

Alcohol intervention strategy among tuberculosis patients: a pilot study from South India

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SUMMARY

BACKGROUND: Alcohol dependence has been a major cause of treatment non-adherence in tuberculosis (TB) management. There is an urgent need to develop a feasible, acceptable alcohol intervention programme to ensure treatment completion.

METHODOLOGY: Four of the 10 Chennai Corporation zones in Chennai, South India, were randomly selected: two each for the experimental and control arms of the study. TB patients registered from August 2013 to January 2014 with the Revised National Tuberculosis Control Programme were assessed using the Alcohol Use Disorder Identification Test (AUDIT) scale. The intervention consisted of four individual counselling sessions at months 0, 2, 4 and 6 conducted by highly trained interventionists.

RESULTS: Of 872 TB patients, 298 (31%) were found to have alcohol use disorders. The numbers of TB

patients in the experimental and control arms were respectively 113 (38%) and 185 (62%). The proportion of patients with favourable treatment outcomes was higher in the intervention than in the control group (87% vs. 62%, $P = 0.04$). Overall adherence to anti-tuberculosis treatment was significantly higher in the intervention group ($P = 0.02$).

CONCLUSION: Study findings suggest that alcohol interventions could be effective in ensuring favourable TB treatment outcomes and adherence. This calls for a large cluster randomised trial for greater generalisability. Tested alcohol-intervention strategies should be recommended to promote treatment adherence among TB patients who consume alcohol.

KEY WORDS: alcohol use disorder; treatment adherence; alcohol dependence; TB

DESPITE the widespread global effort to control tuberculosis (TB), it remains a chronic infectious disease with high morbidity and mortality in several parts of the world.^{1–3} It is of concern that in India, 2.1 million new cases (i.e., >20% of global incident cases) occur per year.⁴ While 40% of the Indian population is infected with TB, only 10% develop the disease.⁴ Diverse factors contribute to the development of TB, but several studies have reported a strong association between alcohol use and risk of TB.^{5–9} In addition to the role played by alcohol in the onset of TB, there is also strong evidence of the adverse effects of alcohol use disorders (AUDs) on TB treatment outcomes.^{10–12} This includes delays in diagnosis, non-adherence to anti-tuberculosis treatment, treatment failure, death and default, as well as higher relapse rates.^{13,14} The prevalence of AUDs among TB patients has been reported to range between 10% and 50%.¹⁵

Like many other countries, India faces challenges posed by poverty and high rates of alcohol depen-

dence among men.¹⁶ TB clinics in India do not regularly screen patients for AUD, and the information available in patient records is limited to information on whether or not the patient consumes alcohol. The present study is based on an earlier study carried out in South India that reported an alcohol consumption of 29% among TB patients, with 52% having a score of >8 on the Alcohol Use Disorder Identification Test (AUDIT) scale.^{17,18} That study pointed out that treatment outcomes were unsatisfactory for >10% of those patients with AUD, and that hazardous drinking led to chronic treatment default, treatment failure and death. The present study investigated the acceptability of and the urgent need for an alcohol intervention programme, and offers suggestions on the type of intervention that could be feasible.

The present pilot study was conducted based on a previous study to generate evidence on the feasibility of using an alcohol intervention in a TB programme

whereby a structured intervention manual was given to TB patients who consumed an excessive amount of alcohol.^{*19}

METHODS

Setting and participants

For administrative purposes, Chennai City is divided into 10 corporation zones and 155 divisions. This was a pilot, two-arm, parallel-cluster randomised trial carried out in four zones (TB units) where TB investigations and treatment are offered through the Revised National Tuberculosis Control Programme (RNTCP). The four zones were divided into two strata, two of which were high-prevalence and two were low-prevalence zones. Within each stratum, one zone was allocated to the intervention arm and the other to the control arm. Here the zones were the units of randomisation (clusters); data were collected from individual patients (participants). This design overcomes the problem of 'contamination' (interaction) between the control and intervention arms.

