Published in final edited form as:

Subst Use Misuse. 2013 June ; 48(9): 784–792. doi:10.3109/10826084.2013.793715.

Training and Fidelity Monitoring of Alcohol Treatment Interventions Integrated into Routine Tuberculosis Care in Tomsk, Russia: the IMPACT effectiveness trial

Hilary Smith Connery, MD, PhD^{1,2}, Shelly F. Greenfield, MD, MPH^{1,2}, Viktoria Livchits, MD³, Lana McGrady, MS⁴, Nickolette Patrick, MPH⁵, Charmaine Lastimoso, MA⁶, Jessica Hart⁶, A. Katrina Nelson, MPH⁶, Alan Shields, PhD^{1,7}, Yekaterina P. Stepanova, MD⁸, Lidiya Y. Petrova, MD⁸, Oleg V. Anastasov, MD^{8,9}, Olga I. Novel'tseva, MD⁸, Sonya Shin, MD, MPH^{2,6,10}, and (On behalf of the Tomsk Tuberculosis Alcohol Working Group)

¹ McLean Hospital, 115 Mill Street, Belmont, MA, 02478 USA

² Harvard Medical School, 25 Shattuck Street, Boston, MA 02115 USA

³Partners in Health Representative Office in Russian Federation

⁴ Eastern Tennessee State University

⁵ Northeastern Regional Training and Medical Consultation Consortium

⁶ Division of Global Health Equity, Brigham and Women's Hospital

⁷ Mapi values.com ©

⁸ Tomsk Oblast Clinical Tuberculosis Hospital, Timiryazev, Novaya Str 1. Russian Federation, Tomsk 634009

⁹ Siberian State Medical University, TB Department, Moscovski Trakt 2, Russian Federation, Tomsk 634050

¹⁰ Department of Infectious Diseases, Brigham and Women's Hospital

Keywords

alcohol use disorders; alcohol interventions; tuberculosis; behavioral interventions; fidelity monitoring; cross-cultural clinical trials; effectiveness trials

Introduction

Effectiveness trials are designed to test the efficacy of well-described, empirically supported therapies (EST) when conducted in “real world” community treatment settings, where clinician and patient heterogeneity is greater. Effectiveness trials are necessary to determine how, where, and when EST may be successfully applied to improve an identified illness or

All correspondence to: Hilary S. Connery, MD, PhD McLean Hospital 115 Mill Street Belmont, MA, USA 02478
hconnery@mclean.harvard.edu phone: 617-855-3881 fax: 617-855-2699.

Declaration of Interest

Authors disclose no conflicts of interest at this time.

behavioral syndrome of public health significance. Carroll and Rounsaville (Carroll and Rounsaville 2003) proposed a “hybrid model” for effectiveness research studying treatment of substance use disorders: elements of efficacy trials supporting internal validity are maintained (i.e., randomization to study condition, defined participant population, use of manuals and protocol algorithms to deliver behavioral and pharmacological therapies, use of objective outcome measures and outcomes assessment independent of treatment delivery, and monitoring of treatment fidelity and adherence) and combined with elements relevant to community systems of care and supporting external validity (use of treatment-as-usual control, less restrictive inclusion/exclusion criteria, community clinicians trained to deliver research interventions, and evaluation of cost-effectiveness, clinic acceptance and patient acceptance).

Behavioral health and addiction researchers continue to emphasize the importance of studying treatment integrity and fidelity, as well as sustainability, within community-based effectiveness trials of EST (Borrelli, Sepinwall et al. 2005; Baer, Ball et al. 2007; Carroll and Rounsaville 2007), as well as studying contaminants of EST delivery and receipt that may compromise outcomes (Martino, Ball et al. 2008). Successful dissemination of EST may require adaptation to improve the “fit” of an EST to the cultural and sociological setting in which the EST is implemented (Castro, Jr. et al. 2004; Wainberg, McKinnon et al. 2007).

