

Integrating Tobacco cessation intervention into Directly Observed Treatment Short course (DOTS) under Provincial Tuberculosis Control Program (PTP) Sindh in Karachi, Pakistan; an Implementation Research project

FINAL REPORT

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Introduction

Smoked tobacco use not only increases the risk of acquiring Tuberculosis (TB) but also adversely affects the outcomes of the TB treatment (1, 2). However, more recently, the use of smokeless tobacco has also been found to be associated with poor TB treatment outcomes (3, 4). Given the high burden of tobacco use, both smoked and smokeless, particularly in low and middle income countries (LMICs), World Health Organization (WHO) and International Union Against Tuberculosis and Lung Diseases (IUATLD) jointly published a monograph in 2007 calling for the need of merging efforts to control these two global epidemics (5).

Like many other LMICs, the burden of any form of tobacco use among TB patients is high in Pakistan ranging between 5-14% (6, 7). Unfortunately in the absence of routine data collection on tobacco use habits among diagnosed TB patients under national and provincial TB control programs, these estimates are derived from individual small to middle scale studies. However, According to Pakistan Demographic Health Survey 2012-13, in general population, a total of 45% of men and 6.4% of women aged between 15 and 49 smoke any form of tobacco (8). Smokeless tobacco use is also becoming a problem and according to a study, the burden of exclusive water pipe smoking and chewing tobacco use among women aged 15-49 years in Pakistan is 4% and 2% respectively (9).

With such high burden of smoking in general population and equal high burden of tuberculosis, the dream of a TB free Pakistan remains bleak and the efforts of the national and provincial TB control program (PTP) have limited impact.

A number of intervention trials have been conducted for smoked tobacco among TB patients in many countries including Sudan (10), Indonesia (11, 12), Malaysia (13), China (14), Nepal (15), Bangladesh (16), Iran (17) and Pakistan (18). These studies report promising smoking cessation (abstinence) rates.

In Pakistan, Siddiqi K and associates (18), in their (cluster randomized) trial on TB suspects in southern Punjab, used behavioural support intervention using WHO's 5As approach and Bupropion (an antidepressant and smoking cessation aid). The prospects of abstinence were increased to 7.4 and 8.2 times for behavioural support only and behavioural support plus bupropion intervention respectively.

However, very little is known regarding the feasibility of integrating cessation intervention for both smoked and smokeless tobacco into national/regional TB control programs. In order to

implement tobacco cessation intervention in the PTP as a routine treatment protocol, there is still lot to learn from the evidences available. This implementation research was named project NIJAAT loosely based on the Urdu word (to break free from) reflecting its aim ‘Nicotine and Tobacco Abstinence among TB patients’.

Objectives

1. To explore the barriers and enablers towards successful tobacco cessation among TB patients registered for DOTS at Ojha Institute of Chest Diseases, Karachi
2. To implement tobacco cessation intervention among TB patients registered for DOTS at Ojha Institute of Chest Diseases, Karachi
3. To evaluate the effectiveness of tobacco cessation intervention among TB patients registered for DOTS at Ojha Institute of Chest Diseases, Karachi

Data & Methods

Study Design

Quasi Experiment (Pre and Post Test without Control)

Study Setting

This study was conducted at Iqbal Yad Chest Clinic (IYCC), Ojha Institute of Chest Diseases (OICD), Dow University of Health Sciences (DUHS), Karachi. This is one of the largest TB treatment centres in Pakistan which receives patients from both within and outside the city.

Study Population

All pulmonary TB patients enrolled at the IYCC, DUHS for the treatment under Directly Observed Treatment Short Course (DOTS).

Inclusion criteria

- 1) All patients diagnosed with pulmonary tuberculosis aged 18 years and above.
- 2) Registered under DOTS at Iqbal Yad Chest Clinic.
- 3) Report to use any form of smokeless tobacco or have smoked 100 plus cigarettes/ beedi or any other form of smoked tobacco in past and currently use any form of smoked tobacco at least once a week.

Exclusion criteria

- 1) Drug resistant tuberculosis
- 2) Extra pulmonary tuberculosis in addition to pulmonary tuberculosis
- 3) Pregnancy
- 4) Residence outside of Karachi

Sample size

Using OpenEpi.com sample size calculator, taking the effect size (69% abstinence among patients with smoking cessation intervention compared to 13.8% in control group) reported by Siddiqi et al (18), at 99% confidence level and 90% power, minimum required sample size was calculated to be 50. This study however screened a total of 98 pulmonary TB patients.

