



## Preliminary validation of an instrument to assess social support and tuberculosis stigma in patients' families

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**Setting:** Ribeirão Preto, São Paulo, Brazil.

**Objective:** To develop and validate a preliminary instrument for assessing social support and tuberculosis (TB) stigma in families of TB patients.

**Design:** A literature review on social support and TB stigma was used to generate the theoretical domains for the instrument. A focus group was then conducted with TB patients and their families to revise the domains. Reviewers were invited to judge the appropriateness of the items in the instrument. A cross-sectional survey was carried out among 110 family members to assess the factorial structure using principal component analysis and confirmatory factor analysis to assess construct validity. Reliability was assessed in terms of internal consistency using Cronbach's alpha.

**Results:** After semantic validation and a pilot study, 23 items were selected for the scale. Examination of the factorial structure of the 16 items that were factorable using principal component analysis led to the extraction of two factors. The 16-item instrument was assessed for construct validity with confirmatory factor analysis, which confirmed a model with four items for each dimension.

**Conclusion:** The study analysed the psychometric properties of an instrument that is still in its preliminary stages. Other studies on a similar scale in the Brazilian setting are required.

The relevance of tuberculosis (TB) stigma and its different expressions and characteristics in the field of public health have been widely discussed in the international context.<sup>1,2</sup> In Brazil, the TB health challenge is strongly influenced by social determinants and shows a direct relationship with poverty and social exclusion, of which stigma is an important component.<sup>3,4</sup>

The term stigma was originally described by Goffman to refer to a devalued or undesirable social attribute.<sup>5</sup> This attribute may be a physical or social issue that provokes negative feelings and consequently causes the individual to become marginalised or excluded from social relationships.<sup>6,7</sup>

As many people do not want to be identified as TB patients they do not seek out health care services for a TB diagnosis, and may even refuse treatment. Recent studies in different settings that have investigated the impact of TB stigma on the lives of patients and family members suggest that this phenomenon is more common in developing countries.<sup>1,2,4,8-12</sup>

Stigma has been associated with lower self-esteem,

depression, feelings of being misunderstood and ashamed, poor medication adherence, fewer successful social interactions, reduced help seeking and poor recovery.<sup>2,9,10</sup> Authors have, however, pointed out that social support may be used to tackle the negative effects of stigma and increase the patient's self-esteem, thus increasing adherence to treatment.<sup>13</sup>

A study on human immunodeficiency virus (HIV) infection reported that social support was inversely associated with levels of stigma.<sup>14</sup> This evidence led us to hypothesise that this association may also be observed in the case of TB. However, this inverse association between social support and stigma was found only in the context of HIV; no similar studies on TB have been published.

Qualitative studies have contributed to the identification of the determinants of stigma in families and its consequences;<sup>15,16</sup> one such study reported that social support was an important element in overcoming stigma among patients.<sup>16</sup> However, due to the design of these studies, the conclusions reached did not have external validity. We therefore suggested that complementary, transversal, analytical and quantitative studies are necessary to advance the investigation.<sup>17</sup>

The use of reliable, validated instruments is a challenge to the realisation of quantitative studies on family TB support and stigma, as no instruments have been formally validated and adapted to Brazilian settings. The present study aimed to construct and validate a preliminary scale to investigate social support and stigma among families of TB patients.

### METHODS

#### Study design and site

This cross-sectional study was conducted in Ribeirão Preto, SP, Brazil, which is considered a priority area for TB control.

#### Selection and content validity of scale items

In the first phase of the study, we constructed the scale domains and defined correlated items. Based on the literature review, possible effects of stigma<sup>1,2,8,9,12,14,18,19</sup> (Table 1; factor 2) and aspects of social support<sup>12,20</sup> (Table 1; factor 1) were identified. The composition of the constructs was also based on the expertise and knowledge of researchers in the field of TB, who defined the main points of the scale domains.

