



Adaptation and Validation of the Instrument Treatment Outcomes Profile to the Chilean Population



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ABSTRACT

This study aims to psychometrically validate the Chilean version of the treatment outcomes profile (TOP), an instrument that can be used by treatment centers to monitor the results of drug and alcohol treatments. Specifically, this study is interested in evaluating the inter-rater reliability, concurrent validity, change sensitivity and discriminant and construct validity of this instrument. The TOP was modified to reflect the Chilean context and then applied in three successive stages: an initial application at the beginning of treatment, a retest after 1 week, and a follow up after a month. The sample was composed of 411 users of different types of drugs who were in treatment centers in the three largest regions of the country. The TOP reliability was greater than .75 for most items. Regarding concurrent validity, all the coefficients were in the expected direction and statistically significant. Change over time, as measured by Cohen's *d* statistic and the Reliable Change Index, was significant for most items. Users in treatment for less than 3 months showed higher alcohol consumption (odds ratio [OR] = 1.07; 95% confidence interval [95% CI]: 1.01–1.13), poorer psychological health (OR = 0.94; 95% CI: 0.87–1.00), fewer days worked (0.56; 0.95–0.99) and poorer housing conditions (OR = 2.76; 95% CI: 1.22–6.23) than did their counterparts who had more than 3 months of treatment. Researchers extracted six components with eigenvalues greater than one, accounting for 69.0% of the total variance. In general, the Chilean TOP is a reliable and valid mechanism to monitor outcomes of people treated for problems with drug and alcohol abuse in Chile, but further validation work is required in some dimensions.

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1. Introduction

Outcome monitoring systems represent an important tool for the treatment of problems related to alcohol and drug consumption. These systems relay important information about a patient's progress and allow treatment centers to provide more effective and efficient interventions, guiding and changing the patient's therapy as it progresses (Ling, Farabee, Liepa, & Wu, 2012; Torres Hernández & Fernández Gómez, 2004). In the United States, for example, the Institute of Medicine has explicitly recommended the development and implementation of patient monitoring systems in treatments for substance abuse (Institute of Medicine, 2006), and there has been an overall trend towards the systematic collection of information from all publicly funded treatment providers (Substance Abuse & Mental Health Services Administration's (SAMHSA), 2014). Other countries, such as Australia and England, are actively seeking to create outcome monitoring systems that will offer

guidance to clinics about how their programs are being implemented and whether they are successful (Marsden et al., 2008; Ryan et al., 2014). In 2009, the Chilean National Service for Prevention and Rehabilitation of Drug and Alcohol (SENDA) launched the Treatment and Information Management System (SISTRAT) to monitor the demand for, and delivery of, treatment for substance use disorders both within the National Health Service and among the non-governmental sector. Approximately 270 service providers (approximately 90% of the treatment centers of the country) report to this system, and more than 10,000 service user episodes were recorded in 2012 (SENDA-MINSAL, 2013).

In 2011, SENDA began to incorporate a minimum set of outcome measures into the SISTRAT. After assessing the suitability of a variety of outcome instruments, SENDA contacted the authors of the treatment outcomes profile (TOP) to explore the possibility of adapting this instrument for the Chilean experience. The TOP was chosen for its brevity and usefulness in supporting clinical practice.

The TOP was developed in 2006 and implemented nationally in 2007 by the English National Treatment Agency for Substance Misuse (NTA). The TOP is a single page instrument of 20 items, used by clinicians in

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Table 1
Summary of changes made to TOP.

Section	Description of change
Section 1: Substance use	Items referring to substances rarely used in Chile were removed from the instrument (e.g. 'opiates, crack and amphetamines'); and others were added ('cocaine paste' and 'sedatives') given their high patterns of use within Chilean treatment populations. The low level of reliability found in all measurements concerning the use of sedatives and tranquilizers, suggests that consistently reporting the use of these substances is complicated for users. When this result was presented to the experts, they advised to keep this item in the TOP so as not to lose any relevant information, but to consider the result in light of the influence of the small proportion of people reporting consumption.
Section 2: Injecting risk behavior	This section was removed because injectable drugs are rarely used in Chile.
Section 3: Crime	The items of the TOP referring to criminal activity were adjusted to reflect the Chilean context. Shoplifting and drug selling were kept; theft from or of a vehicle, other property theft or burglary, fraud, forgery and handling stolen goods and committing assault or violence were removed; and theft, fights, number of domestic violence incidents during the last 28 days were included. With the exception of the last item (number of domestic violence incidents during the last 28 days), the other items were simplified to report any participation (yes/no) within the past 4 weeks.
Section 4: Health and social functioning	The items 'acute housing problem' and 'at risk of eviction' were removed and changed for the items 'No stable place to live' and 'Poor housing conditions'.

diverse drug and alcohol treatment settings, that captures key data about recent (in the past month) substance use, injecting behaviors, measures of social functioning (education, employment and housing), criminal activity, and overall quality of life and physical and psychological health. The TOP is designed to help review clients' progress towards attaining personal treatment goals and has demonstrated efficiency as a monitoring mechanism and performance measurement (Marsden et al., 2009; Marsden et al., 2011). The instrument's psychometric properties were examined in an English drug treatment population and shown to be valid, reliable and sensitive to change (Marsden et al., 2008). The TOP has also been adapted and validated for local use in Australia (Ryan et al., 2014).

