

Original Research

Validation of Thyroid-Specific Quality of Life questionnaire Thypro-39 in Brazilian Portuguese

Jônatas Catunda de Freitas ^{1,2,*}, Lucas Barbosa Sampaio ², Emile Nycolle da Silva Souza ², Maria Luiza Viana Sampaio ², Lucas Antônio Martins Lira ²

¹ Postgraduate program in Medical-Surgical Sciences, Federal University of Ceará, Fortaleza, Ceará, Brazil.

² Christus University Center, Fortaleza, Ceará, Brazil.

* Correspondence: gepccpuc@gmail.com.

Abstract: The purpose of the study is to validate ThyPRO-39 questionnaire to Brazilian Portuguese. The validated Portugal Portuguese version of ThyPRO-39, provided by the questionnaire developer, was used to adapt it to Brazilian Portuguese and these changes were validated by a translator. A cross-sectional study was carried out on people with thyroid disease, who were invited to participate in the research through the study author's social media. Each participant accessed the link, accepted the research terms and answered 2 quality of life questionnaires, SF-36 and ThyPRO-39br. The ThyPRO-39br questionnaire was validated by 3 complementary techniques: convergent validation comparing the results obtained in both questionnaires, internal consistency validation of the ThyPRO-39br responses and clinical validation. The study occurred between August 2020 and October 2020 and included 516 participants. Results obtained in both questionnaires, SF-36 and ThyPRO-39br, showed moderate correlation in all similar scales, Cronbach's alpha was higher than 0.7 in 10 of the 12 scales, and the clinical validation showed that results obtained were compatible with the expected for the patient diagnosis. Regarding the convergent validation between the ThyPro-39br and SF-36 questionnaires, the strongest correlations were found between the final composite score of ThyPRO-39br and SF-36 functional capacity (-0.591, $p < 0.001$), impact on daily life and physical aspects (-0.568, $p < 0.001$), and anxiety and mental health (-0.541, $p < 0.001$). The ThyPRO-39br version was satisfactorily validated through 3 different methods and is available for future thyroid diseases quality of life research in Brazil.

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1. Introduction

Most thyroid diseases need chronic treatment that has to be done properly to optimize the patient's quality of life [1]. Hormonal changes, such as hypothyroidism or hyperthyroidism, and structural changes, such as nodules, cysts and goiter, may arise related to incurable autoimmune diseases such as Hashimoto's thyroiditis and Graves' disease, or treatments, such as radioiodine therapy and total thyroidectomy [2]. Few patients with thyroid disease are clearly symptomatic. In Hashimoto's thyroiditis, thyroid nodules and thyroid cancer, patients can remain asymptomatic for years or decades. On the other hand, many of the symptoms are nonspecific, such as fatigue, fluid retention, dry skin, changes in mood, changes in sleep and bowel habits, and are present in up to 17% of the population even with normal thyroid hormone levels [3].

The treatment of hormonal disorders such as hypothyroidism and hyperthyroidism are indicated based on laboratory tests results such as TSH and free T4 [2]. However, it is

common that some patients do not feel improvement of symptoms even if they are properly treated and have normal test results, referring lower quality of life [4]. What is the reason for the therapeutic failure in these cases: wrong diagnosis, overlapping of other diseases, inadequate treatment or perception of poor health status simply by the diagnosis of thyroid disease? The answer can be found through the use of questionnaires on quality of life [5].

Health related quality of life can be defined as the overall impact that diseases and their treatment cause in all relevant dimensions of life, a subjective concept that includes physical, mental and social aspects of well-being, and only can be evaluated by the patient himself [6]. Thyroid-related patient-reported outcome-39 (ThyPRO-39) is the most used thyroid disease quality of life questionnaire, because is superior to generic questionnaires for addressing specific aspects of thyroid diseases, such as various symptoms and the effect of the disease on the patient's psychological state [7]. It is superior to other thyroid disease questionnaires too because covers all thyroid diseases instead of evaluating only hyperthyroidism [8] or hypothyroidism [9], since problems commonly coexist (for example, goiter and hyperthyroidism) and the treatment of one disease leads to another (for example, hyperthyroidism treatment with radioiodine therapy leads to hypothyroidism) [10].

