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Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol

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Title: Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol

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Key words: Tuberculosis (TB), TB screening, referral, sexual minority, health facility based TB screening

ABSTRACT

Introduction

Although Bangladesh has a generalized Tuberculosis (TB) epidemic, the HIV prevalence is low among general populations, and 3.9% among key populations (KPs). Despite the high posibility of HIV-TB co-infection, scientifically tested approaches for increasing TB case detection among sexual minority people are yet to be developed and implemented in Bangladesh. Such approaches could foster service delivery linkages between communities and the government health system. Findings of this experimental research are likely to provide new insights for program managers and policy planners for adopting a similar approach in order to enhance TB referral, thus ultimately increasing TB case detections and reducing the likelihood of TB-related mortalities and morbidities, irrespective of HIV status.

Methods and analysis

This operational research will follow a quasi-experimental design, applying both qualitative and quantitative methods, in two drop-in centers (DICs) in three phases. Phase 1 will encompass baseline data collection and development of a community-based TB screening approach. In phase 2, the newly developed intervention will be implemented, followed by end-line data collection in phase 3. Qualitative data collection will be continued throughout all phases. The baseline and end-line data will be compared both in the intervention and comparison areas to measure the impact of the intervention.

Ethics and dissemination:

Ethical approval was obtained from the Institutional Review Board (IRB) of International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). The findings will be disseminated through diverse scientific forums including peer-reviewed journals, presentation at conferences and among the policy makers for policy implication. The study started in January 2019 and will continue until June 2020.

Article summary

Strengths and limitations of this study

- The study adopts a mixed method design, which will validate results from quantitative and qualitative strands in order to explicitly understand the research problem.
- The study will use a community-based approach, thus ensuring the involvement of the sexual minority population at all phases of the study to ensure the internal validity of the findings.
- This study will develop an approach of detecting TB cases for the first time among sexual minority people through an integrated model, which will harness service delivery linkages with the government health system for achieving sustainability.
- This study will follow a quasi-experimental design rather than a randomized controlled trial.
- This study will be conducted in two service centers only, therefore the results obtained from this study cannot be generalized for the whole sexual minority population. Nonetheless, the approach may help in informing the policy makers.

INTRODUCTION

Human immunodeficiency virus (HIV) epidemic poses as an impediment to the effective control of tuberculosis (TB) worldwide.[1] Clinical evidence has alluded to a causal relationship between TB and HIV.[2] HIV is considered as the most predominant risk factor for the development of *Mycobacterium tuberculosis* (MTB) infection to TB disease.[3] Likewise, TB infection accelerates the progression of HIV infection to Acquired Immunodeficiency Syndrome (AIDS), reduces survival and even predisposes the infected individual to premature death.[4] On the global scale, an estimated 10.0 million (range 9.0–11.1 million) people were newly diagnosed with TB in 2017, which also constituted to 9% (around one million) of the People Living with HIV (PLHIV).[5] An estimated 1.3 million TB deaths ensued across the globe in 2017, in addition to 300,000 (range 266,000–335,000) deaths from TB among PLHIV.[5] This is because PLHIV are 29 (26-31) times more likely to contract TB than those who are not living with HIV.[6] In this context, TB is considered as the leading preventable cause of death especially among PLHIV.[7]

Bangladesh is a country with generalized TB epidemic, though it has a low HIV prevalence of less than 0.01% among general populations. However, HIV surveillance findings demonstrated that 3.9% of the key populations (KPs) at risk of HIV contracted HIV infection.[8] Between 1999 to 2002, a study conducted by International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) among 958 patients to determine HIV prevalence among patients with TB in Dhaka showed that the estimated TB/HIV co-infection was 0.1%.[9] Nonetheless, recent data reported by Government of Bangladesh (GoB) from 2009 to 2014 showed that merely 1% of the registered TB patients in the country were documented to have HIV.[10] In 2017, the prevalence of HIV among the diagnosed TB patients (n=3,917) was 0.36% whereas approximately 16% of the PLHIV (n=559) were tested positive for TB, thus illustrating bidirectional upward trends in TB/HIV co-infection rates over the years.[11] Moreover, despite of being a high TB burden country, TB case detection rate (the yearly number of newly notified cases per 100,000 population) in Bangladesh is still unsatisfactory as at a 67% case detection rate as of 2017.[5]

In Bangladesh, TB control interventions are being implemented in healthcare facilities throughout the country, from the central to peripheral levels. HIV prevention programs are primarily concentrated in 23 priority districts based on concentration of HIV positive cases and KPs.[12] Thus, there is inadequate linkage between TB and HIV prevention programs, that engendering low identification of TB cases among KPs. To foster a functional collaboration between TB and HIV programmes, GoB designed a roadmap of collaboration between the National Tuberculosis Program (NTP), AIDS/STD Program (ASP), key stakeholders (BRAC, icddr,b, Save the Children, etc.) and implementing partners (Damien Foundation, CARE,B, etc.) since 2009. These mechanisms aim to institute programmatic linkages at each level of healthcare, albeit with unsatisfactory outcomes.[10]

Worldwide, KPs, including sexual minority people [i.e., males who have sex with males (MSM), male sex workers (MSW) and transgender women (locally known as hijra)], people who inject drug (PWID), female sex workers (FSW), and PLHIV, are considered vulnerable to TB.[13] These populations are particularly susceptible to TB infection due to their hidden and hard-to-reach nature along with their unwillingness to visit healthcare facilities.[14] [15] In particular, sexual minority people are more vulnerable not only because of their propensity to contract TB/HIV co-

infections but also their highly stigmatized nature.[16] Case notification rates also remain low among these populations due to the implementation of passive case detection strategies which often exclude marginalized populations, thus leaving them undiagnosed and untreated for TB.[17] [18] Experiences of some countries have shown that successful implementation of active case finding strategies, when embedded with HIV services, resulted in increased TB case detection, especially for these groups of populations.[19] [20]

Several studies have suggested that TB screening should be encompassed in an integrated HIV intervention, while also addressing the other healthcare needs of PLHIV. For example, a community outreach model was adopted in rural Mozambique, where TB, HIV, malaria and nutritional services are packaged in a single service delivery point, which helped improve acceptability and satisfaction.[21] However, the acceptability of TB screening programs among MSM has not been a substantial point of focus in research or program implementation. In fact, many NTP programs in low- and middle-income countries (LMICs) are oblivious to the role that MSM may serve in TB epidemics. As evidenced by programmatic data, MSM are more rooted in higher income countries.[22] The acceptability of TB screening was found to range from 43% to 91% in many of the studied countries, although the underlying reasons were not specified.[23] TB screening service acceptability among transgender women is also an understudied area. The reach and recruitment rates of transgender cases were hard to quantify since many of the studies used word of mouth or peer referrals through snowball sampling.[24]

In Bangladesh, 77% of the transgender women (locally known as *hijra*) articulated their willingness to provide sputum samples.[17] [23] According to Mitchell et. al. (2013), it was inconvenient to reach transgender participants through traditional contact techniques.[24] Rather, the Center for Disease Control (CDC) recounted an experience where they attempted to recruit transgender women through exploring their residences, social networks and other social spheres as well as common social spheres.[25] Transgender women in New York and Bangladesh, alike, indicated that they felt more comfortable visiting a community-based healthcare facility, particularly if they did not disclose their sexual orientation and if the facilities were catered to sexual minority populations.[17]

icddr,b is currently performing verbal TB screening[1] for sexual minority people through Drop-in Centre (DIC) based TB screening approach. Programmatic evidence showed that this approach is not working efficiently in increasing the number of presumptive TB case identifications and referrals, and active TB case detection. During the preceding six-month period (i.e., July 2018-December 2018) of inception of the study, only 146 (around 16%) were screened for TB, using the verbal TB screening form during clinic sessions, yet none were referred as presumptive cases [2] (Programme data of icddr,b). National data also demonstrated that additional efforts are required to identify TB cases among highly vulnerable KPs.[10]

A survey conducted in Bangladesh showed the controls had significantly poorer knowledge on TB transmission, mode of transmission, suggestive symptoms and availability of free treatment than the TB cases.[26] Evidence shows that the knowledge is an essential precursor for successful uptake of TB services and case detection. Knowledge levels and healthcare-seeking behaviors can also contain the spread of TB among KPs.[27]

Despite high possibility of TB/HIV co-infection, a scientifically tested approach for increasing TB case detection among sexual minority people is yet to be developed and implemented in Bangladesh. Therefore, a community-based TB screening approach will be tested among sexual minority people. Such an approach is expected to encourage sustainable service delivery linkages between community systems and the Government health systems. Findings of this study are likely to provide new insights for program managers and policy planners for developing and implementing a community-based TB screening approach to enhance TB referral which ultimately increase TB case detection among sexual minority people.

RESEARCH OBJECTIVES

Primary Objective: To develop and assess a community-based TB screening approach to enhance TB referral for increasing case detection among sexual minority people in Dhaka city, Bangladesh

[1] It is a standardized verbal questionnaire for investigating presumptive TB cases on the presence of the following symptoms and signs: cough for more than two weeks, haemoptysis, chest pain, breathlessness, evening rise of temperature/night sweating, anorexia, and weight loss/weakness.

[2] Presumptive TB case refers to a patient who manifests symptoms or signs which are suggestive of TB (formerly known as a TB suspect).

Secondary Objectives:

1. To understand barriers and scopes of the existing TB screening approach for sexual minority people
2. To measure knowledge of TB among the participants
3. To develop and implement a community-based TB screening approach
4. To assess the impact of community-based TB screening approach on TB screening, presumptive TB case referral, TB case detection and knowledge related on TB

METHODS AND ANALYSIS

Research design

Under the operational research framework, by applying mixed methods (i.e. qualitative and quantitative) approach, the study will follow a quasi-experimental design with enlisted sexual minority people in selected DICs.[28] Both pre-intervention and post-intervention measurements will be facilitated among non-randomly selected control groups.[29] The participants of intervention site will be compared with the participants of the comparison site. To measure changes between two time points, baseline and end-line in the outcome of interest between the two groups, an analysis will be conducted.

Research plan

The study will ensue through the following phases adopted from the operational research framework recommended by WHO and the Global Fund [30] : Figure 1 shows the activities of this study:

Phase 1: Formative phase

a. Qualitative data collection to explore implementation barriers and scopes of existing TB screening approach
b. Survey on socio-demographic characteristics, knowledge and risk behavior related to TB among the sexual minority people of the both intervention and comparison catchment areas
c. Development of community-based TB screening approach

d. Baseline data on the number of TB screening, referral of presumptive TB cases to Directly observed treatment, short-course (DOTS, also known as TB-DOTS) centers, and TB case detection within existing DIC STI clinic-based approach of TB screening at both intervention and comparison sites during the preceding six months.

Phase 2: Intervention phase

a. Implementation of community-based TB screening intervention
b. Qualitative data collection to identify implementation facilitators and challenges of community-based TB screening approach

Phase 3: Comparison phase

a. End-line data collection in both intervention and comparison sites on the number of TB screening, referral of presumptive TB cases to DOTS centers, and TB case detection. The end-line data will be compared with the base-line data are both intervention and comparison sites
b. Post-test to measure knowledge change as a result of behavior change intervention (BCI) among sexual minority people in the intervention DIC area and comparison DIC area at the end of the intervention period, of whom the latter will not get BCI. Comparisons will subsequently be drawn within and between these two areas

Study location

This experimental study will be conducted in two DICs (i.e., Jatrabari and Darus Salam DIC) in Dhaka city (Figure 2). These DICs are operated by a non-government organization (NGO) namely Bandhu Social Welfare Society (BSWS), under the Global Fund project of icddr,b. The intervention site, Jatrabari DIC, is located in the southern part of Dhaka city. Darus Salam DIC, the comparison site, is in the western part of Dhaka city (Mirpur). These DICs will be selected purposively due similar profiles in terms of duration of service delivery, the concentration of HIV positive cases, and number of sexual minority people served.

Study population

All the sexual minority people enlisted for HIV prevention services in these two DICs will be selected for this study. Operational definitions for the MSM, MSW and *hijra* are provided in

Table 1 which are currently used in the provision of HIV prevention services to sexual minority people.[31]

Table 1: Definitions of the MSM, MSW and *hijra*

Population	Operational definitions
Males who have sex with males (MSM)	Males who have had sex with males (with consent) within the last 1 year irrespective of whether or not they have sex with women or have a social or personal gay or bisexual identity, but do not sell sex
Male sex workers (MSW)	Male who sell sex to other males in exchange of money or gifts in the last 3 months
Hijra	Those who identify themselves as part of a traditional *hijra* sub-culture and who maintain the guru-chela hijra hierarchy

For qualitative interview the following research participants will be recruited purposively in this research:

1. Sexual minority people (MSM, MSW and *hijra*)
2. DIC staff (i.e., DIC managers, medical assistants, outreach supervisors, and peer educators)
3. Staff of adjacent DOTS centers (i.e., physicians, nurses, technicians etc.)
4. Experienced program managers and researchers working with KPs
5. Program managers (PMs) of national tuberculosis programme (NTP)
6. Representative from principal and sub recipients of the Global Fund (GF) project

Inclusion criteria

1. All sexual minority people are aged 18 years or more, and enlisted in the service list of the intervention site (for intervention)

2. According to the sample size, a subset of sexual minority people of both intervention and control areas (for survey)
3. Health service providers and other staff members of the intervention and control DICs (for qualitative interview only)
4. Senior management staff members of the PR and SRs, staff of adjacent DOTS center, experienced programme managers of NTP and researchers working with KPs (for qualitative interview only)
5. Those who provide verbal and / or written consent to participate in this study

Exclusion criteria

Participants who refuse to participate in this research, and sexual minority people who are not enlisted in the intervention DIC. In addition, minors under 18 years of age will be excluded from the study.

