

The Hopkins symptoms checklist in 25 items: translations in Castilian, Galician, Catalan, French, Greek, Italian, Polish, Bulgarian and Croatian synthesis

Tanguy Le Bris

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UNIVERSITE DE BRETAGNE OCCIDENTALE. FACULTE DE MEDECINE ET DES SCIENCES DE LA SANTE DE BREST.

THÈSE DE DOCTORAT en MÉDECINE

DIPLOME D'ÉTAT

SPÉCIALITÉ: Médecine Générale

THE HOPKINS SYMPTOMS CHECKLIST IN 25 ITEMS: TRANSLATIONS IN CASTILIAN, GALICIAN, CATALAN, FRENCH, GREEK, ITALIAN, POLISH, BULGARIAN AND CROATIAN SYNTHESIS.

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Le 8 juin 2017

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Serment d'Hippocrate

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences.

Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

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Admis(e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les moeurs.

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Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé(e) si j'y manque.

Autorisation d'imprimer

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Faculté de Médecine

AUTORISATION D'IMPRIMER

Présentée par Monsieur le Professeur LE RESTE Jean Yves

Titre de la thèse

THE HOPKINS SYMPTOMS CHECKLIST IN 25 ITEMS: TRANSLATIONS IN CASTILIAN, GALICIAN, CATALAN, FRENCH, GREEK, ITALIAN, POLISH, BULGARIAN AND CROATIAN SYNTHESIS.

ACCORD DU PRESIDENT DU JURY DE THESE SUR L'IMPRESSION DE LA THESE ;
OUI

En foi de quoi la présente autorisation d'imprimer sa thèse est délivrée à Mr LE BRIS Tanguy Né le 12 mars 1989 à Concarneau

Fait à BREST, le 10 Mars 2017

VISA du Doyen de la faculté A BREST, le 12-04-17

Le Doyen,

C. BERTHIOU

Le Président du Jury de Thèse,

Liste des abréviations

EGPRN: European General Practice Research Network

FPDM: Family Practice Depression and Multimorbidity

HSCL-25: Hopkins Symptom Checklist - 25 items

DSM: Diagnostic and Statistical Manual of Mental disorders

RAND/UCLA: Research and Development Corporation and the University of

California Los Angeles

PT: Pilot Team

GP: General Practician

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Resumé

Introduction:

La dépression est la deuxième maladie chronique rencontrée en soins primaires. Les variations interindividuelles et interculturelles peuvent modifier l'expression des symptômes.

L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) a permis de sélectionner la Hopkins Symptom Checklist en 25-items (HSCL-25) comme la plus appropriée a diagnostiquer la dépression selon les critères d'efficacité, de reproductibilité et d'ergonomie versus DSM.

L'objectif était de synthétiser les traductions linguistiques, effectué à partir de l'anglais, préalablement réalisés en Galicien, Castillan, Catalan, Français, Italien, Grec, Croate, Bulgare, Allemand, Polonais.

Méthode :

Une traduction aller-retour par une procédure Delphi a été réalisée pour obtenir un consensus. Un panel de médecins généralistes experts a été recruté par un investigateur national (NI) dans chaque pays. Les données quantitatives ont été faites grâce à une échelle de Likert. Les consentements et l'anonymat ont été guaranti par les NI. Les traductions retour ont été réalisées à l'aveugle de l'original.

Résultats:

Le panel d'experts répondait aux critères d'inclusion. Une seule ronde delphi à été nécessaire en Pologne, Bulgarie, Castille et Catalogne, concernant l'Allemagne, une version existait déjà, les items ont été acceptés avec des remarques, deux rounds furent nécessaires en France, Croatie, Grèce, Galice et en Italie après désaccord des experts sur certains items. Aucun autre round n'a été nécessaire.

Discussion:

Le choix d'une méthode de traduction Aller-Retour par procédure Delphi adaptée et la qualité du panel d'experts garantissent une traduction fidèle de la HSCL-25. L'intérêt de ces traductions à partir de l'anglais est dans l'enseignement, la recherche et la pratique en soins primaires.