The original ThyPRO questionnaire contains 85 questions distributed in 13 categories scored from 0 to 100, higher score meaning more impact on quality of life. In 2015 an abbreviated version with only 39 questions, the ThyPRO-39, was developed and is recommended as an alternative to the original version, because maintains the results quality and is answered faster [10]. The abbreviated version contains: 4 physical symptoms scales (goiter, eye, hypothyroidism and hyperthyroidism symptoms); 7 well-being, physical, mental and social function scales (anxiety, depressivity, tiredness, cognitive complaints, emotional susceptibility, impaired social life, impaired daily life); a cosmetic complaints scale; a single scale about overall quality of life impact; and composite scale which summarizes the result of the seven well-being and function scales [10].

Since 2009, ThyPRO questionnaire has been applied in a variety of thyroid disorders clinical investigation, such as autoimmunity marker's role in primary hypothyroidism quality of life in Danish patients [11], the impact of different treatments on quality of life in multinodular goiter, Graves' disease and subclinical hypothyroidism [12–15], in studies carried out on Serbian, Danish and Indian populations. Initially, its use was proposed for benign diseases, and thyroid cancer was an exclusion criterion. Later, ThyPRO application in patients with thyroid cancer was validated [16] and has been used in several studies on thyroid cancer quality of life studies [7].

Originally written in Danish and English, ThyPRO has already been translated and culturally validated in several languages such as German, Dutch, Italian, Portugal Portuguese, French, Swedish, Serbian, Polish, Romanian, Bulgarian, Greek, Arabic, Simplified Chinese, Traditional Chinese, Hebrew, Hindi and Tamil and most translated versions were subjected to cross-cultural validation [6]. However, a ThyPRO Brazilian Portuguese version wasn't available and its application in the Brazilian population had never occurred. The aim of the present study was to validate the ThyPRO-39 Brazilian Portuguese version as a tool for analyzing the thyroid diseases patient's quality of life.

2. Material and Methods

2.1 Study design

This is a cross-sectional observational study in which two health related quality of life questionnaires were applied on thyroid disease patients to validate ThyPRO-39 Brazilian Portuguese version. The study included patients with thyroid disorders who became aware of the research through social media and accepted to participate. Was allowed to participate only people from 18 years of age with any thyroid disease (goiter, hypothyroidism, hyperthyroidism, thyroid nodule and thyroid cancer).

Data collection was performed through a digitally applied questionnaire on Google Forms platform, carried out between August 2020 and October 2020. The research was disseminated on the study author's social media (YouTube channel - Dr Jônatas Catunda, Instagram profile @drjonatascatunda and Facebook page - Dr Jônatas Catunda), which together have more than 170.000 subscribers. On these channels, there are more than 500 free videos about thyroid disease and head and neck surgery with high quality and made for patients. Something unexpected that happened was that the research participants themselves actively and voluntarily shared information about the study and the access link in thyroid disease patients' groups on Facebook and Whatsapp.

2.2 Cultural adaptation for Brazilian portuguese

The validated Portugal Portuguese version of the ThyPRO-39 questionnaire [18] provided by Torquil Watt, questionnaire developer, was used as a basis for cultural adaptation. Few modifications were made to adapt it to Brazilian Portuguese and these changes were validated by a language specialist with scientific knowledge.

2.3 Health related quality of life instruments

Were used the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) already validated in Brazil and available in Brazilian Portuguese [17], and the Thyroid-Related Patient-Reported Outcome 39 Brazilian Portuguese version (ThyPRO-39br). ThyPRO-39 responses are scored from 0 to 4, following a Likert scale (where " 0 " is equal to " no " and " 4 " is equal to " much "), always considering the perception of patient during the past four weeks. The results are distributed in 13 scales that generate a score from 0 to 100 for each of them, the higher the score the greater the impact on quality of life. The SF-36 questionnaire has 11 questions and 36 items, bringing results in 9 components scored from 0 to 100, the more points the better the quality of life.

2.4 Statistical analysis

The collected data were stored and organized in a spreadsheet using Google Sheets, passed through anonymization process and analyzed using the SPSS version 21. Qualitative or nominal variables were expressed as absolute counting and relative frequency through percentages, being compared with the chi-square test. Student's t or Mann-Whitney tests were used to compare two groups, and the Kruskal-Wallis test (Dunn's post test) was used for comparisons between 3 groups. All analyzes considered $p < 0.05$ as significant.

