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ORIGINAL ARTICLE / ARTIGO ORIGINAL

Translation and cultural adaptation into Brazilian Portuguese of the Finnish Diabetes Risk Score (FINDRISC) and reliability assessment

Tradução e adaptação transcultural para o português brasileiro do Escore Finlandês de Risco de Diabetes (FINDRISC) e avaliação da confiabilidade

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ABSTRACT: Introduction: The Finnish Diabetes Risk Score (FINDRISC) is a tool that was initially developed to predict the risk of developing type 2 diabetes mellitus in adults. This tool is simple, quick to apply, non-invasive, and low-cost. The aims of this study were to perform a translation and cultural adaptation of the original version of FINDRISC into Brazilian Portuguese and to assess test-retest reliability. **Methodology:** This work was done following the ISPOR Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes Measures. Once the final Brazilian Portuguese version (FINDRISC-Br) was developed, the reliability assessment was performed using a non-random sample of 83 individuals attending a primary care health center. Each participant was interviewed by trained registered dietitians on two occasions with a mean interval of 14 days. The reliability assessment was performed by analyzing the level of agreement between the test-retest responses of FINDRISC-Br using Cohen's kappa coefficient and the intraclass correlation coefficient (ICC). **Results:** The steps of ISPOR guidelines were consecutively followed without major problems. Regarding the reliability assessment, the questionnaire as a whole presented adequate reliability (Cohen's kappa = 0.82, 95%CI 0.72 – 0.92 and ICC = 0.94, 95%CI 0.91 – 0.96). **Conclusion:** FINDRISC was translated into Brazilian Portuguese and culturally adapted following standard procedures. FINDRISC-Br has thus become available for use and has potential as a screening tool in different Brazilian settings and applications.

Keywords: Diabetes mellitus. Screening. Translating. Brazil. Reproducibility of results.

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RESUMO: Introdução: O Escore Finlandês de Risco de Diabetes (FINDRISC) é um instrumento que inicialmente foi desenvolvido para prever o risco de desenvolver diabetes mellitus tipo 2 em adultos. Esse instrumento é simples, rápido de aplicar, não invasivo e de baixo custo. Os objetivos deste estudo foram descrever o processo de tradução e adaptação transcultural do FINDRISC para o português do Brasil e avaliar a sua confiabilidade teste-reteste. **Metodologia:** O projeto foi conduzido de acordo com as recomendações dos Princípios de Boas Práticas para o Processo de Tradução e Adaptação Transcultural de Medidas de Resultados Relatados pelo Paciente desenvolvidas pela ISPOR. Uma vez desenvolvida a versão final em português brasileiro (FINDRISC-Br), realizou-se a avaliação da confiabilidade usando uma amostra não aleatória de 83 indivíduos atendidos em uma unidade de atenção básica. Cada participante foi entrevistado por nutricionistas registradas treinadas em duas ocasiões com intervalo médio de 14 dias. A avaliação da confiabilidade foi realizada por meio da análise do nível de concordância entre as respostas do teste-reteste, utilizando-se o coeficiente kappa de Cohen e o coeficiente de correlação intraclassa (CCI). **Resultados:** As etapas das diretrizes da ISPOR foram seguidas consecutivamente sem maiores problemas. Em relação à avaliação da confiabilidade do teste-reteste, o questionário como um todo apresentou confiabilidade adequada (kappa de Cohen = 0,82; IC95% 0,72 – 0,92 e CCI = 0,94; IC95% 0,91 – 0,96). **Conclusão:** O FINDRISC foi traduzido e adaptado transculturalmente para o português do Brasil seguindo procedimentos padronizados. O FINDRISC-Br já está disponível para uso e tem potencial para ser usado como ferramenta de rastreamento em diferentes cenários brasileiros.

Palavras-chave: Diabetes mellitus. Rastreamento. Tradução. Brasil. Reprodutibilidade dos testes.