Sampling Technique and procedure

Consecutive Sampling

Data Collection

Formative phase

A total of 12 In-depth interviews were conducted among TB patients selected through purposive sampling, who used tobacco to assess and optimize the behaviour change communication toolkit already used and reported by Siddiqi K et al (7) in Pakistan. The toolkit (annex-I) was judged to be appropriate for the use for tobacco cessation intervention for this study

Intervention phase

The study screened all pulmonary TB patients consecutively, registering at IYCC for treatment. Screening was carried out using questionnaire (annex-II) through volunteers. Two data collectors were hired and trained for counselling (provision of intervention) and carbon monoxide assessment (using PICO Smokerlyzer Multi2 with 250 PICO ADV- Bedfont Scientific Limited, UK). Cut-off for labelling smokers was used at ≥ 7 ppm of CO. Patients who reported to be tobacco users were enrolled into the study after obtaining informed written consent. Since all TB patients enrolled were smoked tobacco users, exhaled carbon monoxide was used to assess smoking status and abstinence. In addition to cessation intervention, patients were provided with leaflets (annexure IV) and Brochures for project NIJAAT (annexure III) to spread the knowledge regarding tobacco cessation among TB patients and their family members. Follow-up cards (annexure V) were used for the recording of follow-ups.

Post Intervention phase

In-depth Interviews were conducted with 5 TB patients after the intensive phase (2 months of anti-tuberculosis therapy and tobacco cessation intervention) to assess the effectiveness of the intervention.

Data Analysis

Data were entered and analysed using IBM SPSS v20 (Chicago, IL). Means and standard deviations were calculated for continuous variables where standard deviations are expressed within parenthesis. Frequencies and percentages were calculated and reported for all categorical variables. Effectiveness of the interventions was assessed as percentage of patients attaining abstinence at the end of intensive phase (2 months of TB treatment as per DOTS routine). Intensive phase is the phase after which a pulmonary TB patient should ideally become non-infectious while the remaining 4 months or more treatment is to completely cure the patient.

Monitoring, supervision and quality control

Monitoring was routinely carried out by principal investigator and co-principal investigators whereas quality control was assessed during monthly meetings with the data collectors and project staff.

Results

Formative Phase

A total of 12 TB patients were selected through judgemental sampling for In-Depth Interviews (IDIs) to explore the enablers and barriers towards tobacco cessation in order to modify Behaviour Change Communication tools during March and April 2017. The BCC intervention tool was optimized in the light of findings of IDIs.

Intervention Phase

A total of 98 Pulmonary TB patients were initially screened for use of tobacco and baseline characteristics using predesigned and pretested questionnaire in Urdu. Mean age of the patients was 34.01 (14.06) years while 75 (76%) of them were males. A total of 58 (59%) TB patients were smoked tobacco users while 6 of them used smokeless tobacco as well. All 58 patients provided informed written consent and were enrolled in the study and were provided with behaviour change communication intervention (tobacco cessation counselling) every 15 days as integrated part of DOTS treatment. Comparison between the baseline socio-demographic characteristics of TB patients according to tobacco use is provided in table 01. Mean number of counselling sessions provided to the patients was 8.26 (2.33).

Smoked tobacco use

Among patients who used tobacco all were male and 30 (60%) reported to smoke daily while 3 (5%) reported to smoke 3-4 times a week and 25 (43%) reported to smoke less than 3 times a week. Mean number of cigarettes smoked was 12.47 (18.12) cigarettes while the mean age of smoking initiation was 16.34 (4.73) years. Thirty two (fifty five percent) patients reported to smoke their first cigarette of the day within one hour of waking up in the morning. A total 26 (44.83) patients admitted to continue smoking even if they are sick in bed, while 33 (56.89%) reported to attempt quitting while the most common reason to start smoking again was nicotine withdrawal symptoms reported by 27 (46.55%) patients.

At baseline mean quit motivation score among these patients was 3.28 (1.01) on a scale of 1 to 4. Of these patients 55 (95%) reported that according to them their family members/spouse will very much support their decision if they decide to quit tobacco use while only 1 reported that they will not support at all. Fagerström nicotine dependence score analysis revealed that 29 (50%) of the TB patients were 'highly nicotine dependent', 21 (36%) were 'moderately dependent' while 8 (14%) were 'minimally dependent on nicotine'. Nine out of all 58 TB patients reported the use of cannabis.

Anxiety and depressive symptoms were measured using Aga Khan University Anxiety Depression Scale (AKUADS) using cut-off of > 20 scores and above. Employing this cut-off, a total of 14 (24%) of these patients were labelled as having symptoms of anxiety and depression.

Abstinence Rate

At the end of 2 months of intensive phase of anti-tuberculosis therapy coupled with tobacco cessation counselling, a total of 36 (62.1) patients had achieved abstinence with a mean value of exhaled carbon monoxide as 5.61 (1.51) ppm. Among those who failed to achieve abstinence the mean value of exhaled carbon monoxide levels were 9.40 (3.13) at the end of intensive phase of treatment. Binary logistic regression revealed no statistically significant associations between independent variables and successful abstinence. Table 02 and 03 shows comparison of mean carbonmonoxide (CO) at each follow up and comparison of baseline characteristics of TB patients respectively.