This article describes the adaptation of the TOP for the Chilean context and the psychometric evaluation of the tool in a sample of people in treatment for substance use disorders. Specifically, the study's goal was to determine the inter-rater reliability, concurrent validity and change sensitivity, as well as the instrument's discriminant and construct validity.

2. Methods

The validation of the TOP in Chile focused largely on the validation made by the authors of the original instrument (Marsden et al., 2008). The methodology used for this project can be categorized into two parts: (i) adaptation of the instrument to the Chilean context and (ii) a psychometric validation.

2.1. Adaptation of the instrument to the Chilean context

To validate the TOP for use in Chile, researchers began by translating the instrument and making small adjustments to reflect the typical drugs and behaviors of individuals accessing treatment for drug and alcohol abuse in Chile. This process of adaptation was evaluated by a committee of experts in the treatment of drug and alcohol abuse in Chile which included three psychiatrists, two clinical psychologists and one public health policy researcher with years of experience with the Chilean treatment system and with drugs user in the country. After a first expert revision, the instrument was pre-tested with a small sample of 10 people who were being treated for substance use disorder. During this stage of the study the original authors of the instrument visited Chile to train and advise the team from SENDA working on the TOP. The work with the authors encompassed the revision of the Spanish version of the TOP, including the translation process and the concepts and words used, as well as the design and the methodological protocol for the validation study.

As can be seen in detail in Table 1, the major modifications made to the original instrument included changing some of the substances evaluated, removing the section on injectable drugs and adjusting the section on crime. The reason for these changes was to adapt the instrument to the Chilean reality as much as possible. For example injectable drugs are rarely used in Chile, and the types of crimes included in the

original version are not really applicable to the people in treatment and drug users in the Chilean context. All these changes were discussed with the group of experts that acted as advisors for the research.

2.2. Procedures and psychometric evaluation

The study applied the TOP in three stages: an initial test, a re-test after 7 days and a follow-up assessment after 30 days.

In total, 411 subjects participated in the test stage. During this phase, researchers also administered a short socio-demographic questionnaire, a urinalysis test for drugs, and four other questionnaires: (1) the Patient Health Questionnaire (PHQ15), (2) the General Health Questionnaire (GHQ12), (3) the WHO Quality of Life (WHOQOL-BREF 26) and (4) the Social Functioning Questionnaire (SFQ). The drug urinalysis was performed on 25% of the participants chosen randomly. The questionnaires and urinalysis were administered by trained clinicians working in the treatment centers and asked questions regarding patients' experiences during the 4 weeks prior to the date of the administration of the TOP.

In total, 325 (79.1%) subjects completed the re-test. In this phase, the TOP was re-administered by a different clinician from the same treatment center. The reference period for the questions was the same 4 weeks prior to the first evaluation that had been examined during the test phase.

In total, 289 (70.3%) subjects participated in the follow-up stage. During this stage, the TOP was again administered to the same participants, this time by a member of the research team. To contrast immediate and longer-term in-treatment change, two groups were recruited on a 2: 1 basis: the first, in current treatment for less than 3 months; the second, in treatment for more than 3 months. There is well-established literature (Brorson, Ajo Arnevik, Rand-Hendriksen, & Duckert, 2013; Lopez-Goni et al., 2010) that confirms that after 3 months in treatment it is possible to start distinguishing changes in the therapeutic process and there are greater chances of successfulness of treatment completion. For the group in treatment for less than 3 months, the initial TOP application was at the beginning of treatment. For the group in treatment for more than 3 months, however, we asked them to describe the 28 days before they had entered the treatment when answering the first (test) and second (retest) TOP application.

Cases were lost because: (a) the subjects refused to continue participating in the study, (b) the subjects resided outside the geographic area demarcated for the study, (c) the subjects had a physical or personal problem that did not allow them to appropriately answer the questionnaire and (d) the subjects were busy or not found at their home after three attempts.

2.3. Subjects

The sample consisted of 411 patients from 46 treatment centers (which included public and private residential and ambulatory centers), in the three largest regions of Chile (Valparaíso, Biobío and Metropolitana) (Table 2).

Table 2
Treatment centers organized by region, programs and achieved sample.

Region	Program	Test		Re-test		Follow-up	
		<3 months	>3 months	<3 months	>3 months	<3 months	>3 months
Metropolitana	Ambulatory	112	79	88	60	72	57
	Residential	65	36	50	32	48	27
Valparaíso	Ambulatory	31	13	27	10	13	5
	Residential	6	3	3	3	6	2
Biobío	Ambulatory	12	44	12	41	12	41
	Residential	6	4	4	2	4	2
Total		232	179	184	148	155	134

The residential treatment centers mostly work with a therapeutic community model and with a bio-psychosocial approach. They vary in size, but on average they attend between 15 and 20 people a month, and the estimated time of the treatment is 12 months. The ambulatory treatment centers, which represent 80% of the centers in the country, also use a bio-psychosocial approach and a model of community care. They work with between 15 and 25 patients per month and with treatments that last for an average of 8 months. Both types of centers offer individual, group and family therapy, which are conducted by multidisciplinary teams and accredited technicians.