A focus group (FG) was then conducted to verify and revise the domains initially constructed. In this phase, eight subjects were randomly selected to partic-

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#### KEY WORDS

psychometrics; validation studies; family relations; social stigma; tuberculosis

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**TABLE 1** The version of the instrument obtained in the exploratory factorial analysis

		Loading	Communality*	Alpha item total	Alpha item deleted
Factor 1: items†					
51	I was guided by the health care team regarding the TB medication.	0.747	0.304	0.592	0.723
52	The health care team includes me in the care.	0.776	0.323	0.665	0.705
55	My family member trusts me and my advice.	0.443	0.071	0.360	0.769
56	We talk about TB.	0.486	0.132	0.328	0.778
59	I have been examined at the clinic where my relative is receiving anti-tuberculosis treatment.	0.583	0.246	0.509	0.742
60	I follow the medication intake of my family member.	0.729	0.252	0.562	0.731
61	I am prepared to follow the medication regimen.	0.637	0.160	0.457	0.754
Factor 2: items‡					
40	My family member asks me to keep the TB a secret.	0.670	0.459	0.516	0.763
41	I feel ashamed because my family member has TB.	0.461	0.278	0.347	0.784
42	I hide the fact that that my family member has TB from the community.	0.754	0.575	0.647	0.744
43	My family member hides his/her diagnosis from the community.	0.782	0.612	0.673	0.737
44	I avoid talking about TB in the presence of other family members or neighbours.	0.473	0.233	0.356	0.790
47	I'm afraid that someone will see me at the health care clinic where my relative is being treated.	0.574	0.375	0.453	0.777
48	I substitute another word for TB in my conversations with my family member.	0.502	0.265	0.372	0.782
49	I substitute another word for TB in the conversations with my friends.	0.752	0.569	0.622	0.749
50	I've noticed changes in my family member since the TB diagnosis.	0.500	0.251	0.390	0.785

\*Communalities before rotation.

†Alpha pattern 0.769.

‡Alpha pattern 0.795.

TB = tuberculosis.

ipate in the FG at a specialised TB facility. Of the 4 subjects who attended this group, 2 were TB patients and 2 family members; 2 of the subjects were male and 2 female, aged 26–71 years; the majority had not completed elementary education.

Based on the statements obtained during this phase, the researchers developed the initial version of the scale, which was composed of 23 items with five answer options: 1 (never), 2 (seldom), 3 (sometimes), 4 (often) and 5 (always). The pilot scale was submitted to 10 reviewers to evaluate the clarity and pertinence of the items.<sup>21</sup>

Researchers from several areas (public health, epidemiology, anthropology, the social sciences and nursing) were invited to act as reviewers. Participants were selected on the basis of their resumes (*Curriculum Lattes*), available on the online platform (<http://lattes.cnpq.br>). In this phase, participants were asked to assess the cultural, semantic and theoretical aspects of each item of the questionnaire. It was decided that those items in the questionnaire with a >70% level of agreement among reviewers would be retained.

### Study population and sampling

The study population consisted of family members (age ≥18 years) of TB patients of both sexes living with the patients. The exclusion criteria were family members of patients who were hospitalised for a long period or were not at home after three visits paid by the researchers.

For the semantic validation of the questionnaire, sample size was determined based on theoretical saturation.<sup>22</sup> Being a family member of a TB patient was the sole eligibility criteria. Basic sample units were selected according to the dimension 'educational level'.<sup>22</sup> Subjects with no education, and those with mid-level ed-

ucation and higher education were therefore included in the sample. A minimum of two subjects per dimension (level of education) was defined.

Exploratory factor (EFA) and confirmatory factor analyses (CFA) were carried out using data collected at baseline among family members of TB patients. The study sample was defined as set down by authors of previous studies, who defined a minimum sample size of 100 subjects as fully adequate for inferring robust factorial structures and empirical clarity.<sup>23–25</sup>

### Semantic validation

The main goal of semantic validation was to ascertain whether the items of the scale would be understood by every subject in the target population.<sup>21,26</sup> The following criterion was adopted for the data collected from 10 family members of TB patients who agreed to participate in the study and share their ideas regarding each item. When it was correctly understood, an item was retained; otherwise, it was reformulated according to suggestions made by the subjects.

### Construct validation: exploratory factor and confirmatory factor analyses

Data for this phase were collected between 25 July and 31 August 2011 by five interviewers who received training before the interviews. The interviews were conducted in the homes of the 110 participants.

