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Improving Health Literacy about Tuberculosis among Drug Users. A Pilot Randomized Controlled Trial

Carmen Aceijas[1*], Tim Weaver[2], Pamela Baez-Caraballo[1], Rafael Bello-Corassa[3], Nerissa Cummings[1,4] and Neelam Devi Sowamber[1]

[1]Middlesex University, Faculty of Science and Technology, Department of Natural Sciences, Faculty of Science and Technology, London, UK
[2]Middlesex University, Faculty of Health and Education, Department of Mental Health and Social Work, London, UK
[3]Federal University of Espírito Santo, Health Sciences Center, Post-graduate Program in Public Health, Vitoria, Espírito Santo, Brazil
[4]Imperial College Healthcare NHS Trust, Department of Infection Prevention and Control, London, UK

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Correspondence should be addressed to
Carmen Aceijas, UK
E-mail: c.aceijas@mdx.ac.uk

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Abstract

Introduction: Despite effective treatment, tuberculosis remains among the top-10 causes of death causing ~1.3 million deaths in 2017. Furthermore, tuberculosis infection rates have increased amongst excluded populations such as people misusing substances.

Objectives and design: We conducted a two London sites pilot randomized controlled trial to test interventions, recruitment, attrition rates and assessment procedures of a parallel, three-arms controlled trial to assess the effectiveness of tuberculosis health literacy interventions among drug dependent (heroin, crack cocaine or heroin and crack cocaine) population in treatment.

Results: Forty-two subjects were recruited to the pilot trial (response rate = 26%) and randomized to three interventions (1st: Information booklet; 2nd: Interactive seminar; 3rd: Interactive seminar + contingency management targeting tuberculosis-health-related action). Baseline and post-intervention tuberculosis knowledge scores were obtained and re-assessed at 2-months follow up. The overall attrition rate was 43%. The knowledge scale had good internal reliability (Cronbach's $\alpha = 0.7$). Statistically significant increases in knowledge scores (baseline to post-intervention = 5.9 points, baseline to follow-up = 4.3) were recorded for the whole sample (CI = 99%; $p < 0.001$ for both analysis), but no statistically significant differences between-groups were observed ($p = 0.7$). Half of participants in the contingency management group achieved their health-action targets.

Conclusion: Health literacy interventions to increase knowledge about tuberculosis among drug users are feasible and achieve promising increases in knowledge and health-related actions but measures to prevent a high attrition rate in a large-scale trial must be introduced. The absence of difference between trial-group outcomes suggests low-intensity interventions may achieve knowledge gain too. Further investigation of contingency management to promote tuberculosis-related health behaviours is needed.

Keywords

Addiction; Health Literacy; Health Promotion; Lung Disease; Tuberculosis

Despite effective treatment, Tuberculosis (TB) remains among the top-10 causes of death causing an estimated global mortality of 1.3 million deaths in 2017 [1] and a leading cause of death among HIV patients [2]. This prompted the first UN high level meeting - United to End TB: An Urgent Global Response to a Global Epidemic -which set up specific targets for

2030: a 90% reduction in the number of TB deaths and an 80% reduction in TB incidence [3].

Between 2000 and 2017 the absolute number of deaths from TB among HIV-negative people worldwide has been estimated to have fallen by 29% (1.8 million in 2000 and 1.3 million in 2017) [1], but the burden of disease has shifted in EU/EEA member states to vulnerable, hard-to-reach, low socio-economic populations including homeless people, prison populations and those who abuse drugs and alcohol [4].

Along with the "UK Tuberculosis Strategy for 2015-2020" [5], updated evidence-based practices for TB management and treatment have been published [6] and the TB infection rate in England declined to 9.2 new cases per 100,000 population in 2017, the first time since records began it falls under 10 per 100,000 population [7]. In 2017 the proportion of TB cases associated with current alcohol misuse was 4.1% (188/4,591), current or a history of drug misuse 5.0% (229/4,603), homelessness 4.7% (217/4,584), and imprisonment 4.4% (197/4,432), having increased from 2016 [7]. London remains the main focal point for TB infection with more annual cases than the Netherlands, Belgium, Greece and Norway combined [8]. Many factors have been associated with an increased risk of TB infection: migration [9], HIV infection, incarceration, living in urban areas, drug and alcohol misuse and malnutrition [10] among others. Hence, there is a case for improving TB knowledge and awareness among people who misuse substances to promote prevention as well as encourage early diagnosis and treatment [11].