Patients were chosen based on random selection; each center prepared a list of all patients who met the inclusion criteria, who were then assigned a random serial number. The inclusion criteria were: (1) patients were between 17 and 64 years old, (2) they were receiving structured treatment for alcohol or substance use disorders at the moment of the test, (3) they were not suffering from acute intoxication at the moment of the test, and (4) they did not have a severe mental problem or acute psychosis. All participants read and signed an informed consent form.

2.4. Instruments

2.4.1. The Chilean Treatment Outcomes Profile (Chilean TOP)

The Chilean TOP is divided into three sections. The first section is about substance use and has six questions on the use of alcohol, marijuana, cocaine paste, cocaine, sedatives and tranquilizers and other problem substances in the past 4 weeks. The second section is about offending behavior and consists of six questions that target the most typical forms of transgression of social norms: shoplifting, theft, drug selling, fights and domestic violence. The third section is about health and social functioning and has seven items related to physical and psychological health, quality of life, work, education and housing. See Appendix A for further detail about the Chilean TOP (in Spanish),

2.4.2. Patient Health Questionnaire 15 (PHQ15)

The PHQ15 consists of 15 questions that assess somatic symptoms and are organized using a Likert scale with three responses options, each of which corresponds to a different point value. The score of the scale ranges between 0 and 30 points, where higher scores reflect the presence of more physical ailments (Kroenke, Spitzer, & Williams, 2002). For the sample used in this study, the Cronbach's alpha was 0.89.

2.4.3. General Health Questionnaire (GHQ12)

The GHQ12 is a self-administered instrument to assess mental health. It evaluates depression, anxiety, social inadequacy and hypochondria. It has 12 items with responses from zero to three points, where higher scores indicate a higher level of mental health, and a total score ranging from 0 to 36 points. This instrument was psychometrically validated in Chile by Garmendia (2007). For the sample used in this study, the Cronbach's alpha was 0.99.

2.4.4. WHO Quality of Life BREF (WHOQOL-BREF 26)

This is a 26 item instrument that measures quality of life and overall satisfaction in four areas: physical health, psychological health, social relationships, and environment. The answers use a Likert scale format

with five response options that range between zero and one. Higher total scores indicate better quality of life. This instrument was psychometrically validated in Chile by Espinoza, Osorio, Torrejon, Lucas-Carrasco, and Bunout (2011). For the sample used in this study, the Cronbach's alpha ranged between 0.56 and 0.81 in the four areas.

2.4.5. Social Functioning Questionnaire (SFQ)

The SFQ is self-administered and assesses respondents' work and home lives, financial concerns, family relationships, sexual activity, social contacts and leisure and recreational time. It consists of eight items with response alternatives ranging from zero to three. The SFQ total score ranges between 0 and 24 points where higher scores indicate a lower level of social functioning (Tyner et al., 2005). For this sample the Cronbach's alpha was 0.98.

2.4.6. Toxicology tests

Twenty-five percent of the sample was selected randomly and received the substance screening instrument Screeners® AutoSplit™. This instrument measures the presence of cocaine and marijuana through a urine sample. This test was implemented during the TOP's first administration (test phase).

2.5. Statistical analyses

2.5.1. Test-Retest reliability

For continuous variables, researchers estimated intraclass correlation coefficients (ICC) in order to check the reliability of the TOP between the test and retest. ICC values ≥ 0.75 showed excellent agreement (Shrout & Fleiss, 1979). For categorical variables, the kappa statistic was calculated and values ≥ 0.61 also showed excellent agreement (Landis & Koch, 1977).

2.5.2. Concurrent validity

The correlations between the TOP and the additional instruments were assessed using Pearson's correlation coefficient (r). The self-reporting questionnaires and the urinalysis test were contrasted using kappa, together with sensitivity, specificity and positive and negative agreement (Cicchetti & Feinstein, 1990).

2.5.3. Change sensitivity

Change sensitivity was observed on patients in treatment for less than 3 months that presented information in both the test and the follow-ups and presented consumption of substance in the test. The assumption before this analysis was that patients at the beginning of the treatment were more likely to change their substance use pattern. Change sensitivity between the TOP administered at the beginning of the treatment and the follow-up evaluation after 28 days was measured with Cohen's d statistic. A value of d equal to 0.2 was considered a small effect size, a value of 0.5 as middle effect size, and a value of 0.8 as large effect size (Howell, 2012). The Reliable Change Index (RCI) (Jacobson & Truax, 1991) and the smallest detectable difference (SDD) (Mitchell, 1979) were also calculated. If the RCI ratio is greater than 1.96, change is considered reliable (α = 0.05); when an SDD exceeds the mean difference in scores, the measure may not be sufficiently sensitive.