The ThyPRO-39br validation was performed by 3 complementary techniques: convergent validation with SF-36, internal consistency validation and clinical validation. The convergent validation between ThyPRO-39 and SF-36 was assessed using Spearman correlations. Internal consistency validation is a form of measurement based on the correlation between different items in the same test, assessing whether different questions produce similar results. It is evaluated by Cronbach's alpha coefficient, which varies from 0 to 1. Values above 0.9 are considered excellent, above 0.8 very good, and above 0.7 it is considered satisfactory internal consistency. Clinical validation was performed by comparing the results obtained in the 13 scales in different subgroups of diagnoses: hypothyroidism, hyperthyroidism, anxiety / depression, to test the results obtained in the different scales of ThyPRO-39br.

2.5 Ethics

The study was approved by the Ethics Committee of the Christus University Center under protocol number 4.079.309 following all the principles and rules that regulate research in human beings, of the National Health Council, Resolution N^o. 466 / 2012. When accessing the survey link, the participant read the consent form and only passed on to the questionnaires if he accepted the survey terms.

3. Review

Table 1 shows the demographic and clinical characteristics of the study subjects. A total of 516 participants answered the survey, with an average age of 37 years. 95.3% (492) were female, 49% (253) had thyroid cancer, 35.3% (182) reported having a thyroid nodule, 31.4% (162) reported hypothyroidism and 10.9% (56) reported hyperthyroidism. Probably had inconsistent results in diagnosis and treatment information, due study design (answered by patients himself without an interviewer and chart review). The average treatment time was 50 months. Three hundred and two participants (58.5%) reported having been diagnosed with anxiety / depression / fibromyalgia, with 20.5% (106) currently undergoing treatment for depression / anxiety. Three hundred participants underwent some type of thyroid surgery, 91.67% of them underwent total thyroidectomy and 8.33% underwent partial thyroidectomy. The main indication for surgery was suspected thyroid cancer, followed by goiter and hyperthyroidism, corresponding to 88.67%, 8.67% and 1.33% respectively.

Table 1. Demographic and clinical characteristics of the study subjects.

	Total (n = 516)	
Age, mean (range)	37.34 ± 9.4	(18-75)
Sex		
Female	492	95.3%
Male	24	4.7%
Current diagnosis		
Thyroid cancer	253	49%
Thyroid nodule	182	35.3%
Hypothyroidismo	162	31.4%
Hyperthyroidism	56	10.9%
Treatment time in months - mean (range) SD	50 ± 67	(1-494)
Another diseases		
Anxiety or depression	106	20.5%
Hypertension / Diabetes / Cholesterol	93	18%
Anemia	18	3.5%
Asthma	15	2.9%
Surgery		
Did not	216	41.9%
Total thyroidectomy	275	53.3%
Partial thyroidectomy	25	4.8%
Indication of surgery		
Cancer or suspected cancer	266	88.67%
Bulky goiter	26	8.67%
Hyperthyroidism	4	1.33%

3.1 Convergent validation between ThyPRO-39br and SF-36

In practically all associations between the ThyPRO-39br scales and the SF-36 scales, there was statistical significance ($p < 0.001$) and Spearman's coefficient with moderate correlations (between 0.4 and 0.7) on similar scales, supporting convergent validation (Table 2). The strongest correlation was between the final composite result of ThyPRO-39br with the functional capacity of SF-36 (-0.591 , $p < 0.001$).

Table 2. Convergent validation between the ThyPRO-39br questionnaire and the SF-36 through Spearman's correlation.

