Effectiveness of Cognitive Behavioral Therapy on Multi-drug Resistant Tuberculosis Patients in Mongolia: 10 years experiences

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Objective: During multidrug-resistant tuberculosis (MDR-TB) treatment, patients face depression and anxiety. This study aims to evaluate the effects of cognitive behavioral therapy (CBT) on the psychological status and risk of loss to follow-up (LTFU) during MDR-TB treatment in Mongolia. **Method:** Eligible participants were randomly assigned to intervention and control groups. Intervention group participants underwent CBT, while control group participants received standard patient education. Psychological status was assessed before and after CBT. MDR-TB treatment outcomes were evaluated as internationally defined. **Results:** The study included a total of 83 patients. After CBT, depression and anxiety levels decreased by 12% and 16%, respectively, in the intervention group, whereas the control group showed a 4% decrease in depression and an 8.5% increase in anxiety levels. MDR-TB treatment outcomes revealed an 8% higher treatment success rate and a fivefold reduction in LTFU rate in the intervention group compared to the control group. In multivariable logistic regression, risk factors associated with increased LTFU were living alone (OR 12.7, p=0.031) and not being provided CBT (OR 16.1, p=0.040). **Conclusion:** Our study suggests that CBT not only alleviates these psychological challenges but also diminishes the risk of LTFU during treatment, leading to improved MDR-TB treatment success.
Keywords: Tuberculosis, Depression, Anxiety, Mental health, Psychotherapy

Introduction

Drug-resistant tuberculosis (DR-TB) continues to pose a significant global health challenge.

In 2022, 176,585 cases of DR-TB were reported worldwide. Of these cases, 85% were MDR/RR-TB (multidrug-resistant/rifampicin-resistant TB)[1], resistant to rifampicin and isoniazid/rifampicin. In comparison, 15% were pre-XDR/XDR-TB, resistant to any fluoroquinolones/any fluoroquinolones, and at least one of Group A drugs in addition to MDR/RR-TB.2 Globally, 175,650 patients with MDR/RR-TB received treatment, reflecting an 8.5% increase from 2021. The MDR/RR-TB treatment success rate was 64% in 2021.[1]

Mongolia is among the seven countries with high MDR/RR-TB burdens. In 2022, 153 laboratory-confirmed cases of DR-TB were diagnosed, with 90% being MDR/RR-TB and 10% being pre-XDR/XDR-TB. MDR/RR-TB treatment success rate is 76.5%. However, unfavorable TB treatment outcomes were observed, with 1.6% being a failure, 10.2% being a loss to follow-up (LTFU) during the treatment, and 14.2% resulting in death.[3] LTFU, during TB treatment, can potentially become a primary source of DR-TB transmission in the community. Several factors contribute to poor treatment adherence and LTFU during MDR-TB treatment, including the lengthy treatment duration, pill burden, side effects of second-line anti-TB drugs, unemployment, disability, financial hardships, addiction, alcohol abuse, nicotine dependence, stigma, discrimination, health system challenges, and medical professionals' attitudes.[4-12]

It is known that psychological support is crucial in enhancing patient treatment adherence, achieving successful treatment outcomes, and reducing loss of control during treatment.[13] In Kazakhstan, 190 patients with a high risk of LTFU on MDR-TB treatment were enrolled in a psychological and social support program. Before the implementation of this program, 23% of 190 MDR-TB patients had not adhered to the drug treatment regimen. In contrast, during the program's implementation, only one patient with alcohol dependence was lost in the treatment. Moreover, 81% of participants self-assessed that they recovered with early diagnosis, quality treatment, and medical staff assistance, 69% with social support, and 50% with psychological support.[14]

The National Tuberculosis Program of Mongolia aimed to introduce psychological support interventions for MDR-TB care and services to enhance treatment adherence, increase the treatment success rate, and reduce LTFU. First, a research team investigated the psychosocial issues of MDR-TB patients treated in Mongolia between 2017 and 2019.

The study revealed that 89% of the respondents demonstrated psychiatric symptoms such as sleep disturbance, depression, and anxiety, while 63% faced psychosocial problems caused by MDR-TB. The majority of patients required psychological care during MDR-TB treatment.[15] Building on these findings, we have developed a "Cognitive behavioral therapy (CBT) program for patients with MDR-TB." The objective of our study was to investigate the effects of cognitive behavioral therapy (CBT) on the psychological stress and risk of loss to follow-up (LTFU) among MDR-TB patients in Mongolia.