Health Literacy (HL) has been conceptualized as "the cognitive and social skills which determine the motivation and abilities of individuals to gain access to, understand and use information in ways which promote and maintain good health" [12,13]. Studies show that individuals with low HL more often engage in high-risk behaviours, make poor use of healthcare [14,15] and record poorer health outcomes [14-16]. In infectious diseases generally, evidence suggests that low HL levels may be associated with failure to engage in protective health behaviours (e.g. vaccinations, medication adherence and self-care) [17]. In the case of TB, research shows that hard-to-reach populations, including drug-using populations, have low awareness about TB clinical onset, how to access diagnostic and treatment services, to self-administer medication, and the dangers of developing resistance to TB medications [4].

Different approaches may be needed to raise TB HL within hard-to-reach populations [4]. For instance, nurse case management combined with TB education can improve treatment adherence and completion among homeless populations [18] and counseling combining health education with strategies to strengthen patients' self-efficacy can increase adherence among people with poor HL [19]. Adjunctive Contingency Management (CM) to promote engagement with treatment and the attainment of health behaviours consistent with treatment goals is also recommended [20,21]. The combination of educational interventions and CM has achieved better treatment adherence and treatment completion - one of the biggest challenges when treating TB-among drug users [22]. This study tested trial procedures, estimated recruitment and attrition rates, and obtained preliminary measures on the effectiveness of an enhanced intervention to increase TB HL among drug users. It also assessed the feasibility of using CM to target TB-related behavioural actions among drug service users.

Materials and Methods

Design and interventions: We conducted a three-arm parallel pilot Randomized Controlled Trial (RCT) [23,24] with three study points (T_0 = baseline, T_1 = post-intervention and T_2 = 2-months follow-up) (Figure 1). The standard intervention (Group 1= G1) was a bespoke TB information booklet with user-friendly language and content specific to drug users/prison populations. The enhanced intervention delivered to both Groups 2 (G2) and 3 (G3), was a 1-hour seminar comprising: (a) an interactive quiz about TB, (b) a visual presentation during which participants interventions/questions fostered a dynamic and interactive environment, and (d) participants' written feedback. Contents were mapped in both booklet and seminars to secure comparability of interventions regarding their contents.

The enhanced intervention + CM (G3) consisted of the seminar plus a brief one-to-one meeting with a researcher at which participants were invited to target an agreed TB-related action which, if completed and evidenced within two months (T_2), was reinforced by a £10 voucher (i.e., CM).

Settings, participants and randomization: Two Westminster Drug Project (WDP) sites in London hosted this study between April and July 2017. Eligible participants were active service users, over 18 years old and in heroin and/or crack treatment (sample frame = 348). We were able to contact 164 (47%) and allocated those who consented to participate to each of the trial groups using a random permuted size-3 block protocol.

Ethical procedures: The project was approved by WDP Medicines Management Committee and Ethics approval was granted by the Natural Sciences ethics committee (Middlesex University, Ref.: 2233). Eligible service users received written and oral study information. Those who agreed to participate