Sample size and sampling

Quantitative component

To conduct the baseline survey, in both the intervention and comparison sites, the sample size was calculated using the following standard formula [32] :

$$n = D\frac{\{z_{1-x}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_1(1-p_1)+p_2(1-p_2)}\}^2}{(p_2 - p_1)^2}$$

In the above formula:

D=Design effect=2 (due to cluster sampling method)

p_1= Assumed proportion of the outcome variable at the time of baseline survey

p_2= The target proportion at the end line, so that (p2-p1) is the magnitude of change that we want to be able to detect

p (bar)=$(p_1+p_2)/2$

$Z_{1-\alpha}$=The Z-score corresponding to desired level of significance=1.645[32]

$Z_{1-\beta}$= The Z-score corresponding to desired level of power=0.83[32]

The sample size was calculated in order to detect 20% changes (1-way change detectable) in the knowledge of TB between two time points with the design effect of 2.0, 95% confidence level and 80% power. Separate sample sizes were calculated for each of the categories and were adjusted for 5% drop-outs during the interview (Table 2). Finally, the largest sample size (N~160) will be selected to conduct the baseline survey in the intervention and comparison areas. A literature review was carried out in order to find out estimates of TB knowledge in terms of cause, route of transmission and prevention. The results depicted that the knowledge of cause, routes of transmission and prevention of TB ranged from 2-44%, 22-88% and 14-68%, respectively. It is worth mentioning that all the findings were from the general population and no literature was found among the sexual minority populations. Thereafter, using programmatic experience among sexual minority population in Bangladesh, suitable values were assumed to calculate sample sizes (Table 2).

Table 2: Proposed sample size to conduct survey with sexual minorities (MSM, MSW, transgender) in Bangladesh (January 2019- June 2020)

Indicators used in the calculation of sample size	Suitable values assumed for the sexual minority people	1-way change detect-able	Design effect	Required Sample Size*
Knowledge of TB:				
1. Cause of TB: Percentage of beneficiaries correctly identify that TB is caused by bacteria	40%	20%	2.0	159
2. Route of transmission of TB: Percentage of beneficiaries mentioned that TB is transmitted by air (by talking/by coughing/sneezing/ spitting TB germs)	50%	20%	2.0	152
3. Methods of prevention: Percentage of beneficiaries mentioned that TB can be prevented by taking BCG vaccination/covering	50%	20%	2.0	152

Indicators used in the calculation of sample size	Suitable values assumed for the sexual minority people	1-way change detect-able	Design effect	Required Sample Size*
mouth and nose when TB patient is coughing/ sneezing/ spitting/ talking				

The baseline survey will be conducted using time location sampling (TLS).[28] The trained interviewers will interview sexual minority people at all congregating areas (spots) at a particular time window, usually between 5-10 pm. After collecting the list of spots and the sexual minority people covered throughout each spot, the total sample size will be proportionately distributed among each spot. In each spot, the respondents will be randomly chosen for interview to collect data on socio-demographic characteristics, knowledge of and risk behaviors pertaining to TB, etc. Identification numbers (IDs) from the mother list will be used to avoid duplications during the survey.

Qualitative component:

Non-probabilistic purposeful maximum diversity sampling will be used in the qualitative component.[33] Based on our previous experience of working with sexual minority people, we plan to facilitate in-depth interviews (IDIs) with 15-18 sexual minority people, 10-15 key informants interviews (KIIs) with service providers. In addition, two focus group discussions (FGDs) will be conducted with sexual minority people and service providers. The sample size may vary depending on the points of data saturation and redundancy.

Data collection method

Qualitative data collection

Several qualitative data collection approaches will be employed, such as IDIs with the sexual minority people, KIIs with the service providers and FGDs with sexual minority people and service providers.

Quantitative data collection

Survey on socio-demographic characteristics, knowledge of and risk behavior related to TB

Survey on socio-demographic characteristics, knowledge of and risk behaviors related to TB will be conducted among selected numbers of sexual minority people of both intervention and comparison areas during baseline and end line surveys at an approximate interval of six months.

Baseline and end line programmatic quantitative data collection

At the start and end of the intervention phase of the study, data will be collected from programme report of the Global Fund project of icddr,b on the total number of beneficiaries screened for TB, total number of referred cases for presumptive TB and number of TB case detections within the extant STI clinic-based TB screening approach as well as the new intervention approach at both the intervention and comparison sites.

Data collection tool

A structured TB screening format will be used for verbal TB screening via a semi-structured questionnaire in standard Bengali. This questionnaire will encompass guidelines about the socio-demographic profile, knowledge of and risk behaviors related to TB. Moreover, open-ended guidelines will be used for qualitative interviews and FGDs. All the guidelines and questionnaires will be field tested. Based on field-testing, these data collection tools may need to be refine, where appropriate, in order to facilitate the data collection process. All qualitative and quantitative interviews will be conducted in standard Bengali.

Outcome variables

Data to measure outcome variables will be extracted from the ongoing HIV prevention programme from both intervention and comparison areas. These data will be expressed in terms of percentage points to assist statistical analysis. The outcome measures are defined as follows:

1. Number of TB screenings: Number of beneficiaries screened for TB at the community, which will be expressed as percentage points in relation to the total number of beneficiaries enlisted in the mother-list.

2. Number of presumptive TB case referrals: Number of beneficiaries referred to DOTS centers for TB testing, which will be expressed as percentage points in relation to the total number of beneficiaries screened at the community.
3. Number of TB case detections: Number of beneficiaries who will be tested positive for TB, which will be expressed as a percentage points in relation to the total number of presumptive cases tested.

Data on knowledge related to TB will be collected from quantitative surveys at the beginning of intervention (baseline) and after six months of intervention (end line) both in the intervention and comparison areas. This outcome variable will measure the knowledge of TB, as defined below.[34]

1. Cause of TB: Correctly able to identify that TB is caused by bacteria
2. Route of transmission of TB: TB is transmitted by air (by talkingcoughing/sneezing/spitting TB germs)
3. Methods of prevention: TB can be prevented by taking BCG vaccination/covering mouth and nose when TB patient is coughing/sneezing/spitting/talking

Data Analysis

Quantitative data

Statistical analysis will be conducted using Stata version 13.0 (Stata Corp Inc., College Station, Texas, USA). Epi Info (Version 6.03; Centres for Disease Control and Prevention, Atlanta, Georgia, USA) will be used for data entry. The populations and measurements will be presented through descriptive statistics. Differences in the outcome variables between intervention and comparison groups at the baseline and at end line will be determined by the independent t-test for parametric continuous data, $\chi 2$ or Fishers's exact test for categorical data, and Wilcoxon rank-sum test for non-parametric continuous data. Differences in the outcome variables within intervention and comparison areas between two time points will be determined using the paired t-test for parametric continuous data whereas, Wilcoxon signed rank test for non-parametric continuous data and $\chi 2$ or Fishers's exact test for categorical data. p-values of <0.05 will be considered as a significant level in all comparisons. In addition, 95% confidence interval (CI) will be reported for all quantitative and categorical variables in the study.

Qualitative data

Data will be collected using digital recorders and systematically stored on the computer on a daily basis for a prolonged timeframe, adhering to the requirement of Institutional Review Board (IRB) and data policy of icddr,b. In addition, data collection and data analysis processes will occur in synergy, as qualitative data collection and analysis is an ongoing and reflexive process, and this process will allow for the identification of saturation points.[35 36] All qualitative data will be analyzed manually by adopting line by line content, contextual and thematic analysis strategies; and coding and re-coding data into themes and subthemes. The results will be summarized and presented keeping in mind the local context, and some of the findings will be presented verbatim in order to substantiate or reflect noteworthy ideas and perspectives.

ETHICS AND DISSEMINATION

Participation in the research process will be voluntary. To ensure maximum congeniality of the informants, verbal consent will be attained from sexual minority people during IDIs and FGDs whereas written consent will be obtained from representative of PRs and SRs, service providers from DOTs centers, experienced program managers, and researchers during KIIs and FGDs. Verbal written consent will also be taken from sexual minority people prior to the quantitative survey, as well as the pre- and post-test phases. Experiences of working with sexual minority people suggest that many sexual minority people withhold information about their identities and practices that characterize them as a KP (e.g., involvement in sex trade, sexual orientation) in written form in apprehension of identity disclosure. Structural barriers such as criminalization of same-sex behaviour and socio-religious stigma impede the uptake of written consent from sexual minority people.

Research participants will be briefed about the objectives of the study, the data collection process, and topics of discussion. The researchers ascertained the anonymity of the participants' responses. Moreover, no identifying information will appear in the data collection tools. If any research participant declines the recording of his responses, researchers will take written notes.

During intervention, if any participant is tested positive for TB, then s/he will be linked to the adjacent DOTS center, to ensure treatment and follow-up the treatment adherence.

Ethical clearance was obtained from icddr,b's Institutional Review Board (IRB) which follows international ethical standards to ensure confidentiality, anonymity, and informed consent.

Study findings will initially be disseminated at the organization and then subsequently, among policymakers and relevant stakeholders to inform the policy for implication. In addition, findings will be disseminated to a diverse audience via different scientific forums such as peer-reviewed journals, and presentations at national and international conferences. Further dissemination initiatives include translational and implementation strategies such as the impact of findings in the national policy. The study commenced in January 2019 and is anticipated to continue until June 2020.

Patient and public involvement

For this study, none of the patients or members of the general public will be involved.

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AUTHOR CONTRIBUTIONS

GS drafted the protocol and revised it with inputs from all co-authors. SIK is the senior and corresponding author of this manuscript and was responsible for the overall supervision of information summarization, exchange and management, analysis of information, and drafting of the manuscript. MMR and MNMK also supervised overall information extraction and assisted in the drafting of the manuscript. GG also managed information extraction and helped in writing the manuscript. SMK, SDI and MR reviewed the manuscript and provided valuable suggestions for the overall improvement of the article. SB, RSB, SA and AKMMR All authors have read and approved the final manuscript.

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COMPETING INTERESTS

All authors declare that they have no competing interests.

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List of Table(s)

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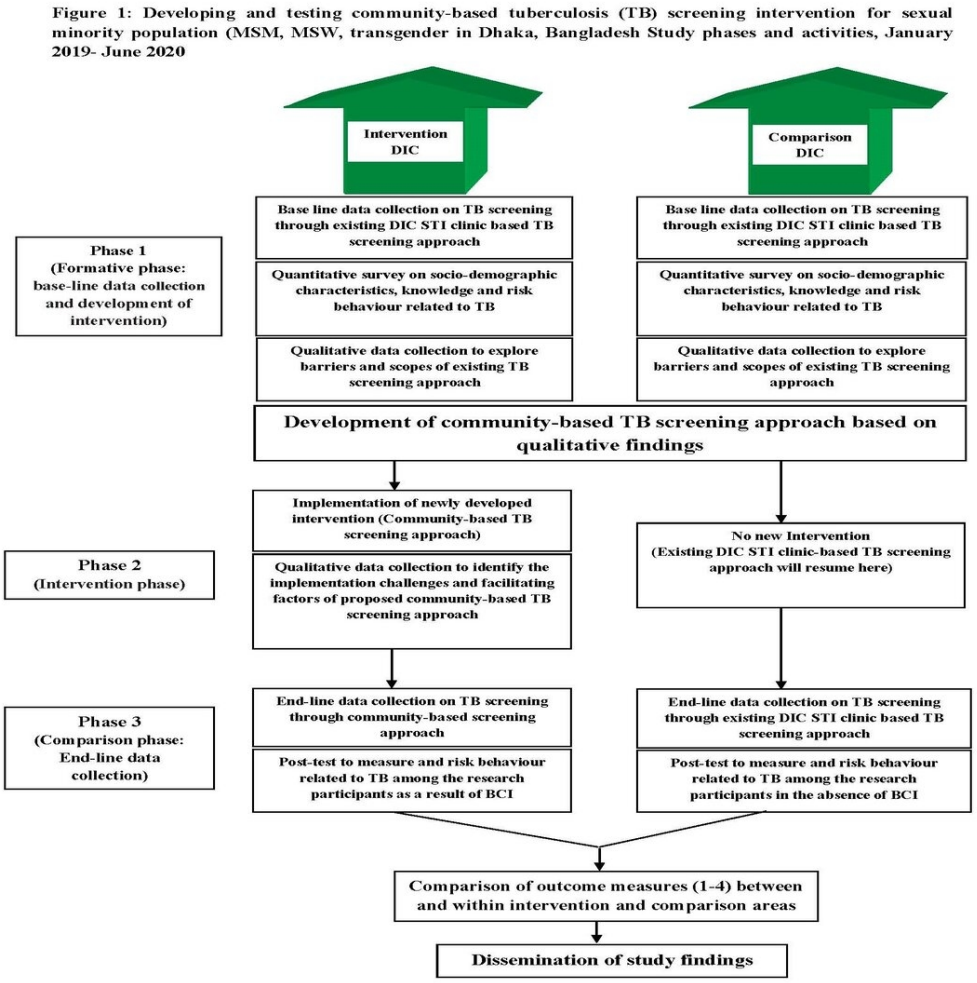

