EVALUATION OF IMPLEMENTATION OF THE BEHAVIORAL INTERVENTION FOR PEOPLE LIVING WITH HIV AND TB

"TUBERCULOSIS IS CURABLE"

SUMMARY OF THE ANALYTICAL REPORT

KYIV – 2017

BACKGROUND

In Ukraine, tuberculosis (TB) remains the leading cause of death among all diseases directly associated with the HIV infection[1]. The reasons for low efficiency of treatment of HIV/TB co-infection include inadequate organization of treatment of TB patients with emphasis on inpatient treatment, poor organization of treatment supervision, and lack of psycho-social support to patients during treatment and management of side effects[2]. The purpose of the trial is to assess the extent to which the behavioral intervention "TB is Curable," which combines social support with enhanced motivational counseling, improves adherence to outpatient supervision and treatment of people living with HIV/AIDS (PLWHA) PLWHA with HIV/TB co-infection. With the support of the United States Agency for International Development (USAID) RESPOND Project, the intervention was implemented by local offices of the All-Ukrainian PLWH Network in the period from June 2015 till November 2016 in the cities of Mykolaiv, Odessa, and Kryvy Rih.

INTERVENTION

The intervention includes 5 individual counseling sessions. The intervention lasts for 5 months or until completion of the treatment course, as determined by the physician. The first 3 weeks are the intensive intervention period. This is followed by the maintenance period. Counseling sessions are "linked" to patients' visits to the health care facility. During the intervention period (unnecessarily after completion of the sessions), the social worker called each client, based on an agreed-upon schedule, to make sure that the client was continuing to take the recommended medication as well as to provide psycho-social support and encourage the practice of positive behaviors.

The general scheme of the intervention's implementation is as follows:

- The physician refers the client to the social worker using the referral form.
- Session 0 (Introduction). Content: (1) to sign the consent form to participate in the intervention; (2) to schedule the sessions according to duration of outpatient treatment.
- Session 1 "Organization of the TB treatment process and its expected impact on the lifestyle." Held in the first 3 weeks after the start of outpatient treatment, i.e. after discharge from the hospital. Content: (1) to assess the client's awareness of the TB treatment process and the procedure of receiving or taking the medications; (2) to provide the required information about the trial and medication; (3) to discuss how controlled treatment will impact daily life; (4) to identify opportunities and obstacles to reaching the goal of improved health; (5) to define the behavior plan for the period of treatment; (6) to assist in referral (if necessary).
- Session 2 "The patient's routine and side effects: the first two weeks after the start of treatment." Held in the first 3 weeks after the start of outpatient treatment, i.e. after discharge from the hospital. Content: (1) to discuss the early days of taking the drugs, the state of health; (2) to discuss side effects: their manifestations and how to respond to them; (3) to identify the side effects in the event of which the physician/ supervisor must be notified.
- Session 3 "Individual safety and infection control in the domestic environment." Held in the first 3 weeks after the start of outpatient treatment, i.e. after discharge from the hospital. Content: (1) to update the knowledge of TB transmission pathways; (2) to discuss tuberculosis infection hazards at home; (3) to discuss infection control measures.
- Session 4 "Planning own resources for further treatment and examination." Held in the medium phase of the outpatient treatment course (3 months after initiation of outpatient treatment). Content: (1) to re-evaluate the client's risk of treatment

[1] HIV infection in Ukraine Newsletter Issue 46.

[2] MoH (2016). Tuberculosis in Ukraine: an analytical and statistical handbook.

interruption, to support his/her progress; (2) to update the knowledge on TB prevention for PLWH and the need for regular preventive examinations; (3) to discuss the plan of passing the required examinations and medical interventions, to identify the resources needed, including financial ones.

- Session 5 "Support network." Held at the end of the outpatient treatment course (5 months after initiation of outpatient treatment). Content: (1) to support the progress made; (2) to discuss options of getting support in the process of taking TB drugs and its provision to other patients.

METHODS

The trial had a partially randomized experimental design with repeated measurements 3 and 6 months after the baseline assessment.

Data collection period – from June 2015 to November 2016. In the absence of clients meeting inclusion criteria, randomization was halted in March 2016; since April 2016 the control group was recruited separately without randomization in the city of Dnipro.

The group of intervention participants was compared with the control group. The control group received the standard package of prevention services for people living with HIV-TB based on NGO capacities: harm reduction and social support for people living with HIV-TB. During the trial period, all trial sites implemented two interventions for PLHIV with TB "Social support during outpatient TB treatment" and "Social support for treatment of HIV-positive people with HIV/TB co-infection within the Global Fund's "Investments to impact the TB and HIV epidemics"[3]. Members of the control group did not receive counseling sessions under the "Tuberculosis is Curable" intervention.

Inclusion criteria: PLWHA aged 18 and older with a confirmed diagnosis of HIV/TB co-infection; those that belong to the 1st-3rd TB dispensary group[4]; outpatient TB treatment indicated; able and agree to provide two contacts through which it is possible to connect with the subject; agree to sign the written consent. Exclusion criteria for trial participants: more than 14 days from the start of TB treatment (first discharge of the drug); TB active form; the diagnosis of MDR TB.