The study population included all new TB patients aged ≥ 18 years registered for anti-tuberculosis treatment with the RNTCP from August 2013 to January 2014. In our previous study, the overall prevalence of AUD in these four zones was 14% (range 7.8–26).¹⁷ To assess the effectiveness of alcohol intervention among TB patients with AUDs, the zones were stratified based on AUD prevalence and divided into experimental and control arms, with one high and one low alcohol prevalence zone selected for each arm. The intervention zones received the intervention programme, while the control group received RNTCP standard of care.²⁰

The intervention consisted of four individual sessions at months 0, 2, 4 and 6, with each session lasting approximately 45–60 min. Interventionists were counsellors who underwent intensive training in screening for alcohol use using AUDIT, conducting interviews using a semi-structured interview schedule and alcohol intervention counselling. The AUDIT scale was administered to determine patients' alcohol consumption based on self-reporting. The intervention was designed based on a community participatory approach in which patients, families and health care providers were involved in finalising the topics for the interventions, as well as the intervention format. This extensive training led to the design of a structured intervention manual and visual aids in the form of flip-charts with images to explain the basic facts relating to: TB; the effect of alcohol on the human body, the family, on society, and on TB; alcohol being a risk factor to developing TB; the

influence of alcohol on adherence to TB treatment; and treatment outcomes.

Recruitment and procedure

TB patients aged ≥ 18 years registered for anti-tuberculosis treatment in the four study zones were recruited for alcohol screening after providing written consent. Patients were screened to estimate the level of alcohol use and prevalence of AUD, which was defined as 'alcohol abuse' or 'alcohol dependence'. The World Health Organization AUDIT scale was used to screen for AUDs among TB patients.^{21,22} The AUDIT scale has been internationally validated among primary health care patients,²³ and was used previously in Chennai among patients with TB.^{16,19}

Alcohol Use Disorder Identification Test scale

The AUDIT scale is a 10-item screening questionnaire for hazardous and harmful alcohol consumption and alcohol-related problems; it is sensitive to early detection of high-risk drinking.²¹ The total AUDIT score reflects the patient's level of alcohol risk, with the minimum score being 8. Alcohol use is categorised as 'low risk', 'hazardous', 'harmful' and 'dependence'. Total scores of respectively 8–15, 16, 17–19 and ≥ 20 indicate hazardous use, alcohol abuse, 'harmful' use and alcohol dependence.¹¹

All 298 participants recruited in both arms had assessments at baseline and at 3 and 6 months using semi-structured interviews covering basic sociodemographic information, treatment details (from the TB register available at the TB unit) and treatment adherence. Alcohol consumption was tested using the AUDIT scale at baseline and month 6. The alcohol intervention was initiated within 15 days of the start of treatment, and included four individual counselling sessions at months 0, 2, 4 and 6 of treatment.

Adherence to anti-tuberculosis treatment in all patients was noted at two time points, one at the end of the intensive phase at 2 months and again at the end of treatment at 6 months. Adherence was classified as 'regular', 'irregular', and 'default or lost to follow-up'. 'Regular adherence' was defined as intake of the required number of doses within the specified periods (the 2-month intensive phase and the 4-month continuation phase). 'Irregular adherence' was defined as the intake of the required number of doses but not within the specified periods. 'Default' or 'lost to follow-up' refers to patients who did not take their medications for a continuous period of 2 months. Standard RNTCP definitions (cured, treatment completion, treatment failure, default, death and transferred out) were used to determine treatment outcomes.

*The manual and flip-chart are available on request from the corresponding author.

Table 1 Sociodemographic and clinical characteristics of study participants

	Overall n (%)	Intervention group n (%)	Control group n (%)
Age, years, mean (95%CI)	44 (42–46)	45 (44–45)	43 (41–44)
Marital status			
Single	52 (17)	16 (14)	36 (20)
Married	214 (72)	91 (81)	123 (67)
Separated/divorced/widowed	32 (11)	6 (05)	26 (14)
Education			
No formal qualification	52 (18)	20 (18)	32 (17)
Primary school	71 (24)	31 (27)	40 (22)
Middle school	82 (28)	31 (27)	51 (28)
High school	77 (26)	26 (23)	51 (28)
College/professional	15 (05)	5 (04)	10 (05)
Occupation			
Unemployed	79 (27)	30 (27)	49 (27)
Daily wage earner	121 (41)	45 (40)	76 (41)
Self-employed	31 (10)	16 (14)	15 (08)
Salaried	61 (21)	21 (19)	40 (22)
Other	6 (02)	1 (01)	5 (03)
Monthly family income, INR*			
<2 500	14 (05)	3 (03)	11 (06)
2 500–5 000	98 (33)	37 (33)	61 (34)
5 001–10 000	117 (40)	48 (43)	69 (38)
>10 000	64 (22)	24 (21)	40 (22)
TB treatment			
Category I (new cases)	226 (76)	83 (74)	143 (77)
Category II (retreatment cases)	72 (24)	30 (27)	42 (23)
AUDIT			
Low risk	32 (11)	10 (09)	22 (12)
Hazardous level	109 (37)	53 (47)	56 (30)
Harmful level	59 (20)	22 (20)	37 (20)
Dependence	98 (33)	28 (25)	70 (38)
Total	298 (100)	113 (100)	185 (100)

* 1 INR = US\$0.015 as of 13 April 2017.