Figure 1: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study phases, January 2019- June 2020

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Figure 2: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study location/area, January 2019-June 2020

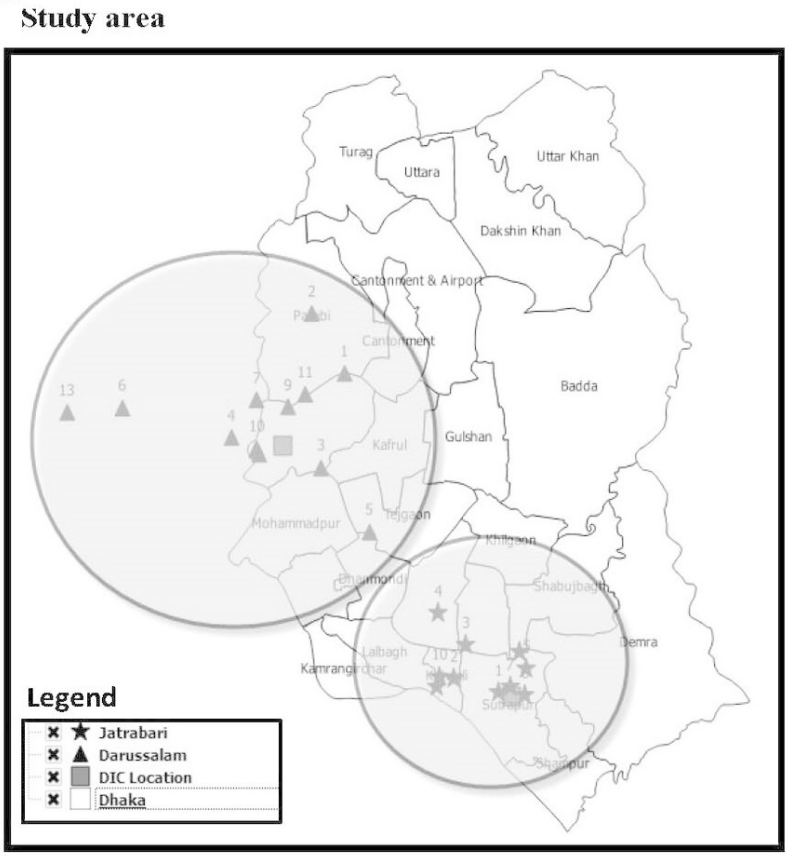

Figure 2: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study location/area, January 2019-June 2020

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Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol

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Title: Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol

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Key words: Tuberculosis (TB), TB screening, referral, sexual minority, health facility based TB screening

ABSTRACT

Introduction

Although Bangladesh is a country of generalized Tuberculosis (TB) epidemic, the HIV prevalence is low among general populations, and 3.9% among key populations (KPs). Despite the high possibility of HIV-TB co-infection, scientifically tested approaches for increasing TB case detection among sexual minority people are yet to be developed and implemented in Bangladesh. Such approaches could foster service delivery linkages between communities and the government health system. Findings of this experimental research are likely to provide new insights for program managers and policy planners for adopting a similar approach in order to enhance TB referral, thus ultimately increasing TB case detections and reducing the likelihood of TB-related mortalities and morbidities, irrespective of HIV status.

Methods and analysis

This operational research will follow a quasi-experimental design, applying both qualitative and quantitative methods, in two drop-in centers (DICs) in three phases. Phase 1 will encompass baseline data collection and development of a community-based TB screening approach. In phase 2, the newly developed intervention will be implemented, followed by end-line data collection in phase 3. Qualitative data collection will be continued throughout the first and second phases. The baseline and end-line data will be compared both in the intervention and comparison areas to measure the impact of the intervention.

Ethics and dissemination:

Ethical approval was obtained from the Institutional Review Board (IRB) of International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). The findings will be disseminated through diverse scientific forums including peer-reviewed journals, presentation at conferences and among the policy makers for policy implication. The study started in January 2019 and will continue until June 2020.

Article summary

Strengths and limitations of this study

- The study adopts a mixed method design, which will validate results from quantitative and qualitative strands in order to explicitly understand the research problem.
- The study will use a community-based approach, thus ensuring the involvement of the sexual minority population at all phases of the study to ensure the internal validity of the findings.
- This study will develop an approach of detecting TB cases for the first time among sexual minority people through an integrated model, which will harness service delivery linkages with the government health system for achieving sustainability.
- This study will follow a quasi-experimental design rather than a randomized controlled trial.
- This study will be conducted in two service centers only, therefore the results obtained from this study cannot be generalized for the whole sexual minority population. Nonetheless, the approach may help in informing the policy makers.

INTRODUCTION

Human immunodeficiency virus (HIV) epidemic poses as an impediment to the effective control of tuberculosis (TB) worldwide.[1] Clinical evidence has alluded to a causal relationship between TB and HIV.[2] HIV is considered as the most predominant risk factor for the development of *Mycobacterium tuberculosis* (MTB) infection to TB disease.[3] Likewise, TB infection accelerates the progression of HIV infection, reduces survival and even predisposes the infected individual to premature death.[4] On the global scale, an estimated 10.0 million (range 9.0–11.1 million) people were newly diagnosed with TB in 2018, which also constituted to 8.6% of the People Living with HIV (PLHIV).[5] An estimated 1.2 million (range, 1.1–1.3 million) deaths due to TB disease occurs across the globe in 2018, in addition to 251,000 (range, 223,000–281,000) TB deaths happened among PLHIV.[5] This is because PLHIV are 29 (26-31) times more vulnerable to TB than HIV negative individual.[6] In this context, TB is considered as the leading preventable cause of death especially among PLHIV.[7]

Bangladesh is a country with generalized TB epidemic, though it has a low HIV prevalence of less than 0.01% among general populations.[8] [9] However, HIV surveillance findings demonstrated that 3.9% of the key populations (KPs) at risk of HIV contracted HIV infection.[10] Between 1999 to 2002, a study conducted by International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) among 958 patients to determine HIV prevalence among patients with TB in Dhaka demonstrated an estimated 0.1% TB/HIV co-infection.[11] Nonetheless, recent data reported by Government of Bangladesh (GoB) from 2009 to 2014 showed that merely 1% of the registered TB patients in the country were documented to have HIV.[12] In 2017, the prevalence of HIV among the diagnosed TB patients (n=3,917) was 0.36% whereas approximately 16% of the PLHIV (n=559) were tested positive for TB, thus illustrating bidirectional upward trends in TB/HIV co-infection rates over the years.[13] Moreover, despite of being a country of high TB burden, TB case detection rate (the yearly number of newly notified cases per 100,000 population) in Bangladesh is still unsatisfactory as at a 75% case detection rate as of 2018.[5]

In Bangladesh, TB control interventions are being implemented in healthcare facilities throughout the country, from the central to peripheral levels. HIV prevention programs are primarily concentrated in 23 priority districts based on concentration of HIV positive cases and KPs.[14] Thus, there is inadequate linkage between TB and HIV prevention programs, that engendering low identification of TB cases among KPs. To foster a functional collaboration between TB and HIV programmes, GoB designed a roadmap of collaboration between the National Tuberculosis Program (NTP), AIDS/STD Program (ASP), key stakeholders (BRAC, icddr,b, Save the Children, etc.) and implementing partners (Damien Foundation, CARE,B, etc.) since 2009 with an aim to institute programmatic linkages at each level of healthcare, albeit with unsatisfactory outcomes.[12]

Worldwide, KPs, including sexual minority people [i.e., males who have sex with males (MSM), male sex workers (MSW) and transgender women (locally known as hijra)], people who inject drug (PWID), female sex workers (FSW), and PLHIV, are considered vulnerable to TB.[15] These populations are particularly susceptible to TB infection due to their hidden and hard-to-reach nature along with their unwillingness to visit healthcare facilities.[16] [17] In particular, sexual

minority people are more vulnerable not only because of their propensity to contract TB/HIV co-infections but also their highly stigmatized nature.[18] Case notification rates also remain low among these populations due to the implementation of passive case detection strategies which often exclude marginalized populations, thus leaving them undiagnosed and untreated for TB.[19] [20] Experiences from some countries have shown that successful implementation of active case finding strategies, resulted in increased detection of TB case, especially for hidden and/or hard-to-reach populations.[21] [22] For example, a recent study conducted in tribal India revealed that active case finding interventions contributed to a 52% increase in testing rates and 84% increase in TB case notifications.[23] Similarly, a recent quasi-experimental study that was conducted in Cambodia showed that the TB case notification rates were significantly higher ($p < 0.05$) among the intervention group (which adopted active case finding) compared to the control group (which employed passive case finding).[24] Likewise, a recent cohort study conducted in China documented that early case detection rates significantly increased among the higher-risk groups, such as PLHIV.[25]

Several studies have suggested that TB screening should be encompassed in an integrated HIV intervention, while also addressing the other healthcare needs of PLHIV. For example, a community outreach model was adopted in rural Mozambique, where TB, HIV, malaria and nutritional services are packaged in a single service delivery point, which helped improve acceptability and satisfaction.[26] However, the acceptability of TB screening programs among MSM has not been a substantial point of focus in research or program implementation. In fact, many NTP programs in low- and middle-income countries (LMICs) are oblivious to the role that MSM may contribute in TB epidemics. As evidenced by programmatic data, MSM are more rooted in higher income countries.[27] The acceptability of TB screening was found to range from 43% to 91% in many of the studied countries, although the underlying reasons were not specified.[28] TB screening service acceptability among transgender women is also an understudied area. The reach and recruitment rates of transgender cases were hard to quantify since many of the studies used word of mouth or peer referrals through snowball sampling.[29]

In Bangladesh, 77% of the transgender women (locally known as *hijra*) articulated their willingness to provide sputum samples.[19] [28] According to Mitchell et. al. (2013), it was inconvenient to reach transgender participants through traditional contact techniques.[29] Rather,

the Center for Disease Control (CDC) recounted an experience where they attempted to recruit transgender women through exploring their residences, social networks and other social spheres as well as common social spheres.[30] Transgender women in New York and Bangladesh, alike, indicated that they felt more comfortable visiting a community-based healthcare facility, particularly if they did not disclose their sexual orientation and if the facilities were catered to sexual minority populations.[19]

icddr,b is currently performing verbal TB screening[1] for sexual minority people through Drop-in Centre (DIC) based TB screening approach. Programmatic evidence showed that this approach is not working efficiently in increasing the number of presumptive TB case identifications and referrals, and active TB case detection. During the preceding six-month period (i.e., July 2018-December 2018) of inception of the study, only 146 (around 16%) were screened for TB, using the verbal TB screening form during clinic sessions, yet none were referred as presumptive cases [2] (Programme data of icddr,b). National data also demonstrated that additional efforts are required to identify TB cases among highly vulnerable KPs.[12]

A survey conducted in Bangladesh showed the controls had significantly poorer knowledge on mode of transmission, suggestive symptoms and availability of free treatment than the TB cases.[31] Evidence shows that the knowledge is an essential precursor for successful uptake of TB services and case detection. Knowledge levels and healthcare-seeking behaviors can also contain the spread of TB among KPs.[32]

Despite high possibility of TB/HIV co-infection, a scientifically tested approach for increasing TB case detection among sexual minority people is yet to be developed and implemented in Bangladesh. Therefore, a community-based TB screening approach will be tested among sexual minority people. Such an approach is expected to encourage sustainable service delivery linkages between community systems and the Government health systems. Findings of this study are likely to provide new insights for program managers and policy planners for developing and implementing a community-based TB screening approach to enhance TB referral which ultimately increase TB case detection among sexual minority people.

[1]" It is a standardized verbal questionnaire for investigating presumptive TB cases on the presence of the following symptoms and signs: cough for more than two weeks, haemoptysis, chest pain, breathlessness, evening rise of temperature/night sweating, anorexia, and weight loss/weakness".

[2] Presumptive TB case refers to a patient who manifests symptoms or signs which are suggestive of TB (formerly known as a TB suspect).

RESEARCH OBJECTIVES

Primary Objective: To develop and assess a community-based TB screening approach to enhance TB referral for increasing case detection among sexual minority people in Dhaka city, Bangladesh

Secondary Objectives:

1. To understand barriers and scopes of the existing TB screening approach for sexual minority people
2. To measure knowledge of TB among the participants
3. To develop and implement a community-based TB screening approach
4. To assess the impact of community-based TB screening approach on TB screening, presumptive TB case referral, TB case detection and knowledge related on TB

METHODS AND ANALYSIS

Research design

Under the operational research framework, by applying mixed methods (i.e. qualitative and quantitative) approach, the study will follow a quasi-experimental design with enlisted sexual minority people in selected DICs.[33] Both pre-intervention and post-intervention measurements will be facilitated among non-randomly selected control groups.[34] The participants of intervention site will be compared with the participants of the comparison site. To measure changes between two time points, baseline and end-line in the outcome of interest and between the two groups, an analysis will be conducted.