ThyPRO-39br scales	SF-36 scales								
	Physical funcion	Social function	Role physical	Role emotional	Mental health	Vitality	Bodily pain	General health	Change in health
Goiter symptoms	-, 345 **	-, 124 **	-, 272 **	-, 213 **	-, 201 **	-, 102 *	,383 **	, 163 **	, 175 **
Hyperthyroidism symptoms	-, 453 **	-, 096 *	-, 342 **	-, 320 **	-, 329 **	-, 217 **	, 460 **	, 211 **	, 178 **
Hypothyroidism symptoms	-, 469 **	-, 168 **	-, 356 **	-, 362 **	-, 286 **	-, 192 **	,453 **	, 240 **	, 227 **
Eye symptoms	-, 477 **	-, 147 **	-, 351 **	-, 321 **	-, 316 **	-, 187 **	,458 **	, 223 **	, 157 **
Tiredness	-, 478 **	-, 162 **	-, 397 **	-, 376 **	-, 377 **	-, 262 **	, 418 **	, 246 **	, 252 **
Cognitive complaints	-, 374 **	-0.026	-, 316 **	-, 339 **	-, 369 **	-, 216 **	, 355 **	, 169 **	, 151 **
Anxiety	-, 442 **	0.049	-, 371 **	-, 483 **	-, 541 **	-, 247 **	, 413 **	, 164 **	, 204 **
Depressivity	-, 446 **	-0.063	-, 346 **	-, 463 **	-, 494 **	-, 205 **	, 394 **	, 215 **	, 256 **
Emotional susceptibility	-, 447 **	-0.041	-, 384 **	-, 431 **	-, 513 **	-, 303 **	, 436 **	188 **	, 270 **
Impaired social life	-, 442 **	-, 111 *	-, 404 **	-, 418 **	-, 370 **	-, 167 **	, 424 **	, 140 **	, 180 **
Impaired daily	-, 570 **	-, 108 *	-, 568 **	-, 475 **	-, 460 **	-, 266 **	, 543 **	, 227 **	, 281 **
Cosmetic complaints	-, 421 **	-, 136 **	-, 365 **	-, 366 **	-, 279 **	-, 157 **	, 399 **	, 218 **	, 181 **
Overall QoL impact	-, 549 **	-, 095 *	-, 490 **	-, 444 **	-, 356 **	-, 246 **	, 470 **	, 231 **	, 353 **
Composite scale	-, 591 **	-0.078	-, 520 **	-, 554 **	-, 574 **	-, 313 **	, 544 **	, 243 **	, 297 **

* The correlation is significant at the 0.05 (bilateral) level.

** The correlation is significant at the 0.01 (bilateral) level.

Similar scales in the 2 questionnaires are highlighted.

3.2 Validation of the internal consistency of the ThyPRO-39br questionnaire

The Table 3 shows the reliability of the internal consistency of ThyPRO-39br. Cronbach's alpha was higher than 0.7 in 10 of the 12 scales, and in two scales, symptoms of hyperthyroidism (0.647) and eye symptoms (0.688), did not reach the recommended standard of 0.7 but it was very close, possibly due to small proportion of patients with Graves' disease (5%) participating in the research. For cognitive complaints (0.904) and composite scale (0.948), Cronbach's alpha results were excellent, above 0.9.

3.3 Clinical validation

On symptoms of hypothyroidism scale, the group of patients who reported hypothyroidism had a higher average score than those without hypothyroidism (37.0) (Table 4). The group of patients who reported hyperthyroidism had higher mean scores on goiter symptoms (29.9), hyperthyroidism symptoms (41.4) and eye symptoms (33.3) scales than those who did not report hyperthyroidism. The group of patients who re-

ported being under treatment for Anxiety / Depression had higher scores on the Anxiety (63.4) and Depression (57.3) scales than the others. The average scores obtained on the scales are compatible with what was expected for the diagnosis of patients, confirming the clinical validation of the questionnaire.

Table 3. Scores descriptive statistics and internal consistency validation of ThyPRO-39br.

Scales	Average	DP	Variation	Cronbach's alpha
ThyPRO-39br				
Goiter symptoms	22.7	20.8	2-84	0.810
Hyperthyroidism symptoms	34.2	20.2	2-90	0.647
Hypothyroidism symptoms	34.1	25.4	0-100	0.746
Eye symptoms	31.7	22.8	1-89	0.668
Tiredness	54.3	12.9	0-92	0.882
Cognitive complaints	49.2	27.6	1-95	0.904
Anxiety	51.1	27.0	1-96	0.890
Depressivity	47.2	27.4	0-97	0.836
Emotional susceptibility	53.9	25.0	1-95	0.761
Impaired social life	33.2	29.5	0-100	0.761
Impaired daily	40.0	30.7	0-98	0.829
Cosmetic complaints	41.0	31.5	1-96	0.824
Overall QoL impact	50.1	37.3	0-100	NA*
Composite scale	48.8	20.6	5.7-95.4	0.948
SF-36				
Physical function	68.0	26.3	0-100	
Social function	49.7	14.2	0-100	
Role physical	46.6	42.5	0-100	
Role emotional	37.9	42.7	0-100	
Mental health	53.9	9.9	20-76	
Vitality	53.1	9.8	20-80	
Bodily pain	41.9	26.1	0-100	
General health	54.2	11.9	20-95	
Change in health	48.8	28.0	0-100	

SD standard deviation, NA not applicable.