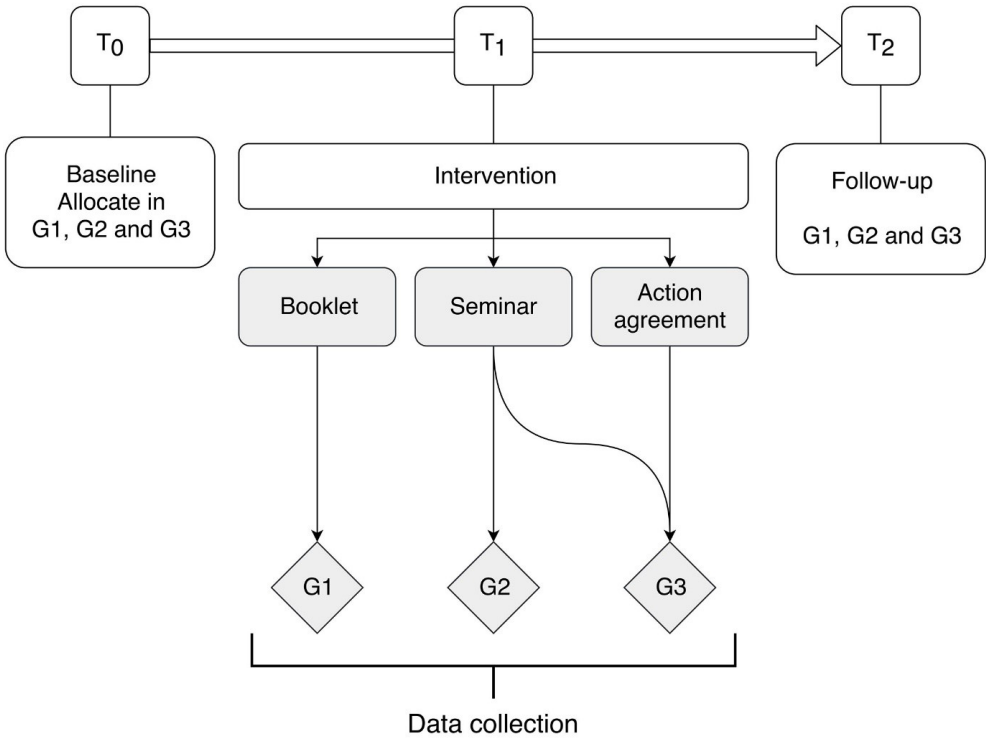

Figure 1: RCT to improve Health Literacy regarding TB among Drug Users. Study Design at a glance. London, 2017.

signed a consent form. Participants received £5 and £10 supermarket vouchers at each study point for their participation.

Data collection instruments: Three questionnaires were piloted at each study point. The T_0 questionnaire surveyed socio demographic characteristics, general health (SF12v2®) [25,26], drug use, prison history, alcohol (CAGE) [27], smoking (FTND) [28], and TB knowledge. The T_1 and T_2 questionnaires included the TB knowledge scale only. The TB scale (16 items) was constructed from the Knowledge, Attitudes and Practices (KAP) and the TB Knowledge Assessment Questionnaire (TKAQ) [29] plus ad hoc items and measured knowledge in a range from 0 (No knowledge) to 21 (High knowledge) (Box 1).

Data collection procedures: At T_0 the baseline questionnaire was implemented. At T_1: G1 participants were invited to read the TB booklet while G2 and G3 participants were invited to a TB seminar. In all cases the TB knowledge scale was re-applied afterwards. At T_2 participants completed the TB knowledge scale once again. G3 participants were additionally asked for evidence of their completed target action.

Data analysis: Descriptive statistics was conducted to describe the sample' sociodemographic characteristics, general health, drug, alcohol and tobacco use, prison history and TB knowledge scores. SF-12v2® standardized T scores were calculated for each health domain [26]. Cronbach's alpha was used to evaluate the internal reliability of the TB knowledge scale. Paired Samples t test at 99% CI was run to measure knowledge change. ANCOVA was used to test between-groups knowledge change. Data analysis was undertaken using SPSS v. 21.

Results

A 3-weeks recruitment period was used to repeatedly contact all eligible participants in the sample frame with valid contact details (164 out of the 348 records). Eighty-three (50.6%) declined to participate (overwhelming majority for personal reasons), while 81 (49.4%) agreed to a scheduled appointment where consent and baseline measures could be obtained. Forty-two attended and all consented to study participation (response rate = 25.6%). The overall attrition rate was 43%, but attrition was higher in G2 and G3 than G1 (Figure 2).

Is TB caused by?

Bacteria Virus Parasite I don't know

How can a person get TB?