Material and Method

Study design

In this study, we used a randomized controlled trial design. The National Tuberculosis Program of Mongolia started the shorter regimen of MDR-TB treatment in 2020. Therefore, bacteriologically confirmed all MDR-TB patients who enrolled in shorter regimens included in this study according to the inclusion and exclusion criteria.

Study participants

The shorter treatment regimen for MDR-TB was implemented under the National Tuberculosis Program of Mongolia in 2017. In Mongolia, the number of cases receiving shorter treatment regimens was 45 in 2017 and 53 in 2018 and rose to 96 in 2019. Due to the small number of MDR-TB patients treated with this new regimen annually, our study included a total of 83 MDR-TB patients who enrolled in MDR-TB treatment with a shorter regimen between 2020 and 2021 nationwide. Inclusion criteria were patients aged 18 years and above, enrolled in MDR-TB treatment with a short regimen, having no history of psychological disorder treatment, and capable of providing informed consent.

To prevent sampling errors, participants were ordered based on the date MDR-TB treatment started. Participants numbered 1 and 2, 4 and 5, 7 and 8, etc., were included in the control group, while participants numbered 3, 6, 9, etc., were included in the intervention group. 27 patients were allocated to the intervention group, while 56 patients were assigned to the control group. When selecting the intervention and control groups, we did not match the two groups.

Data collection

Our team developed a questionnaire to study socio-demographic characteristics, TB treatment, and mental health status. Psychological status was assessed using the translated versions of the 20-item Zung Self-Rating Depression Scale (SDS) and the 20-item Zung Self-Rating Anxiety Scale (SAS).[16,17]

To assess depression levels, the SDS was utilized, with each question scored from 1 to 4 points based on responses: "a little of the time," "some of the time," "good part of the time," and "most of the time." Final scores were categorized as normal (25 to 49), mild depression (50 to 59), moderate to major depression (60 to 69), and severe to extreme major depression (70<).[16]

Similarly, SAS scores ranged from 1 to 4 points, with classifications of average (20-44), mild to moderate anxiety (45 to 59), marked to severe stress (60 to 74), and extreme anxiety (>75).[17]

The study also used the translated version of the Alcohol Use Disorders Identification Test (AUDIT) and the Fagerstrom test for nicotine dependence to assess alcohol abuse and tobacco smoking, respectively. AUDIT scores were classified as no risk (0), low risk (1 to 7), medium risk (8 to 15), high risk (16 to 19), and addiction (20 to 40). The Fagerstrom test for nicotine dependence was classified as no dependence (0), low dependence (1 to 2), low to moderate dependence (3 to 4), moderate dependence (5 to 7), and high reliance (8 and above).[18,19]

Intervention

Participants in the intervention group underwent CBT through peer group counseling three times per week for one month at the beginning of MDR-TB treatment, following a 12-step process: "Why I am here?", "The first step, ""Denial, ""The power of belief, ""Relationship, ""Respect ourselves, ""Understanding yourself, ""Iced feelings, ""Family, ""Tuberculosis and Stigma, ""The continuation of treatment, "and "Working with yourself. "

Participants in the control group received patient education information about MDR-TB at the baseline of MDR-TB treatment.

Evaluating the intervention

To assess the effectiveness of CBT on the psychological status of MDR-TB patients, psychological status was measured with the SAS and SDS at the baseline (pre-CBT) and the end of the intensive phase of MDR-TB treatment (post-CBT) and compared between the intervention and control groups. Treatment outcomes were assessed as internationally defined.[21]

Statistical Analysis

Differences in frequencies were tested using the chi-square or Fisher's exact tests where applicable. A two-sided P value of less than 0.05 was considered statistically significant. The following risk factors were analyzed for association with LTFU: sex, age, education, household size, employment, depression, anxiety, alcohol dependence, previous tuberculosis treatment, and CBT. Multivariable logistic regression analysis, including all independent variables, was carried out to determine risk factors for LTFU results.

Cronbach's alpha was calculated for each scale to assess internal consistency. Cronbach's alpha was classified as excellent (0.9≤α), good (0.8≤α≤0.9), acceptable (0.7≤α≤0.8), questionable (0.6≤α≤0.7), poor (0.5≤α≤0.6), unacceptable (α<0.5). In this study, the value of Cronbach`s alpha above 0.5 is deemed acceptable.22 Analyses were performed using Stata v15.0 (Stata, College Station, Texas, USA).

Ethical Statement

The Institutional Review Board of the Mongolian National University of Medical Sciences (2020/3-05) granted ethical approval in June 2020, and informed consent was obtained from all study participants.