To verify the dimensionality of the scale, construct validation procedures were used based on DeVellis' theories, in which exploratory factorial analysis, item communality, item-item correlations and total items are considered.<sup>27</sup>

To perform EFA, two criteria were considered: high coefficients of correlation between variables, and normal distribution of the data. For the first criterion, the Kayser-Meyer-Olkin (KMO) test was used, according to which values near zero indicate correlation between variables, while values near 1 indicate no correlation. In this study, EFA was performed when KMO coefficients were  $<0.5$ .<sup>28</sup> To confirm the second criterion, Bartlett's sphericity test was performed.

Using the principal component method, factors with values  $>1.0$  and consistent with the theoretical constructs of the study were extracted.<sup>25</sup> Extraction was based on the varimax rotation method with Kaiser normalisation when intercorrelation between items and factors through factorial loading was observed. Items with a factorial loading of  $<0.40$  were excluded from the scale. The internal consistency of the scale was analysed using Cronbach's  $\alpha$ ; values  $>0.70$  were considered acceptable.<sup>25</sup>

Taking into consideration factorial loading tests and measures of fit, such as the comparative fit index (CFI), root mean square (RMSEA), normed fit index (NFI) and goodness-of-fit index (GFI), CFA was used to confirm psychometric properties.

The following index values were adopted as satisfactory adjustment criteria for the data model: CFI  $> 0.90$ ; RMSEA  $\leq 0.08$ ; GFI  $> 0.90$ ; NFI  $> 0.90$ , per the study by Tucker and Lewis.<sup>29</sup> For data analysis, Statsoft Statistics (version 12.0; Dell, Round Rock, TX, USA), SPSS (version 19.0, Statistical Package for the Social Sciences, Chicago, IL, USA) and Lisrel (version 9.1; Scientific Software International, Skokie, IL, USA) programmes were used.

### Ethical aspects

The study was approved by the Research Ethics Committee of the University of São Paulo at Ribeirão Preto College of Nursing (Protocol 1292/2011). Informed consent was provided by all the study participants.

## RESULTS

Of the subjects who took part in the semantic validation phase, 8 (80%) were female, with a mean age of 53 years; 4 participants (40%) were illiterate, 4 (40%) had 1–7 years of schooling and 2 (20%) had  $\geq 8$  years of schooling. Of the 110 subjects recruited for the construct validation study (Table 2), ages varied from 18 to 84 years; 85 participants were female (77.3%), 58 had received incomplete elementary schooling (52.7%) and 44.6% had an income between 1 and 2.5 times the minimum wage.

Applying the Kaiser criteria to the EFA, eight factors with eigenvalues  $>1.0$  were identified (Figure 1); however, only two were supported by the theoretical domains defined for the study. These factors explained 31.1% of the data variance, with a KMO sample adequacy measurement of 0.687. Using Bartlett's sphericity test, the factorability of the sample was verified ( $\chi^2 = 724.37$ ,  $P < 0.0001$ ).

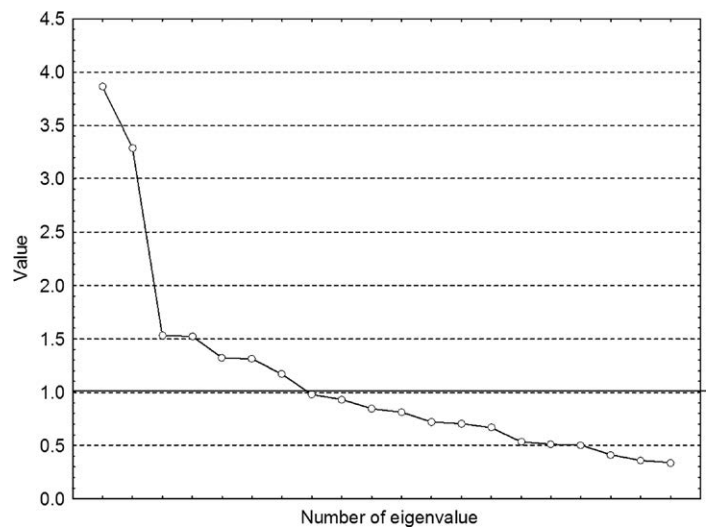
Of the 23 items, seven were eliminated using EFA due to factorial loadings  $<0.40$ , the stipulated scale item acceptance value. The original domains constructed thus resulted in two factors that were nominated as social support (7 items) and TB stigma (9 items), both with good Cronbach's  $\alpha$  of respectively 0.76 and 0.79 (Table 1). Silent data and outliers were not identified using EFA. It was observed that all the items of the instrument presented an asymmetrical pattern, which is a favourable condition for the performance of the CFA.