INTRODUCTION

The Finnish Diabetes Risk Score (FINDRISC) is a tool developed by Finnish researchers to predict the risk of developing type 2 diabetes mellitus (T2DM) within ten years among adults aged 35–64 years¹⁻³. FINDRISC is one of the most commonly used questionnaires to identify people at high risk for T2DM in different populations of the world⁴⁻⁸ and has several advantages over other risk scores^{9,10}. Other than predicting the risk of T2DM, it has also been shown to detect undiagnosed T2DM^{11,12} and hepatic steatosis¹³ and to predict drug-treated hypertension, cardiovascular events, and total mortality^{14,15}. FINDRISC is composed of eight parameters: age, body mass index, waist circumference, physical activity, diet (fruit, vegetable, and berry consumption), personal history of antihypertensive drug use, personal history of hyperglycemia (including previous gestational diabetes), and family history of diabetes. Each response is scored according to associated risk, with a final sum score range of 0–26 points^{1,2}.

The FINDRISC questionnaire has been applied previously in some studies in Brazil^{13,16-19}. However, they used a simple translation of the original tool, not following standard procedures. Therefore, we decided to produce a new Brazilian Portuguese version of FINDRISC in accordance with standard procedures, intending to contribute to an increasing use of more reliable tools. In this paper, we report the process of translation and cross-cultural adaptation of the original version of FINDRISC into Brazilian Portuguese, and its test-retest reliability assessment.

METHODOLOGY

SETTING AND SUBJECTS

This study took place in a primary care health center managed by the Botucatu Medical School of Universidade Estadual Paulista “Júlio de Mesquita Filho” (UNESP). This center serves a population of more than 40,000 inhabitants, corresponding to 30% of the population in Botucatu, State of São Paulo, Brazil. Individuals aged 18 years or older were invited to participate in the study as they were waiting for an appointment at the primary care health center. Those with cognitive problems and/or with a previous diagnosis of DM were not included. This study was performed between July and September of 2017. Interviews were conducted in two stages, from Monday to Friday, in the mornings and afternoons, with an average of 6 to 7 subjects interviewed sequentially. The first stage (test) involved the following procedures: inviting subjects to participate in the study; assessing the eligibility criteria; explaining to subjects the two stages of the study; reading and signing by the subjects of the informed consent form; anthropometric measurements; applying the questionnaire; and scheduling the second interview. The second stage (retest) involved: anthropometric measurements and application of the questionnaire.

The interviews were performed in a consulting room by three registered dietitians, who also performed the anthropometric measurements. Bodyweight and height were measured with minimal clothing and bare feet, using a scale with a coupled stadiometer (MIC-200PPA, Micheletti, São Paulo, Brazil). Standing height was measured with the head positioned in the Frankfurt plane. Waist circumference was measured using a measuring tape at the level of the navel. Body mass index (BMI) was calculated as body weight in kilograms divided by body height in meters squared.

The interviewers were trained before the application of the questionnaire. The training program consisted of two sessions. In the first session, the questionnaire was read, the interviewers were provided with an overview of the anthropometric measurements, and doubts were clarified. The second session was to test and train the interviewers. In this session, the interviewers conducted ten mock interviews, while the instructor (E. M. B.) provided corrective feedback.

The research protocol was submitted to and approved by the Human Research Ethics Committee of the Botucatu Medical School of UNESP (approval number 1,357,626) and written informed consent was obtained from all subjects.

TRANSLATION AND CULTURAL ADAPTATION

The translation and cultural adaptation process were conducted following the recommended principles of good practice for the translation and cultural adaptation for patient-reported

outcomes measures developed by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force²⁰. According to the ISPOR guidelines the process consists of ten steps:

1. Preparation;
2. Forward translation;
3. Reconciliation;
4. Back translation;
5. Back translation review;
6. Harmonization;
7. Cognitive Debriefing;
8. Review of cognitive debriefing results and finalization;
9. Proofreading;
10. Final report.

In our case, eight steps were followed. We did not include *Step 6. Harmonization*, since it is used for cross-cultural adaptations of the same instrument for multiple languages at the same time. Further, *Step 7. Cognitive debriefing* and *Step 8. Review of cognitive debriefing results and finalization* were unified in a single step named *Understanding*.