Results

Socio-demographic characteristics

This study included 83 patients. Table 1 summarises the socio-demographic characteristics of the participants. The mean ±SD age of the patients was 40.10±1.5 years, and 57% were male. 45% of the participants had a secondary education. 57% were married, and 40% were unemployed. Other sociodemographic characteristics of the study respondents are shown in Table 1.

Table 1. Socio-demographic characteristics of the study participants (n=83)

Characteristics	n (%)	Intervention group	Control group	P-value
Sex				0.813
Male	47(61.8)	24(63.2)	23(60.5)	
Female	47 (57%)	14(36.8)	15(39.5)	
Age				
15-24	12 (14%)	4 (15%)	8 (14.3%)	0.036
25-34	18 (22%)	6 (22%)	12 (21.4%)	0.260
35-44	19 (23%)	7 (26%)	12 (21.4%)	0.031
45-54	18 (22%)	7 (26%)	11 (19.7%)	0.096
55 and above	16 (19%)	3 (11%)	13 (23.3%)	
Education				
None or elementary school	7 (8%)	2 (7%)	5 (9%)	
Middle school	14 (17%)	5 (19%)	9 (16%)	
High school	37 (45%)	9 (33%)	28 (50%)	
College or higher degrees	25 (30%)	11 (41%)	14 (25%)	
Marriage status				
Unmarried	25 (30%)	11 (41%)	14 (25%)	
Married	47 (57%)	13 (48%)	34 (61%)	
Divorced	8 (10%)	2 (7%)	6 (11%)	
Widowed	3 (3%)	1 (4%)	2 (3%)	
Household size				
Alone	13 (16%)	4 (15%)	9 (16%)	
With family member	70 (84%)	23 (85%)	47 (84%)	
Employment				
Employed	50 (60%)	21 (78%)	29 (52%)	
Unemployed	33 (40%)	6 (22%)	27 (48%)	0.023

P - value calculated with Pearson's Chi-Square Test; p-value is considered as a significant less than 0.05

Medico-psychological status

Out of 83 participants, 60% were primarily treated with MDR-TB, 66.3% were diagnosed with RR-TB. According to AUDIT, 46%, 32%, 15%, and 7% of patients were classified as no risk, low risk, high risk to addiction, and medium risk level of alcohol use, respectively (Cronbach`s alpha 0.941). Based on the Fagerstrom test for nicotine dependence, 62%, 16%, 13%, and 9% of patients were classified as having no dependence, low dependence, very low dependence, and moderate to high dependence, respectively (Cronbach`s alpha 0.506). At the baseline, 30% of patients were classified as having mild depression and moderate to major depression (Cronbach`s $\alpha$=0.817). In comparison, 19% of patients were classified as having mild to moderate anxiety and marked to severe anxiety (Cronbach`s α =0.863) (Table 2).

Table 2. Medico-psychological status of participants (n=83)

| Characteristics	n (%)	Intervention group	Control group	P-value
Treatment regimen				
Shorter regimen containing injectables	43 (52%)	15 (56%)	28 (50%)	0.635
Shorter regimen containing bedaquiline	40 (48%)	12 (44%)	28 (50%)	
Alcohol dependence				
No	38 (46%)	13 (48%)	25 (45%)	
Low risk	27 (32%)	10 (37%)	17 (30%)	
Medium risk	6 (7%)	4 (15%)	2 (4%)	
High risk, addiction	12 (15%)	0	12 (21%)	
Nicotine dependenc				
No	51 (62%)	17 (63%)	34 (61%)	
Very low dependence	11 (13%)	3 (11%)	8 (14%)	
Low dependence	13 (16%)	5 (19%)	8 (14%)	
Moderate, high dependence	8 (9%)	2 (7%)	6 (11%)	
Depression level				
Normal	58 (70%)	19 (70%)	39 (70%)	
Mild	20 (24%)	6 (22%)	14 (25%)	
Moderate to major	5 (6%)	2 (7%)	3 (5%)	
Anxiety level				
Normal	67 (81%)	21 (78%)	46 (82%)	0.637
Mild to moderate, marked to severe	16 (19%)	6 (22%)	10 (18%)	
MDR-TB treatment outcome				
Treatment success	63 (76%)	23 (81%)	41 (73%)	
Failure	1 (1%)	0	1 (2%)	
Loss to follow-up	12 (15%)	1 (4%)	11 (20%)	
Died	7 (8%)	4 (15%)	3 (5%)	

P-value calculated with Pearson's Chi-Square Test; Abbreviations: MDR-TB, multi-drug resistant tuberculosis

1. Effect of CBT on psychological status

At the end of the intensive phase, ten patients were excluded from the study due to death and LTFU. Thus, we evaluated how CBT affects the psychological status of MDR-TB patients among the remaining 73 participants.