Research plan

The study will ensue through the following phases adopted from the operational research framework recommended by WHO and the Global Fund [35] : Figure 1 shows the activities of this study:

Phase 1: Formative phase

a. Qualitative data collection to explore implementation barriers and scopes of existing TB screening approach

b. Survey on socio-demographic characteristics, knowledge and risk behavior related to TB among the sexual minority people of the both intervention and comparison catchment areas
c. Development of community-based TB screening approach
d. Baseline data on the number of TB screening, referral of presumptive TB cases to Directly observed treatment, short-course (DOTS, also known as TB-DOTS) centers, and TB case detection within existing DIC STI clinic-based approach of TB screening at both intervention and comparison sites

Phase 2: Intervention phase

a. Implementation of community-based TB screening intervention
b. Qualitative data collection to identify implementation facilitators and challenges of community-based TB screening approach

Phase 3: Comparison phase

a. End-line data collection in both intervention and comparison sites on the number of TB screening, referral of presumptive TB cases to DOTS centers, and TB case detection. The comparison will be done between end-line and the base-line data in both intervention and comparison sites
b. Post-test to measure knowledge change as a result of behavior change intervention (BCI) among sexual minority people in the intervention DIC area and comparison DIC area at the end of the intervention period, of whom the latter will not get BCI. Comparisons will subsequently be drawn within and between these two areas

Development of community-based TB screening model

A community-based TB screening model will be developed based on the first phase findings. At the beginning of the second phase, researchers will develop a training module for the peer educators (PEs) based on the need assessment, map TB DOTS centers and devise DOTS referral strategies. Sensitization sessions will be conducted with the DOTS service providers and community leaders. Researchers will train PEs of the intervention area on the TB screening process and then be assigned to serve a separate list of sexual minority people. A work plan will be formulated to screen all sexual minority people at least once during the intervention period.

After taking their verbal consents, they will be screened at spots/residences/*dera* (residence of *hijra* leader) using a simplified structured verbal TB screening form, while maintaining confidentiality. If the case is negative, post-screening information and counseling will be provided and they will be encouraged to seek support if suspected with TB symptoms. If screened positive, they will undergo counseling and be referred to the nearest TB DOTS center for testing, either through self- or accompanied referral. After the test results are ready, the PE or the sexual minority people themselves will collect the report, and if anyone is tested positive s/he will be linked to nearby TB DOTS center for treatment and followed up for adherence. PEs will also conduct specialized educational sessions on TB at outreach sites where they will distribute visual materials and discuss TB risks and routes of transmission.

Study location

This experimental study will be conducted in two DICs (i.e., Jatrabari and Darus Salam DIC) in Dhaka city (Figure 2). These DICs are operated by a non-government organization (NGO) namely Bandhu Social Welfare Society (BSWS), under the Global Fund project of icddr,b. The intervention site, Jatrabari DIC, is located in the southern part of Dhaka city. Darus Salam DIC, the comparison site, is in the western part of Dhaka city (Mirpur). These DICs were selected purposively due to similar profiles in terms of duration of service delivery, the concentration of HIV positive cases, and number of sexual minority people served.

Study population

The sexual minority people enlisted for HIV prevention services in these two DICs will be selected for this study. Operational definitions for the MSM, MSW and *hijra* are provided in Table 1 which are currently used in the provision of HIV prevention services to sexual minority people.[36]

Table 1: Definitions of the MSM, MSW and *hijra*

Population	Operational definitions
Males who have sex with males (MSM)	Males who have had sex with males (with consent) within the last 1 year irrespective of whether or not they have sex with women or have a social or personal gay or bisexual identity, but do not sell sex
Male sex workers (MSW)	Male who sell sex to other males in exchange of money or gifts in the last 3 months
Hijra	Those who identify themselves as part of a traditional *hijra* sub-culture and who maintain the guru-chela hijra hierarchy

For qualitative interview the following research participants will be recruited purposively in this research:

1. Sexual minority people (MSM, MSW and *hijra*)
2. DIC staff (i.e., DIC managers, medical assistants, outreach supervisors, and peer educators)
3. Staff of adjacent DOTS centers (i.e., physicians, nurses, technicians etc.)
4. Experienced program managers and researchers working with KPs
5. Program managers (PMs) of national tuberculosis programme (NTP)
6. Representative from principal and sub recipients of the Global Fund (GF) project

Inclusion criteria

1. All sexual minority people aged 18 years or more, and enlisted in the service list of the intervention site (for intervention)
2. According to the sample size, a subset of sexual minority people of both intervention and comparison areas (for base-line and end-line survey)

3. Health service providers and other staff members of the intervention and control DICs (for qualitative interview only)
4. Senior management staff members of the PR and SRs, staff of adjacent DOTS center, experienced programme managers of NTP and researchers working with KPs (for qualitative interview only)
5. Those who provide verbal and / or written consent to participate in this study

Exclusion criteria

Participants who refuse to participate in this research, and sexual minority people who are not enlisted in the intervention DIC. In addition, minors, below18 years, will not be included in the study.

Study period

The study commenced in January 2019 and is anticipated to continue until June 2020. The Gantt chart is given below (Table 2):

Table 2: Gantt chart

Activities	Year																	
	2019												2020					
	Jan-Mar			Apr-Jun			Jul-Sep			Oct-Dec			Jan-Mar			Apr-Jun		
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1. Training of staff																		
2. Piloting																		
Phase-1																		
1. Baseline data collection:																		
a. Quantitative survey																		
b. Qualitative																		
c. Program data																		

2. Development of intervention model																	
Phase-2: 1. Implementation of Intervention 2. Qualitative data collection																	
Phase-3: End line data collection: a. Quantitative survey b. Program data																	
Data entry, cleaning, analysis and tabulations (quantitative)																	
Data transcription and analysis (Qualitative)																	
Preliminary report writing																	
Final report and dissemination																	

Sample size and sampling

Quantitative component

To conduct the baseline survey, in both the intervention and comparison sites, the calculation of sample size was done using the following standard formula [37] :

$$n = D\frac{\{z_{1-x}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_1(1-p_1)+p_2(1-p_2)}\}^2}{(p_2 - p_1)^2}$$

In the above formula:

D=Design effect=2 (due to cluster sampling method)

p_1= Assumed proportion of the outcome variable at the time of baseline survey

p_2= The target proportion at the end line, so that (p2-p1) is the magnitude of change that we want to be able to detect

p (bar)=$(p_1+p_2)/2$

$Z_{1-\alpha}$=The Z-score corresponding to desired level of significance=1.645[37]

$Z_{1-\beta}$= The Z-score corresponding to desired level of power=0.83[37]

A literature review was carried out in order to find out estimates of TB knowledge in terms of cause, route of transmission and prevention. The results depicted that the knowledge of cause, routes of transmission and prevention of TB ranged from 2-44%, 22-88% and 14-68%, respectively (Table 3).

Table 3: Literature review of the knowledge of TB

Indicators	Estimates of the indicators	Target group	Source
Knowledge of TB:			
1. Cause of TB: Percentage of beneficiaries correctly identify that TB is caused by Bacteria	43.9%	General population	Wandwalo, 2000[38]
	2%	General population	P. Suganthi, 2008[39]
	37.7%	General population	Kelemework, 2017[40]

Indicators	Estimates of the indicators	Target group	Source
2.Route of transmission of TB: Percentage of beneficiaries mentioned that TB is transmitted by air (by talk/by cough/by sneezing/by spitting TB germ)	53.7%	General population	Wandwalo, 2000[38]
	22-34%	General population	Aftab, 2009[41]
	55.5%	General population	Sreeramareddy, 2013[42]
	56%	General population	Shahed Hossain, 2015[31]
	88.0%	General population	Kelemework, 2017[40]
3.Methods of prevention: Percentage of beneficiaries mentioned that TB can be prevented by taking BCG vaccination/covering mouth and nose when TB patient is coughing or sneezing or spitting or talking	14%	General population	Aftab, 2009[41]
	68.2%	General population	Mukhtar, 2012[43]
	29.1-65.7%	General population	Kelemework, 2017[40]

The sample size was calculated in order to detect 20% changes (1-way change detectable) in the knowledge of TB between two time points with the design effect of 2.0, 95% confidence level and 80% power. Separate sample sizes were calculated for each of the categories and were adjusted for 5% drop-outs during the interview (Table 4). Finally, the largest sample size (N~160) will be selected to conduct the baseline survey each in the intervention and comparison areas. It is worth mentioning that all the findings were from the general population and no literature was found among the sexual minority populations. Thereafter, using programmatic experience among sexual minority population in Bangladesh, suitable values were assumed to calculate sample sizes (Table 4).

Table 4: Proposed sample size to conduct survey with sexual minorities (MSM, MSW, transgender) in Bangladesh (January 2019- June 2020)

Indicators used in the calculation of sample size	Suitable values assumed for the sexual minority people	1-way change detect-able	Design effect	Required Sample Size*
Knowledge of TB:				
1. Cause of TB: Percentage of beneficiaries correctly identify that TB is caused by bacteria	40%	20%	2.0	159
2. Route of transmission of TB: Percentage of beneficiaries mentioned that TB is transmitted by air (by talking/by coughing/sneezing/ spitting TB germs)	50%	20%	2.0	152
3. Methods of prevention: Percentage of beneficiaries mentioned that TB can be prevented by taking BCG vaccination/covering mouth and nose when TB patient is coughing/ sneezing/ spitting/ talking	50%	20%	2.0	152

*5% was added in order to adjust drop-out during survey

The baseline survey will be conducted using time location sampling (TLS).[28] The trained interviewers will interview sexual minority people at all congregating areas (spots) at a particular

time window, usually between 5-10 pm. After collecting the list of spots and the sexual minority people covered throughout each spot, the total sample size will be proportionately distributed among each spot. In each spot, the respondents will be randomly chosen for interview to collect data on socio-demographic characteristics, knowledge of and risk behaviors pertaining to TB, etc. Identification numbers (IDs) from the mother list will be used to avoid duplications during the survey. Similar sample size and sampling method will be used to conduct end line survey both in intervention and comparison areas.

Qualitative component:

Non-probabilistic purposeful maximum diversity sampling will be used in the qualitative component.[44] Based on our previous experience of working with sexual minority people, we plan to facilitate in-depth interviews (IDIs) with 15-18 sexual minority people, 10-15 key informants interviews (KIIs) with service providers. In addition, two focus group discussions (FGDs) will be conducted with sexual minority people and service providers. The sample size may vary depending on the points of data saturation and redundancy.

Data collection method

Qualitative data collection

Several qualitative data collection approaches will be employed, such as IDIs with the sexual minority people, KIIs with the service providers and FGDs with sexual minority people and service providers.

Quantitative data collection

Survey on socio-demographic characteristics, knowledge of and risk behavior related to TB

Survey on socio-demographic characteristics, knowledge of and risk behaviors related to TB will be conducted among selected numbers of sexual minority people of both intervention and comparison areas during baseline and end line surveys at an approximate interval of six months.

Baseline and end line programmatic quantitative data collection

At the start and end of the intervention phase of the study, data will be collected from programme report of the Global Fund project of icddr,b on the total number of beneficiaries

screened for TB, total number of referred cases for presumptive TB and number of TB case detections within the extant STI clinic-based TB screening approach as well as the new intervention approach at both the intervention and comparison sites.

Data collection tool

A structured TB screening format will be used for verbal TB screening. The survey will be conducted via a semi-structured questionnaire in standard Bengali. This questionnaire will encompass the socio-demographic profile, knowledge of and risk behaviors related to TB. Moreover, open-ended guidelines will be used for qualitative interviews and FGDs. All the guidelines and questionnaires will be field tested. Based on field-testing, these data collection tools may need to be refined, where appropriate, in order to facilitate the data collection process. All qualitative and quantitative interviews will be conducted in standard Bengali.

Outcome variables

Data to measure outcome variables will be extracted from the ongoing HIV prevention programme from both intervention and comparison areas. These data will be expressed in terms of percentage points to assist statistical analysis. The outcome measures are defined as follows:

1. Number of TB screenings: Number of beneficiaries screened for TB at the community, which will be expressed as percentage points in relation to the total number of beneficiaries enlisted in the mother-list.
2. Number of presumptive TB case referrals: Number of beneficiaries referred to DOTS centers for TB testing, which will be expressed as percentage points in relation to the total number of beneficiaries screened at the community.
3. Number of TB case detections: Number of beneficiaries who will be tested positive for TB, which will be expressed as a percentage points in relation to the total number of presumptive cases tested.

Data on knowledge related to TB will be collected from quantitative surveys at the beginning of intervention (baseline) and after intervention (end line) both in the intervention and comparison areas. This outcome variable will measure the knowledge of TB, as defined below.[45]

1. Cause of TB: Correctly able to identify that TB is caused by bacteria

2. Route of transmission of TB: TB is transmitted by air (by talking/ coughing/ sneezing/ spitting TB germs)
3. Methods of prevention: TB can be prevented by taking BCG vaccination/covering mouth and nose when TB patient is coughing/sneezing/spitting/talking

Data Analysis

Quantitative data

Statistical analysis will be conducted using Stata version 13.0 (Stata Corp Inc., College Station, Texas, USA). Epi Info (Version 6.03; Centres for Disease Control and Prevention, Atlanta, Georgia, USA) will be used for data entry. The populations and measurements will be presented through descriptive statistics. Differences in the outcome variables between intervention and comparison groups at the baseline and at end line will be determined by the independent t-test for parametric continuous data, $\chi 2$ or Fishers's exact test for categorical data, and Wilcoxon rank-sum test for non-parametric continuous data. Differences in the outcome variables within intervention and comparison areas between two time points will be determined using the paired t-test for parametric continuous data whereas, Wilcoxon signed rank test for non-parametric continuous data and $\chi 2$ or Fishers's exact test for categorical data. p-values of <0.05 will be considered as a significant level in all comparisons. In addition, 95% confidence interval (CI) will be reported for all quantitative and categorical variables in the study.