TEST-RETEST RELIABILITY

After producing the final Brazilian Portuguese version of FINDRISC (FINDRISC-Br), the test-retest reliability of the tool was assessed following Mokkink et al.²¹. To establish the test-retest reliability of FINDRISC-Br, the level of agreement between the test-retest responses of FINDRISC-Br was checked. The average interval between the first and second interviews was two weeks^{22,23}. Cohen's kappa coefficients²⁴ and intraclass correlation coefficients (ICC)²⁵ and their 95% confidence intervals (95%CI) were estimated. Both coefficients were calculated for each item of the FINDRISC questionnaire and further for the FINDRISC total score. We considered good reliability when kappa and ICC estimates were > 0.80 and > 0.75 , respectively^{24,25}. Statistical analysis was performed with the software package SAS 9.4 (SAS Institute, Inc., Cary, NC, USA).

RESULTS

TRANSLATION AND CULTURAL ADAPTATION

Figure 1 summarizes the different steps in the translation and cultural adaptation process of FINDRISC.

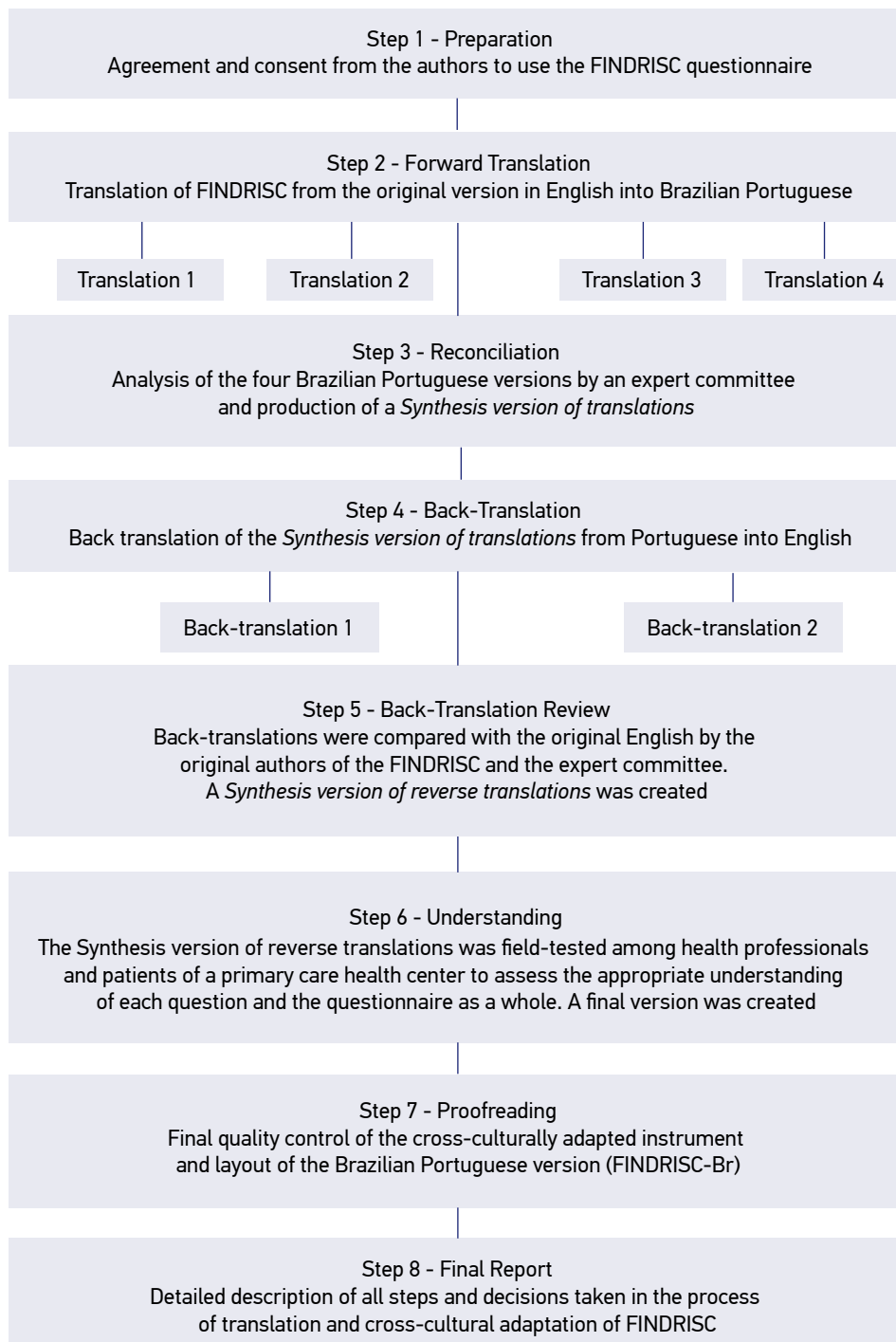


Figure 1. Flow diagram of the steps taken in the process of translation and cross-cultural adaptation of the Finnish Diabetes Risk Score (FINDRISC), according to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines.