At the baseline, based on SDS, 32% of participants in the intervention group and 27% in the control group had mild to
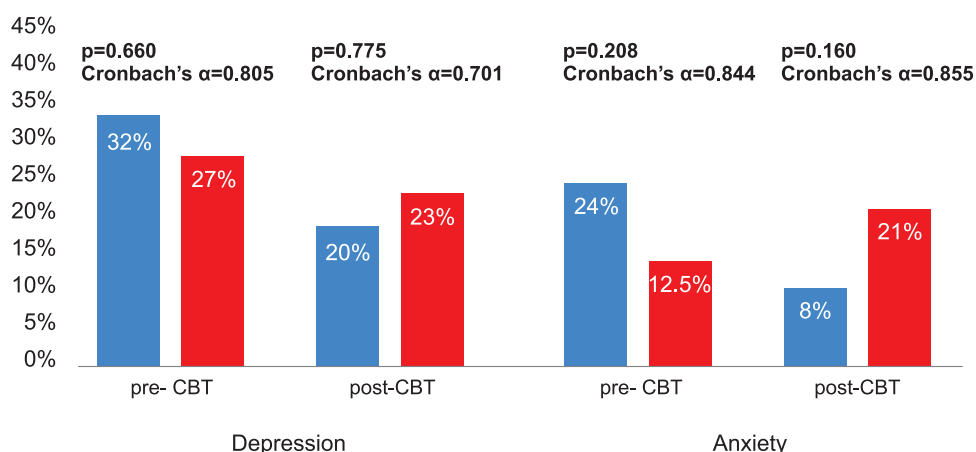
Figure 1. Comparison of the psychological status of MDR-TB patients in pre- and post-CBT (n=73)

moderate depression (P=0.660, Cronbach`s α=0.805), while based on SAS, 24% of participants in the intervention group and 12.5% in the control group had mild to moderate anxiety and marked to severe anxiety (P=0.208, Cronbach`s α=0.844).

At the end of the intensive phase of MDR-TB treatment, depression and anxiety levels they decreased by 12% and 16%, respectively, in the intervention group. However, the depression level decreased by 4%, and the anxiety level increased by 8.5% in the control group (Figure 1).

The P-value was calculated using the Pearson Chi-Square Test, which was significantly less than 0.05. Abbreviations include

MDR-TB, Multi-Drug resistant tuberculosis, and CBT, cognitive behavioral therapy.

Effect of CBT on treatment outcomes

The treatment success rate was 8% higher, and loss to follow-up was five times lower, but death was three times higher in the intervention group compared to the control group (Table 2).

Risk factors influencing LTFU

When analyzing risk factors influencing LTFU during MDR-TB treatment, family members (P=0.018), alcohol dependence (P=0.019), and CBT (P=0.047) were significantly associated with LTFU (Table 3).

Table 3. Association of LTFU with other factors (n=83)

Categories		LTFU No	Yes	P-value
Sex	Male	38 (54%)	9 (75%)	0.216
	Female	33 (46%)	3 (25%)	
Age	15-39	36 (51%)	6 (50%)	1.000
	40 above	35 (49%)	6 (50%)	
Education	Secondary	51 (72%)	7 (58%)	0.497
	Post-secondary	20 (28%)	5 (42%)	
Household size	Alone	8 (11%)	5 (42%)	0.018
	With family members	63 (89%)	7 (58%)	
Employment	Employed	44 (62%)	6 (50%)	0.528
	Unemployed	27 (38%)	6 (50%)	
Depression	No	50 (70%)	8 (67%)	
	Yes	21 (30%)	4 (33%)	0.518
Anxiety	No	58 (82%)	9 (75%)	0.419
	Yes	13 (18%)	3 (25%)	
Alcohol dependence	Low risk	59 (83%)	6 (50%)	0.019
	High risk	12 (17%)	6 (50%)	
Previous TB treatment	No	45 (63%)	5 (42%)	0.206
	Yes	26 (37%)	7 (58%)	
CBT	No	45 (63%)	11 (92%)	0.047
	Yes	26 (37%)	1 (8`%)	

P-value calculated with Fisher`s Exact Test; P-value is considered as a significant less than 0.05; Abbreviations: LTFU, loss to follow-up; CBT, cognitive behavioral therapy

According to the binary logistic regression analysis, the risk of LTFU during MDR-TB treatment was 5.6 times greater (P=0.013) for patients living alone compared to patients living with family and 4.9 times higher (P=0.016) for patients who are drinking alcohol compared to non-users. However, patients not enrolled in the CBT had a 6.3 times greater risk (P=0.085) of LTFU during the MDR-TB treatment compared to patients who received the

above treatment (CBT). However, no statistically significant relationship was observed.