Global alcohol consumption is increasing, with a reported 2.5 million deaths worldwide in 2008 (WHO 2008), yet effectiveness trials transporting EST for alcohol use disorders cross-culturally and internationally have not been reported for either pharmacological or psychosocial interventions (Kaner, Beyer et al. 2007; Anton 2008; McQueen, Howe et al. 2009). We report on the challenges of conducting the IMPACT (Integrated Management of Physician-delivered Alcohol Care for Tuberculosis patients) study, a randomized, controlled effectiveness trial of two empirically-supported alcohol interventions integrated into routine tuberculosis (TB) care in Russia: 1) oral naltrexone (NTX) plus Brief Behavioral Compliance Enhancement Therapy (BBCET) (Johnson, Rosenthal et al. 2007), and 2) a culturally-adapted, brief Behavioral Counseling Intervention (BCI) (USDHS 2003). Here we describe clinician selection, training and supervision, and ongoing monitoring of fidelity and adherence of EST implementation, including physician opinions about fidelity and adherence strategies. The discussion addresses challenges of adapting and implementing empirically-supported alcohol interventions in a community setting where language and cultural norms differ significantly from previous efficacy and effectiveness trial settings for these interventions. Further considerations for collaborative, international effectiveness trials in addiction research are recommended based on findings.

Methods

Study Setting

The Tomsk TB Hospital is the only inpatient TB Hospital in Tomsk Oblast, a province in western Siberia. Most patients are rural subsistence farmers who live in an extended family setting and rely on their family for social support.

Although the detrimental effects of alcohol use on the Russian population are well known, current alcohol use disorder (AUD) treatment options are limited, especially away from capital cities. Patients in the TB hospital have access to free addictions services provided on-site by an addictions specialist (“narcologist”) and a psychologist. Outpatient services at an addictions treatment center are also available, but generally require a referral from another provider. Outpatient narcologists are often hesitant to treat TB patients because of the infection risk. Moreover, patients often refuse alcohol care to avoid out-of-pocket costs of care and stigmatizing registry with Narcology services, which can result in loss of one's driver's license or employment. Alcoholics Anonymous (AA) groups have been available in Tomsk since 1998, but patients do not attend on-site AA group sessions offered at the hospital because patients are typically not treatment-seekers (i.e. pre-contemplative stage) and because open discussion of personal challenges around alcohol use is not considered culturally appropriate in Russia, particularly in an intimate hospital setting (Mathew, Shields et al. 2009). Private, religious-based rehabilitation centers serve paying patients using the 12-step method outside of the city of Tomsk, but are too expensive for poor local patients.

Training and Fidelity Protocol

The clinical trial included 200 hospitalized TB patients and took place between July 2007 and October 2010. The rationale and methods for this study have been described elsewhere (Greenfield, Shields et al. 2010). Here, we provide details of fidelity procedures. The fidelity team was comprised of a lead coder (HC) with clinical research expertise in the delivery of behavioral interventions, and three bilingual coders/supervisors (LM, NP, VL) who had backgrounds in public health and/or psychology and were familiar with Russian and American medical cultures. Sixteen TB physicians without prior formal training in behavioral interventions or alcohol care were recruited for study intervention delivery.

The study team (SG, AS, HC, SS) developed a trainer manual, course materials, and a physician manual for initial and follow-up sessions for each behavioral intervention (BCI, BBCET, BCI plus BBCET). Materials were reviewed by TB physicians and a Russian narcologist for feedback on content, format and cultural appropriateness. Two U.S. trainers (SS, VL) completed a 2-day course led by behavioral experts (SG, AS, HC), and in turn led a 3-day training course in Tomsk for TB study physicians covering study design, theoretical basis for study interventions, content and style components of interventions, videotapes demonstrating interventions performed correctly and incorrectly, and participant role-play using “real life examples” (e.g. smoking cessation among physician smokers). Each physician then practiced individual mock interviews with VL, receiving feedback until they were comfortable delivering both interventions. For certification, audio-taped interviews of role-play sessions by each physician were rated for adherence with pre-determined certification criteria.

For ongoing fidelity and adherence assessment, we developed bilingual fidelity assessment scales and manuals for initial and follow-up encounters in all intervention arms. BCI assessment covered three domains of physician procedural, interventional and style adherence. Procedural adherence assessed delivery of the “five As” (Whitlock, Orleans et al. 2002). Interventional adherence assessed providing individualized feedback, education, and

specific strategies to reduce drinking. Style adherence assessed motivational interviewing elements adapted from Lane et al., with scores ranging from 0 (non-adherent) to 4 (highly adherent) (Lane, Huws-Thomas et al. 2005). BBCET assessed intervention adherence using categorical ratings adapted from Johnson et al. (Johnson, Rosenthal et al. 2007). Since each physician delivered all study arms, assessments were designed to identify treatment adherence as well as contamination (e.g. delivery of motivational interviewing or therapeutic counseling in a non-BCI encounter, or naltrexone-related discussions in a non-BBCET encounter).