Conclusion:

Une traduction de la HSCL-25 est disponible dans 9 langues européennes. La prochaine étape est une analyse culturelle de la traduction qui assurera la reproductibilité sémantique entre la version originale et la traduction.

Abstract

Introduction:

Depression is the second most common chronic disorder in primary care. Interindividual and cross-cultural variations can alter the expression of symptoms.

The 25-item Hopkins Symptom Checklist (HSCL-25) was selected by the Family Practice Depression and Multimorbidity (FPDM) study of the European General Practice Research Network (EGPRN) as the most appropriate to diagnose depression according to criteria efficiency, reproducibility and ergonomics versus DSM.

The objective was to synthesize the linguistic translations previously produced in Galician, Castilian, Catalan, French, Italian, Greek, Croatian, Bulgarian, German, Polish.

Method:

Backward-forward translation by Delphi rounds was used to make consensus. A panel of general practitioners (Gp) experts was recruited by a national investigator (NI) in each country. The quantitative data was made with a Likert scale. Consents and anonymity were guaranteed by NI. The backward translation was carried out blind from the original.

Results:

The panel complies with the inclusion criteria. A single round delphi was needed in Poland, Bulgaria, Germany, Castile and Catalonia, a German version already existed, items were accepted with commantaries. Two were necessary in France, Croatia, Greece, Galicia, Italy after experts disagreed on few items. No more rounds were necessaries.

Discussion:

Delphi procedure and the quality of the panel of experts guarantee a validated and reliable translation of the HSCL-25. The interest of these translations from English is in teaching, research and practice in primary care.

Conclusion:

A translation of the HSCL-25 is available in 9 European languages. The next step is a cultural analysis of the translation which will ensure the semantic reproducibility between the original version and the translation.

1-Introduction

Depression is the second most common chronic disorder seen by primary care physicians (1), first responders in most European Countries (2,3). The multi-morbid patients over 50 years are especially at risk (4–10).

Prevalence and incidence rates of depression are different according to regions and European countries (11-15). These Variations can be explained by différences in the health care system, practices, concepts and objectives as well as cultural variations in the expression of the disease (25, 16-22).

Depression combinate associated various symptoms. It is a syndromic disease difficult to diagnose. Patients often have difficulty assessing their psychological pain to doctors (23, 24), thus, clinicians may underestimate or overestimate the contrary, the severity of the disease (25-26). The difficulties to diagnose and assess the severity of depression lie in this inter-individual variability (27). Those difficulties may lead to inappropriate care and causes public health problems (28–31).

Diagnostic and Statistical Manual of Mental Disorders (DSM) can be considered as a diagnostic and categorical gold standard to diagnose depression (32). It is rarely used by practitioners (33, 34). General Practitioners (GPs') seem to be uncomfortable with the definition of depression and can result in delayed diagnosis and a no optimum care (25, 35-37).

Collaborative primary care mental health models can improve care and outcomes for patients. With this aim, the EGPRN developed collaborative research in Primary Care Medicine throughout Europe. This network requires a reliable, efficient and ergonomic tool which will take into account cultural and linguistic differences across Europe (38). International experts from different cultures, speaking different languages and with different health systems have to undertake a consensus (39), to identify such tools. These tools have to be acceptable and informative for both GPs and for secondary care (Psychiatrist, Psychologist) and to improve their collaboration (40-42). Screening for depression can bring added value to the identification of the condition if it can be undertaken in a routine manner in the doctor's surgery' but only if followed by good-quality treatment, either in primary care or in specialized psychiatric care (43).

The family practice depression and multi-morbidity study (FPDM) started in 2011. The first step was a systematic literature review in order to select the candidate tools. This systematic review investigated all diagnostic tools that were validated for depression versus DSM-IV/5, in adult patients excluding pregnant and post-partum women. At the end of this step, seven tools were selected (44,45).

The second step was a consensus procedure aiming to select a single tool among the seven candidates. The method chosen to reach a consensus was RAND/UCLA (Research ANd Development corporation / University of California Los Angeles) procedure. (46) HSCL-25 was designated to be the most appropriate tool for depression diagnostic in adult patients in Family practice in Europe, according to its criteria combined of effectiveness, reliability and ergonomics (47).