Step 1: preparation

Translation to Brazilian Portuguese of FINDRISC began after obtaining permission from the original authors, Dr. Jaana Lindström and Dr. Jaako Tuomilehto.

Step 2: direct translation

Four independent FINDRISC translations were obtained, from the original version in English into Brazilian Portuguese. Two versions were carried out by two professional bilingual translators whose first language was Brazilian Portuguese, fluent in English and resident in Brazil. A third version had been performed previously by some of the present authors, R.S.R. and J.A.M.C., who used it to screen hepatic steatosis¹³. The fourth version was produced by coauthor K.C.P.M., a registered dietician with experience in public health and fluent in English.

Step 3: reconciliation

An expert committee analyzed the four Brazilian Portuguese versions and produced a *Synthesis Version of Translations* adapting the terms to the culture of the target population. The expert committee was formed by three physicians and two registered dietitians with experience in public health or internal medicine, and also by one of the professional bilingual translators that participated in Step 2.

Step 4: back translation

The *Synthesis Version of Translations* was then back-translated into English by two other independent professional translators. Both translators were native English speakers and fluent in Brazilian Portuguese with no previous knowledge of the original version of FINDRISC in English.

Step 5: back-translation review

The authors of FINDRISC and the expert committee compared both back-translations with the original English version, looking for discrepancies. In this process, the semantic, idiomatic, experiential, and conceptual equivalences between versions were assessed²⁶, and a *Synthesis version of reverse translations* was created.

Step 6: understanding

The *Synthesis version of reverse translations* was field-tested on 17 health professionals (physicians, dieticians, nurses, and nursing technicians) and 15 subjects from the same primary care health center to check whether every question and the questionnaire as a whole were adequately understood. A Likert-type scale was used with the guiding question 'Do you understand what was asked?'. Scores ranged from 0 ('I did not understand anything') to 5 ('I understood perfectly and have no doubts'). Values ≥ 3 were taken as an indication of satisfactory comprehension²⁷. The interviewer simply read each item and recorded its score. Results showed 100% comprehension of FINDRISC-Br by health professionals and subjects alike. No adjustments being needed, this Brazilian Portuguese version became final.

Step 7: proofreading

Final review of FINDRISC's translation and cross-cultural adaptation was carried out. The text of FINDRISC-Br was formatted and minor spelling and grammatical errors corrected. Further to this, the permission was asked from the Finnish Diabetes Association to use their layout of the FINDRISC questionnaire, which was adopted for FINDRISC-Br (Figure 2).

Step 8: final report

Detailed description of all steps and decisions taken as part of the translation and cross-cultural adaptation process for FINDRISC, thus recording the development of the whole process.

ASSESSMENT OF TEST-RETEST RELIABILITY

A non-random sample of 105 people from the primary care health center was initially enrolled to assess test-retest reliability. Twenty-two of them missed the two-week evaluation (retest), resulting in 83 individuals with test and retest. Reasons for missing retest were: health problems ($n = 4$), occupational commitments ($n = 2$), refusals ($n = 3$), and failure to reach the participant ($n = 13$). No statistical differences were found in baseline FINDRISC-Br scores between participants and non-participants in the re-examination (chi-square test, $p > 0.05$). A descriptive analysis of the first interviews ($n = 83$) is presented in Table 1. The sample was mainly composed by women (74.7%), mean age of 52.3 years (standard deviation = 16.4 years). Almost 40% of subjects scored ≥ 15 on the FINDRISC-Br questionnaire (Table 1).