Compliance with ethical standards was confirmed at the ethical committee of the Ukrainian Institute of Public Health Policy. All participants signed their informed consent before inclusion into the trial.

Geography of the trial: three regional centers (Odessa, Mykolaiv, and Dnipro) and one regional significance city (Kryvy Rih, Dnipropetrovsk region). The trial site in Dnipro was added only to recruit the control group to ensure there would be enough participants.

Sample size: The planned sample size was 325 participants (175 PLWHA/TB in the intervention group and 150 PLWHA/TB in the control group). Calculation of the sample anticipated loss of subjects at the rate of 20% during the 6 months of the trial. In total 243 participants passed baseline assessment (156 individuals or 89% of the entire planned sample in the intervention group and 87 individuals or 58% of the entire planned sample in the control group) (Table 1). The retention rate in the trial after 3 months was 85% in the intervention group and 86% in the control group; after 6 months - 83% in the intervention group and 85% in the control group.

[3] According to data of the Public Health Center (MoH of Ukraine) http://phc.org.ua/pages/diseases/tuberculosis/treatment/social-support.

[4] Guidelines on grouping of TB dispensary contingents of TB facilities and their application. Order of the MoH of Ukraine of 28.10.03 No. 499.

Table 1

Distribution of trial participants in the intervention group and the control group by the assessment period and trial site, persons

	Baseline assessment			3 months			6 months		
	Control	Interven-tion	Total	Control	Interven-tion	Total	Control	Interven-tion	Total
Odessa	29	57	86	28	51	79	25	52	77
Mykolaiv	16	29	45	11	23	34	12	24	36
Kryvy Rih	25	70	95	23	58	81	21	54	75
Dnipro	17	0	17	13	0	13	16	0	16
Total	87	156	243	75	132	207	74	130	204

Data analysis included assessment of fidelity, feasibility, and effectiveness of the intervention. During trial implementation, all intervention sessions were audio recorded. Sessions were conducted in Ukrainian or Russian language depending on the mother tongue of clients. A total of 5% of recorded sessions were monitored and evaluated for fidelity of the intervention's implementation: compliance with standards of the protocol and key elements of the sessions, duration of the sessions was also estimated. Feasibility was assessed using recruitment and retention in the intervention indices. Effectiveness indicators included indicators for intervention adherence, awareness of TB, sexual and injection high-risk practices. All effectiveness indicators were modeled as dependent variables in binary log-binomial regressions comparing the intervention and control groups at each assessment. Based on results of regression modeling, relative risks (RR) were estimated and 95% confidence intervals (CI). SPSS, version 20 was used for data entering, cleaning and analysis. Missing data (5%) was excluded from the analysis.

OUTCOMES

Feasibility and fidelity of the intervention's implementation. The intervention was implemented in accordance with the protocol. All the intervention sessions that were subject to monitoring and evaluation (5%) contained the five key elements (Table 2). The challenge was to ensure the full duration of the session. Only 27% of the sessions were of the recommended duration from 45 to 60 minutes. A high level of retention in the intervention was observed.

Table 2

Findings of implementation assessment of "TB is curable" intervention: fidelity and feasibility in three cities of Ukraine, 2015-2016

Indicator	Calculation method	Obtained results	Target indicators
Recruitment index	Numerator: the number of participants who passed the zero session and signed the informed consent to participate in the intervention	156 of 157 persons (99%)	100%
	Denominator: the number of participants who were invited to participate in the intervention.		
Retention index	Numerator: the number of participants who passed all the 5 sessions of the intervention.	131 of 156 persons (84%)	80%
	Denominator: the total number of participants involved in the intervention.		
The proportion of intervention sessions including all the 5 key elements*	Numerator: the proportion of the sessions that, based on monitoring assessment, included all the 5 key elements.	100%	100%
	Denominator: the total number of sessions assessed within the monitoring.		
The average duration of sessions*	Numerator: the total duration of sessions assessed within the monitoring.	Average value: 30 min. Median value: 27 min. (min. - 10 min., max. - 62 min.)	45 min.
	Denominator: the total number of sessions assessed within the monitoring.		
The proportion of sessions that lasted 45 to 60 minutes*	Numerator: the number of sessions that lasted 45 to 60 minutes.	27%	100%
	Denominator: the total number of sessions assessed within the monitoring.		

* According to the medical forms.

The socio-demographic profile of the participants. The median age of participants was 39 years (± 11 years). The proportion of women in the sample was 40%. Most participants (74%) had primary or secondary education; the proportion of individuals with incomplete or complete higher education was only 8%. More than half of PLWHA/TB involved in this intervention (52%) do not have a permanent partner. The income level is rather low: 65% reported earning UAH 1,500 per month (less than the subsistence level). More than a third of participants (34%) prior to participating in the trial had the experience of staying in detention facilities. About half of the respondents (47%) had a history of injection drug use; 7% reported they had injected drugs in the last 30 days.