Qualitative data

Data will be collected using digital recorders and systematically stored on the computer on a daily basis for a prolonged timeframe, adhering to the requirement of Institutional Review Board (IRB) and data policy of icddr,b. In addition, data collection and data analysis processes will occur in synergy, as qualitative data collection and analysis is an ongoing and reflexive process, and this process will allow for the identification of saturation points.[46 47] All qualitative data will be analyzed manually by adopting line by line content, contextual and thematic analysis strategies; and coding and re-coding data into themes and subthemes. The results will be summarized and presented keeping in mind the local context, and some of the findings will be presented verbatim in order to substantiate or reflect noteworthy ideas and perspectives.

Patient and public involvement

As mentioned in the "Study population" section, sexual minority people, enlisted under the intervention and comparison DICs, will be included to explore the research questions and measure outcomes on TB screening, TB presumptive case referral, TB case detection and TB knowledge. While this research did not directly engage them in the design or conceptualization of the study, researchers planned to involve them throughout the data collection and analysis period. The study participants will be first engaged before the data collection period, when they will be preliminarily oriented about the study objectives and procedure. They will also be involved in facilitating access to and recruiting additional participants, including hidden and hard-to-reach sexual minority people. To design a viable and context-specific community-based TB screening model and optimize selection of actors (i.e. community health workers, existing peer educator, new peer volunteer as TB screener, etc.) for engagement in TB screening, insights will be sought from sexual minority people and service providers via formative research. Member checking sessions will be also conducted to verify correct findings and interpretative analyses. Sexual minority people will be the key recipients of the intervention. GRIPP2 reporting checklist for patient and public involvement is available in supplementary Table 1.

ETHICS AND DISSEMINATION

Participation in the research process will be voluntary. To ensure maximum congeniality of the informants, verbal consent will be attained from sexual minority people during IDIs and FGDs whereas written consent will be obtained from representative of PRs and SRs, service providers from DOTs centers, experienced program managers, and researchers during KIIs and FGDs. Verbal and / or written consent will also be taken from sexual minority people prior to the quantitative survey, as well as the pre- and post-test phases. Experiences of working with sexual minority people suggest that many sexual minority people withhold information about their identities and practices that characterize them as a KP (e.g., involvement in sex trade, sexual orientation) in written form in apprehension of identity disclosure. Structural barriers such as criminalization of same-sex behaviour and socio-religious stigma impede the uptake of written consent from sexual minority people.

Research participants will be briefed about the objectives of the study, the data collection process, and topics of discussion. The researchers ascertained the anonymity of the participants'

responses. Moreover, no identifying information will appear in the data collection tools. If any research participant declines the recording of his responses, researchers will take written notes.

During intervention, if any participant is tested positive for TB, then s/he will be linked to the adjacent DOTS center, to ensure treatment and follow-up the treatment adherence.

Ethical clearance was obtained from icddr,b's Institutional Review Board (IRB) which follows international ethical standards to ensure confidentiality, anonymity, and informed consent.

Study findings will initially be disseminated at the organization and then subsequently, among policymakers and relevant stakeholders to inform the policy for implication. In addition, findings will be disseminated to a diverse audience via different scientific forums such as peer-reviewed journals, and presentations at national and international conferences. Further dissemination initiatives include translational and implementation strategies such as the impact of findings in the national policy.

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AUTHOR CONTRIBUTIONS

Golam Sarwar drafted the manuscript and revised it with inputs from all co-authors. Sharful Islam Khan is the senior and corresponding author of this manuscript and was responsible for the overall supervision of information summarization, exchange and management, analysis of information, and drafting of the manuscript. Md. Masud Reza and Mohammad Niaz Morshed Khan also supervised overall information extraction and assisted in the drafting of the manuscript. Gorkey Gourab also managed information extraction and helped in writing the manuscript. Shaan Muberra Khan, Samira Dishti Irfan and Mahbubur Rahman reviewed the manuscript and provided valuable suggestions for the overall improvement of the manuscript.

Sayera Banu, Rupali Sisir Banu, Shahriar Ahmed and A K M Masud Rana all authors have read, review and approved the final manuscript.

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COMPETING INTERESTS

None declared.

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List of Table(s)

List of Figure(s)

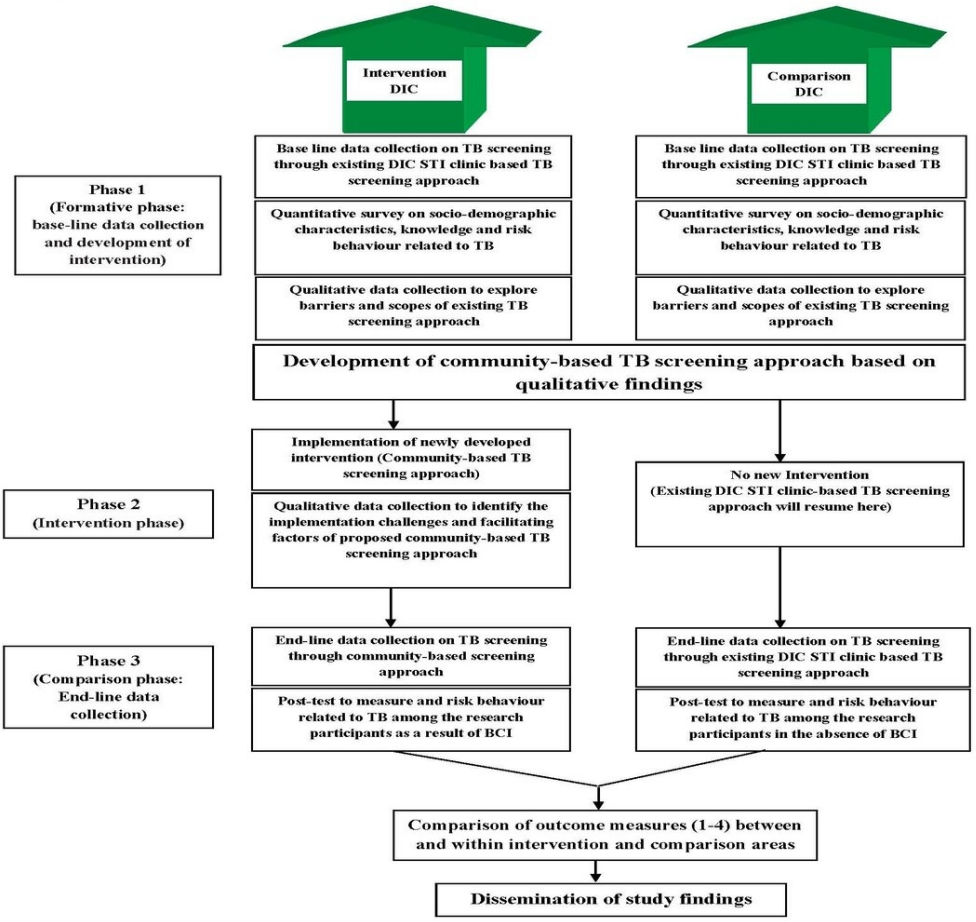

Figure 1: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study phases, January 2019- June 2020

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Figure 2: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study location/area, January 2019-June 2020

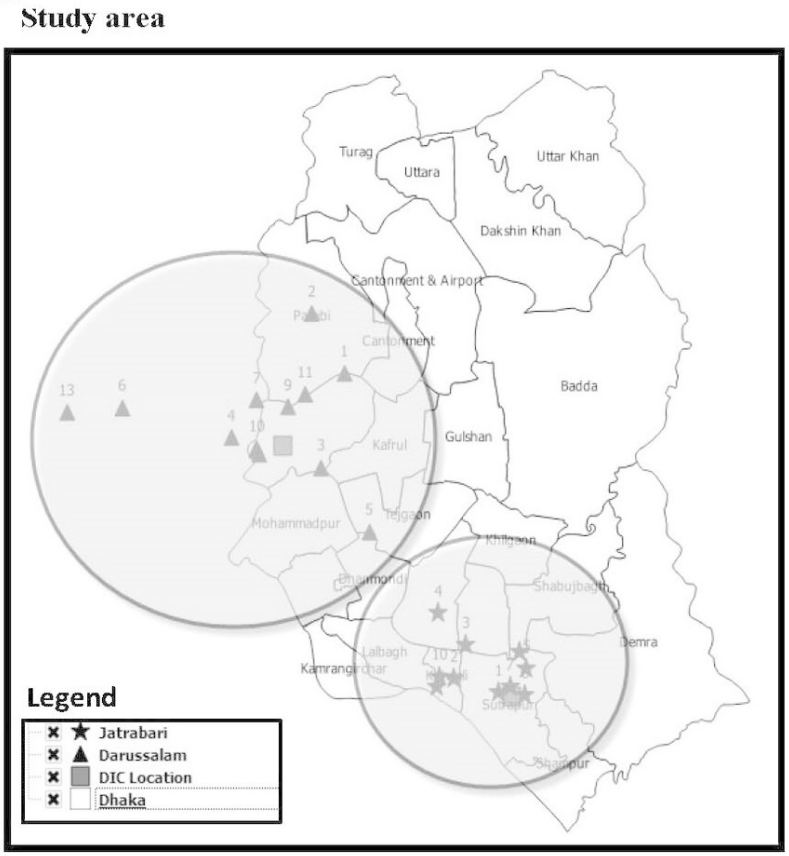

Figure 2: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study location/area, January 2019-June 2020

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Supplementary table 1: GRIPP2 long form for the study entitled "Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol"

Section and topic	Item	Reported on page No
Section 1: Abstract of paper		
1a: Aim	Report the aim of the study	Page 5 (line No: 18-24)
1b: Methods	Describe the methods used by which patients and the public were involved	Page 5 (line No: 28-38)
1c: Results	Report the impacts and outcomes of PPI in the study	Not applicable
1d:Conclusions	Summarise the main conclusions of the study	Not applicable
1e: Keywords	Include PPI, "patient and public involvement," or alternative terms as keywords	Not applicable
Section 2: Background to paper		
2a: Definition	Report the definition of PPI used in the study and how it links to comparable studies	Page 7 (line No: 48-55), Page 8 (line No: 3-49)
2b: Theoretical underpinnings	Report the theoretical rationale and any theoretical influences relating to PPI in the study	Page 9 (line No: 15-26)
2c: Concepts and theory development	Report any conceptual models or influences used in the study	Operational research framework, Page 10 (line No: 29-35)
Section 3: Aims of paper		
3: Aim	Report the aim of the study	Page 9 (line No: 42-51)
Section 4: Methods of paper		
4a: Design	Provide a clear description of methods by which patients and the public were involved	Page 17 (line No: 37-46), Page 18 (line No: 54-56), Page 19 (line No: 3-44, 55-39, 41-56) Page 20 (line No: 3-7)
4b: People involved	Provide a description of patients, carers, and the public involved with the PPI activity in the study	Page 12 (line No: 38-45), Page 13 (line No: 3-53) Page 14 (line No: 3-20)
4c: Stages of involvement	Report on how PPI is used at different stages of the study	Page 22 (line No: 10-28)

4d: Level or nature of involvement	Report the level or nature of PPI used at various stages of the study	Not applicable
Section 5: Capture or measurement of PPI impact		
5a: Qualitative evidence of impact	If applicable, report the methods used to qualitatively explore the impact of PPI in the study	Not applicable
5b: Quantitative evidence of impact	If applicable, report the methods used to quantitatively measure or assess the impact of PPI	Page 20 (line No: 27) Page 21 (line No: 3-6)
5c: Robustness of measure	If applicable, report the rigour of the method used to capture or measure the impact of PPI	Page 10 (45-55) Page 11 (3-40)
Section 7: Study results		
6: Economic assessment	If applicable, report the method used for an economic assessment of PPI	Not applicable
7a: Outcomes of PPI	Report the results of PPI in the study, including both positive and negative outcomes	Not applicable
7b: Impacts of PPI	Report the positive and negative impacts that PPI has had on the research, the individuals involved (including patients and researchers), and wider impacts	Not applicable
7c: Context of PPI	Report the influence of any contextual factors that enabled or hindered the process or impact of PPI	Not applicable
7d: Process of PPI	Report the influence of any process factors, that enabled or hindered the impact of PPI	Not applicable
7ei: Theory development	Report any conceptual or theoretical development in PPI that have emerged	Not applicable
7eii: Theory development	Report evaluation of theoretical models, if any	Not applicable
7f: Measurement	If applicable, report all aspects of instrument development and testing (eg, validity, reliability, feasibility, acceptability, responsiveness, interpretability, appropriateness, precision)	Page 21 (line No: 16-36)
7g: Economic assessment	Report any information on the costs or benefit of PPI	Not applicable
Section 8: Discussion and conclusions		
8a: Outcomes	Comment on how PPI influenced the study overall.	Not applicable

	Describe positive and negative effects	
8b: Impacts	Comment on the different impacts of PPI identified in this study and how they contribute to new knowledge	Not applicable
8c: Definition	Comment on the definition of PPI used (reported in the Background section) and whether or not you would suggest any changes	Not applicable
8d: Theoretical underpinnings	Comment on any way your study adds to the theoretical development of PPI	Not applicable
8e: Context	Comment on how context factors influenced PPI in the study	Not applicable
8f: Process	Comment on how process factors influenced PPI in the study	Not applicable
8g: Measurement and capture of PPI impact	If applicable, comment on how well PPI impact was evaluated or measured in the study	Not applicable
8h: Economic assessment	If applicable, discuss any aspects of the economic cost or benefit of PPI, particularly any suggestions for future economic modelling.	Not applicable
8i: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so that others can learn from this study	Not applicable

BMJ Open

Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Infectious diseases, HIV/AIDS
Keywords:	Tuberculosis < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES, HIV & AIDS < INFECTIOUS DISEASES

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Title: Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol

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Key words: Tuberculosis (TB), TB screening, referral, sexual minority, health facility based TB screening

ABSTRACT

Introduction

Although Bangladesh is a country of generalized Tuberculosis (TB) epidemic, the HIV prevalence is low among general populations, and 3.9% among key populations (KPs). Despite the high possibility of HIV-TB co-infection, scientifically tested approaches for increasing TB case detection among sexual minority people are yet to be developed and implemented in Bangladesh. Such approaches could foster service delivery linkages between communities and the government health system. Findings of this experimental research are likely to provide new insights for program managers and policy planners for adopting a similar approach in order to enhance TB referral, thus ultimately increasing TB case detections and reducing the likelihood of TB-related mortalities and morbidities, irrespective of HIV status.