The test and retest agreement levels are shown in Table 2. Although some items of the questionnaire presented coefficients lower than 0.8, the questionnaire as a whole presented high reliability (Cohen's kappa = 0.82, 95%CI 0.72 – 0.92 and ICC = 0.94, 95%CI 0.91 – 0.96).

FORMULÁRIO DE AVALIAÇÃO DE RISCO DE DIABETES TIPO 2 (ESCALA FINDRISC)

Marque com "X" a resposta adequada e some seus pontos

1. Idade

- () Abaixo de 45 anos (0 ponto)
 () 45 a 54 anos (2 pontos)
 () 55 a 64 anos (3 pontos)
 () Acima de 64 anos (4 pontos)

2. Índice de massa corporal

- () Abaixo de 25 kg/m² (0 ponto)
 () 25 a 30 kg/m² (1 ponto)
 () Maior que 30 kg/m² (3 pontos)

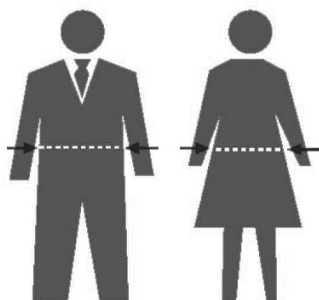
3. Circunferência da cintura medida na altura do umbigo (figura)

HOMENS

- () Menos de 94 cm
 () 94 a 102 cm
 () Mais de 102 cm

MULHERES

- () Menos de 80 cm (0 ponto)
 () 80 a 88 cm (3 pontos)
 () Mais de 88 cm (4 pontos)



4. Pratica atividade física diariamente durante pelo menos, 30 minutos, no trabalho e/ou durante o tempo livre (incluindo as atividades da vida diária)?

- () Sim (0 ponto)
 () Não (2 pontos)

5. Com que frequência come verduras, legumes e frutas?

- () Todos os dias (0 ponto)
 () Não como todos os dias (1 ponto)

6. Você toma regularmente ou já tomou medicação para pressão alta?

- () Não (0 ponto)
 () Sim (2 pontos)

7. Você já apresentou glicemia (açúcar no sangue) elevada (ex. num exame de rotina, durante um problema de saúde ou durante a gravidez)?

- () Não (0 ponto)
 () Sim (5 pontos)

8. Você tem alguém na família que foi diagnosticado com diabetes (do tipo 1 ou tipo 2)?

- () Não (0 ponto)
 () Sim: avós, tia, tio, primos de primeiro grau (mas não os pais, irmãos ou filhos) (3 pontos)
 () Sim pais, irmãos ou filhos (5 pontos)

Pontuação total

O risco de desenvolver diabetes tipo 2, nos próximos 10 anos, é:

- Menor que 7 pontos** RISCO BAIXO; estima-se que 1 em cada 100 indivíduos irá desenvolver a doença
7 a 11 pontos RISCO DISCRETAMENTE AUMENTADO; estima-se que 1 em cada 25 indivíduos irá desenvolver a doença
12 a 14 pontos RISCO MODERADO; estima-se que 1 em cada 6 indivíduos irá desenvolver a doença
15 a 20 pontos RISCO ALTO; estima-se que 1 em cada 3 indivíduos irá desenvolver a doença
Maior que 20 pontos RISCO MUITO ALTO; estima-se que 1 em cada 2 indivíduos irá desenvolver a doença

Figure 2. Brazilian version of Finnish Diabetes Risk Score (FINDRISC) questionnaire.

Table 1. Characteristics of subjects included test-retest reliability (n = 83).

Variable	N	%
Gender		
Male	21	25.30
Female	62	74.70
Age group (years)		
< 45	23	27.71
45–54	15	18.07
55–64	24	28.92
> 64	21	25.30
Body-mass index (kg/m²)		
< 25	17	20.48
25–30	34	40.96
> 30	32	38.55
Waist circumference (cm)		
Man < 94, woman < 80	10	12.05
Man 94–102, woman 80–88	15	18.07
Man > 102, woman > 88	58	69.88
Physical activity ≥ 30 min/day		
Yes	59	71.08
No	24	28.92
Daily consumption of fruit and vegetables		
Every day	66	79.52
Not every day	17	20.48
Personal history of use of antihypertensive drugs		
No	44	53.01
Yes	39	46.99
Personal history of hyperglycemia		
No	67	80.72
Yes	16	19.28
Family history of diabetes		
No	31	37.35
Yes: grandparent, aunt, uncle or first cousin	15	18.07
Yes: parent, brother, sister or own child	37	44.58
FINDRISC score		
< 7	12	14.46
7–11	22	26.51
12–14	16	19.28
15–20	29	34.94
> 20	4	4.81

FINDRISC: Finnish Diabetes Risk Score.