Table 3
Sample characterization ($n = 411$).*

	Less than 3 months	More than 3 months	Total	Statistic	p value
Demographics					
Women: n (%)	69 (26.1)	49 (33.3)	118 (28.7)	$\chi^2(1) = 2.38$	0.12
Men: n (%)	195 (73.9)	98 (66.7)	293 (71.3)		
Age: Mean (SD) ^a	34.50 (9.44)	37.68 (9.59)	35.64 (9.61)	$t^c = -1.81$	0.03
Relationship status					
Married: n (%)	53 (20.6)	26 (18.1)	79 (19.7)	$\chi^2(5) = 3.11$	0.87
Live-in partner: n (%)	38 (14.8)	27 (18.8)	65 (16.2)		
Widowed: n (%)	2 (0.8)	1 (0.7)	3 (0.7)		
Divorced: n (%)	7 (2.7)	6 (4.2)	13 (3.2)		
Separated: n (%)	26 (10.1)	10 (6.9)	36 (9)		
Single without a partner: n (%)	89 (34.6)	52 (36.1)	141 (35.2)		
Single with a partner: n (%)	42 (16.3)	22 (15.3)	64 (16)		
Education					
Elementary school uncompleted: n (%)	30 (11.7)	17 (11.8)	47 (11.7)	$\chi^2(8) = 9.44$	0.49
Elementary school completed: n (%)	34 (13.2)	14 (9.7)	48 (12)		
High school uncompleted: n (%)	56 (21.8)	30 (20.8)	86 (21.4)		
High school completed: n (%)	68 (26.5)	40 (27.8)	108 (26.9)		
Technical school uncompleted: n (%)	22 (8.6)	10 (6.9)	32 (8)		
Technical school completed: n (%)	23 (8.9)	15 (10.4)	38 (9.5)		
University uncompleted: n (%)	10 (3.9)	13 (9)	23 (5.7)		
University completed: n (%)	13 (5.1)	4 (2.8)	17 (4.2)		
Housing status					
Renter: n (%)	23 (9.1)	19 (13.3)	42 (10.6)	$\chi^2(6) = 5.17$	0.73
Makes mortgage payments: n (%)	13 (5.1)	7 (4.9)	20 (5)		
Owner: n (%)	54 (21.3)	28 (19.6)	82 (20.7)		
Living with friends or family: n (%)	134 (52.8)	74 (51.7)	208 (52.4)		
Living in housing owned by another: n (%)	16 (6.3)	7 (4.9)	23 (5.8)		
Other: n (%)	9 (3.5)	4 (2.8)	13 (3.3)		
Employment status					
Working full time: n (%)	74 (28.9)	49 (33.8)	123 (30.7)	$\chi^2(8) = 18.55$	0.029
Working part time: n (%)	17 (6.6)	21 (14.5)	38 (9.5)		
Working sporadically: n (%)	29 (11.3)	10 (6.9)	39 (9.7)		
Unemployed and looking for a job: n (%)	24 (9.4)	16 (11)	40 (10)		
Student: n (%)	3 (1.2)	4 (2.8)	7 (1.7)		
Unemployed and not looking for a job: n (%)	86 (33.6)	35 (24.1)	121 (30.2)		
Housewife: n (%)	19 (7.4)	6 (4.1)	25 (6.2)		
Retired: n (%)	1 (0.4)	3 (2.1)	4 (1)		
Substance use (used in past 4 weeks)					
Alcohol: n (%)	107 (41)	44 (29.9)	151 (37.0)	$\chi^2(1) = 6.63$	0.036
Days used: Mean (SD)	2.12 (4.40)	1.42 (3.64)	1.87 (4.15)	$t = 1.63$	0.05
Marijuana: n (%)	45 (17)	15 (10.2)	60 (14.6)	$\chi^2(1) = 3.54$	0.06
Days used: Mean (SD)	1.11 (4.26)	0.72 (3.76)	0.97 (4.09)	$t = 0.92$	0.17
Cocaine paste: n (%)	65 (24.6)	13 (8.9)	78 (19)	$\chi^2(2) = 16.84$	0.000
Days used: Mean (SD)	1.78 (5.39)	0.32 (1.54)	1.25 (4.46)	$t = 3.21$	0.0007
Cocaine: n (%)	24 (9.1)	12 (8.2)	36 (8.8)	$\chi^2(1) = 0.10$	0.75
Days used: Mean (SD)	0.49 (2.52)	0.24 (1.12)	0.40 (2.13)	$t = 1.16$	0.12
Sedatives: n (%)	8 (3)	8 (5.4)	16 (3.9)	$\chi^2(1) = 1.46$	0.22
Days used: Mean (SD)	0.35 (2.73)	0.59 (3.65)	0.44 (3.09)	$t = -0.73$	0.23

^a Standard deviation.

^b Chi-square test for independence.

^c t -statistic difference of means.

* Missing values and "do not know/no answer" responds are not reported.

2.5.4. Discriminant and construct validity

Discriminant validity was performed using multiple logistic regression analysis. The dependent variable was whether the user belonged to the group that had received less than 3 months of treatment or to the group with more than 3 months of treatment. We used the criteria of less than/more than 3 months of treatment to identify two groups with different levels of progress in the treatment. The 3 month cut-off has been thoroughly analyzed in clinical and epidemiological literature and is considered a good predictor of therapeutic success (Girón García, 2007; Hawkins, Baer, & Kivlahan, 2008; Simpson, 1981; Simpson, Joe, & Rowan-Szal, 1997). The detailed items from the three sections of the TOP—substance use, offending behavior, and health and social functioning—were used as the independent variables. Construct validity was explored via a factor analysis using a polychoric correlation matrix for the total scores for all substance use, transgression of social norms and social functioning variables. The analysis used the principal components factor method to analyze the correlation matrix and the varimax rotation method to rotate the loadings.

All analyses were done using Stata 13.1 (StataCorp. College Station, TX).