Through handshakes
Through the air when a person with TB coughs or sneezes
Through sharing dishes/eating from the same plate
Through touching items in public places (door knobs, handles in transportation, etc.)
Sexual transmission from infected person
Kissing an infected person
Through infected blood transfusion
Other (please explain) Do not know

Which of the following is the best screening test TB?

Blood test Urine test Chest X ray Saliva and sputum examination

Skin test Do not know

Can TB be cured?

Yes No Do not know

Box 1: Sample of questions used to assess health literacy regarding Tuberculosis.

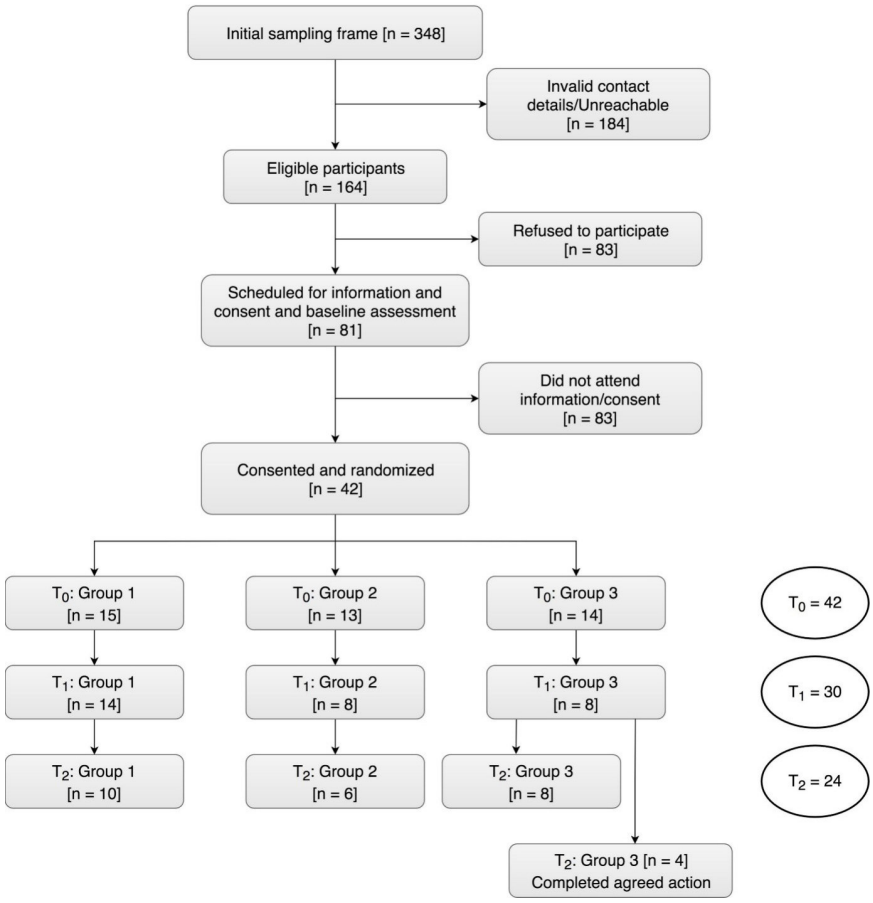

Figure 2: RCT to improve Health Literacy regarding TB among Drug Users. Recruitment flowchart. London, 2017.

Participants were mostly men (79%) with a mean age of 45.9 years old (SD = 10; range = 23-65). Sixty-one per cent were white and 20% had mixed ethnicity. Most (60%) lived alone, 29% in a family unit, 43% in their own property/ privately rented and 41% in social housing. Most (76%) were unemployed/receiving sickness benefits while 12% worked. More than half (57%) had been in prison (Table 1).