The third step consisted in translating this tool in the language of every country taking part in the FPDM study, following the same formal consensus method (48), with the support of European General Practice Research Network (EGPRN).

The HSCL-25 was translated in 10 different European languages (Croatian, Greek, Polish, Bulgarian, Italian, Galician, Castilian, Catalan, French and German) with the same Delphi consensus method adapted for Forward-Backward translation was followed for each.

The aim of this study was the linguistic synthesis translation.

2-Method

2.1. Definition of HSCL-25

The HSCL-25 is a self-report questionnaire on the existence and severity of both anxiety and depression symptoms during the previous week, used to identify psychiatric illness in primary care (49). It includes 25 items: 10 items about anxiety and 15 about depression (50). The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is \geq 1,55. A cut-off value of \geq 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment" (51,52). The HSCL-25 was used in primary care in family planning services, among refuges and among migrants (53–55).

For the translation to retain the same meaning as the original, a Forward-Backward translation (47)(56) was conducted following a formal consensus method, the Delphi procedure. Formal consensus is an appropriate method to reach a solid consensus transparently on a little investigated subject (57). Delphi procedure, reliable and efficient is used frequently in health care as a rigorous way to reach consensus in defined clinical areas (58-61). It is a systematic interactive method which involves a panel of experts using iterative procedures. It can be done quickly to make a single convergent final recommendation. This process requires to follow four rules: anonymity of participants (ensures responses reliability and avoids contamination), iteration (allows participants to refine their views in the light of the progress of the group's work), control feedback (under the responsibility of the investigator), statistical aggregation of group's responses to allow a quantitative and qualitative analysis of the data (46)(62-64).

2.2. Consents and anonymity

In each country, the Investigator was the National investigator (NI). He asked the participants for their signed consent (annex 2), anonymized the expert responses and delivered an identification number for later identification. The name of each expert was not transmitted to others (46). Only NI's consent was sent to the team of investigators (annex 3, annex 4). As the study involved no patient, it didn't require an ethics committee's decision.

2.3. Participants

Pilot Team (PT): The EGPRN French team was familiar with the Delphi methodology. It requested the consent of each national investigator as well as voluntary participation in the study and an absence of conflict of interest statement. It ensured that the whole process followed the protocol. It didn't take part in the translation phases or in Delphi rounds. The Forward-Backward translation had to be validated by the daily board of the study, composed of members of EGPRN all active within the research process.

National Investigators (NI): The NIs' were in charge of recruiting translators and experts. They acted between each phase and between two Delphi rounds. They didn't act when a Delphi round was running.

Translators: The NIs' selected translators to make up two translation teams. Translators had to be knowledgeable about health care terminology. The Forward translation team involved one member of the GPs' research group and one official translator in every country. The Backward translation team involved one (or two) GP(s') and one official translator (46). The two teams should not have involved the same person (65).

Experts panel: Initially, 20 to 30 experts were recruited in order to keep at least 15 participants until the end of the last round (according Delphi's quality standards criterias. The selection criteria for every expert were: being native to country of origin and speaking their native language; being an English speaker; being a GP. Over half had to have teaching or research activities. In order to assess the representativeness of the panel by its maximum variation, the experts informed their gender, area of practice, years of practice and publications.

2.4. Forward Translation

The PT sent the HSCL-25 original English version to the NI who sent it to the Forward translation team. This team translated HSCL-25 from English to language of the country aiming to retain the same meaning as the original.

There were 32 elements to translate: the introductory sentence, the 25 items, the 4 adjectives corresponding to the proposals, and two sentences relating to the use of the survey (explanatory sentence).

An exception for Germany, a German version of the HSCL-25 already existed. The forward translation was not performed. The Delphi procedure was applied directly to the German version. This made it possible to verify the quality of this translation for a qualitatively representative panel of GP.