3. Results

3.1. Description of the study group

The sample was mainly composed of men (71.3%), predominantly single without a partner (35.2%) and with a high school diploma (27%). The most frequently used substances were alcohol (37%), cocaine paste (19%), marijuana (14.6%), and cocaine (8.8%); no other drugs were reported in more than 5% of the sample. Sixty-three percent of the subjects started their treatment within the last 3 months, and 37% began treatment more than 3 months ago. The group that had been in treatment for less than 3 months presented a higher level of consumption, and included more people that used multiple substances and that reported having a greater average number of days of consumption. Additional demographic data are available in Table 3.

Table 4
Inter-rater reliability (n = 332).

Measure (past 4 weeks)	Test	Retest	Kappa	Mean difference	ICC ^b (95% CI) ^c ***
Substance use					
Alcohol: n (%)	151 (37.1)	109 (33.23)	0.79		
Days used: mean ± SD ^a	5.04 ± 5.53	4.41 ± 5.02		0.61 (t = 0.91)*	0.54 (0.46, 0.61)
Units on typical day: mean ± SD	8.39 ± 11.22	7.81 ± 9.33		0.26	0.67 (0.38, 0.97)
Marijuana: n (%)	59 (14.39)	43 (13.03)	0.79		
Days used: mean ± SD	6.74 ± 8.84	6.81 ± 8.83		−0.06	0.93 (0.84, 1.03)
Units on typical day: mean ± SD	2.59 ± 3.89	2.25 ± 2.22		0.34	0.98 (0.94, 1.01)
Cocaine paste: n (%)	73 (18.2)	56 (17.18)	0.79		
Days used: mean ± SD	6.95 ± 8.44	5.80 ± 7.16		1.15 (t = 0.82)*	0.90 (0.75, 1.04)
Units on typical day: mean ± SD	19.32 ± 23.35	15.39 ± 22.60		3.92 (t = 0.95)*	0.98 (0.94, 1.00)
Cocaine: n (%)	35 (8.54)	25 (7.58)	0.64		
Days used: mean ± SD	4.71 ± 5.79	4.25 ± 4.76		0.46	0.80 (0.52, 1.08)
Units on typical day: mean ± SD	8.97 ± 15.20	6.50 ± 9.15		2.47	0.95 (0.88, 1.02)
Sedatives and tranquilizers: n (%)	16 (3.90)	12 (3.63)	0.32		
Days used: mean ± SD	11.18 ± 11.51	9.08 ± 11.57		2.10 (t = 0.47)*	0.01 (0.00, 0.29)
Units on typical day: mean ± SD	5.15 ± 13.52	6.30 ± 12.09		−1.14	0.00 (0.00, 0.34)
Behavior that transgresses social norms					
Shoplifting: n (%)	36 (8.76)	20 (6.04)	0.77		
Theft: n (%)	4 (0.97)	2 (0.60)	**		
Drug selling: n (%)	4 (0.97)	5 (1.52)	**		
Fights: n (%)	36 (8.76)	25 (7.55)	0.65		
Number of days with fights in past 4 weeks: mean ± SD	1.63 ± 1.94	1.50 ± 1.10		0.13	0.36 (0.00, 0.91)
Incidents of domestic violence: n (%)	49 (11.92)	26 (7.85)	0.55		
Number of days with domestic violence in past 4 weeks: mean ± SD	2.87 ± 5.50	3.66 ± 6.66		−0.78	0.90 (0.71, 1.09)
Health and social functioning					
Physical health: mean ± SD	13.47 ± 4.56	13.61 ± 4.54		−0.13	0.38 (0.15, 0.59)
Psychological health: mean ± SD	12.23 ± 4.62	13.19 ± 4.68		−0.64 (t = −1.53)*	0.41 (0.17, 0.63)
Quality of life: mean ± SD	14.07 ± 4.72	14.48 ± 4.47		−0.40 (t = −1.17)*	0.45 (0.20, 0.69)
Days of paid work: mean ± SD	16.60 ± 8.48	16.80 ± 8.28		−0.19	0.81 (0.62, 0.98)
Days of college/school: mean ± SD	9.20 ± 8.22	10.93 ± 8.97		−1.73	0.97 (0.94, 1.01)
No stable place to live: n (%)	36 (8.76)	26 (7.85)	0.62		
Poor housing conditions: n (%)	54 (13.13)	46 (13.94)	0.36		

^a Standard deviation.

^b Interclass correlation coefficient.

^c Confidence interval.

* p < 0.05.

** Due to the low number of cases and the data distribution, it was not possible to calculate statistics.

*** The ICC is calculated with all the cases that have valid data for each variable and corresponds approximately to the total n of the group.

3.2. Inter-rater reliability

As shown in Table 4, the following measures presented low inter-rater reliability: sedatives and tranquilizers (kappa = .32, ICC = .01), physical health (ICC = .38), psychological health (ICC = .41), and quality of life (ICC = .45). The rest of the measures exhibited good inter-rater reliability. The use of substance measurements with higher coefficients were alcohol (kappa = .79), cannabis (kappa = .79), cocaine paste (kappa = .79) and cocaine (kappa = .64) use.

3.3. Concurrent validity

The correlation between the TOP section on psychological health and the GHQ12 total score was r = −.57 (p < 0.001); between the section on physical health and the PHQ15 total score, the correlation was r = −.46 (p < .001), between the section on quality of life and WHOBREF total score, the correlation was r = 0.60 (p < .001). All coefficients obtained were in the expected direction and statistically significant. The correlation matrix between aspects of the TOP and the other validation measures can be found in Supplementary data 1.