Coders reviewed and rated a random selection of 10% of study encounters, stratified by physician and intervention. A subset of encounters were translated monthly into English and coded by lead coder and bilingual coders to ensure ongoing calibration of coding efforts. The fidelity team held weekly, then monthly, conference calls to discuss protocol adherence and maintain supervision consistency. In addition, based on feedback from the Russia-based team, the fidelity team made iterative adjustments: the content and format of interventions were unchanged but supervision was provided to physicians on-site to best integrate these within routine TB care. To minimize protocol violation and drift, the site coordinator (VL) provided individualized feedback to physicians within eight weeks of a recorded encounter. Feedback was intentionally motivational in style, highlighting competency and providing specific, structured directions for improving protocol adherence.

A physician was “redlined” if an encounter omitted core protocol elements or included content inappropriate to protocol. The fidelity team reviewed redlined encounters together and developed performance improvement plans with the physician, which permitted continued study participation along with intensified monitoring and supervision. If improvement was not observed, the physician would complete current cases but no new subjects treated by that physician could be enrolled pending recertification. Physician recertification was never needed.

Physicians met monthly with the site coordinator and quarterly with supervisors via teleconference, received quarterly newsletters and participated in yearly refresher trainings. The fidelity team identified areas of improvement and developed training materials to address these topics using transcript excerpts, sample scripts representing common problems, and questions to elicit topical discussion. Newly-hired physicians were trained using original training materials and “mentoring” by veteran study physicians. Booster trainings were intensified during the course of the study to sustain interest and develop physician intervention skills.

Qualitative Analysis

Focus groups were conducted with physicians to understand the perceived strengths and weaknesses of study interventions. In order to capture change in doctor attitudes during the study period, focus groups were conducted in October 2008 and June 2009. Study team members conducted audio-taped focus groups using semi-structured questionnaires after obtaining informed verbal consent among participating physicians. Data were coded using a codebook pre-designed by the fidelity team. General themes were identified and are presented here.

This research was approved by the Partners Human Subjects Committee at the Brigham and Women's Hospital and by the Ethics Committee of State Research Center of Virology and Biotechnology “Vector” in Novosibirsk, Russia.

Results

Based on our qualitative assessment, we identified four challenges to maintaining fidelity to behavioral interventions. Here we describe these areas, as well as strategies to address each challenge, and changes observed over time.

First, study physicians initially expressed skepticism toward behavioral interventions. Several expressed bias toward pharmacological interventions. During trainings and initial interviews, physicians called the BCI intervention “useless” and worried about how to “justify the use of BCI with patients.” The study team identified this bias early in the study and attributed this largely to the physicians’ lack of prior experience delivering manualized behavioral interventions and the medical culture in Russia which tended to place greater value in pharmacologic treatments over behavioral interventions. The team explicitly discussed this skepticism with TB physicians, who were encouraged to maintain objective curiosity toward all treatment conditions. Motivational incentives to learn and practice counseling interventions included encouragement from the clinic medical director and resident narcologist, and translation and dissemination of literature supporting the efficacy of behavioral strategies on drinking outcomes. We also emphasized advantages of working collaboratively with patients, provided individual supervision, involved them in publications and conferences, and provided financial compensation to physicians for data collection.

Second, physicians were hesitant initially to tape-record their encounters, both out of concerns of patient privacy and a perception of being “graded” on performance. Through newsletters and group discussions, we spent considerable time clarifying the rationale of fidelity monitoring as an inherent part of evaluating the study itself rather than physician competency. Furthermore, refusal to accept audio-taping on the part of the patient was rare. Over time, the reluctance to audiotape encounters waned and became accepted as a “routine” part of the study.

Third, patient-centered discussion of alcohol use in detail and goal-setting was culturally unfamiliar in this setting. Both patients and providers were often uncomfortable with counseling based on motivational interviewing, as Russian medical culture relies on a more paternalistic patient-provider relationship. Study physicians therefore received ongoing training in strategies to elicit patient participation (e.g., open-ended questions, empathic statements, humor) and to encourage patients to explore their own resources for achieving abstinence. This cultural paradigm shift was taken up more readily by trained physicians than by the patients themselves. Physicians’ described early BCI sessions as “failures,” but by the end claimed that they received no negative feedback from patients. By the end of the study, physicians reported “having their mentality radically changed,” learning to “see alcoholism as a sickness instead of a bad habit,” and “having more patience” with their patients.