In Table 3, distinct results for the indices used to evaluate the adequacy of the factorial models can be observed. The final column represents the reference values; in Model 1 all the indices

**TABLE 2** Sociodemographic characteristics of the study participants

Characteristics	<i>n</i>	%
Sex		
Female	85	77.3
Male	25	22.7
Age, years		
18–38	33	30.0
39–59	50	45.4
$\geq 60$	27	24.6
Education		
Did not complete elementary school	58	52.7
Completed elementary school	16	14.6
High school	32	29.0
University	4	3.7
Marital status		
Single	26	23.7
Married	66	60.0
Divorced	6	5.4
Windowed	12	10.9
Income (minimum wage)*		
$<1$	26	23.7
1–2.5	49	44.6
2.6–5	28	25.4
5.1–10	6	5.4
$>10$	1	0.9

\*The minimum wage was R\$600 (reais, equivalent to US\$312.50) at the time of data collection.



**FIGURE 1** Graph of eigenvalues.

achieved were unsatisfactory; in Model 2 the RMSEA ( $>0.08$ ) was outside the reference standards of quality-of-fit; Model 3 was the only model with satisfactory indices. Figure 2 shows the three models, items and their respective correlations with factors 1 and 2.

## DISCUSSION

This study aimed to develop and validate an instrument for the evaluation of support and stigma among families of TB patients. The first version of the instrument included 23 items. This ver-

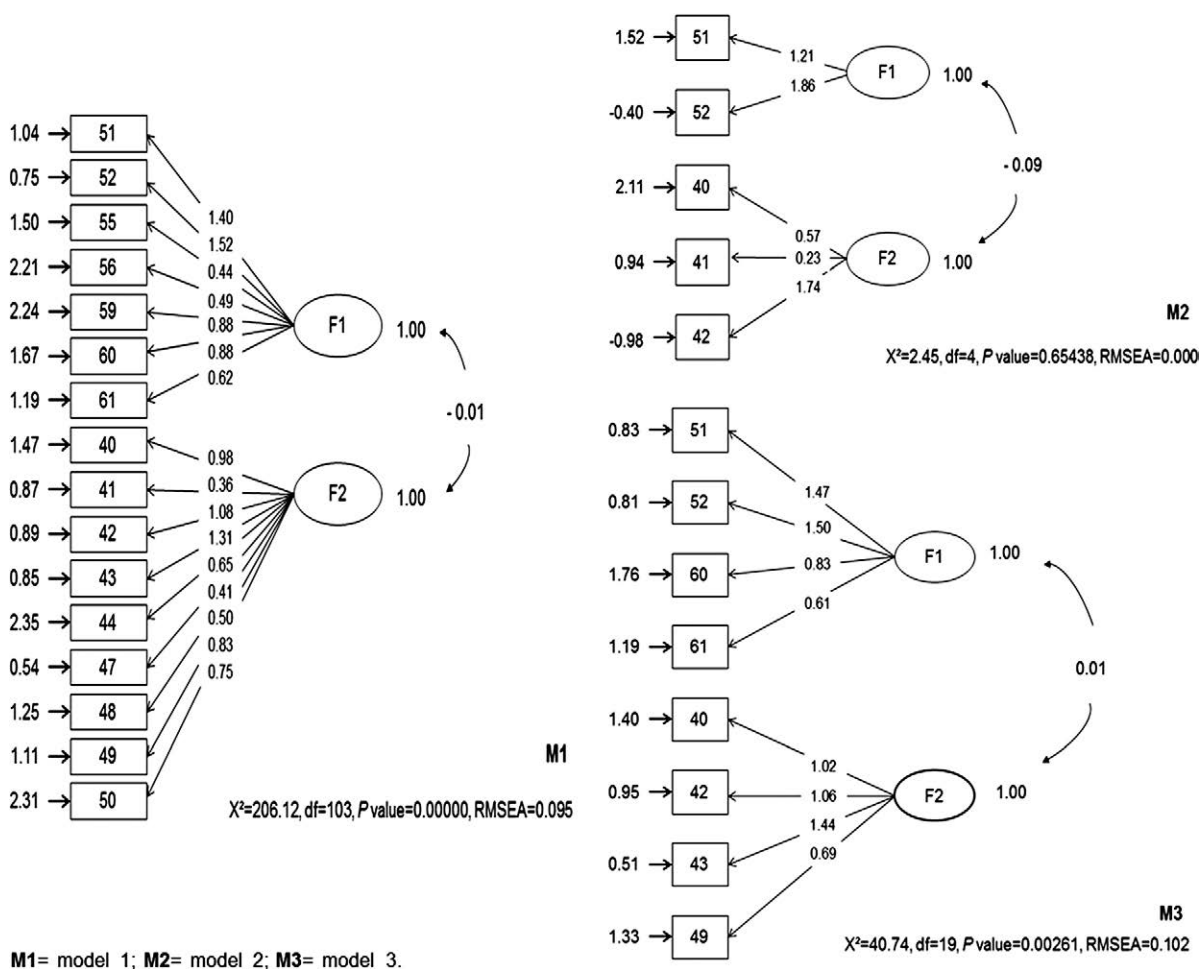
**TABLE 3** Fit indices of the models tested for the instrument to assess social support and stigma attached to tuberculosis in patient families