2.5. Delphi rounds

At the beginning of the first round, NIs' sent by mail the original English version and translated version in Galician, Castilian, Catalan, Bulgarian, Greek, Croatian, Italian, French, German, Polish with the entire rules of procedure. GPs' experts received records individually. NIs didn't use a mailing list in order to assure anonymity which increases the reliability of responses and avoids contamination (discussion between experts).

Experts expressed their level of agreement on each proposal by using a 1 to 9 Likert scale. This Likert scale was an agree/disagree scale, symmetric, odd, that measured the intensity of their feelings on each proposal, taking into account the maintenance of the meaning between the original and the translation proposal, the ergonomics and the ease of understanding. Experts rated the proposal from 1 (absolutely no agreement) to 9 (fully agreement) and had to comment when rating less than 7. Consensus was defined for an excerpt's translation when it was rated 7 or above by over 70% of the panel (66), so it was accepted directly and didn't enter the following rounds; if not (proposal didn't reach consensus), the NI and the Forward official translator synthesized experts comments to propose a new translation proposal for this excerpt. Time between two rounds had to be less than four weeks. The following round began when the NI sent to the experts separately for each excerpt that didn't reach consensus: the original English version, the unaccepted proposal with all the experts' comments on this proposal, the new proposal. Experts rated the new proposal in the same way as the first round. The following rounds rolled out in an identical manner. This process was repeated until all excerpts found a consensual translation. The number of rounds was not limited (67).

At the Delphi procedures end, there were a HSCL-25 consensual versions in different European languages.

2.6. Backward translation

NI sent the final Galician, Castilian, Catalan, Bulgarian, Greek, Croatian, Italian, French, German or polish version of HSCL-25 to the backward translation team who had to translate it into English. The translators should not have the knowledge of the original version (blind-back translation principle). Finally, he sent the Backward English version to the PT (68).

3-Results

3.1. Forward

The NI submitted the questionnaire to one official translator who was knowledgeable about health care terminology and GPs' researchers whose native language were the country where they worked. A consensual Forward translation of HSCL-25 was proposed.

3.2. Panel

11 experts from 8 European countries participated in the RAND / UCLA. They were all GPs', EGPRN members, and fluent in English. The panel was composed of 72.7% women. 90.9% of experts practiced in urban areas of more than 5 000 inhabitants and 9.1% worked in urban areas from 2000 to 5000 inhabitants. In terms of qualifications, 72.7% were teachers and researchers, 27.3% were only researcher. The average of international publications per leader was 13.8, for a total of 152 publications. The average of years of practice was 21.3 years, and 12.4 in terms of years of research (Table 1).

| Experts | Gender | Country | University Statement | Number of inhabitants | Office type | International publication number | Years of practice | Years of research |
|---------|-----------------------------|---------------------|----------------------|-----------------------|--------------------------------|--|-------------------|-------------------|
| 1 | F | Spain (Galicia) | Teacher/Researcher | >5000 | GPs group office | 15 | 20 | 14 |
| 2 | F | Spain (Cataluna) | Teacher/Researcher | >5000 | GPs group office | 13 | 22 | 25 |
| 3 | F | Greece | Teacher/Researcher | >5000 | GPs and paramedic group office | 14 | 30 | 18 |
| 4 | М | Italy | Researcher | >5000 | GPs group office | 23 | 7 | 6 |
| 5 | F | Germany | Researcher | 2000 to 5000 | Practice stop since 2 years | 19 | 23 | 5 |
| 6 | М | Poland | Teacher/Researcher | >5000 | GPs group office | 20 | 30 | 12 |
| 7 | F | Croatia | Teacher/Researcher | >5000 | Alone | 6 | 20 | 12 |
| 8 | F | Croatia | Teacher/Researcher | >5000 | GPs group office | 18 | 30 | 20 |
| 9 | F | Bulgaria | Teacher/Researcher | >5000 | GPs group office | 9 | 14 | 12 |
| 10 | F | Germany | Researcher | >5000 | GPs group office | 4 | 18 | 7 |
| 11 | М | France | Teacher/Researcher | >5000 | GPs group office | 11 | 20 | 5 |
| | Male: 27,3% Female:72,7% | | | | | Average=13,8 | Averge=21,3 | Average=12,4 |

Table 1 : Leader panel

F = female

M = male

GPs = General Practician

The NI obtained experts consents and asked them for their characteristics (Table 2).