DISCUSSION

This paper provides the first official Brazilian Portuguese version of FINDRISC in alignment with ISPOR guidelines. In the past, translation and cross-cultural adaptation of such tools amounted to be a simple translation or, at best, performing comparisons between the original tool and its back-translation²⁸. The ISPOR guidelines were developed to reduce the heterogeneity of methods. These guidelines have been used extensively to translate and adapt health questionnaires in Brazil²⁹⁻³² and across the world^{33,34}.

The present translation and cultural adaptation of FINDRISC took place without unexpected difficulties. Question number 5, which refers to the consumption of fruits, vegetables, and berries in the original version, needed to be adapted and the term “berries” was dropped in line with Brazilian culture and commonly available varieties of food in the country. The assessment of test-retest reliability of FINDRISC-Br showed Cohen’s kappa and ICC values higher than 0.8 for the questionnaire as a whole, showing adequate reliability. However, the level of agreement was below 0.8 for two questions: physical activity and consumption of fruits and vegetables. We believe that these two questions were those most sensitive in the questionnaire since participants might have changed their answer at retest due to social desirability bias. This bias, well known in epidemiology, regards participants either denying undesirable characteristics or attributing themselves desirable characteristics³⁵.

The FINDRISC questionnaire was originally developed as a tool to predict T2DM in Finland¹. Nowadays it is used around the world^{3,8,36}, being easy to use, quick to apply, non-invasive, and low-cost. FINDRISC has also become useful to screen T2DM in populations previously not known to have T2DM^{11,12}. FINDRISC-Br could be used in Brazil in, either way,

Table 2. Test-retest agreement levels for the Brazilian version of the Finnish Diabetes Risk Score (FINDRISC-Br) items in terms of Cohen’s kappa coefficients and intraclass correlation coefficients (ICC) with the corresponding 95% confidence intervals (95%CI).

FINDRISC variables	Kappa (95%CI)	ICC (95%CI)
Age (years)	0.97 (0.92 – 1.00)	0.96 (0.94 – 0.98)
Body-mass index (kg/m ²)	0.92 (0.85 – 0.99)	0.96 (0.93 – 0.97)
Waist circumference (cm)	0.93 (0.86 – 0.99)	0.95 (0.93 – 0.97)
Physical activity ≥ 30 min/day	0.79 (0.64 – 0.94)	0.79 (0.69 – 0.86)
Daily consumption of fruit and vegetables	0.63 (0.41 – 0.84)	0.63 (0.48 – 0.74)
Personal history of use of antihypertensive drugs	0.93 (0.85 – 1.00)	0.93 (0.89 – 0.95)
Personal history of hyperglycemia	0.96 (0.88 – 1.00)	0.96 (0.94 – 0.98)
Family history of diabetes	0.87 (0.77 – 0.96)	0.88 (0.82 – 0.92)
FINDRISC total score	0.82 (0.72 – 0.92)	0.94 (0.91 – 0.96)

to predict T2DM prospectively and to screen for previously undiagnosed T2DM. T2DM is a public health problem in Brazil, where almost half of people with diabetes are unaware of their condition³⁷. Since T2DM is mostly asymptomatic during the first years of the disease onset, screening with a simple and inexpensive tool such as FINDRISC-Br is warranted.

This study may present some limitations. First, we did not validate FINDRISC-Br and therefore do not know yet the cut-off values for our population. Second, we used a non-random sample, which could bias the scores we found.

CONCLUSION

FINDRISC was translated into Brazilian Portuguese and culturally adapted following standard procedures, thus producing FINDRISC-Br. Validation is still needed, but already in the meantime, we believe that FINDRISC-Br has good potential as a reliable screening tool in different Brazilian settings and applications.

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