	G1		G2		G3		Total	
	n (15)	% (35.7)	n (13)	% (31.0)	n (14)	% (33.3)	n (42)	% (100)
Gender								
Man	11	26.2	11	26.2	11	26.2	33	78.6
Woman	4	9.5	2	4.8	3	7.1	9	21.4
Age								
23-38	2	4.8	4	9.5	5	11.9	11	26.2
39-49	4	9.5	4	9.5	5	11.9	13	31.0
>50	9	21.4	5	11.9	4	4.8	18	42.9
Education								
<Graduate	13	31.0	13	31.0	11	26.2	37	88.1
>Graduate	2	4.8	0	0.0	3	7.1	5	11.9
Ethnicity								
White	10	24.4	7	17.1	8	19.5	25	61.0
South Asian	1	2.4	1	2.4	1	2.4	3	7.3
Caribbean	1	2.4	2	4.9	0	0.0	3	7.3
Mixed	2	4.9	3	7.3	3	7.3	8	19.5
Other	0	0.0	0	0.0	2	4.9	2	4.9
Religion								
Christianity	11	26.8	5	12.2	5	12.2	21	51.2
Islam	1	2.4	1	2.4	2	4.9	4	9.8
Other	2	4.9	3	7.3	1	2.4	6	14.6
None	1	2.4	4	9.8	5	12.2	10	24.4
Sexuality								
Heterosexual	14	34.1	12	29.3	12	29.3	38	92.7
Bisexual	1	2.4	0	0.0	1	2.4	2	4.9
Other	0	0.0	1	2.4	0	0.0	1	2.4
Living….								
Alone	8	19.0	9	21.4	8	19.0	25	59.5
Spouse/partner/family	5	11.9	4	9.5	3	7.1	12	28.6
Other	2	4.8	0	0.0	3	7.1	5	11.9
Living arrangements								
Privately rented/owned	5	11.9	6	14.3	7	16.7	18	42.9
Social housing	6	14.3	6	14.3	5	11.9	17	40.5
Homeless	2	4.8	0	0.0	1	2.4	3	7.1
Other	2	4.8	1	2.4	1	2.4	4	9.5
Work status								
Employed	3	7.1	1	2.4	1	2.4	5	11.9
Unemployed/benefits	11	26.2	11	26.2	10	23.8	32	76.2
Other	1	2.4	1	2.4	1	2.4	5	11.9
Ever been in prison								
Yes	9	21.4	8	19.0	7	16.7	24	57.1
No	6	14.3	5	11.9	7	16.7	18	42.9

Table 1: Sample socio-demographic characteristics by trial group. London, 2017.

G1 = Group 1 (Standard intervention / control group) G2 = Group 2. Intervention group (Enhanced intervention) G3 = Intervention group (Enhanced intervention + contingency management)

Fifty-one per cent of the sample was in drug treatment for use of both crack-cocaine and heroin, 33% used heroin only and the rest (15%) crack/cocaine only. The majority (62%) had used heroin in the last three months, 41% cannabis and 62% crack-cocaine. Although 39% of the sample had shared injecting equipment, only 4% had done so in the last year. The vast majority (93%) smoked and 54% had moderate nicotine dependence. Half drank alcohol and amongst these, 52% drank at potentially harmful levels as per CAGE scores. Drug use behaviours with high TB transmission risk were explored by questions focusing on sharing and drug use proximal to users: of the 33 participants (79%) who had inhaled heroin 41% shared equipment sometimes/rarely while 14% shared most/all of the time. Spliff sharing happened sometimes and most/all the time among 58% and 26% respectively of the 19 participants who smoke cannabis/marihuana (Table 2).

