

In-home Intervention Improves Outcomes of Tuberculosis Patients in Zimbabwe, Africa



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Introduction

- Tuberculosis (TB) is a curable infection that continues to kill 5,000 people worldwide every day, especially in developing countries such as those in sub-Saharan Africa.
- Patient non-adherence secondary to poverty and lack of education and transportation (distance to treatment facility) contribute to the mortality rate from TB and the prevalence of TB in Zimbabwe, Africa.
- In recent years, Partners in Health launched a program in Haiti with in-home local health workers to ensure patients are taking their medications.
- In Zimbabwe, a developing country with a 70% poverty rate and on the World Health Organization's Stop TB list, the slow decline in mortality rate from TB is a global health burden warranting intervention.

Hypothesis

- In-home visits by local health workers to supervise patient medication adherence to anti-TB medications via direct observational therapy (DOT) will increase the number of TB cases cured after an 8-month period.

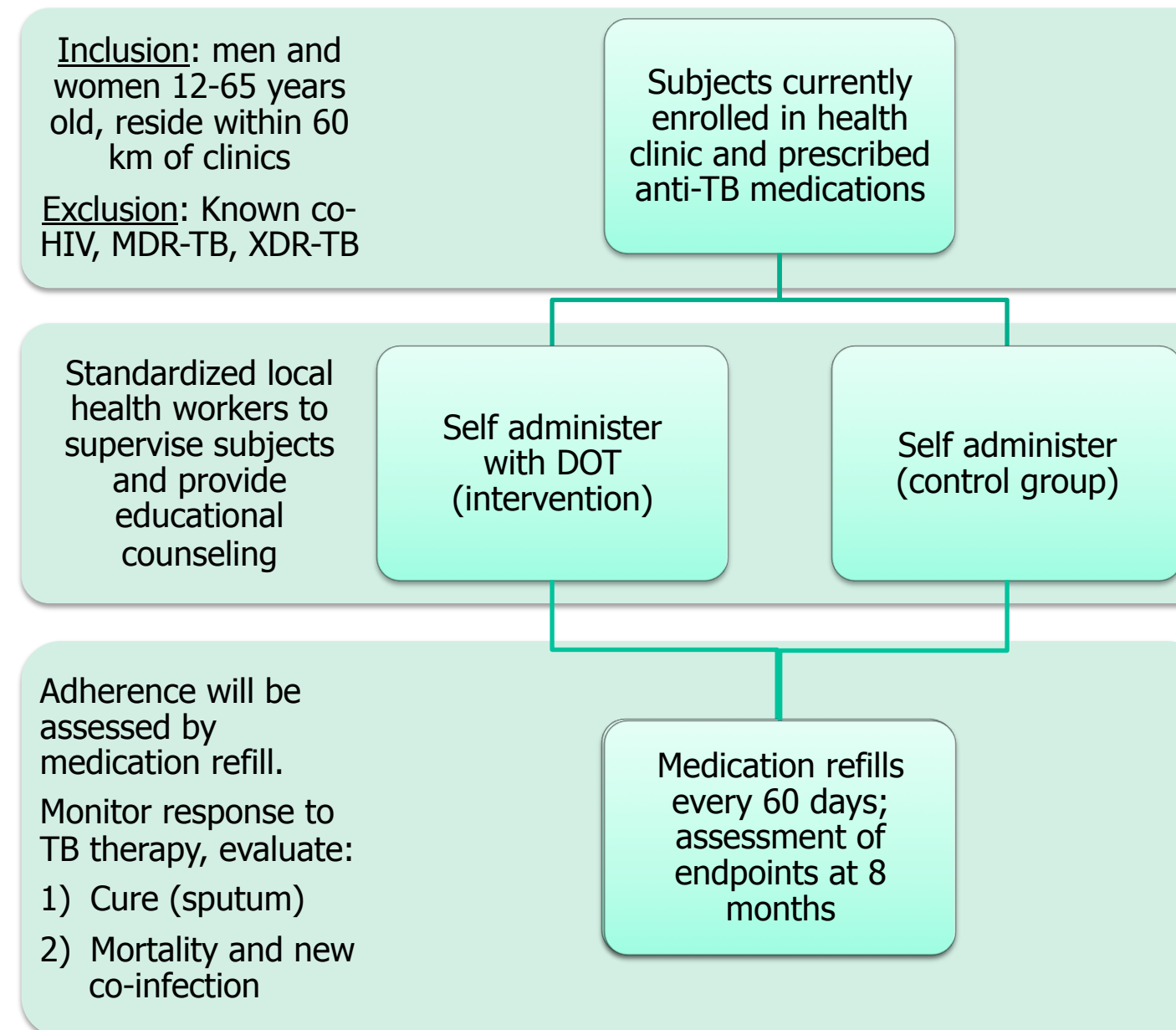
Specific Aims

- To determine the effectiveness of supervised anti-TB medication administration, by trained local health workers, on medication adherence in Zimbabwe, Africa.
- To assess the impact of DOT with self-administration of anti-TB medication on TB cure after an 8-month period as a primary endpoint.
- To determine and compare mortality and incidence of new HIV-TB co-infection between the two groups of patients after an 8-month period as secondary endpoints.

Methods

This study will be a prospective, randomized controlled trial:

- Control group: self-administration of anti-TB medications
- Intervention: self-administration of anti-TB medications with DOT from local health workers



Data Analysis

- Normal distribution will be assumed for all data generated.
- Medication adherence will be measured using the ratio of the number of days with medication to total number of study days. Total number of refills during the study period will be used to calculate this ratio. The mean ratio for each group will be compared using a Student's t-test.
- The impact of DOT on TB cure and mortality will be assessed using a multivariate logistic regression model that accounts for the covariates: age, gender, race, income, HIV status, and a co-morbidities score.
- A sample size of 519 patients will be necessary to detect a 30% difference in TB cure between the two groups with a 80% power of test and an alpha level of 0.05.

Conclusions

- We expect to see at least a 30% increase in the number of TB cases that are cured when patients receive DOT as compared to the control group not receiving DOT after 8 months.
- We also expect to see improvement in TB medication adherence in patients receiving DOT as compared to control group after 8 months.
- However, there may be no measureable difference in mortality between the two groups after 8 months.

Limitations and Future Direction

- **Limitations:** Only patients without known co-HIV, MDR-TB, and XDR-TB infections will be studied (limited to a focus group).
- **Future Direction:** Establish long term efficacy over a five year intervention of DOT in Zimbabwe, to assess the trend in mortality rate.