Methods and analysis

This operational research will follow a quasi-experimental design, applying both qualitative and quantitative methods, in two drop-in centers (DICs) in three phases. Phase 1 will encompass baseline data collection and development of a community-based TB screening approach. In phase 2, the newly developed intervention will be implemented, followed by end-line data collection in phase 3. Qualitative data collection will be continued throughout the first and second phases. The baseline and end-line data will be compared both in the intervention and comparison areas to measure the impact of the intervention.

Ethics and dissemination:

Ethical approval was obtained from the Institutional Review Board (IRB) of International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). The findings will be disseminated through diverse scientific forums including peer-reviewed journals, presentation at conferences and among the policy makers for policy implication. The study started in January 2019 and will continue until June 2020.

Article summary

Strengths and limitations of this study

- The study adopts a mixed method design, which will validate results from quantitative and qualitative strands in order to explicitly understand the research problem.
- The study will use a community-based approach, thus ensuring the involvement of the sexual minority population at all phases of the study to ensure the internal validity of the findings.
- This study will develop an approach of detecting TB cases for the first time among sexual minority people through an integrated model, which will harness service delivery linkages with the government health system for achieving sustainability.
- This study will follow a quasi-experimental design rather than a randomized controlled trial.
- The study will be conducted in two service centers only, therefore the findings generated from this study may not be generalized for the whole sexual minority people; nonetheless, the approach is expected to help in informing the policy makers.

INTRODUCTION

Human immunodeficiency virus (HIV) epidemic poses as an impediment to the effective control of tuberculosis (TB) worldwide.[1] Clinical evidence has alluded to a causal relationship between TB and HIV.[2] HIV is considered as the most predominant risk factor for the development of *Mycobacterium tuberculosis* (MTB) infection to TB disease.[3] Likewise, TB infection accelerates the progression of HIV infection, reduces survival and even predisposes the infected individual to premature death.[4] On the global scale, an estimated 10.0 million (range 9.0–11.1 million) people were newly diagnosed with TB in 2018, which also constituted to 8.6% of the People Living with HIV (PLHIV).[5] An estimated 1.2 million (range, 1.1–1.3 million) deaths due to TB disease occurs across the globe in 2018, in addition to 251,000 (range, 223,000–281,000) TB deaths happened among PLHIV.[5] This is because PLHIV are 29 (26-31) times more vulnerable to TB than HIV negative individual.[6] In this context, TB is considered as the leading preventable cause of death especially among PLHIV.[7]

Bangladesh is a country with generalized TB epidemic, though it has a low HIV prevalence of less than 0.01% among general populations.[8] [9] However, HIV surveillance findings demonstrated that 3.9% of the key populations (KPs) at risk of HIV contracted HIV infection.[10] Between 1999 to 2002, a study conducted by International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) among 958 patients to determine HIV prevalence among patients with TB in Dhaka demonstrated an estimated 0.1% TB/HIV co-infection.[11] Nonetheless, recent data reported by Government of Bangladesh (GoB) from 2009 to 2014 showed that merely 1% of the registered TB patients in the country were documented to have HIV.[12] In 2017, the prevalence of HIV among the diagnosed TB patients (n=3,917) was 0.36% whereas approximately 16% of the PLHIV (n=559) were tested positive for TB, thus illustrating bidirectional upward trends in TB/HIV co-infection rates over the years.[13] Moreover, despite of being a country of high TB burden, TB case detection rate (the yearly number of newly notified cases per 100,000 population) in Bangladesh is still unsatisfactory as at a 75% case detection rate as of 2018.[5]

In Bangladesh, TB control interventions are being implemented in healthcare facilities throughout the country, from the central to peripheral levels. HIV prevention programs are primarily concentrated in 23 priority districts based on concentration of HIV positive cases and KPs.[14] Thus, there is inadequate linkage between TB and HIV prevention programs, that engendering low identification of TB cases among KPs. To foster a functional collaboration between TB and HIV programmes, GoB designed a roadmap of collaboration between the National Tuberculosis Program (NTP), AIDS/STD Program (ASP), key stakeholders (BRAC, icddr,b, Save the Children, etc.) and implementing partners (Damien Foundation, CARE,B, etc.) since 2009 with an aim to institute programmatic linkages at each level of healthcare, albeit with unsatisfactory outcomes.[12]

Worldwide, KPs, including sexual minority people [i.e., males who have sex with males (MSM), male sex workers (MSW) and transgender women (locally known as hijra)], people who inject drug (PWID), female sex workers (FSW), and PLHIV, are considered vulnerable to TB.[15] These populations are particularly susceptible to TB infection due to their hidden and hard-to-reach nature along with their unwillingness to visit healthcare facilities.[16] [17] In particular, sexual

minority people are more vulnerable not only because of their propensity to contract TB/HIV co-infections but also their highly stigmatized nature.[18] Case notification rates also remain low among these populations due to the implementation of passive case detection strategies which often exclude marginalized populations, thus leaving them undiagnosed and untreated for TB.[19] [20] Experiences from some countries have shown that successful implementation of active case finding strategies, resulted in increased detection of TB case, especially for hidden and/or hard-to-reach populations.[21] [22] For example, a recent study conducted in tribal India revealed that active case finding interventions contributed to a 52% increase in testing rates and 84% increase in TB case notifications.[23] Similarly, a recent quasi-experimental study that was conducted in Cambodia showed that the TB case notification rates were significantly higher ($p < 0.05$) among the intervention group (which adopted active case finding) compared to the control group (which employed passive case finding).[24] Likewise, a recent cohort study conducted in China documented that early case detection rates significantly increased among the higher-risk groups, such as PLHIV.[25]

Several studies have suggested that TB screening should be encompassed in an integrated HIV intervention, while also addressing the other healthcare needs of PLHIV. For example, a community outreach model was adopted in rural Mozambique, where TB, HIV, malaria and nutritional services are packaged in a single service delivery point, which helped improve acceptability and satisfaction.[26] However, the acceptability of TB screening programs among MSM has not been a substantial point of focus in research or program implementation. In fact, many NTP programs in low- and middle-income countries (LMICs) are oblivious to the role that MSM may contribute in TB epidemics. As evidenced by programmatic data, MSM are more rooted in higher income countries.[27] The acceptability of TB screening was found to range from 43% to 91% in many of the studied countries, although the underlying reasons were not specified.[28] TB screening service acceptability among transgender women is also an understudied area. The reach and recruitment rates of transgender cases were hard to quantify since many of the studies used word of mouth or peer referrals through snowball sampling.[29]

In Bangladesh, 77% of the transgender women (locally known as *hijra*) articulated their willingness to provide sputum samples.[19] [28] According to Mitchell et. al. (2013), it was inconvenient to reach transgender participants through traditional contact techniques.[29] Rather,

the Center for Disease Control (CDC) recounted an experience where they attempted to recruit transgender women through exploring their residences, social networks and other social spheres as well as common social spheres.[30] Transgender women in New York and Bangladesh, alike, indicated that they felt more comfortable visiting a community-based healthcare facility, particularly if they did not disclose their sexual orientation and if the facilities were catered to sexual minority populations.[19]

icddr,b is currently performing verbal TB screening[1] for sexual minority people through Drop-in Centre (DIC) based TB screening approach. Programmatic evidence showed that this approach is not working efficiently in increasing the number of presumptive TB case identifications and referrals, and active TB case detection. During the preceding six-month period (i.e., July 2018-December 2018) of inception of the study, only 146 (around 16%) were screened for TB, using the verbal TB screening form during clinic sessions, yet none were referred as presumptive cases [2] (Programme data of icddr,b). National data also demonstrated that additional efforts are required to identify TB cases among highly vulnerable KPs.[12]

A survey conducted in Bangladesh showed the controls had significantly poorer knowledge on mode of transmission, suggestive symptoms and availability of free treatment than the TB cases.[31] Evidence shows that the knowledge is an essential precursor for successful uptake of TB services and case detection. Knowledge levels and healthcare-seeking behaviors can also contain the spread of TB among KPs.[32]

Despite high possibility of TB/HIV co-infection, a scientifically tested approach for increasing TB case detection among sexual minority people is yet to be developed and implemented in Bangladesh. Therefore, a community-based TB screening approach will be tested among sexual minority people. Such an approach is expected to encourage sustainable service delivery linkages between community systems and the Government health systems. Findings of this study are likely to provide new insights for program managers and policy planners for developing and implementing a community-based TB screening approach to enhance TB referral which ultimately increase TB case detection among sexual minority people.

[1]" It is a standardized verbal questionnaire for investigating presumptive TB cases on the presence of the following symptoms and signs: cough for more than two weeks, haemoptysis, chest pain, breathlessness, evening rise of temperature/night sweating, anorexia, and weight loss/weakness".

[2] Presumptive TB case refers to a patient who manifests symptoms or signs which are suggestive of TB (formerly known as a TB suspect).

RESEARCH OBJECTIVES

Primary Objective: To develop and assess a community-based TB screening approach to enhance TB referral for increasing case detection among sexual minority people in Dhaka city, Bangladesh

Secondary Objectives:

1. To understand barriers and scopes of the existing TB screening approach for sexual minority people
2. To measure knowledge of TB among the participants
3. To develop and implement a community-based TB screening approach
4. To assess the impact of community-based TB screening approach on TB screening, presumptive TB case referral, TB case detection and knowledge related on TB

METHODS AND ANALYSIS

Research design

Under the operational research framework, by applying mixed methods (i.e. qualitative and quantitative) approach, the study will follow a quasi-experimental design with enlisted sexual minority people in selected DICs.[33] Both pre-intervention and post-intervention measurements will be facilitated among non-randomly selected control groups.[34] The participants of intervention site will be compared with the participants of the comparison site. To measure changes between two time points, baseline and end-line in the outcome of interest and between the two groups, an analysis will be conducted.

Research plan

The study will ensue through the following phases adopted from the operational research framework recommended by WHO and the Global Fund [35] : Figure 1 shows the activities of this study:

Phase 1: Formative phase

a. Qualitative data collection to explore implementation barriers and scopes of existing TB screening approach

b. Survey on socio-demographic characteristics, knowledge and risk behavior related to TB among the sexual minority people of the both intervention and comparison catchment areas
c. Development of community-based TB screening approach
d. Baseline data on the number of TB screening, referral of presumptive TB cases to Directly observed treatment, short-course (DOTS, also known as TB-DOTS) centers, and TB case detection within existing DIC STI clinic-based approach of TB screening at both intervention and comparison sites

Phase 2: Intervention phase

a. Implementation of community-based TB screening intervention
b. Qualitative data collection to identify implementation facilitators and challenges of community-based TB screening approach

Phase 3: Comparison phase

a. End-line data collection in both intervention and comparison sites on the number of TB screening, referral of presumptive TB cases to DOTS centers, and TB case detection. The comparison will be done between end-line and the base-line data in both intervention and comparison sites
b. Post-test to measure knowledge change as a result of behavior change intervention (BCI) among sexual minority people in the intervention DIC area and comparison DIC area at the end of the intervention period, of whom the latter will not get BCI. Comparisons will subsequently be drawn within and between these two areas

Development of community-based TB screening model

A community-based TB screening model will be developed based on the first phase findings. At the beginning of the second phase, researchers will develop a training module for the peer educators (PEs) based on the need assessment, map TB DOTS centers and devise DOTS referral strategies. Sensitization sessions will be conducted with the DOTS service providers and community leaders. Researchers will train PEs of the intervention area on the TB screening process and then be assigned to serve a separate list of sexual minority people. A work plan will be formulated to screen all sexual minority people at least once during the intervention period.

After taking their verbal consents, they will be screened at spots/residences/*dera* (residence of *hijra* leader) using a simplified structured verbal TB screening form, while maintaining confidentiality. If the case is negative, post-screening information and counseling will be provided and they will be encouraged to seek support if suspected with TB symptoms. If screened positive, they will undergo counseling and be referred to the nearest TB DOTS center for testing, either through self- or accompanied referral. After the test results are ready, the PE or the sexual minority people themselves will collect the report, and if anyone is tested positive s/he will be linked to nearby TB DOTS center for treatment and followed up for adherence. PEs will also conduct specialized educational sessions on TB at outreach sites where they will distribute visual materials and discuss TB risks and routes of transmission.