	G1		G2		G3		Total	
	n	%	n	%	n	%	n	%
Drug treatment demand (n=39)								
Heroin	4	10.3	6	15.4	3	7.7	13	33.3
Crack cocaine	3	7.7	0	0.0	3	7.7	6	15.4
Both	6	15.4	6	15.4	8	15.4	20	51.3
Heroin use (n=42)								
Never	1	2.4	0	0.0	2	4.8	3	7.1
Ever	5	11.9	1	2.4	3	7.1	9	21.4
Last year	1	2.4	2	4.8	1	2.4	4	9.5
Last 3 months	8	19.0	10	23.8	8	19.0	26	61.9
Street methadone (n=42)								
Never	9	21.4	9	21.4	8	19.0	26	61.9
Ever	4	9.5	2	4.8	2	4.8	7	16.7
Last year	1	2.4	1	2.4	2	4.8	4	9.5
Last 3 months	1	2.4	1	2.4	3	7.1	5	11.9
Injected drugs (n=42)								
Never	8	19.0	3	7.1	8	19.0	19	45.2
Ever	5	11.9	7	16.7	2	4.8	14	33.3
Last year	1	2.4	1	2.4	2	4.8	4	9.5
Last 3 months	1	2.4	2	4.8	2	4.8	5	11.9
Shared injecting equipment (n=23)								
Never	2	8.7	6	26.1	5	21.7	13	56.5
Ever	3	13.0	4	17.4	2	8.7	9	39.1
Last year	1	4.3	0	0.0	0	0.0	1	4.3
Inhaled heroin (n=42)								
Never	4	9.5	0	0.0	5	11.9	9	21.4
Ever	5	11.9	1	2.4	4	9.5	10	23.8
Last year	1	2.4	4	9.5	2	2.4	7	16.7
Last 3 months	5	11.9	8	19.0	3	7.1	16	38.1
Shared inhaling equipment (n=29)								
Never	5	17.2	4	13.8	4	13.8	13	44.8
Rarely/sometimes	3	10.3	6	20.7	3	10.3	12	41.4
Most/all the time	2	10.3	1	3.4	1	3.4	4	13.8
Cannabis/marihuana use (n=42)								
Never	2	4.8	1	2.4	3	7.1	6	14.3
Ever	7	16.7	4	9.5	7	16.7	18	42.9
Last year	0	0.0	1	2.4	0	0.0	1	2.4

	G1		G2		G3		Total	
	n	%	n	%	n	%	n	%
Last 3 months	6	14.3	7	16.7	4	9.5	17	40.5
Shared splifs (last year/3 months) (n=19)								
Never	3	15.8	0	0.0	0	0.0	3	15.8
Sometimes	2	10.5	7	36.8	2	10.5	11	57.9
All the time	1	5.3	2	10.5	2	10.5	5	26.3
Alcohol use (n=42)								
Yes	7	16.7	6	14.3	8	19.0	21	50.0
No	8	19.0	7	16.7	6	14.3	21	50.0
Potential alcohol problem (n=21)								
Yes	2	9.5	4	19.0	5	23.8	11	47.6
No	5	23.8	2	9.5	3	14.3	10	52.4
Smoking dependence (n=39)								
Low	0	0.0	1	2.6	0	0.0	1	2.6
Low to moderate	0	0.0	4	10.3	9	23.1	13	33.3
Moderate	10	10.3	7	17.9	4	10.3	21	53.8
High	3	7.7	1	2.6	0	0.0	4	10.3

Table 2: Drug, alcohol use and risk behaviours regarding TB by trial group. London 2017.

G1 = Group 1 (Standard intervention / control group) G2 = Group 2. Intervention group (Enhanced intervention)
G3 = Intervention group (Enhanced intervention + contingency management)

Most SF-12v2® health dimensions scores were considerably below general population norm, with the exception of Physical Functioning (mean = 45.2, SD = 12.1, range = 22.1-56.5) and Vitality (mean = 50.9, SD = 11.0, range = 27.6-67.9) where mean scores were close to general population norms (Figure 3).