According to the multiple logistic regression analysis, patients living alone had a 12.7 times greater risk of LTFU during MDR-TB treatment compared to patients living with family (P=0.031). Patients who did not enroll in the CBT had a 16.1 times greater risk (P=0.040) of LTFU during MDR-TB treatment compared to patients who received the CBT (Table 4).

Table 4. Risk factors associated with LTFU (n=83)

Categories		Unadjusted OR (95%CI)	P-value	Adjusted aOR (95%CI)	P-value
Sex	Male	2.6 (0.65-10.43)	0.176	2 (0.32-12.14)	0.459
	Female	Ref		Ref	
Age	15-39	0.97 (0.29-3.30)	0.964	0.3 (0.05-1.28)	0.243
	40 above	Ref		Ref	
Education	Secondary	0.5 (0.16-1.93)	0.350		0.098
	Post-secondary	Ref			0.497
Household size	Alone	5.6 (1.44-21.98)	0.013	12.7 (1.26-127.48)	0.031
	With family members	Ref		Ref	
Employment	Employed	Ref	0.436	Ref	0.610
	Unemployed	1.6 (0.48-5.57)		0.7 (0.13-3.29)	
Depression	No	Ref	0.793	Ref	0.729
	Yes	1.2 (0.32-4.39)		1.4 (0.24-7.64)	
Anxiety	No	Ref	0.589	Ref	0.403
	Yes	1.5 (0.35-6.27)		2.2 (0.34 -14.78)	
Alcohol dependence	Low risk	Ref	0.016	Ref	0.490
	High risk	4.9 (1.35-17.87)		1.9 (0.30-12.03)	
Previous TB treatment	No	Ref	0.164	Ref	0.319
	Yes	2.4 (0.70-8.41)		2.1 (0.48 -9.38)	
CBT	No	6.3 (0.78-52.07)	0.085	16.1 (1.14-228.04)	0.040
	Yes	Ref		Ref	

Abbreviations: OR, odd`s ratio; an OR, adjusted odd`s ratio; CI, confidence interval; LTFU, loss to follow-up; CBT, cognitive behavioral therapy

Discussion

In this study, we identified that alcohol dependence is higher among MDR-TB patients, alcohol abuse associated with LTFU, MDR-TB patients face psychological problems, and CBT can reduce depression and anxiety of MDR-TB patients but also prevent LTFU during treatment.

Alcohol use is one of the main challenges in TB care and services. In a study by Mohanarani Suhadev, et al.[23], 14% of study participants were hazardous drinkers. In our study, 22% of study participants were dangerous drinkers. Alcohol consumption negatively impacts tuberculosis treatment. Relapse, LTFU, and mortality among tuberculosis patients are considerably increased by alcohol drinking[24]; in a study conducted by K Slama, et al.[25], alcohol usage is a significant risk factor for LTFU. In our research, we found that alcohol consumption is a risk factor for LTFU during MDR-TB treatment. To reduce alcohol consumption in alcohol-dependent patients, the NTP of Mongolia should ensure

the implementation of linking with narcology care and services.

Mental health is the state in which a person is free from mental illness and can live, work, study, and contribute to society by adapting to society and the environment. A person can be mentally healthy if the basic human needs - physical, psychological, and social - are met.[26]

The lengthy duration of MDR-TB treatment (9-18 months), coupled with pain and suffering, adverse drug reactions, loss of working ability, financial problems, medical expenses, and social/family stigma, negatively influenced the psychological well-being of MDR-TB patients. Other researchers found out that MDR-TB patients face depression and anxiety during the treatment period. Walker I.F.'s study reported that 22.2% of 135 patients with MDR-TB had depression and 15.6% had anxiety, while Bhaware G.M.'s study reported that 35.95% of 267 patients had depression and 25.84% had anxiety. In our research, 30% of the 83

participants had depression, and 19% had anxiety, which is similar to the results of the above study.