Intervention effectiveness assessment findings (Table 3). There is no evidence of higher effectiveness of the "Tuberculosis is Curable" intervention compared with the standard package of services to improve treatment adherence, awareness, and to reduce risky behavior in the short- (3 months) and long-term (6 months) prospects. Based on self-reported adherence to TB treatment, a link was found between the intervention and 100% intake of the prescribed drugs during the assessment after 3 months; however, this effect disappears following the last assessment. Analysis of adherence indicators, based on medical form data, which were assessed only after 6 months, revealed no intervention effect. There were statistically significant differences between the intervention and control groups in their awareness of the risks of TB treatment interruption during the assessment after 6 months; in the short term (assessment after 3 months) no such differences were detected.

Table 3

Assessment of effectiveness of the "Tuberculosis is curable" intervention for PLWHA with TB

	Assessment after 3 months			Assessment after 6 months		
	I	C	RR (95% CI)	I	C	RR (95% CI)
Started TB treatment (ref.: did not start)*	-	-	-	130/156 (83%)	74/87 (85%)	0.98 (0.88-1.10)
Completed the 90-day TB treatment without long interruptions in the drugs' intake (14 or more days consecutively) and continued treatment if there was the need (ref.: interrupted treatment)*	-	-	-	126/156 (81%)	73/87 (84%)	0.96 (0.85-1.09)
Received all doses of anti-TB drugs from all the prescriptions (ref.: did not receive all doses)*	-	-	-	117/156 (75%)	67/87 (77%)	0.97 (0.84-1.13)
Took all doses of anti-TB drugs from all the prescriptions in the last 30 days (ref.: did not take all doses)**	68/132 (52%)	20/75 (27%)	1.93 (1.28-2.91)	102/130 (78%)	64/74 (86%)	0.91 (0.80-1.03)
Took all doses of ART drugs from all the prescriptions in the last 90 days (ref.: did not received all doses) (from all patients on ART)**	92/118 (78%)	46/67 (69%)	1.14 (0.94-1.37)	98/123 (80%)	45/64 (70%)	1.13 (0.94-1.36)
Know TB transmission ways (ref.: did not correctly answer ≥1 question out of the 5)**	43/132 (33%)	31/75 (41%)	0.79 (0.55-1.14)	48/130 (37%)	27/74 (37%)	1.01 (0.70-1.47)
Know TB prevention in the environment ways (ref.: did not correctly answer ≥1 question out of the 5)**	31/132 (24%)	19/75 (25%)	0.93 (0.57-1.52)	20/130 (15%)	14/74 (19%)	0.81 (0.44-1.51)
Know the risks of TB treatment interruption (ref.: did not correctly answer ≥1 question out of the 4)**	94/132 (71%)	45/75 (60%)	1.19 (0.96-1.47)	105/130 (81%)	42/74 (57%)	1.42 (1.15-1.77)
Did not use a sterile needle during the last injecting drug use (ref.: used it)**	0/6 (0%)	0/7 (0%)	-	0/2 (0%)	0/7 (0%)	-
Did an injection with a needle previously used for injection by another person in the past 30 days (ref.: used a sterile needle)**	0/6 (0%)	0/7 (0%)	-	0/2 (0%)	0/7 (0%)	-
Not always used condoms during vaginal or anal sex in the last 30 days (ref.: always used them)**	18/67 (27%)	15/46 (33%)	0.82 (0.46-1.46)	17/66 (26%)	10/39 (26%)	1.00 (0.51-1.97)

* According to the medical forms.

** According to interviews (self-report).

I - the intervention group, C - the control group, RR - the relative risk, CI - confidence interval, ref. - the reference group.

Trial limitations include:

- Early termination of randomization (March 2016) due to lack of trial participants to meet the criteria;
- Non-randomized comparison due to the additional recruitment of control group participants in the city of Dnipro – a city where the intervention was not implemented; under-performance of the planned sample;
- Contamination of the control group in the randomized part of the trial, participants in the both groups could obtain services within one organization and by the same staff; participants in the intervention and control groups could communicate with each other;
- Limitations associated with clinical data: availability of information only on received doses of drugs, not taken ones, cases of violation of quality requirements for filling drug logbooks ("advance" filling); the systematic error due to references to information in the indicators determined based on participants' self-reporting.

CONCLUSIONS AND DISCUSSION

The "TB is Curable" intervention cannot be recommended for implementation in Ukraine due to lack of evidence to prove its higher effectiveness compared to the standard set of services for people living with HIV-TB. Lack of the intervention's effect proves that availability of such motivational counseling in addition to social support cannot be considered a practice that leads to changes in treatment adherence. However, further studies are required to assess effectiveness of motivational sessions for people living with HIV-TB in the absence of social support. Further efforts should be aimed at assessing the intervention's effects with a larger sample size and within a longer-term perspective, determining effectiveness of interventions on high-risk injection behavior and high-risk sexual behavior. It is advisable to revise structural components of the intervention in particular to pay more attention to involving the innovative systems reminding of therapy intake.

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