Study location

This experimental study will be conducted in two DICs (i.e., Jatrabari and Darus Salam DIC) in Dhaka city (Figure 2). These DICs are operated by a non-government organization (NGO) namely Bandhu Social Welfare Society (BSWS), under the Global Fund project of icddr,b. The intervention site, Jatrabari DIC, is located in the southern part of Dhaka city. Darus Salam DIC, the comparison site, is in the western part of Dhaka city (Mirpur). These DICs were selected purposively due to similar profiles in terms of duration of service delivery, the concentration of HIV positive cases, and number of sexual minority people served.

Study population

The sexual minority people enlisted for HIV prevention services in these two DICs will be selected for this study. Operational definitions for the MSM, MSW and *hijra* are provided in Table 1 which are currently used in the provision of HIV prevention services to sexual minority people.[36]

Table 1: Definitions of the MSM, MSW and *hijra*

Population	Operational definitions
Males who have sex with males (MSM)	Males who have had sex with males (with consent) within the last 1 year irrespective of whether or not they have sex with women or have a social or personal gay or bisexual identity, but do not sell sex
Male sex workers (MSW)	Male who sell sex to other males in exchange of money or gifts in the last 3 months
Hijra	Those who identify themselves as part of a traditional *hijra* sub-culture and who maintain the guru-chela hijra hierarchy

For qualitative interview the following research participants will be recruited purposively in this research:

1. Sexual minority people (MSM, MSW and *hijra*)
2. DIC staff (i.e., DIC managers, medical assistants, outreach supervisors, and peer educators)
3. Staff of adjacent DOTS centers (i.e., physicians, nurses, technicians etc.)
4. Experienced program managers and researchers working with KPs
5. Program managers (PMs) of national tuberculosis programme (NTP)
6. Representative from principal and sub recipients of the Global Fund (GF) project

Inclusion criteria

1. All sexual minority people aged 18 years or more, and enlisted in the service list of the intervention site (for intervention)
2. According to the sample size, a subset of sexual minority people of both intervention and comparison areas (for base-line and end-line survey)

3. Health service providers and other staff members of the intervention and control DICs (for qualitative interview only)
4. Senior management staff members of the PR and SRs, staff of adjacent DOTS center, experienced programme managers of NTP and researchers working with KPs (for qualitative interview only)
5. Those who provide verbal and / or written consent to participate in this study

Exclusion criteria

Participants who refuse to participate in this research, and sexual minority people who are not enlisted in the intervention DIC. In addition, minors, below18 years, will not be included in the study.

Study period

The study commenced in January 2019 and is anticipated to continue until June 2020. The Gantt chart is given below (Table 2):

Table 2: Gantt chart

Activities	Year																	
	2019												2020					
	Jan-Mar			Apr-Jun			Jul-Sep			Oct-Dec			Jan-Mar			Apr-Jun		
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1. Training of staff																		
2. Piloting																		
Phase-1																		
1. Baseline data collection:																		
a. Quantitative survey																		
b. Qualitative																		
c. Program data																		

2. Development of intervention model																	
Phase-2: 1. Implementation of Intervention 2. Qualitative data collection																	
Phase-3: End line data collection: a. Quantitative survey b. Program data																	
Data entry, cleaning, analysis and tabulations (quantitative)																	
Data transcription and analysis (Qualitative)																	
Preliminary report writing																	
Final report and dissemination																	

Sample size and sampling

Quantitative component

To conduct the baseline survey, in both the intervention and comparison sites, the calculation of sample size was done using the following standard formula [37] :

$$n = D\frac{\{z_{1-x}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_1(1-p_1)+p_2(1-p_2)}\}^2}{(p_2 - p_1)^2}$$

In the above formula:

D=Design effect=2 (due to cluster sampling method)

p_1= Assumed proportion of the outcome variable at the time of baseline survey

p_2= The target proportion at the end line, so that (p2-p1) is the magnitude of change that we want to be able to detect

p (bar)=$(p_1+p_2)/2$

$Z_{1-\alpha}$=The Z-score corresponding to desired level of significance=1.645[37]

$Z_{1-\beta}$= The Z-score corresponding to desired level of power=0.83[37]

A literature review was carried out in order to find out estimates of TB knowledge in terms of cause, route of transmission and prevention. The results depicted that the knowledge of cause, routes of transmission and prevention of TB ranged from 2-44%, 22-88% and 14-68%, respectively (Table 3).

Table 3: Literature review of the knowledge of TB

Indicators	Estimates of the indicators	Target group	Source
Knowledge of TB:			
1. Cause of TB: Percentage of beneficiaries correctly identify that TB is caused by Bacteria	43.9%	General population	Wandwalo, 2000[38]
	2%	General population	P. Suganthi, 2008[39]
	37.7%	General population	Kelemework, 2017[40]

Indicators	Estimates of the indicators	Target group	Source
2.Route of transmission of TB: Percentage of beneficiaries mentioned that TB is transmitted by air (by talk/by cough/by sneezing/by spitting TB germ)	53.7%	General population	Wandwalo, 2000[38]
	22-34%	General population	Aftab, 2009[41]
	55.5%	General population	Sreeramareddy, 2013[42]
	56%	General population	Shahed Hossain, 2015[31]
	88.0%	General population	Kelemework, 2017[40]
3.Methods of prevention: Percentage of beneficiaries mentioned that TB can be prevented by taking BCG vaccination/covering mouth and nose when TB patient is coughing or sneezing or spitting or talking	14%	General population	Aftab, 2009[41]
	68.2%	General population	Mukhtar, 2012[43]
	29.1-65.7%	General population	Kelemework, 2017[40]

The sample size was calculated in order to detect 20% changes (1-way change detectable) in the knowledge of TB between two time points with the design effect of 2.0, 95% confidence level and 80% power. Separate sample sizes were calculated for each of the categories and were adjusted for 5% drop-outs during the interview (Table 4). Finally, the largest sample size (N~160) will be selected to conduct the baseline survey each in the intervention and comparison areas. It is worth mentioning that all the findings were from the general population and no literature was found among the sexual minority populations. Thereafter, using programmatic experience among sexual minority population in Bangladesh, suitable values were assumed to calculate sample sizes (Table 4).

Table 4: Proposed sample size to conduct survey with sexual minorities (MSM, MSW, transgender) in Bangladesh (January 2019- June 2020)

Indicators used in the calculation of sample size	Suitable values assumed for the sexual minority people	1-way change detect-able	Design effect	Required Sample Size*
Knowledge of TB:				
1. Cause of TB: Percentage of beneficiaries correctly identify that TB is caused by bacteria	40%	20%	2.0	159
2. Route of transmission of TB: Percentage of beneficiaries mentioned that TB is transmitted by air (by talking/by coughing/sneezing/ spitting TB germs)	50%	20%	2.0	152
3. Methods of prevention: Percentage of beneficiaries mentioned that TB can be prevented by taking BCG vaccination/covering mouth and nose when TB patient is coughing/ sneezing/ spitting/ talking	50%	20%	2.0	152

*5% was added in order to adjust drop-out during survey

The baseline survey will be conducted using time location sampling (TLS).[28] The trained interviewers will interview sexual minority people at all congregating areas (spots) at a particular

time window, usually between 5-10 pm. After collecting the list of spots and the sexual minority people covered throughout each spot, the total sample size will be proportionately distributed among each spot. In each spot, the respondents will be randomly chosen for interview to collect data on socio-demographic characteristics, knowledge of and risk behaviors pertaining to TB, etc. Identification numbers (IDs) from the mother list will be used to avoid duplications during the survey. Similar sample size and sampling method will be used to conduct end line survey both in intervention and comparison areas.

Qualitative component:

Non-probabilistic purposeful maximum diversity sampling will be used in the qualitative component.[44] Based on our previous experience of working with sexual minority people, we plan to facilitate in-depth interviews (IDIs) with 15-18 sexual minority people, 10-15 key informants interviews (KIIs) with service providers. In addition, two focus group discussions (FGDs) will be conducted with sexual minority people and service providers. The sample size may vary depending on the points of data saturation and redundancy.

Data collection method

Qualitative data collection

Several qualitative data collection approaches will be employed, such as IDIs with the sexual minority people, KIIs with the service providers and FGDs with sexual minority people and service providers.

Quantitative data collection

Survey on socio-demographic characteristics, knowledge of and risk behavior related to TB

Survey on socio-demographic characteristics, knowledge of and risk behaviors related to TB will be conducted among selected numbers of sexual minority people of both intervention and comparison areas during baseline and end line surveys at an approximate interval of six months.

Baseline and end line programmatic quantitative data collection

At the start and end of the intervention phase of the study, data will be collected from programme report of the Global Fund project of icddr,b on the total number of beneficiaries

screened for TB, total number of referred cases for presumptive TB and number of TB case detections within the extant STI clinic-based TB screening approach as well as the new intervention approach at both the intervention and comparison sites.

Data collection tool

A structured TB screening format will be used for verbal TB screening. The survey will be conducted via a semi-structured questionnaire in standard Bengali. This questionnaire will encompass the socio-demographic profile, knowledge of and risk behaviors related to TB. Moreover, open-ended guidelines will be used for qualitative interviews and FGDs. All the guidelines and questionnaires will be field tested. Based on field-testing, these data collection tools may need to be refined, where appropriate, in order to facilitate the data collection process. All qualitative and quantitative interviews will be conducted in standard Bengali.

Outcome variables

Data to measure outcome variables will be extracted from the ongoing HIV prevention programme from both intervention and comparison areas. These data will be expressed in terms of percentage points to assist statistical analysis. The outcome measures are defined as follows:

1. Number of TB screenings: Number of beneficiaries screened for TB at the community, which will be expressed as percentage points in relation to the total number of beneficiaries enlisted in the mother-list.
2. Number of presumptive TB case referrals: Number of beneficiaries referred to DOTS centers for TB testing, which will be expressed as percentage points in relation to the total number of beneficiaries screened at the community.
3. Number of TB case detections: Number of beneficiaries who will be tested positive for TB, which will be expressed as a percentage points in relation to the total number of presumptive cases tested.

Data on knowledge related to TB will be collected from quantitative surveys at the beginning of intervention (baseline) and after intervention (end line) both in the intervention and comparison areas. This outcome variable will measure the knowledge of TB, as defined below.[45]

1. Cause of TB: Correctly able to identify that TB is caused by bacteria

2. Route of transmission of TB: TB is transmitted by air (by talking/ coughing/ sneezing/ spitting TB germs)
3. Methods of prevention: TB can be prevented by taking BCG vaccination/covering mouth and nose when TB patient is coughing/sneezing/spitting/talking

Data analysis

Quantitative data

Statistical analysis will be conducted using Stata version 13.0 (Stata Corp Inc., College Station, Texas, USA). Epi Info (Version 6.03; Centres for Disease Control and Prevention, Atlanta, Georgia, USA) will be used for data entry. The populations and measurements will be presented through descriptive statistics. Differences in the outcome variables between intervention and comparison groups at the baseline and at end line will be determined by the independent t-test for parametric continuous data, $\chi 2$ or Fishers's exact test for categorical data, and Wilcoxon rank-sum test for non-parametric continuous data. Differences in the outcome variables within intervention and comparison areas between two time points will be determined using the paired t-test for parametric continuous data whereas, Wilcoxon signed rank test for non-parametric continuous data and $\chi 2$ or Fishers's exact test for categorical data. p-values of <0.05 will be considered as a significant level in all comparisons. In addition, 95% confidence interval (CI) will be reported for all quantitative and categorical variables in the study.

Qualitative data

Data will be collected using digital recorders and systematically stored on the computer on a daily basis for a prolonged timeframe, adhering to the requirement of Institutional Review Board (IRB) and data policy of icddr,b. In addition, data collection and data analysis processes will occur in synergy, as qualitative data collection and analysis is an ongoing and reflexive process, and this process will allow for the identification of saturation points.[46 47] All qualitative data will be analyzed manually by adopting line by line content, contextual and thematic analysis strategies; and coding and re-coding data into themes and subthemes. The results will be summarized and presented keeping in mind the local context, and some of the findings will be presented verbatim in order to substantiate or reflect noteworthy ideas and perspectives.

Patient and public involvement

As mentioned in the "Study population" section, sexual minority people, enlisted under the intervention and comparison DICs, will be included to explore the research questions and measure outcomes on TB screening, TB presumptive case referral, TB case detection and TB knowledge. While this research did not directly engage them in the design or conceptualization of the study, researchers planned to involve them throughout the data collection and analysis period. The study participants will be first engaged before the data collection period, when they will be preliminarily oriented about the study objectives and procedure. They will also be involved in facilitating access to and recruiting additional participants, including hidden and hard-to-reach sexual minority people. To design a viable and context-specific community-based TB screening model and optimize selection of actors (i.e. community health workers, existing peer educator, new peer volunteer as TB screener, etc.) for engagement in TB screening, insights will be sought from sexual minority people and service providers via formative research. Member checking sessions will be also conducted to verify correct findings and interpretative analyses. Sexual minority people will be the key recipients of the intervention. GRIPP2 reporting checklist for patient and public involvement is available in supplementary Table 1.