The results of the urine test were compared with participants' self-reports of consumption during the week prior to the TOP application (Table 5). The results showed acceptable concordance, sensitivity and specificity.

3.4. Change sensitivity

The values presented in Table 6 correspond to the change sensitivity analysis for the group with less than 3 months in treatment. The table also shows that the differences between the scores of the first

measurement with the follow-up were low to moderate. The TOP was able to identify some reliable changes in patient behavior, including, for example, with the variables of domestic violence (with an RCI of 16.7%) and psychological health (with an RCI of 16.2%), which showed the highest percentages of change. The TOP was not able to detect changes when examining the variables that measured average consumption in a typical day of cocaine paste or marijuana. It could be that reliable improvement was not detected because those who improved have actually stopped consuming the relevant drug altogether. Indeed, when observing the data it is possible to see that both the number of people who were using cocaine paste decreases from 70 to 12 and those who were using marijuana drops from 55 to 13.

3.5. Discriminant and construct validity

Multiple logistic regressions contrasted TOP test scores among service users in treatment for less than or more than 3 months. After adjustment for gender and age, being in treatment for less than 3 months was associated with alcohol consumption (odds ratio [OR] = 1.07; 95% confidence interval [95% CI]: 1.01–1.13), poorer psychological health (OR = 0.94; 95% CI: 0.87–1.00), fewer days worked (OR = 0.56; 95% CI: 0.95–0.99) and poor housing conditions (OR = 2.76; 95% CI: 1.22–6.23).

Factor analysis considered the total scores for all items, except for sedatives and tranquilizers. The inclusion of these variables results in six factors with eigenvalue greater than one, accounting for 69.0% of the total variance. The factors obtained were: shoplifting, theft, fights, drug selling and domestic violence (20.0% of the variance); physical health, psychological health and quality of life (12.2%); stable place to live and poor housing conditions (10.0%); days of alcohol use, days cocaine use and days of paid work (9.5%); days of cocaine paste and other substances

Table 5
Validity of self-reported (SR) drug use and urine test (UT).*

Measure (week before test)	Specificity	SR-	UT-	Sensitivity	SR+	UT+	kappa
Cocaine (n = 63)	91%	53	54	56%	10	9	.44
Marijuana (n = 61)	100%	56	53	57%	5	8	.74

* Results for amphetamines and opiates are not reported due to the low number of cases.

use (9.4%); and days of marijuana use and days of college/school (7.9%). A table with the loading factor can be found in Supplementary data 2.

4. Discussion

The Chilean version of the TOP shows acceptable reliability and validity in most of the analyses, suggesting that this instrument can improve the monitoring system of patients in drug treatment. However, further validation work and analyses in key areas are needed. For instance, several items, mostly the ones related with crime and health and the items on the use of sedatives and tranquilizers, did not reach the reliability thresholds. Second, the variables that measured average consumption in a typical day of cocaine paste or marijuana did not present cases that reached reliable levels of change. However, the last point could be explained by both the small numbers of cases available to perform the test and the high number of people that have stopped using drugs entirely between the test and the follow-up. Additionally, for the purpose of the validation study, we requested that clients recall pre-admission substance use, which may be subject of recall bias and could have distorted some of the results. Third, some of the psychometrical results did not have a clear clinical or epidemiological meaning because of their magnitude or statistical significance. For example, the discriminant analysis shows that the TOP allows analysts to identify groups with better or worse performance in treatment, however most of these results were only slightly above or under the null value (although most of them were statistically significant). Also, the factor analysis performed shows a grouping of items around six factors, some of them clearly identified with sections of the instrument, such as crime and self-reported health. However, there are other factors that group together items from different sections, suggesting that the construct needs further examination.

Table 6
Change sensitivity, group with less than 3 months in treatment (n = 179).*

Measure (last 4 weeks)	Test		Follow up		Cohen's d	SDD ^a	RCI % ^b
	M	SD	M	SD			
Alcohol (n = 70)							
Days used	4.88	5.19	1.47	3.40	.77	5.21	11.60
Units on typical day	9.94	11.72	3.63	5.82	.68	8.15	6.62
Marijuana (n = 29)							
Days used	6.21	7.73	2.24	5.66	.59	5.33	10.30
Units on typical day	2.28	1.09	.75	1.11	.82	2.86	.00
Cocaine paste (n = 40)							
Days used	6.95	8.32	1.69	5.04	.77	5.78	15.00
Units on typical day	20.76	24.06	4.59	13.68	.81	7.68	.00
Cocaine (n = 14)							
Days used	4.85	5.76	.13	.35	1.19	5.44	14.32
Units on typical day	15.78	21.71	1.33	3.99	.95	9.55	14.31
Sedatives and tranquilizers (n = 4)**							
Days used	15.50	9.11	.00	.00			
Units on typical day	2.50	2.12	.00	.00			
Number of days with domestic violence in past 4 weeks (n = 19)	1.26	0.73	0.21	0.53	1.68	1.90	16.70
Physical health (n = 178)	11.62	4.80	13.98	3.90	.54	5.06	9.55
Psychological health (n = 179)	12.80	4.90	14.62	4.07	.40	4.96	16.20
Quality of life (n = 179)	13.47	4.56	15.02	4.10	.35	4.88	13.41
Days of paid work (n = 179)	15.57	8.81	13.41	10.08	.22	5.18	7.80
Days of college/school (n = 179)	16.4	8.04	12.00	8.39	.59	2.67	2.42

* The data shown in the table include the number of cases that presented information in both test and follow-ups and presented consumption of substance in the test.