Fourth, although the behavioral interventions were well-designed, refinement of how to integrate these interventions seamlessly into routine TB care was ongoing throughout the trial. Ongoing discussion between the U.S.-based study team and Russian providers included topics such as: the degree of physician-patient contact within the inpatient setting between “monthly” study encounters; “treatment as usual” procedures for alcohol detoxification and resuming study and TB treatment following binge drinking episodes; availability and acceptability of other forms of addictions care (e.g., AA groups); and areas of improvement in the BCI manual. Regarding the latter topic, early in the study implementation physicians did not clearly distinguish between advising the patient to stop drinking versus advising a reduction in drinking; this was due to a Russian translation selected for the manual which contained contextual ambiguity such that physician advice often fused together “stopping or reducing drinking” into a single option. This was detected as a recurring theme in physician focus groups where physicians complained interview guides were “unclear and watered down.” A corrective script translation was developed to distinguish abstinence goal from reduced drinking goal, and re-training was provided to physicians. Physicians expressed satisfaction in the adaptation of the guide and attributed the improvement to the interdisciplinary team of IMPACT collaborators.

Discussion

Effectiveness trials require additional fidelity monitoring elements to maximize successful implementation. These include examining clinician attitudes toward delivering interventions and shaping positive attitudes toward new interventions; providing financial and time incentives for staff participating in trials; enlisting the support of administrators and leaders at study sites; modifying training tools for treatment delivery to suit local needs; investing in re-training, booster training, and training new staff rapidly during staff turnover; and assessing patient acceptance and cost-effectiveness (Johnson-Kozlow, Hovell et al. 2008). Cross-cultural and international effectiveness trials add further complexity to ensure fidelity, including accurate linguistic translations, culturally appropriate intervention adaptations, and a bilingual study implementation team (Leventhal and Friedman 2004; Devieux, Malow et al. 2005; Wainberg, McKinnon et al. 2007).

The IMPACT fidelity and adherence monitoring experience highlights two recommendations for cross-cultural effectiveness trials. First, frequent supervision is essential to adequately adapt interventions to local programs and culture while still maintaining intervention fidelity (Castro, Jr. et al. 2004; Wainberg, McKinnon et al. 2007). Regular meetings with physicians to clarify concerns around tape-recording, patient acceptance of intervention, and adaptation of the BCI manual were crucial for the improved delivery of BCI. Bidirectional communication allowed the U.S.-based team to accurately understand the context of study intervention delivery within local medical services and also allowed rapid fidelity feedback and reinforcement of key study concepts to study physicians (Deviux, Malow et al. 2005). Our findings are consistent with others who have observed that willingness to partake in a behavioral intervention increases provider adherence to the intervention (Dusenbury, Brannigan et al. 2003; Leventhal and Friedman 2004; Perrin, Burke et al. 2006). We found that IMPACT physicians became increasingly committed to study interventions through positive experiences with patient participants and bidirectional

feedback and refresher training with the fidelity team. In conclusion, fidelity monitoring for cross-cultural effectiveness trials requires, above all, close communication between central monitoring and study sites and a standardized, but dynamic approach to ongoing fidelity assessment.

Acknowledgments

Research was supported in part by grants R01 AA016318 from the National Institute of Health (SS) and K24 DA 019855 (SFG) from the National Institute on Drug Abuse Clinical trial registration identification number: NCT00675961

Glossary

Alcohol Use Disorder (as defined by the DSM-IV):

1. A maladaptive pattern of alcohol abuse leading to clinically significant impairment or distress, as manifested by one or more of the following, occurring within a 12-month period:
 - a. Recurrent alcohol use resulting in failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions or expulsions from school; or neglect of children or household).
 - b. Recurrent alcohol use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine).
 - c. Recurrent alcohol-related legal problems (e.g., arrests for alcohol-related disorderly conduct).
 - d. Continued alcohol use despite persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the alcohol (e.g., arguments with spouse about consequences of intoxication or physical fights).
2. These symptoms must never have met the criteria for alcohol dependence.

Alcohol Dependence	a cluster of behavioral, cognitive, and physiological phenomena that may develop after repeated alcohol use. Typically, these phenomena include a strong desire to consume alcohol, impaired control over its use, persistent drinking despite harmful consequences, a higher priority given to drinking than to other activities and obligations, increased alcohol tolerance, and a physical withdrawal reaction when alcohol use is discontinued.
Alcohol Use Disorder Identification Test (AUDIT)	A method of screening, via brief assessment, for excessive drinking, alcohol dependence, and consequences of harmful drinking published by the World Health Organization (WHO).