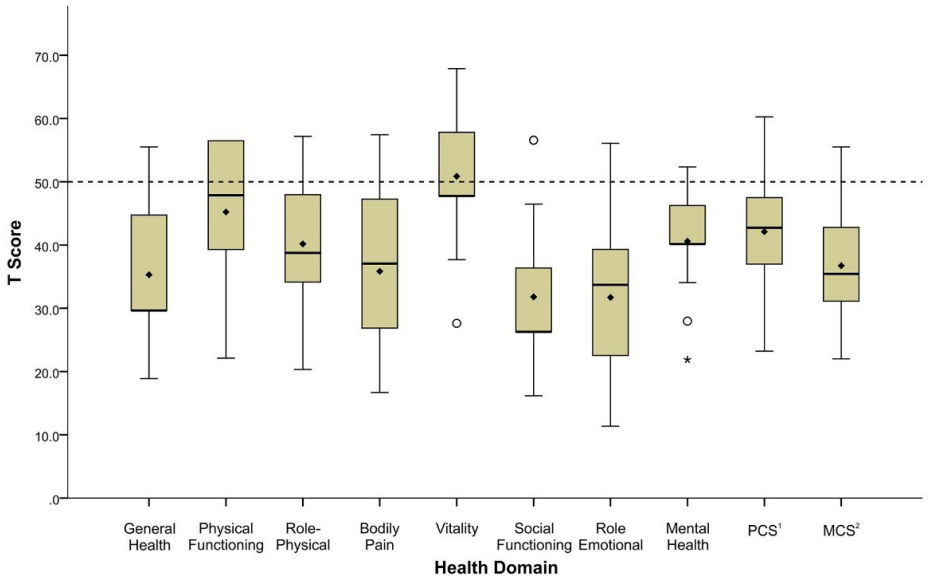

Figure 3: RCT to improve Health Literacy regarding TB among Drug Users. Health status. SF12 normative scores. London, 2017.

[1]Mental Component Summary score; [2]Physical Component Summary score.
Dotted line: Reference mean score of the normative population (U.S. 1998 general population).
Black points: Mean score of each health domain.

One participant had been diagnosed as TB positive (and successfully completed treatment.) HCV prevalence was 33.3% but they all were HIV negative. Analysis of cumulative exposure to risk factors for TB (Drug abuse, Homelessness, HIV and/or HCV and exposure to high population density such as imprisonment) shows that while 100% exhibited at least one risk factor (drug abuse),38% reported exposure to two risk factors,29% to three, and 2% had exposure to four TB risk factors.

The internal reliability of the TB knowledge scale was good (Cronbach's $\alpha = 0.706$). TB knowledge average score increased 5.9 for the whole sample from T_0 to T_1, from 11.5 at T_0 (SD = 3.9, range = 0-18) to 17.4 at T_1 (SD = 3.2, range = 10-21). Even though the average score at T_2 declined to 15.8 (SD = 2.5, range = 10-19) it still represented 4.3 points (20% increase) from T_0 (Table 3).

	T_0		T_1			T_2			
	Mean/SD	Range	Mean/SD	Range	T_1-T_0 MD	Mean	Range	T_2 - T_0 MD	T_2 - T_1 MD
G1	11.7/3.5	5-16	16.9/3.6	10-21	5.2	15.4/2.5	11-18	3.7	-1.5
G2	11.7/3.1	4-17	16.7/3.4	11-21	5.0	15.3/1.6	13-17	3.6	-1.4
G3	11.1/5.2	0-18	18.9/1.8	16-21	7.8	16.5/3.1	10-19	5.4	-2.4
All	11.5/3.9	0-18	17.4/3.2	10-21	5.9	15.8/2.5	10-19	4.3	-1.6

Table 3: Knowledge scores and mean differences across study points by trial group and whole sample. London, 2017.

G1 = Group 1 (Standard intervention / control group) G2 = Group 2. Intervention group (Enhanced intervention)
G3 = Intervention group (Enhanced intervention + contingency management)

The increase of knowledge for the 31 observations with data from T_1 compared to T_0 revealed a MD = 4.9 (SD = 2.9; 99% CI = 3.4-6.4) and was statistically significant (t_{30} = -9.261; $p = 0.000$). This was also the case for the knowledge increase at T_2 compared with T_0 (n = 24; MD = 2.8; SD = 2.4; 99% CI = 1.4-4.1; $t_{23} = 5.667$; $p = 0.000$). However, ANCOVA analysis did not reveal statistically significant pre-post-intervention differences between groups (F = 0.104; $p = 0.7$). Loss of follow up in G3 (T_0 = 14 participants, T_2 = 8) compromised our assessment of whether CM promoted TB health-related behavioural actions. Amongst the 8 G3 participants who reached follow-up, 50% provided acceptable evidence of completion of the target action agreed at T_1. Actions ranged from personal preventive measures (e.g. request TB screening from GP) to public health-oriented actions such as conversations with friends about TB.