Factors associated with abstinence

Univariate and multivariable analyses were used to find factors associated with successful abstinence. However, none of the independent variables were found to be significantly associated with successful abstinence.

Post intervention phase

In-depth Interviews showed promising results related to the uptake of the routine tobacco cessation intervention with routine DOTS. Patients identified that despite their past attempts to quit use of tobacco, they were unsuccessful however, the integration of tobacco cessation counselling within DOTS have really helped them in attaining abstinence. They also suggested that the counselling sessions should be made more interactive like the use of videos etc.

Table 01

Baseline socio-demographic characteristics of all TB patients screened, according to tobacco use (n=98)

	Tobacco users n=58	Non-Tobacco users n=40	p-value*
Age	36.11 (13.16)	31.90 (14.97)	0.08
Gender			
Male	58 (100)	17 (43)	--
Female	0 (0)	23 (57)	
Education (in years)	3.6 (4.99)	4.27 (4.89)	0.58
Occupation			
Unemployed	12 (19)	8 (20)	0.15
Salaried job	29 (50)	24 (60)	
Self employed	18 (31)	8 (20)	
Household income (in PKR)			
<5000	3 (5)	3 (7)	<0.01
5000-9990	6 (10)	3 (7)	
10000-14999	15 (26)	14 (35)	
15000-19999	13 (23)	6 (15)	
≥20000	21 (36)	14 (35)	
Type of residence			
House	19 (33)	14 (35)	0.28
Flat/apartment	34 (59)	25 (62)	
Hut (Jhonpri)	3 (5)	1 (3)	
Homeless/Refugee	2 (3)	0 (0)	
Mean Family size	7.46 (5.74)	7.37 (3.53)	0.25

*Comparisons are made between groups (tobacco users and non-users) using independent sample t-test and one-way ANOVA. Values in parenthesis show standard deviation across mean for education in years and family size. Percentages are rounded off to the nearest integer.

Table 02

Comparison of mean carbon monoxide levels at baseline and subsequent follow-ups till the end of intensive phase treatment (2 months) among patients enrolled for tobacco cessation intervention (n=58)

Abstinence	Baseline	1st FU	2nd FU	3rd FU	4th FU
Achieved	8.22 (2.19)	6.75 (2.52)	6.18 (3.31)	6.11 (1.05)	5.61 (1.51)
Not achieved	9.09 (2.96)	10.50 (4.51)	9.5 (4.94)	12.04 (5.65)	9.40 (3.13)

Table 03

Comparison of baseline characteristics of TB patients who achieved abstinence and those who fail to achieve (n=58)

Characteristics	Abstinence at 2 months		p-value
	Achieved	Not achieved	
Age	34.88 (13.93)	37.57 (11.85)	0.46
Education in years	3.85 (5.06)	3.36 (4.99)	0.72
Baseline motivation to quit score	3.26 (0.69)	3.30 (1.38)	0.91
Baseline CO levels	8.22 (2.19)	9.09 (2.95)	0.21
Fagerström nicotine dependence score	6.28 (1.59)	7.41 (1.46)	0.02*
Anxiety and Depression symptoms score	18.23 (15.47)	14.09 (10.01)	0.28
Ever attempted quitting			
Yes	19 (58)	14 (42)	0.37
No	12 (67)	6 (33)	

Discussion

Project NIJAAT an implementation research project was first of its kind in the province of Sindh aimed at integrating tobacco cessation interventions within DOTS program run under the government.

The proportion of patients achieving abstinence were comparable to those reported from different studies from the region where El Sony et al from Sudan reported an abstinence rate of 66% among patient who received Behaviour Change Communication (BCC) in Sudan (10). Similarly, in 2015, Lin Y et al (14) reported that out of 244 TB patients, 64% reported abstinence after 6 months following brief advice intervention in TB patients. Another study from Indonesia (11) reported a quit rate 67% at the completion of the TB treatment if given brief advice regarding smoking cessation.

We found out that there was no statistically significant difference in baseline characteristics between patients who successfully achieved abstinence at two months except for the Fagerström nicotine dependence scores. Furthermore we were unable to detect any statistically significant associations between independent variables with successful cessation. Likely explanation for this could be a sample size inadequate to achieve statistical power.

There was a downward trend in the mean Carbon monoxide (CO) levels with every follow-up among patients who successfully achieved abstinence contrary to a rather haphazard trend among patients who failed to achieve abstinence.

The uptake of the intervention by the clinic staff was adequate where we tried to integrate the counselling into routine DOTS. However, since the currently used register and report tools (R&R tools used to record data of patients registered for DOTS) by the provincial TB control programs do not measure the use of tobacco among these patients, there is a dire need to incorporate this information into these registers so that burden of tobacco use can be routinely measured in TB patients registering for DOTS treatment.

Policy Recommendations

As indicated earlier, the lack of routine recording of tobacco use among TB patients registering for DOTS under PTP warrant the inclusion of this information into the R&R tools.

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