | 82.9 | 31.9 | 50.9 (26.8–75.2) | <0.001 | 0.00049 |
| Male | 69.8 | 44.1 | 25.6 (5.4–45.9) | 0.018 | 0.00024 |
| Female | 115.6 | 45.5 | 70.1 (29.5–110.6) | 0.002 | 0.00065 |
| For >14 years (%) | 193.7 | 118.2 | 75.5 (55.6–95.5) | <0.001 | 0.00060 |
| Male | 184.7 | 149.4 | 35.3 (4.2–66.5) | 0.027 | 0.00038 |
| Female | 235.9 | 170.9 | 64.9 (15.6–114.4) | 0.011 | 0.00098 |

By season (%)

| Variable | Intervention | Control | Mean difference (95%CI) | P - value | ICC * |
|----------|--------------|---------|-------------------------|----------|-------|
| Spring | 227.1 | 104.2 | 122.9 (70.9–174.9) | <0.001 | 0.00136 |
| Winter | 138.5 | 80.8 | 57.7 (36.2–79.2) | <0.001 | 0.00013 |
| Autumn | 136.2 | 114.2 | 21.8 (1.9–41.2) | 0.294 | 0.00061 |
| Summer | 169.5 | 87.4 | 82.0 (50.9–113.1) | <0.001 | 0.00069 |

*ICC - intraclass correlation coefficient.

*CDR - case detection rate.

DOI:10.1371/journal.pone.0005443.t002
Generalizability

The results of our study could be applied in settings with low health service coverage (low DOTS coverage and limited number of TB laboratories), where HEWs have the first contact with the people to provide health education, and collect and transport sputum specimens to diagnostic units. This makes the service patient-centred, to improve case finding and treatment adherence [22]. Our study area is a densely populated agrarian community, typical of the rural population on the Ethiopian highlands. It could also be applied in areas with a shortage of health workers, especially laboratory technicians, with or without adequate health service coverage. The findings of the study were disseminated to managers of TB programmes in the southern region and at national level. We believe our findings are relevant for policy formulation on community TB care in Ethiopia. With limited health care coverage and shortage of health workers, similar to that in many developing countries, we believe that our findings are applicable to similar settings.

In conclusion, involving HEWs in TB control improved the CDR and TSR for smear-positive patients and females in particular. It could be used as an option to improve the trend in low CDR and provide patient-centred services in high-burden countries. However, the cost-effectiveness of enhanced case finding and treatment outcome needs further study.

Supporting Information

Checklist S1  CONSORT Checklist
Found at: doi:10.1371/journal.pone.0005443.s001  (0.06 MB DOC)

Protocol S1  Trial Protocol
Found at: doi:10.1371/journal.pone.0005443.s002  (0.27 MB DOC)

Acknowledgments

We are grateful to Regional Health Bureau, Sidama Zone Health Department, Dale and Wonsho Woreda Health Office and TB programme coordinators for their technical and material support. We are grateful to health workers and laboratory technicians in the health facilities and HEWs in the intervention kebeles. We are also thankful to TB patients who voluntarily participated in the study. Special thanks go to Dr. Estifanos Biru for his technical support and provision of resources for data analysis.

Author Contributions

Conceived and designed the experiments: DGD BL. Performed the experiments: DGD. Analyzed the data: DGD BL. Wrote the paper: DGD BL. Supervised the conduct of the experiment: BL.

Table 3. Treatment success rates of smear-positive tuberculosis cases in southern Ethiopia, 2006/07.

| Variable | Intervention | Control | Mean difference (95%CI) | P - value | ICC* |
|----------|--------------|---------|------------------------|-----------|------|
| TSR for all (%) | 89.3 | 83.1 | 6.2 (1.4–10.9) | 0.012 | 0.00052 |
| Male | 87.0 | 84.3 | 2.7 (–4.8–0.2) | 0.471 | 0.00117 |
| Female | 90.9 | 81.1 | 9.9 (1.6–18.2) | 0.202 | 0.00035 |
| For ≤14 years (%) | 91.3 | 88.9 | 2.4 (–17.4–22.2) | 0.805 | 0.00028 |
| Male | 87.5 | 75.0 | 12.5 (–64.6–89.6) | 0.657 | 0.00003 |
| Female | 93.3 | 100 | –6.7 (–31.4–18.0) | 0.578 | 0.00017 |
| For >14 years (%) | 88.9 | 80.8 | 8.2 (2.6–13.8) | 0.005 | 0.00029 |
| Male | 88.0 | 80.4 | 7.6 (–1.5–16.6) | 0.101 | 0.00009 |
| Female | 89.8 | 81.3 | 8.6 (–0.1–17.3) | 0.05 | 0.00019 |
| By season (%) | | | | | |
| Spring | 89.1 | 89.6 | –0.6 (–10.0–8.9) | 0.906 | 0.00024 |
| Winter | 84.1 | 93.8 | –9.9 (–20.9–1.6) | 0.090 | 0.00004 |
| Autumn | 73.3 | 68.2 | 5.2 (–15.4–25.8) | 0.619 | 0.00013 |
| Summer | 83.6 | 89.5 | –5.9 (–22.4–10.7) | 0.470 | 0.00018 |

*ICC - intraclass correlation coefficient.
1 treatment success rate.

doi:10.1371/journal.pone.0005443.t003
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