Fit index	Model 1	Model 2	Model 3	Reference values*
$\chi^2$	206.118	40.740	2.446	†
df	103	19	4	†
$\chi^2/df$	2	2.14	0.61	$\chi^2/df < 3$
Goodness-of-fit index	0.813	0.921	0.991	>0.9
Adjusted goodness-of-fit index	0.754	0.851	0.967	>0.9
Comparative fit index	0.847	0.929	1	>0.9
Root mean square error of approximation	0.096	0.102	0.062	$\leq 0.08$

\*Reference values defined by Tucker and Lewis.<sup>29</sup>

†Undefined.

df = degree of freedom.

**FIGURE 2** Tested models of confirmatory factor analysis.

sion was sent to reviewers who were asked to decide on the suitability of each item in the instrument. The criterion of at least 70% agreement was set to decide which items should be retained in the second version of the instrument. As all the items fitted the criteria, none were excluded. During semantic validation, items misunderstood by the subjects were reviewed according to their suggestions. The relevance of each item was also evaluated during this phase. The theoretical background that supported the validation of this instrument identified two separate dimensions: social support and stigma attached to TB. When the instrument

was developed, the items were related to either one of these dimensions.

EFA was used to explore data structure and identify eight factors with eigenvalues  $>1$ ; however, only two of these factors were consistent with the theoretical model defined for investigation. Following Hair et al.'s recommendations,<sup>25</sup> the two with greater variance and that were consistent with the study theory were thus chosen.

Hair et al. stressed that excesses in statistics should be avoided, with a focus on the theoretical basis of the study, which often de-

finds interpretations differently from numbers. In this phase, some items in each dimension with a weak correlation with that dimension were excluded (i.e., factorial loading <0.4).

This technique proved valuable in identifying the underlying theoretical construct of instruments.<sup>30</sup> However, each item presented saturations in the various factors with values >1. As it is not compulsory for each item to explain only one factor in the construct validity, CFA was used.

From the hypothesis of association between the items and the theoretical constructs investigated, it was found that only Model 3 presented satisfactory indices with respect to the goodness-of-fit of the confirmatory factorial model. These indices are consistent with the standards established in the scientific literature.<sup>29</sup> However, the model is presented with a reduced number of items, indicating the need for further studies to validate the theoretical model and the factorial structure of the scale.

Although a minimum criterion of 100 subjects, represented in the validation of social construct instruments in scientific literature, was adopted for the study,<sup>23–25</sup> this number may have affected the results. The limitation refers to the number of patients and families affected by TB, 100–120 cases per year in the city under study, the location of these families and the difficulty of talking about the stigma related to the disease.