Study limitations

One of the major limitations is unlike RCT, the quasi-experimental study design is unable to establish a strong causal association between intervention and outcome due to the lack of randomization.[48] However, to overcome this limitation, a similar comparison group will be assigned, which will not receive the intervention. Moreover, qualitative methods will be integrated with quasi-experimental methods to support or refute the findings of the quantitative evaluation and to assess the effectiveness of the intervention. Thus, the causal inference will be strengthened. Another potential limitation might be the chance of insufficient control of some confounding factors, which may influence or contaminate the outcome.[49] This limitation will be mitigated through employing pre- and post intervention measurement, and statistical analyses that adjust ('control') the confounder(s). In addition, any positive or negative findings that may influence the expected outcome will be documented and reported to describe the context broadly within which generally causal relationships are constructed and deconstructed. Since the study will adopt the non-probabilistic purposive sampling approach because of the stigmatized and

hidden nature of the sexual minority people, this may incur selection bias.[49] Therefore, maximum variation sampling will be attempted to minimize this bias.

ETHICS AND DISSEMINATION

Participation in the research process will be voluntary. To ensure maximum congeniality of the informants, verbal consent will be attained from sexual minority people during IDIs and FGDs whereas written consent will be obtained from representative of PRs and SRs, service providers from DOTs centers, experienced program managers, and researchers during KIIs and FGDs. Verbal and / or written consent will also be taken from sexual minority people prior to the quantitative survey, as well as the pre- and post-test phases. Experiences of working with sexual minority people suggest that many sexual minority people withhold information about their identities and practices that characterize them as a KP (e.g., involvement in sex trade, sexual orientation) in written form in apprehension of identity disclosure. Structural barriers such as criminalization of same-sex behaviour and socio-religious stigma impede the uptake of written consent from sexual minority people.

Research participants will be briefed about the objectives of the study, the data collection process, and topics of discussion. The researchers ascertained the anonymity of the participants' responses. Moreover, no identifying information will appear in the data collection tools. If any research participant declines the recording of his responses, researchers will take written notes.

During intervention, if any participant is tested positive for TB, then s/he will be linked to the adjacent DOTS center, to ensure treatment and follow-up the treatment adherence.

Ethical clearance was obtained from icddr,b's Institutional Review Board (IRB) which follows international ethical standards to ensure confidentiality, anonymity, and informed consent.

Study findings will initially be disseminated at the organization and then subsequently, among policymakers and relevant stakeholders to inform the policy for implication. In addition, findings will be disseminated to a diverse audience via different scientific forums such as peer-reviewed journals, and presentations at national and international conferences. Further dissemination initiatives include translational and implementation strategies such as the impact of findings in the national policy.

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AUTHOR CONTRIBUTIONS

Golam Sarwar drafted the manuscript and revised it with inputs from all co-authors. Sharful Islam Khan is the senior and corresponding author of this manuscript and was responsible for the overall supervision of information summarization, exchange and management, analysis of information, and drafting of the manuscript. Md. Masud Reza and Mohammad Niaz Morshed Khan also supervised overall information extraction and assisted in the drafting of the manuscript. Gorkey Gourab also managed information extraction and helped in writing the manuscript. Shaan Muberra Khan, Samira Dishti Irfan and Mahbubur Rahman reviewed the manuscript and provided valuable suggestions for the overall improvement of the manuscript. Sayera Banu, Rupali Sisir Banu, Shahriar Ahmed and A K M Masud Rana all authors have read, review and approved the final manuscript.

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COMPETING INTERESTS

None declared.

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List of Table(s)

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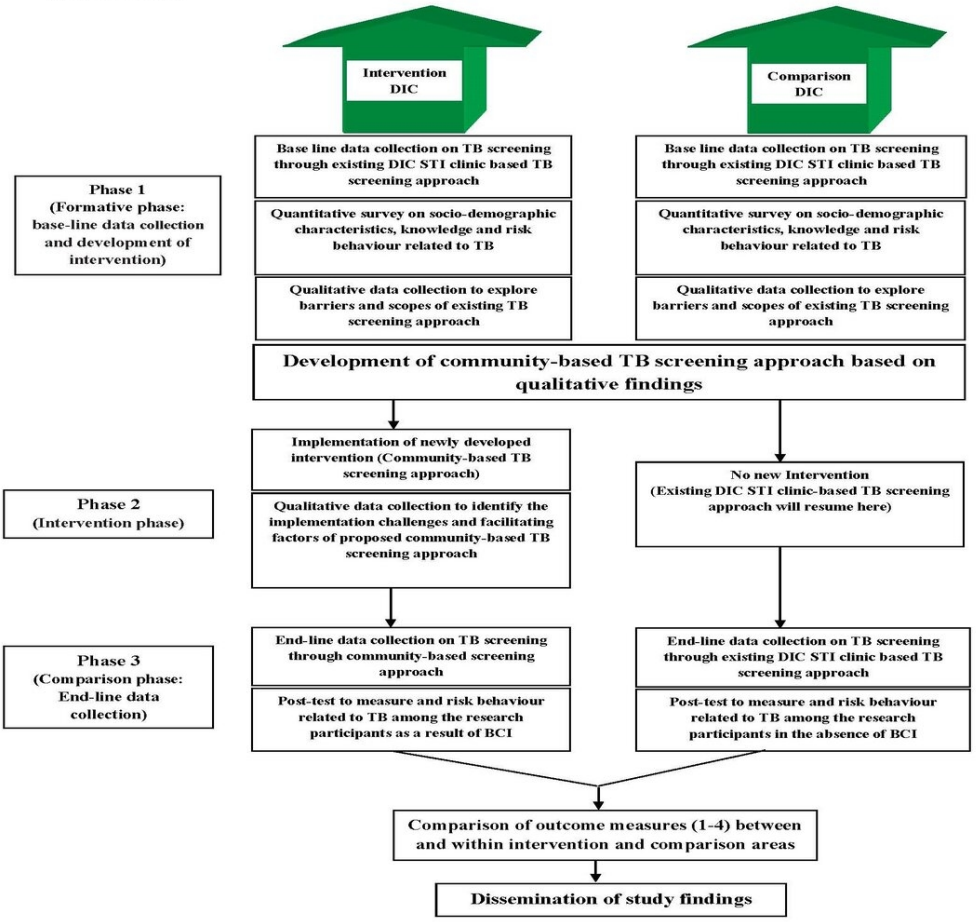

Figure 1: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study phases, January 2019- June 2020

91x91mm (300 x 300 DPI)

Figure 2: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study location/area, January 2019-June 2020

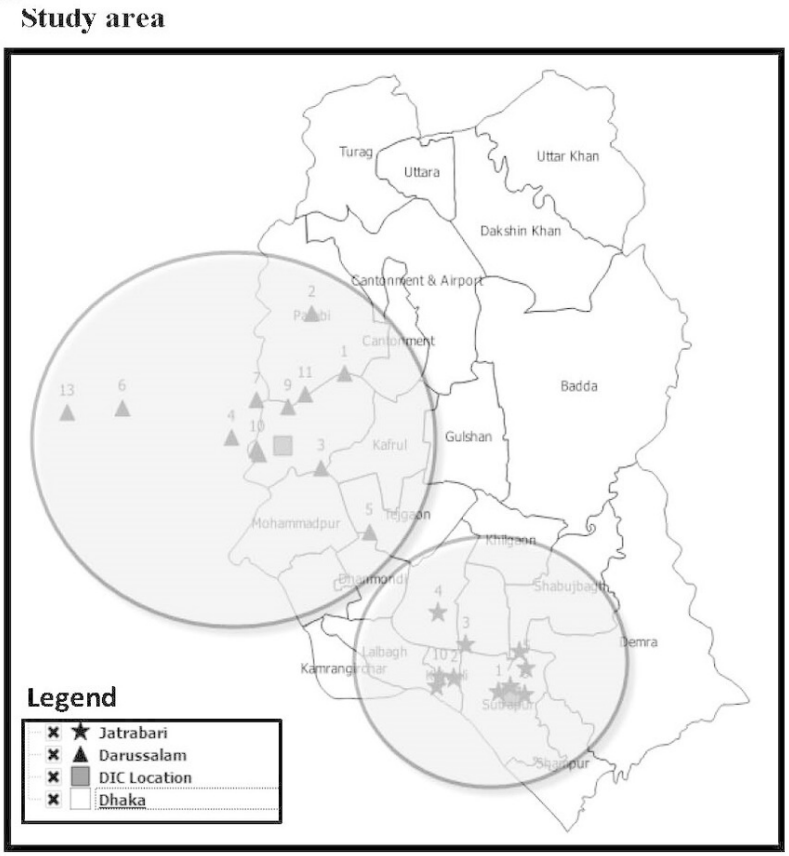

Figure 2: Developing and testing community-based tuberculosis (TB) screening intervention for sexual minority population (MSM, MSW, transgender in Dhaka, Bangladesh Study location/area, January 2019-June 2020

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Supplementary table 1: GRIPP2 long form for the study entitled "Developing and testing community-based tuberculosis (TB) screening intervention to increase TB referral, case detection and knowledge among sexual minority people in urban Bangladesh: A mixed-methods study protocol"

Section and topic	Item	Reported on page No
Section 1: Abstract of paper		
1a: Aim	Report the aim of the study	Page 5 (line No: 18-24)
1b: Methods	Describe the methods used by which patients and the public were involved	Page 5 (line No: 28-38)
1c: Results	Report the impacts and outcomes of PPI in the study	Not applicable
1d:Conclusions	Summarise the main conclusions of the study	Not applicable
1e: Keywords	Include PPI, "patient and public involvement," or alternative terms as keywords	Not applicable
Section 2: Background to paper		
2a: Definition	Report the definition of PPI used in the study and how it links to comparable studies	Page 7 (line No: 48-55), Page 8 (line No: 3-49)
2b: Theoretical underpinnings	Report the theoretical rationale and any theoretical influences relating to PPI in the study	Page 9 (line No: 15-26)
2c: Concepts and theory development	Report any conceptual models or influences used in the study	Operational research framework, Page 10 (line No: 29-35)
Section 3: Aims of paper		
3: Aim	Report the aim of the study	Page 9 (line No: 42-51)
Section 4: Methods of paper		
4a: Design	Provide a clear description of methods by which patients and the public were involved	Page 17 (line No: 37-46), Page 18 (line No: 54-56), Page 19 (line No: 3-44, 55-39, 41-56) Page 20 (line No: 3-7)
4b: People involved	Provide a description of patients, carers, and the public involved with the PPI activity in the study	Page 12 (line No: 38-45), Page 13 (line No: 3-53) Page 14 (line No: 3-20)
4c: Stages of involvement	Report on how PPI is used at different stages of the study	Page 22 (line No: 10-28)

4d: Level or nature of involvement	Report the level or nature of PPI used at various stages of the study	Not applicable
Section 5: Capture or measurement of PPI impact		
5a: Qualitative evidence of impact	If applicable, report the methods used to qualitatively explore the impact of PPI in the study	Not applicable
5b: Quantitative evidence of impact	If applicable, report the methods used to quantitatively measure or assess the impact of PPI	Page 20 (line No: 27) Page 21 (line No: 3-6)
5c: Robustness of measure	If applicable, report the rigour of the method used to capture or measure the impact of PPI	Page 10 (45-55) Page 11 (3-40)
Section 7: Study results		
6: Economic assessment	If applicable, report the method used for an economic assessment of PPI	Not applicable
7a: Outcomes of PPI	Report the results of PPI in the study, including both positive and negative outcomes	Not applicable
7b: Impacts of PPI	Report the positive and negative impacts that PPI has had on the research, the individuals involved (including patients and researchers), and wider impacts	Not applicable
7c: Context of PPI	Report the influence of any contextual factors that enabled or hindered the process or impact of PPI	Not applicable
7d: Process of PPI	Report the influence of any process factors, that enabled or hindered the impact of PPI	Not applicable
7ei: Theory development	Report any conceptual or theoretical development in PPI that have emerged	Not applicable
7eii: Theory development	Report evaluation of theoretical models, if any	Not applicable
7f: Measurement	If applicable, report all aspects of instrument development and testing (eg, validity, reliability, feasibility, acceptability, responsiveness, interpretability, appropriateness, precision)	Page 21 (line No: 16-36)
7g: Economic assessment	Report any information on the costs or benefit of PPI	Not applicable
Section 8: Discussion and conclusions		
8a: Outcomes	Comment on how PPI influenced the study overall.	Not applicable

	Describe positive and negative effects	
8b: Impacts	Comment on the different impacts of PPI identified in this study and how they contribute to new knowledge	Not applicable
8c: Definition	Comment on the definition of PPI used (reported in the Background section) and whether or not you would suggest any changes	Not applicable
8d: Theoretical underpinnings	Comment on any way your study adds to the theoretical development of PPI	Not applicable
8e: Context	Comment on how context factors influenced PPI in the study	Not applicable
8f: Process	Comment on how process factors influenced PPI in the study	Not applicable
8g: Measurement and capture of PPI impact	If applicable, comment on how well PPI impact was evaluated or measured in the study	Not applicable
8h: Economic assessment	If applicable, discuss any aspects of the economic cost or benefit of PPI, particularly any suggestions for future economic modelling.	Not applicable
8i: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so that others can learn from this study	Not applicable