Several studies emphasized integrating psychosocial care into TB patient management to support mental health.[30,32,33] National TB Program of India, Ethiopia, Nepal, Kazakhstan, and Mexico successfully introduced psychosocial care into MDR-TB care and services—a study conducted by Xiaowei Zuo, et al.[33] showed in the intervention group, depression was 2.05 times lower (1.74-2.37, P=0.001), and anxiety level was 1.72 times lower (1.47-1.99, p=0.001) compared to the control group. Therefore, the researchers emphasized that CBT reduced depression and anxiety in TB patients. Our study included 27 participants in the intervention group treated with CBT at the beginning of MDR-TB treatment. Post-treatment psychological symptoms showed a 1.6-fold reduction in depression in the intervention group compared to the pre-treatment period.

In contrast, the control group's depression (23%) was similar to the pre-treatment period (27%) (P= 0.775, Cronbach's alpha=0.701). The level of anxiety decreased by three times in the intervention group and increased by 1.7 times in the control group (P=0.160, Cronbach`s alpha=0.855) after CBT. CBT reduces depression and anxiety by enhancing knowledge of MDR-TB treatment, adverse reactions, and coping with stress. Although it was found that CBT did not have a statistically significant relationship in reducing the depression and anxiety of the participants, the Cronbach's alpha coefficient of the depression and anxiety test was higher than 0.7, so the test was considered reliable. The research team concluded that CBT effectively reduced depression and anxiety in MDR-TB patients.

Several studies highlighted the effectiveness of psychological care in improving treatment adherence, treatment success, and reducing LTFU among MDR-TB patients.[33-37] According to the study of Janmeja A K[36], the success rate of TB treatment in patients who underwent psychotherapy was 1.7 times higher than in the control group and 3.1 times less in the control loss of the treatment process in a study by Sushil C Baral, et al.[38], treatment success rates were 1.3 times higher in MDR-TB patients who received psychological counseling compared to the control group, and LTFU was three times lower. In our study, the treatment success rate in patients who underwent CBT was 1.1 times higher than in the control group, and the LTFU rate was five times lower. The multiple logistic regression analysis showed patients who were not enrolled in the CBT had a 16.1 times greater risk

(P=0.040) of LTFU during MDR-TB treatment compared to patients who received the CBT.

In our study, we found out that the death rate was three times higher in the intervention group compared to the control group. The main reason for death in the intervention group was cardiac conduction disturbance (n=3), while in the control group, it was core pulmonary deficiency (n=3). In the future, researchers should conduct survival analysis studies among MDR-TB patients in Mongolia.

Globally, the factors influencing the LTFU have been studied. In the study of Soedarsono and Ni Made Mertaniasih,[9] gender (P=0.013), unemployment (P=0.010), and low income (P=0.007) are risk factors for LTFU. Thelma E Tupasi, et al.[6] found that severe vomiting (OR 1.10, P=0.03) and alcohol dependence were independent risk factors for treatment non-adherence. Our study's multiple logistic regression analysis showed that living alone (Or, R 12.7, p=0.031) and the absence of CBT (OR 16.1, P=0.040) were independently associated with LTFU during MDR-TB treatment. We have demonstrated that this CBT program can relieve anxiety and depression symptoms and decrease default rates. Furthermore, the National Tuberculosis Program should establish CBT in MDR-TB care and service and provide CBT to all MDR-TB patients in Mongolia.

Our study had several limitations. First, sample size calculation was not conducted, and samples in both groups were programmatically collected based on randomization in the given period. This may have led to an inadequate sample size. Second, this study was conducted during the pandemic of the coronavirus disease 2019 (COVID-19). Therefore, it was difficult for the participants to take the medication under DOTS plus to follow up the monthly examination: sputum smear microscopy, sputum culture test, ECG, blood test, et al. l. In addition, the MDR-TB ward was closed during the lockdown period, so we provided e-CBT among the intervention group instead of classroom CBT to continue our study. We recommend that NTP develop a plan to provide appropriate TB care and services to TB patients during pandemics of infectious diseases. Future researchers should investigate the effectiveness of e-CBT among patients with MDR-TB.

In conclusion, our research underscores the efficacy of combining psychotherapy, particularly CBT, with shorter MDR-TB treatment. The integration of psychological support not only addresses the mental health challenges faced by patients but also contributes to improved treatment outcomes and reduced LTFU.

These findings emphasize the holistic approach needed in the management of MDR-TB, taking into account both the physical and psychological aspects of the disease.

Conflict of Interest

The authors state no conflict of interest.

Acknowledgements

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