CI = confidence interval; INR = Indian rupee; TB = tuberculosis; AUDIT = Alcohol Use Disorder Identification Test.

Statistical analysis

Data were entered, checked for errors in Microsoft Excel™ 2013 and analysed using STATA 9.1 (Stata-Corp, College Station, TX, USA). Data were adjusted for cluster size differences using the SVYSET command.²⁴ The zone was set as the primary sampling unit and high or low prevalence as strata. Pearson's χ^2 statistic was corrected for the survey design with Rao and Scott's second-order correction,²⁵ and converted into an *F*-statistic. The corrected χ^2 test was used to test the association between the intervention and treatment regularity and treatment outcomes. Univariate logistic regression with a linearised Taylor-series variance estimate was performed to determine the effect of the intervention on treatment outcomes and treatment adherence. Statistical significance was determined at 5%.

Ethics statement

The study protocol was approved by the Scientific Advisory Committee and Institutional Ethics Committee of the National Institute for Research in Tuberculosis, Indian Council of Medical Research, Chennai, and Chennai Corporation. Written informed consent was obtained from all study partic-

ipants. The privacy and confidentiality of all participants were ensured.

RESULTS

The sociodemographic profile, TB treatment category and AUDIT scores of the study participants are shown in Table 1. The mean age was 44.0 years (standard deviation [SD] 11); 72% were married. Of the 298 participants, 82% had some form of education, 76% were new Category I smear-positive cases. Baseline demographic profiles and AUDIT scores of the intervention and control groups were comparable.

Treatment adherence in the intervention and control groups

Information on overall treatment adherence was available for 104 (92%) intervention group participants and for 173 (94%) control group participants. Treatment adherence among 72 (66%) patients in the intervention group and 84 (48%) in the control group until the end of the intensive phase was deemed 'regular'. A significant difference of 17% (95% confidence interval [CI] 13.5–19.4; *F*-statistic 11.1, degree of freedom [df] 1,3; *P* = 0.05) was observed.

Table 2 Treatment adherence in the intervention and control groups

Treatment adherence	Intervention group n (%)	Control group n (%)
Intensive phase		
Regular	72 (66)	84 (48)
Irregular	37 (34)	81 (46)
Default	1 (1)	11 (6)
Overall adherence (intensive + continuation phases)		
Regular	41 (39)	31 (18)
Irregular	57 (55)	82 (47)
Default	6 (6)	60 (35)

Overall treatment adherence (during both the intensive and the continuation phases) was significantly higher in the intervention group than in the control group (39% vs. 18%; *F*-statistic 25.9, *df* 1,3; *P* = 0.02). A difference of 21% (95%CI 9.2–29.3) was observed (Table 2).

Unadjusted logistic regression for overall adherence was performed taking regular adherence as the dependent variable and irregular adherence, which included irregular adherence and default, as the reference category. Those in the intervention group were three times more likely to be regularly adherent to treatment than those in the control group (odds ratio [OR] 2.9, 95%CI 1.5–6.0; Table 3).

Comparison of treatment outcomes in the intervention and control groups

A difference in favourable treatment outcomes of 24% (95%CI 3.8–31.1) was observed (Appendix Figure A.1*) between the intervention (87%) and control groups (62%) (*F*-statistic 11.5, *df* 1,3; *P* = 0.04). Univariate logistic regression for favourable treatment outcomes was performed with cured/treatment completed as the dependent variable, and ‘other’, which included failure, death, default and transferred out, as the reference category. Patients in the intervention group had a four times higher possibility of having a favourable outcome than those in the control group (OR 3.9, 95%CI 1.0–15.3; Table 3).

* The appendix is available in the online version of this article, at <http://www.ingentaconnect.com/content/iuatld/ijtd/2017/00000021/00000008/art00019>.

Table 3 Effect of the intervention on adherence and treatment outcome

	Intervention group n (%)	Control group n (%)	OR (95%CI)	<i>P</i> value*
Overall adherence (intensive + continuation phases)				
Regular	41 (39)	31 (18)	2.98 (1.5–6.0)	0.01
Irregular/default	63 (61)	142 (82)	1.0 (Reference)	
Treatment outcome				
Favourable outcomes (cured/treatment completed)	98 (87)	115 (62)	3.9 (1.0–15.3)	0.04
Other (failure, default, death)	15 (13)	70 (38)	1.0 (Reference)	

* Adjusted for clustering.
OR = odds ratio; CI = confidence interval.