Composite International Diagnostic Interview-Substance Abuse Module (CIDI-SAM)	a structured clinical interview consisting of questions that are based on the DSM-IV diagnostic criteria for alcohol use disorders.
Tuberculosis (TB)	an infectious bacterial disease caused by <i>Mycobacterium tuberculosis</i> , which most commonly affects the lungs. It is transmitted from person to person via droplets from the throat and lungs of people with the active respiratory disease. TB is treatable with a six month course of antibiotics.

References

- Anton RF. Naltrexone for the management of alcohol dependence. The New England journal of medicine. 2008; 359(7):715–21. [PubMed: 18703474]
- Baer JS, Ball SA, et al. Training and fidelity monitoring of behavioral interventions in multi-site addictions research. Drug and alcohol dependence. 2007; 87(2- 3):107–18. [PubMed: 17023123]
- Borrelli B, Sepinwall D, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. Journal of Consulting and Clinical Psychology. 2005; 73(5):852–60. [PubMed: 16287385]
- Carroll KM, Rounsaville BJ. Bridging the gap: a hybrid model to link efficacy and effectiveness research in substance abuse treatment. Psychiatric services. 2003; 54(3):333–9. [PubMed: 12610240]
- Carroll KM, Rounsaville BJ. A vision of the next generation of behavioral therapies research in the addictions. Addiction. 2007; 102(6):850–62. discussion 863-9. [PubMed: 17523974]
- Casswell S, Thamarangsi T. Reducing harm from alcohol: call to action. Lancet. 2009; 373(9682): 2247–57. [PubMed: 19560606]
- Castro FG, M. B. et al. The cultural adaptation of prevention interventions: resolving tensions between fidelity and fit. Prevention Science. 2004; 5(1):41–45. [PubMed: 15058911]
- Deveaux JG, Malow RM, et al. Cultural adaptation in translational research: field experiences. Journal of Urban Health. 2005; 82(2 Supplement 3):iii 82–91.
- Dusenbury L, Brannigan R, et al. A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. Health Education Research. 2003; 18(2):237–36. [PubMed: 12729182]
- Greenfield SF, Shields A, et al. Integrated Management of Physician-delivered Alcohol Care for Tuberculosis Patients: Design and Implementation. Alcoholism, clinical and experimental research. 2010; 34(2):317–30.
- Johnson-Kozlow M, Hovell MF, et al. Fidelity issues in secondhand smoking interventions for children. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco. 2008; 10(12):1677–90. [PubMed: 19023822]
- Johnson BA, Rosenthal N, et al. Topiramate for treating alcohol dependence: a randomized controlled trial. JAMA : the journal of the American Medical Association. 2007; 298(14):1641–51. [PubMed: 17925516]
- Kaner EF, Beyer F, et al. Effectiveness of brief alcohol interventions in primary care populations. Cochrane database of systematic reviews. 2007; (2):CD004148. [PubMed: 17443541]

- Lane C, Huws-Thomas M, et al. Measuring adaptations of motivational interviewing: the development and validation of the behavior change counseling index (BECCI). *Patient education and counseling*. 2005; 56(2):166–73. [PubMed: 15653245]
- Leventhal H, Friedman MA. Does establishing fidelity of treatment help in understanding treatment efficacy? . *Health Psychology*. 2004; 23(5):452–6. [PubMed: 15367064]
- Marlatt G, Baer JS, et al. Screening for brief intervention for high-risk college student drinkers: Results from a 2-year follow-up assessment. *Journal of Consulting and Clinical Psychology*. 1998; 66(4):604–15. [PubMed: 9735576]
- Martino S, Ball SA, et al. Community program therapist adherence and competence in motivational enhancement therapy. *Drug and alcohol dependence*. 2008; 96(1-2):37–48. [PubMed: 18328638]
- Mathew T, Shields A, et al. Knowledge, Attitudes, and Practices of Physicians in Tomsk Oblast Tuberculosis Services Regarding Alcohol Use Among Tuberculosis Patients in Tomsk, Russia. *Cult Med Psychiatry*. 2009; 33(4):523–37. [PubMed: 19768525]
- McQueen J, Howe TE, et al. Brief interventions for heavy alcohol users admitted to general hospital wards. *Cochrane database of systematic reviews*. 2009; (3):CD005191. [PubMed: 19588369]
- Perrin KM, Burke SG, et al. Factors contributing to intervention fidelity in a multi-site chronic disease self-management program. *Implementation Science*. 2006; 1:26. [PubMed: 17067388]
- Soyka M, Kranzler HR, et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Substance Use and Related Disorders, Part 1: Alcoholism. *The world journal of biological psychiatry : the official journal of the World Federation of Societies of Biological Psychiatry*. 2008; 9(1):6–23.
- USDHS. *Helping Patients with Alcohol Problems: A Practitioners' Guide*. U. D. o. H. a. H. Services and N. I. o. Health; 2003.
- Wainberg ML, McKinnon K, et al. A model for adapting evidence-based behavioral interventions to a new culture: HIV prevention for psychiatric patients in Rio de Janeiro, Brazil. *AIDS Behavior*. 2007; 11(6):872–883. [PubMed: 17216334]
- Whitlock EP, Orleans CT, et al. Evaluating primary care behavioral counseling interventions: An evidence-based approach. *American Journal Preventive Medicine*. 2002; 22(4):267–284.
- WHO. *Alcohol*. World Health Organization; Geneva: 2008. *Substance Abuse Facts and Figures*..