Another aspect that should be kept in mind is that this study only presents a preliminary version of the scale; the scale should therefore be tested by other studies in Brazilian settings to better demonstrate its psychometric properties. Nevertheless, as there is no validated scale to measure stigma and social support among family members, this study provides important contributions to this field and could act as a starting point.

It is believed that this scale could be helpful to health professionals wishing to improve the quality of care, and also as evidence of the relevance of the inclusion of family members in TB care. Social support is an important factor, as it can reduce or eliminate the negative effects of stigma by helping patients to become self-reliant and motivating them to complete treatment.<sup>13</sup>

In the future, this scale may contribute to the optimisation of available resources for TB control. As multidrug-resistant TB is an important challenge to TB control in the twenty-first century, it is necessary to implement best health practices in communities affected by TB, prevent patient non-adherence and improve drug adherence rates.<sup>31</sup>

Local health care systems should invest in aspects other than biomedical for this disease, aim to improve access to health care services and provide education to raise the awareness of the community about TB. To do this, health care teams need a reliable instrument to identify problems and plan their actions more efficiently.

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**Contexte :** Ribeirão Preto, Brésil.

**Objectif :** Elaborer et valider un instrument préliminaire afin d'évaluer le soutien social et la stigmatisation liée à la tuberculose (TB) dans les familles des patients.

**Schéma :** Une revue de littérature relative au soutien social et à la stigmatisation liée à la TB a permis de générer les domaines théoriques de l'instrument. Un groupe focal a ensuite été réalisé avec des patients tuberculeux et leurs familles afin de revoir ces domaines. Les réviseurs ont été invités à juger le caractère approprié des éléments de l'instrument. Une enquête traversable auprès de 110 membres des familles a été effectuée afin d'évaluer la structures factorielles grâce à l'analyse du composant principal, avec une analyse du facteur de confirmation qui a permis de vérifier la validité

de la construction. La fiabilité a été évaluée par la cohérence interne grâce au coefficient  $\alpha$  de Cronbach.

**Résultats :** Vingt-trois éléments composaient l'échelle après la validation sémantique et l'étude pilote. L'exploration de la structure factorielle des 16 items qui étaient favorables grâce à l'analyse du composant principal a extrait deux facteurs. L'instrument à 16 items a été évalué en termes de validité de la construction avec une analyse du facteur de confirmation qui a confirmé un modèle à quatre items pour chaque dimension.

**Conclusion :** L'étude a démontré les propriétés psychométriques d'un instrument encore au stade préliminaire. Cette échelle doit être testée à travers d'autres études dans le contexte brésilien.

**Marco de referencia:** Ribeirão Preto, en Brasil.

**Objetivo:** Validar una herramienta preliminar de evaluación del apoyo social y los estigmas relacionados con la tuberculosis (TB) en las familias de los pacientes.

**Método:** Mediante una revisión bibliográfica sobre el apoyo social y los estigmas relacionados con la TB se definieron los dominios teóricos de la herramienta. Luego, en un grupo de opinión conformado por pacientes con diagnóstico de TB y sus familiares se verificaron los dominios. Se invitaron revisores con el objeto de juzgar la idoneidad de los elementos de la escala. Se llevó a cabo una encuesta transversal a 110 miembros de las familias de pacientes con el propósito de evaluar la estructura factorial, mediante un análisis de componentes principales y se aplicó un análisis factorial confirmatorio a fin de apreciar la validez conceptual de la escala. Mediante un

análisis de la consistencia interna se examinó la fiabilidad de la escala con medición del coeficiente  $\alpha$  de Cronbach.

**Resultados:** Tras la validación semántica y el estudio preliminar, la escala estaba compuesta por 23 elementos. Se exploró la estructura factorial de los 16 elementos factorizables mediante el análisis de componentes principales y se extrajeron dos factores. La validez conceptual del instrumento de 16 elementos se verificó mediante un análisis factorial confirmatorio, el cual ratificó un modelo con cuatro elementos en cada dimensión.

**Conclusión:** El estudio puso en evidencia las propiedades psicométricas de un instrumento que se encuentra en fases preliminares de desarrollo. Es necesario poner a prueba esta escala en otros estudios en el contexto del Brasil.