Correlation between number of interventions, treatment adherence and treatment outcome

Overall retention for follow-up was high. Of the 113 patients in the intervention group, 86 (76%) completed all four intervention sessions, 12 (11%) attended three sessions and 14 (13%) attended 1–2 sessions. Adherence regularity was 10% in those who attended 1–2 intervention sessions, but 46% in those who attended all four sessions. Although there was an increase in treatment adherence with the number of interventions attended, this was not statistically significant.

Among those who attended 1–2 intervention sessions, 36% had a favourable treatment outcome, compared to 46% of those who attended all four sessions. An association between the number of interventions attended and outcome was observed; however, this was not statistically significant (Table 4).

AUDIT scores at baseline and at month 6 (intervention vs. control group)

The proportion of subjects in the low-risk (score of <8) category increased from 9% to 89% in the intervention group and from 12% to 40% in the control group (*P* = 0.01; Appendix Figure A.2).

Comparison of treatment outcome with AUDIT level

Non-overlapping 95%CIs (indicated by the black vertical lines in Appendix Figure A.3) show that subjects in the intervention group had a significantly higher rate of favourable outcomes than those in the control group at all levels of the AUDIT score, except in the low-risk category. A similar observation was made for the default rate, which was significantly lower in the intervention group (5%) than in the control group (32%) at all levels of the AUDIT score, except at the low-risk level.

DISCUSSION

This is the first study in India to examine the feasibility of alcohol intervention programmes among TB patients with AUDs. Study findings highlight the increase in favourable outcomes (i.e., cured/completed treatment) in TB patients who

Table 4 Association of the number of interventions with treatment adherence and treatment outcome*

	Number of interventions completed		
	1–2 (n = 14, 13%)	3 (n = 12, 11%)	4 (n = 82, 76%)
Treatment outcomes			
Cured/treatment completed	5 (36)	2 (16)	38 (46)
Failure/default/death/ transferred out	9 (64)	10 (84)	44 (54)
Overall adherence			
Regular	1 (10)	2 (17)	38 (46)
Irregular	4 (40)	10 (83)	43 (53)
Default	5 (50)	—	1 (1)

* *P* value adjusted for clustering.

received the intervention. The impact of the intervention was also reflected in the better treatment adherence and reduction in alcohol use, although the difference was not statistically significant.²³ Other studies have also reported better TB treatment outcomes and a greater change in the number of heavy drinking days or severity of addiction among patients who received the intervention.^{26–29} However, some studies have reported no significant impact on TB treatment or alcohol outcomes due to alcohol interventions.^{30,31}

The positive trends in our intervention outcome could be attributed to its design, which was developed using a community participatory approach, where input from TB patients, their families as well as health providers was taken into account for the development and finalisation of the intervention. An intervention manual was used as a guide, as were simple but descriptive flip-charts on relevant topics, with graphic representations where possible. Furthermore, our interventionists underwent intensive training before administering counselling sessions. The intervention was carried out among alcohol-dependent TB patients at four time points between treatment initiation and treatment completion. Our study suggests that the use of four individualised counselling sessions was feasible and could make a difference in treatment outcomes and adherence among participants. Although group sessions were considered, we found that this was not feasible because TB patients received anti-tuberculosis treatment at different locations and getting them to one place at the same time was a challenge. We therefore strongly advocate individual counselling as a more feasible intervention likely to provide positive results.

It is also important to highlight the importance of adherence to alcohol-intervention sessions for improved treatment outcomes. Although this has been reported in studies focusing on interventions for smoking cessation,^{32,33} information on the relationship between adherence and impact in the case of alcohol interventions is scanty. While we observed a

positive trend in the impact of the interventions on TB treatment outcomes, it is reassuring to note that the intervention also led to a significant reduction in alcohol consumption, especially during the intensive phase of treatment, possibly due to persisting symptoms. However, a tendency for patients to relapse into their former drinking habits was observed at the end of treatment, after symptoms had abated. Our findings were encouraging in that a significant reduction in AUDIT scores in the intervention group was observed even at the end of treatment. Other recent studies have also reported a reduction in AUDIT scores over time and, in some cases, even to the complete cessation of alcohol intake as a result of alcohol interventions among TB patients.^{26,30,34}

Our study findings highlight the possible effectiveness of alcohol interventions among TB patients. This strategy has been corroborated by other studies highlighting psychosocial counselling within a patient-oriented programme to support patients with TB or multidrug-resistant TB who over-consume alcohol.^{30,35}

Limitations

The study had some limitations. As our cluster randomised trial had only four clusters, the power to indicate any difference between the two arms is likely to have been very limited. As alcohol consumption was self-reported, findings may have been subject to respondent bias, leading to under- or over-reporting.