** Due to the low number of cases statistics of both days of used and units used on typical day for sedatives and tranquilizers were not calculated.

^a The smallest detectable difference (SDD) at the 95% level of confidence.

^b Proportion of sample exceeding the Reliable Change Index (RCI) in either direction.

In terms of the problem found with the item on sedatives and tranquilizers use, the commission of experts advising the study suggested that researchers not exclude this variable because the low levels of reported consumption in the sample group could explain anomalous results and because the clinical relevance of these substances meant that they were worth continuing to observe. The English and Australian validation process also faced a similar problem. In that case, the item benzodiazepines was not deemed reliable based on the TOP statistical criteria, and therefore this substance was at first removed from the TOP. Nevertheless, given the high prevalence of benzodiazepine use in Australia and the difficulty of differentiating between the misuse of prescribed benzodiazepines and illicitly sourced benzodiazepines, the team in charge of the study reintroduced this item (Ryan et al., 2014). These experiences suggest that special attention is needed for the assessment of these specific behaviors, especially considering the proportion of people treated through sedative and tranquilizer use in Chile (about 10% of people 50 years and older) (SENDA-MINSAL, 2013).

In terms of the questionnaire's administration, it is notable that a high percentage of participants answered most of the questions. This indicates that the instrument is understandable and reaffirms its applicability in Chilean settings.

The use of standardized instruments not only helps treatment centers to monitor the therapeutic process of patients, it also assists in the evaluation of their treatment programs. In this context, even though practitioners in Chile consider different dimensions in assessing therapeutic achievement, they do not have access to standardized instruments that allow for an objective assessment of both the therapeutic progress and the treatment program. Therefore, the validation of the TOP responds to the need for more advanced systems of monitoring, not only in relation to the volume and patterns of drug use, but also to other aspects of the rehabilitation process, such as physical and psychological health, quality of life, work, education and housing.

The TOP is currently being used by some of the treatment centers in the country to monitor the therapeutic process of patients during treatment. In addition, a national pilot implementation process is programmed for 2014, with the goal that it be fully operational in 2015. The plan is that in the short time all the centers in the country would have this tool available to monitor their patients during the treatment. To achieve this goal, in 2013 SENDA carried out a training process to practitioners of all treatment

facilities in the administration of the TOP and in the registration of information that the instrument reveals. Furthermore, in light of the English experience, the TOP will be incorporated into the patient registration system and included as a way for treatment centers to generate automated reports.

The implementation of instruments such as the TOP in other countries has shown to be a useful tool for quick and easy access to the results of a treatment centers (Marsden et al., 2009; Marsden et al., 2011). Having access to this type of information allows both treatment centers, as well as central government agencies, to evaluate practices and make decisions about what treatments are more useful and have larger positive impacts. In this sense, the Chilean TOP represents both a valid and easily-administered instrument for continuous clinical and epidemiological evaluation of patients and treatment outcomes and a

tool that allows state agencies in charge of public drug policy to monitor and evaluate the effectiveness of the national treatment system and to allocate resources based on this data.

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Appendix A. The Chilean Treatment Outcome Profile

Perfil de Resultados de Tratamiento (TOP)

Nombre del Usuario

Fecha de entrevista (dd / mm / año)

(/ /)

Fecha de nacimiento

Nombre del Entrevistador

Sexo: M F

Etapa del Tratamiento: Ingreso En tratamiento
Egreso Seguimiento

Sección 1: Uso de Sustancias

Registrar la cantidad promedio de uso diario y el número de días de uso de sustancias consumidas en las últimas 4 semanas

	Promedio	Última Semana	Semana 3	Semana 2	Semana 1	Total
a. Alcohol	<input type="text"/> Tragos/día	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28
b. Marihuana	<input type="text"/> Pitos/día	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28
c. Pasta Base	<input type="text"/> Papelllos/día	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28
d. Cocaína	<input type="text"/> Gramos/día	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28
e. Sedantes o Tranquilizantes	<input type="text"/> Comprimidos/día	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28
f. Otra sustancia problema	<input type="text"/> Medida/día	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28

Nombre otra sustancia:..... Unidad de medida:.....