Figure 1. (Left) Flow chart of patients enrolled in IMPACT study. (Right) Flow chart of IMPACT fidelity monitoring process
51 patients excluded from analysis because: they withdrew, were lost to follow-up, had MDR-T, did not have TB, had a negative reaction to NTX, declined NTX or were too sick.

BCI-Behavior counseling intervention, NTX- naltrexone only, TAU- treatment as usual

Table 1

Features of IMPACT study design affecting treatment interventions

Site selection	Hospital, day hospital and outpatient clinics specializing in tuberculosis care (majority of participants at hospital site)
Inclusion/exclusion criteria	18 yo, enrolling in tuberculosis (TB) treatment, alcohol use disorder by CIDI-SAM, no opioid use in 30 days, not pregnant/breastfeeding, LFTs $\leq 3 \times$ upper limit normal, eligible if co-occurring medical/psychiatric illness did not interfere with study participation
Treatment as usual	CIWA screening, referral to narcologist (Russian addiction specialist) and staff psychologist (TTAWG), education/pamphlets on alcohol use and tuberculosis risk, alcohol use and HIV risk. Typical narcologist interventions include detoxification and alcohol counseling (this trial excluded disulfiram administration, a commonly considered narcologist intervention)
EST constraints	Absence of available Alcoholics Anonymous (AA) meetings, rejection of AA piloted on-site, and absence of family education referral options (such as Al-Anon)
EST adaptations	1) BBCET/NTX: medical adherence incorporated into DOTS for tuberculosis; 2) BCI: the 5 A's translated to the Russian 5 C's: "Ask about Alcohol Use, Assess, Advise, Assist, and Arrange for Follow-up" translated into Russian as the Cyrillic C's: "[unk] and [unk];" roughly translated as, "Ask, Assimilate/compare (discuss ambivalence), Advise, Assist, and Aid/Facilitate follow-up;" 3) standard drinking card adapted to local custom; 4) all interventions required physicians to clearly advise participants to stop or reduce drinking to support tuberculosis treatment; 5) all interventions occur during routinely scheduled monthly appointments with TB physicians over 6 months
Manual development	NIAAA 2004 <i>Helping Patients with Alcohol: A Health Practitioner's Guide</i> adapted/translated for TB physicians with sample scripts relevant to TB care, lab feedback, motivational interviewing style, and menu of options to achieve drinking goals
Physician selection	Site TB physicians willing to participate in study; none with prior experience or training in delivering behavioral interventions or specialized alcohol interventions
Site supervisor selection and central supervisors	Bilingual physician (VL) trained by central supervisors selected for experience in clinical research implementing psychosocial intervention protocols (HC, AS, SG) and monitoring adherence/fidelity (HC).
Coder selection	Audiotape coders are bilingual and selected for prior mental health/behavioral training in Russia and US(NP, LM); calibration of coding compared with English transcripts (HC)

Abbreviations: TB tuberculosis, CIDI-SAM Composite International Diagnostic Interview- Substance Abuse Module, LFT liver function test, CIWA Clinical Institute Withdrawal Assessment, TTAWG Tomsk Tuberculosis Alcohol Working Group, HIV human immunodeficiency virus, AA Alcoholics Anonymous, BBCET-NTX Brief Behavioral Compliance Enhancement Training- naltrexone, DOTS Directly Observed Treatment, Short Course (for TB), BCI Brief Counseling Intervention, NIAAA National Institute on Alcohol Abuse and Alcoholism