CONCLUSIONS

Screening for alcohol use in TB clinics is an important step in the timely initiation of a structured alcohol intervention programme. This type of intervention strategy also promotes treatment adherence and results in better treatment outcomes. Our study findings suggest that cluster randomised studies with larger sample sizes and power to test the effectiveness of alcohol interventions in programme settings are required.

Acknowledgements

The authors thank the District Tuberculosis Officials in Chennai for their assistance and cooperation and the State Tuberculosis Officer, Tamil Nadu, India, for permission to conduct the study at the RNTCP centres; Chennai Corporation, Chennai, for their support; P N Hariharan and P Balaji for contributing in the intervention part of the study; M Muniyandi for his help in editing the manuscript; the participants who took part in this study; and UNAIDS, a World Health Organization-funded Model DOTS project, for supporting this study financially.

Conflicts of interest: none declared.

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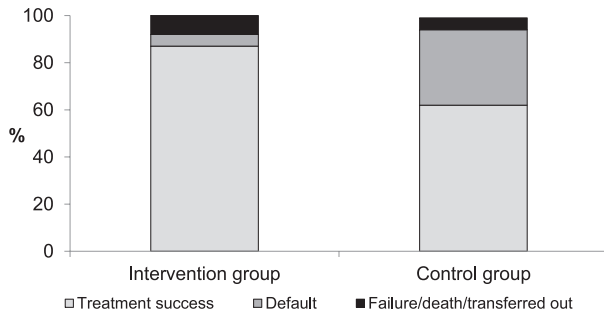


Figure A.1 Comparison of treatment outcomes between the intervention and control groups.

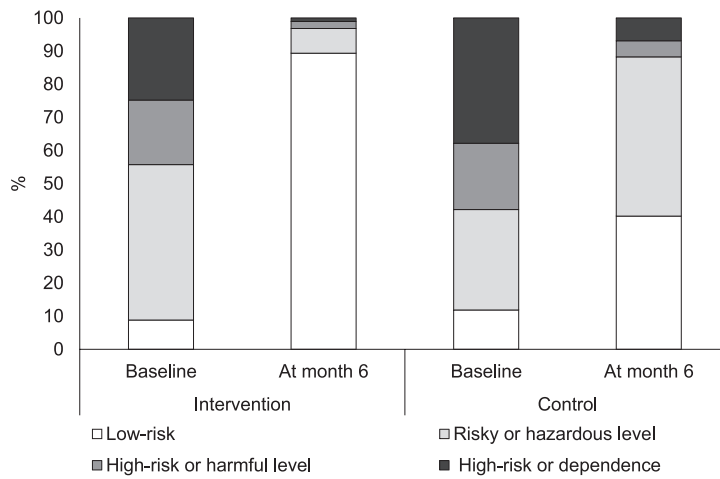


Figure A.2 Changes in AUDIT levels between the intervention and control arms from baseline to month 6. AUDIT = Alcohol Use Disorder Identification Test.

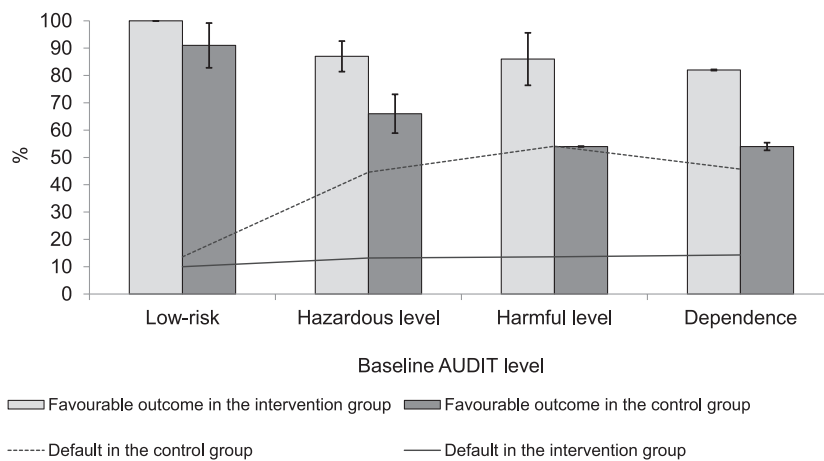


Figure A.3 Comparison of treatment adherence and treatment outcome with AUDIT level. AUDIT = Alcohol Use Disorder Identification Test.