Sección 2: Transgresión a la Norma Social

Registrar hurtos, robos, violencia intrafamiliar y otras acciones cometidas en las últimas 4 semanas.

a. Hurto	Sí <input type="checkbox"/> No <input type="checkbox"/>	Marque "S" o "N" → <input type="text"/>			
b. Robo	Sí <input type="checkbox"/> No <input type="checkbox"/>	Marque "S" o "N" → <input type="text"/>			
c. Venta de droga	Sí <input type="checkbox"/> No <input type="checkbox"/>	Marque "S" o "N" → <input type="text"/>			
d. Riña	Sí <input type="checkbox"/> No <input type="checkbox"/>	Marque "S" o "N" → <input type="text"/>			
e. Violencia Intrafamiliar (Maltrato físico o psicológico)	Última Semana <input type="text"/> 0-7	Semana 3 <input type="text"/> 0-7	Semana 2 <input type="text"/> 0-7	Semana 1 <input type="text"/> 0-7	Total <input type="text"/> 0-28
f. Otra acción:.....	Sí <input type="checkbox"/> No <input type="checkbox"/>	Marque "S" o "N" → <input type="text"/>			

Sección 3: Salud y Funcionamiento Social

a. Calificar el estado de salud psicológica del usuario (ansiedad, depresión y/o problemas emocionales)

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

Mala Buena → 0-20

Registrar los días trabajados y asistidos a institución de educación (Colegio, Instituto, Universidad, Centro de capacitación, etc.) durante las últimas 4 semanas

	Última Semana	Semana 3	Semana 2	Semana 1	Total
b. Días de trabajo remunerado	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28
c. Días asistidos al Colegio o Instituto o Universidad o Centro de capacitación, etc.	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28

d. Calificación del estado de salud física del usuario (grado de síntomas físicos u molestias por enfermedad)

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

Mala Buena → 0-20

Registrar condiciones de vivienda de las últimas 4 semanas

e. Tiene un lugar estable para vivir	Sí <input type="checkbox"/> No <input type="checkbox"/>	Marque "S" o "N" → <input type="text"/>
f. Habita en una vivienda que cumple con las condiciones básicas	Sí <input type="checkbox"/> No <input type="checkbox"/>	Marque "S" o "N" → <input type="text"/>
g. Calificación global de calidad de vida del usuario (Ej: Es capaz de disfrutar de la vida, consigue estar bien con su familia y el entorno)	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Mala <input type="text"/> Buena <input type="text"/> → <input type="text"/> 0-20

TOP SENDA-CHILE 2013

Perfil de Resultados del Tratamiento (TOP)

Acerca del TOP

El Perfil de Resultados del Tratamiento (TOP, siglas del inglés) es una nueva herramienta de monitoreo de resultados del tratamiento de drogas, fue desarrollada por [NHS](#) la de Inglaterra, siendo autorizada su validación en Chile, su utilización es recomendada para todas las modalidades estructuradas de tratamiento. A través de un conjunto simple de preguntas, este instrumento permitirá que usuarios y profesionales sean capaces de obtener datos objetivos y comparables sobre las mejoras reales en la vida de los usuarios, lo que incidirá en la información y mejoras en el desarrollo del plan de atención de éstos. El instrumento como no es autoaplicable debe ser aplicado con el usuario por algún integrante del equipo de tratamiento.

El TOP debe ser completado al inicio del tratamiento de cada usuario, para registrar una **línea base** de comportamiento en el mes **previo** a su aplicación. El seguimiento de los resultados debe ser registrado, como máximo, cada **tres meses** durante el tratamiento para capturar cambios conductuales. También debe ser completado al momento del **egreso** o alta del tratamiento y puede ser utilizado por algunos centros para medir resultados posteriores al alta (**Seguimiento**).

Como completar el TOP

Comience por introducir:

- Nombre e identificador del usuario.
- Nombre de quien aplica el instrumento
- Fecha de la aplicación
- Etapa en la que el TOP está siendo aplicado:
 - Ingreso / -En tratamiento / -Egreso o Alta / -Seguimiento

Tipos de Respuestas:

- Cronología y Frecuencia: Se le solicita al usuario recordar el número de días de las últimas 4 semanas en los cuales realizaron alguna acción, por ejemplo, el número de días de consumo de cocaína. Luego, usted debe sumar e ingresar el total en el recuadro azul.
- Sí o No; una marca sencilla de sí o no, luego debe registrar "S" ó "N" en el recuadro azul.
- Escala de calificación; una escala de 20 puntos desde malo hasta bueno. Junto con el usuario, marque la escala en el lugar apropiado y luego escriba el puntaje correspondiente en el recuadro azul.

Usted debe intentar realizar el cuestionario completo. No deje ningún recuadro azul en blanco. Ingrese "NA" si el usuario se niega a contestar la pregunta o, después de intentarlo, no puede recordar.

Para mayor información, ver el [Manual de aplicación del TOP](#).

Unidades de Conversión de Alcohol

CERVEZA (5)	Lata (350 ml)	1 trago (13,8 gramos)
	Shop (500 ml)	1 trago y medio (19,8 gramos)
	Botella cerveza (1.000ml, 1 litro)	3 tragos (39,5 gramos)
VINO (14)	Copa de vino (media caña, vaso chico, jote) (140 ml)	1 trago (15,5 gramos)
	Vaso de vino, caña (280 ml)	2 tragos (31 gramos)
	Botella de vino (750ml)	6 tragos (83 gramos)
	Caja, Tetrapack (1.000 ml, 1 litro)	8 tragos (111 gramos)
LICORES (40*) (Pisco, ron, vodka, whisky, etc.)	Corto (40 ml)	1 trago (12,6 gramos)
	Combinado simple (40 ml de licor, más bebidas sin alcohol)	1 trago (12,6 gramos)
	Combinado fuerte, cabezón (80 ml de licor, más bebidas sin alcohol)	2 tragos (25,3 gramos)
	Botella (750 ml)	17 tragos (237 gramos)

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Appendix B. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.jsat.2015.03.002>.

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