* Just one question on the scale.

4. Discussion and Conclusion

The main purpose of this research was adapting the ThyPRO-39 questionnaire to Brazilian Portuguese, allowing other researchers to develop studies on thyroid diseases quality of life in Brazil, what would allow to compare their results with international

studies. In addition to ThyPRO-39 be reliable and specific for malignant and benign thyroid diseases, is it's also cross-culturally valid and adopted in several languages [18].

Table 4. Clinic validation - Using ThyPRO-39 to make comparisons between groups - Hypothyroidism, Hyperthyroidism, Anxiety/depression.

	Does not report hypothyroidism (n = 354)		Report Hypothyroidism (n = 162)		p	Does not report Hyperthyroidism (n=430)		Report Hyperthyroidism (n=162)		p	No treatment for anxiety/depression (n=410)		Undergoing treatment for anxiety/ depression (n=106)		p
	Average	DP	Average	DP		Average	DP	Average	DP		Average	DP	Average	DP	
Goiter symptoms	23.4	21.6	21.4	18.7	0.594	21.9	19.9	29.9	25.6	0.031*	21.4	19.9	27.7	23.1	0.012*
Hyperthyroidism symptoms	33.4	20.6	35.9	19.1	0.156	33.3	20.1	41.4	19.6	0.006*	32.7	19.9	40.0	20.2	0.001*
Hypothyroidism symptoms	32.8	25.0	37.0	26.1	0.095	33.1	25.2	42.5	25.4	0.008*	32.5	25.2	40.4	25.1	0.003*
Eye symptoms	30.1	22.1	35.3	23.9	0.017*	31.5	22.9	33.3	21.8	0.438	30.6	22.8	36.3	22.3	0.011*
Tiredness	53.2	13.1	56.9	12.1	0.002*	54.0	12.8	57.2	12.8	0.105	53.5	13.0	57.6	11.6	0.004*
Cognitive complaints	46.4	27.9	55.2	26.1	0.001*	48.7	27.8	53.1	25.9	0.265	47.0	27.1	57.7	28.1	<0.001*
Anxiety	49.8	27.1	53.8	26.9	0.107	50.6	27.3	55.4	24.7	0.221	47.9	26.6	63.4	25.4	<0.001*
Depressivity	45.9	27.2	50.1	27.7	0.094	47.1	27.7	48.3	24.8	0.666	44.6	27.2	57.3	26.0	<0.001*
Emotional susceptibility	52.9	24.4	56.1	26.1	0.146	53.6	25.3	56.2	22.2	0.558	51.7	24.9	62.3	23.5	<0.001*
Impaired social life	32.3	29.3	35.0	29.9	0.285	32.3	29.1	40.5	31.7	0.62	31.0	29.5	41.5	28.0	<0.001*
Impaired daily	37.9	30.7	44.6	30.3	0.013*	39.6	30.6	43.3	31.7	0.39	37.6	30.7	49.0	29.1	<0.001*
Cosmetic complaints	39.1	30.3	45.1	33.7	0.071	40.5	31.7	45.1	29.8	0.245	38.9	31.4	49.3	30.9	0.003*
Overall QoL impact	47.9	37.3	54.9	36.8	0.050*	49.0	36.9	59.4	39.5	0.045*	48.2	37.6	57.3	35.5	0.030*
Composite scale	47.2	20.6	52.2	20.4	0.007*	48.3	20.6	52.8	20.8	0.157	46.5	20.5	57.4	18.9	<0.001*

* Statistically significant result - p <0.05, Mann-Whitney test.