RESUME

CONTEXTE : La dépendance à l'alcool a été une raison majeure de non adhérence à la prise en charge de la tuberculose (TB). Il y a un besoin urgent d'élaborer une intervention faisable et acceptable vis-à-vis de l'alcool afin d'assurer l'achèvement du traitement.

MÉTHODE : Quatre zones sur 10 de la Chennai Corporation ont été sélectionnées de manière aléatoire à Chennai, en Inde du Sud—deux dans le bras expérimental et deux dans le bras témoin. Les patients TB enregistrés entre août 2013 et janvier 2014, sous le Revised National Tuberculosis Control Programme, ont été évalués avec l'échelle AUDIT (Alcohol Use Disorder Identification Test). L'intervention a consisté en quatre sessions de conseil individuel (0, 2, 4 et 6e mois) conduites par des personnes formées à cet effet. Un manuel d'intervention utilisant une approche participative communautaire a été élaboré et utilisé pour guider les sessions.

RÉSULTATS : Sur 872 patients TB, 298 (31%) se sont avérés avoir un problème de consommation d'alcool. Le

nombre de patients TB dans les bras expérimental et témoin a été respectivement de 113 (38%) et de 185 (62%). Le pourcentage de résultats de traitement favorables a été plus élevé dans le groupe d'intervention comparé au groupe témoin (87% contre 62% ; $P=0,04$). L'adhérence d'ensemble au traitement de la TB a été significativement plus élevée ($P=0,02$) dans le groupe d'intervention.

CONCLUSION : Cette étude pilote apporte la preuve qu'une intervention relative à l'alcool pourrait contribuer à assurer un résultat favorable du traitement, notamment grâce à une meilleure adhérence. Les résultats de cette étude pilote appellent un vaste essai randomisé en grappes afin de les généraliser et de faire des recommandations plus solides en faveur de stratégies d'intervention testées vis-à-vis de l'alcool ; ceci permettra de promouvoir l'observance du traitement des patients TB dont la consommation d'alcool pourrait entraver l'adhérence au traitement.

RESUMEN

MARCO DE REFERENCIA: La dependencia del alcohol se ha descrito como una de las principales razones de incumplimiento del tratamiento antituberculoso. Existe la necesidad urgente de elaborar una intervención viable y aceptable que aborde el consumo de alcohol y que fomente la finalización del tratamiento de la tuberculosis (TB).

MÉTODO: De las 10 zonas de la Corporación de Chennai en el sur de la India, se escogieron de manera aleatoria cuatro (dos asignadas al grupo experimental y dos al grupo testigo). Los pacientes registrados en el Programa Nacional Revisado contra la Tuberculosis de agosto del 2013 a enero del 2014 se evaluaron mediante la escala AUDIT (Alcohol Use Disorder Identification Test). La intervención consistió en cuatro sesiones individuales de orientación (al comienzo, al 2°, 4° y 6° mes) realizadas por personal capacitado. Mediante un enfoque comunitario participativo se elaboró un manual que sirvió de guía durante las sesiones.

RESULTADOS: De los 872 pacientes registrados con tuberculosis (TB), 298 presentaban trastornos por

consumo de alcohol (31%). El grupo experimental consistió en 113 pacientes (38%) y el grupo testigo en 185 (62%). El porcentaje de desenlaces terapéuticos favorables fue más alto en el grupo que participó en la intervención que en el grupo testigo (87% contra 62%; $P=0,04$). La observancia global del tratamiento antituberculoso fue significativamente superior en el grupo experimental ($P=0,02$).

CONCLUSIÓN: El presente estudio preliminar pone en evidencia que una intervención que aborde el consumo de alcohol puede ser eficaz para fomentar los desenlaces favorables del tratamiento de la TB y lograr un grado adecuado de observancia terapéutica. Sus resultados justifican la realización de un extenso ensayo clínico aleatorizado por conglomerados que evalúe la posibilidad de generalizar esta intervención y fundamentan una recomendación firme para que se practiquen estrategias validadas que fomenten observancia del tratamiento en los pacientes con diagnóstico de TB, cuyo consumo de alcohol puede obstaculizar el cumplimiento terapéutico.