Discussion

This small pilot RCT aimed to increase HL regarding TB among drug users in treatment and provides estimates of recruitment and attrition rates. In our study a 26% response rate was achieved and an overall 43% attrition rate was suffered across the study timetable. Attrition was substantially different in G1 compared to G2 and G3. This can be explained because the intervention in G1 took place immediately after baseline assessment. Both recruitment and retention rates are notoriously difficult to keep at acceptable levels in research including hard-to-reach populations [30] and the rigour in sampling strategies for experimental designs often prevents from implementing other sampling strategies and correction measures (e.g. snowballing) which introduce selection and gatekeeper biases [31]. However, lessons learnt from this pilot include the need to provide motivating incentives to both participants and participating sites, and facilitating seminar attendance by scheduling them in early evenings.

Despite its small size, this study provides evidence that TB HL among drug users in treatment can be improved. We achieved a statistically significant increment in knowledge across the cohort. Reasons for the lack of differential results between the intervention groups may be explained by the implementation conditions; while a booklet (control intervention) is not different from the standard exposure to information that drug service users might routinely experience, in our study control participants were given time to read the booklet *in situ* and knew they would be asked questions about TB afterwards. This is not the usual implementation of printed-material interventions where people are given the material to take home with no expectation of being quizzed about it. This might explain the very positive results obtained in the control group and the lack of statistically significant differences compared to those exposed to the experimental interventions.

A limitation of this study is the uncertainty about what level of HL our interventions made an impact upon. In his classic taxonomy of HL levels, Nutbeam proposed three levels: functional (basic skills in reading and writing necessary for effective functioning in a health context), interactive (more advanced cognitive literacy and social skills that enable active participation in health care) and critical (the ability

to both critically analyse and use information to participate in actions tackling structural barriers to health [32]. Our TB knowledge scale, directly targeted functional HL, which while a prerequisite to higher level HL, does not enable us to assess whether participants achieved improved interactive and critical HL. This is a shared problem across other fields of infectious diseases where a lack of studies tackling interactive and critical HL has been identified and exacerbated in relation to assessing the impact of TB HL [17].

The lack of validated scales posed an additional challenge. While KAP and TKAQ [29] provided a significant number of items, there were no items that would specifically survey knowledge about TB among drug users. Both KAP and TKAQ include elements of the scales to measure knowledge among syringe exchange programs users in New York City in the mid-90s [33], and more recently in Estonia in 2008/9 [11]. However, these seminal scales were too basic (dichotomous items only) and generic with no specific contents for drug using populations (e.g. the impact of rifampicin on methadone drug clearance and reduction of its half-life, that indicates a concomitant dose increase during treatment with rifampicin) [34]. However, while its psychometric characteristics and unknown, the 16-items knowledge scale developed for this study provides the first instrument specifically designed for drug treatment populations and merits development and testing in further studies.

This study also included an element of CM as recent UK research has also shown that simple positive reinforcement schedules can promote significantly increased adherence to physical health interventions such as Hepatitis B vaccination in drug treatment populations [35]. In our study, CM was applied to provide an incentive for subjects in G3 to engage in TB-related actions. The small study sample size precludes any sophisticated analysis regarding the success of the CM element. However, the completion rate of 50% suggests that inclusion of this element is feasible, should be formally assessed in a further RCT and may merit evaluation of its implementation in routine clinical practice.

Conclusion

This study achieved three significant objectives: Firstly, it demonstrates that it is feasible to deliver therapeutic tools to increase TB HL to people in drug treatment. The two interventions designed are flexible enough to be integrated in drug services health educational activities relating to HIV and HCV, which are already routinely provided. Secondly, it provides evidence that such interventions can be effective in increasing TB HL among this population and may make a difference in how well equipped this population is to protect themselves against this infection. Thirdly, the study demonstrates that it would be feasible to implement full RCT and provides data upon to power that. On the basis of our findings we argue that such a trial is needed to test and identify the therapeutic options that most efficiently and effectively promote the best outcomes.

Acknowledgments

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Declaration of Interest

All authors declare no conflicts of interest in this article.

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