There are several ways to validate the ThyPRO questionnaire for a language. It was found since articles validating the translation only with translators without applying the questionnaire [19] to articles like the present study in which at least 3 different techniques were used to validate the translation. In addition to cultural adaptation by a specialist in the language, a correlation with another quality-of-life questionnaire, the SF-36, an internal consistency validation using Cronbach's alpha and clinical validation through the analysis of subgroup responses was performed. The most used method for ThyPRO-39 translation validation is the internal consistency using Cronbach's alpha (Table 5). In the present study, Cronbach's alpha was greater than 0.7 in 10 of the 12 scales and was very close in the two in which it did not reach this value, symptoms of hyperthyroidism (0.647) and eye symptoms (0.668), possibly due to the small proportion of patients with Graves' Diseases (5%) who are the ones that generally present a higher incidence of these symptoms.

In the 2 studies in which 12 of the 12 scales obtained alpha > 0.7 [20, 21], the answers were collected by an interviewer, which may justify the difference between the present study in which the data collection was digitally done by the patient himself. Clinical validation was analyzed by comparing subgroups and obtained results similar to those published in other studies, such as higher scores on the scales on symptoms in patients

with Hyperthyroidism [13]. The ThyPRO-39br version was satisfactorily validated through 3 different methods and is available for future thyroid diseases quality of life research in Brazil.

Table 5. Similar ThyPRO translation validation studies.

Author	Language	Questionnaires	n	Cronbach's alpha
1 Present study	Portuguese	ThyPRO-39 and SF-36	516	12/10
2 [20]	Romanian	ThyPRO and ThyPRO-39	130	12/12
3 [28]	Greek	ThyPRO and ThyPRO-39	143	NA*
4 [6]	Spanish	ThyPRO and ThyPRO-39	155	12/10
5 [29]	Mandarin	ThyPRO-39, SF-6D, SF-12v2	308	12/06
6 [19]	Polish	ThyPRO	0	NA**
7 [21]	Serbian	ThyPRO	147	12/12

* Study did not use the cronbach alpha in the methodology, only comparing the answers in your language with answers in the original language.

** Study did not apply the translated questionnaire to a sample.

The ThyPRO-39 questionnaire is currently the most relevant in terms of thyroid diseases quality of life and has been used in the main lines of research and innovation in thyroid, such as transoral surgical techniques [22], percutaneous nodule ablation [23], and in several studies and trials [24] [25] because it has great capacity to adapt to different thyroid diseases at different treatment moments. The THYCA-QoL is a thyroid cancer survivors' quality of life questionnaire that also and has been widely used [26]. It works like ThyPRO-39, contains 24 questions each scored from 1 to 4 that assess the thyroid cancer or treatment symptoms that are grouped into seven multiple symptom scales and six single symptom scales. Higher score suggests more impact on quality of life, and they are very specific for changes related to the treatment of thyroid cancer with surgery and radioiodine therapy, such as hoarseness and hypoparathyroidism [27].

Initially, ThyPRO was designed only for benign thyroid diseases, but it has already been validated for use in patients with thyroid cancer [16] and has also been effective in the study of thyroid surgery postoperative period [scales - symptoms of goiter and appearance], being used in studies comparing quality of life before and after surgery [12]. Thus, the ThyPRO-39 questionnaire has an advantage over the use of THYCA-QoL because it can be used in a greater variety of patients, allowing comparisons between subgroups such as before and after surgery and cancer and non-cancer. The disadvantage, however, is that it does not have specific scales for the surgery common complications like hypoparathyroidism.

In this study the questionnaires were answered by the patient himself, through the computer or cell phone, without the presence of an evaluator and without access to medical record, what could had affected the quality of data about diagnosis and treatment, because many times the patient cannot say what he has or the reason for the treatment. On the other hand, this strategy brought several advantages: the data were obtained quickly and on an unprecedented scale in such a short time, responses possibly truer due to the absence of interference from the interviewer, which ensured a high quality in the results due to the size and diversity of the sample.

Among the implications for clinical practice, the strong association between healthy habits (e.g., physical activity, healthy eating, and weight control) and quality of life reinforces the importance of providing such recommendations to patients during their clinical follow-up. Additionally, considering that 41.1% reported having been diagnosed with anxiety/depression/fibromyalgia, actively addressing these conditions is crucial, as

they have the potential to impact quality of life. The present study was carried out in an innovative way digitally and collected data from a very heterogeneous sample. It was possible to validate the adapted version ThyPRO-39br and, from now on, further research can be carried out using this tool to refine the results found, including in a longitudinal way.

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Supplementary Materials: None.

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