14 (Germany) to 31(castille) experts were recruited for the Delphi procedure. In compliance with selection criteria, they were all GPs, all in family practice, all English speakers.

The European panel consisted of 111 (=51,6%) male and 104 (=48.4%) female.

9.7% of experts worked in city <2000 inhabitants, 19.3% in a city between 2000 and 5000 inhabitants and 71% in a city> 5000 inhabitants.

Clinical experience was analyzed according to years of activity: an average of 16.6 years experience.

81.4% (175) were academic researchers and/or teachers. Experts published 156 studies.

| Coi | untry | Greece | Croatia | Poland | Bulgaria | Italy | Galicia | Germany | Castille | Catalonia | France | Number or Average |
|---|--|--------|---------|-----------------|-----------------|--------|---------|-----------------|-----------------|-----------------|--------|-------------------------|
| numbe | r of GPs' | 26 | 16 | 30 | 22 | 18 | 20 | 14 | 31 | 22 | 16 | 215 |
| Candan | Male | 13 | 3 | 12 | 9 | 12 | 14 | 6 | 20 | 13 | 9 | 111 |
| Gender | Female | 13 | 13 | 18 | 13 | 6 | 6 | 8 | 11 | 9 | 7 | 104 |
| | e years of e activity | 10,9 | 19,2 | 11,9 | 20,5 | 17,2 | 22,3 | 16,7 | 19,5 | 15,7 | 12,5 | 16,6 |
| | Number | 24 | 16 | 26 | 8 | 13 | 17 | 9 | 27 | 20 | 15 | 175 |
| Academic researcher and/or teacher | Average years of researching and/or teaching | 5,06 | 11.54 | 13.08 | 7,7 | 14,02 | 13,09 | 10 | 12,02 | 10.5 | 6.26 | 10,33 |
| Publ | ication | 26 | 15 | 10 | 5 | 12 | 19 | 6 | 30 | 22 | 11 | 156 |
| | < 2000 | 38,40% | 6,25% | 25% | 4,50% | 16,70% | 0% | 0% | 0% | 0% | 6,30% | 9,70% |
| Area of | 2000 - 5000 | 34,60% | 6,25% | 37,50% | 22,70% | 11,10% | 0% | 21,40% | 6,50% | 9,10% | 43,75% | 19,30% |
| practice | > 5000 | 26,90% | 87,50% | 37,50% | 72,70% | 72,20% | 100% | 78,60% | 93,50% | 90,90% | 50% | 71% |
| | ants of the d round | 57,70% | 93,75% | No second round | No second round | 94,40% | 100% | No second round | No second round | No second round | 93,75% | |

Table 2: Experts' panel

GPs'= General practicians

3.3. Number of Delphi round

In Poland, Bulgaria, Germany, Castille, Catalonia, there was only one round Delphi, in the others country two rounds were necessary to get final translations.

Almost all proposals were accepted in round one (273/320: 85.3%) (Table 3). Excerpt that did not reach consensus entered the second round, the NI and the Forward official translator synthesized experts comments to propose a new translation proposal for those excerpts. NI sent to the same experts' panel (following the same procedure): the original English version, the unaccepted proposal and all the experts' comments on this proposal, the new proposal. Experts rated the new proposal in the same way as for the first round. The delay between two rounds must be less than four weeks.

| Item/Country | Galicia | Castille | Catalonia | France | Italy | Bulgaria | Croatia | Greece | Germany | Poland |
|---|---------|----------|-----------|--------|-------|----------|---------|--------|---------|--------|
| 1 | С | С | С | С | С | С | С | NC | С | С |
| 2 | С | С | С | С | С | С | NC | С | С | С |
| 3 | С | С | С | NC | NC | С | NC | NC | С | С |
| 4 | С | С | С | С | С | С | С | С | С | C |
| 5 | С | С | С | NC | С | С | С | С | С | С |
| 6 | NC | С | С | NC | NC | С | С | С | С | С |
| 7 | С | С | С | С | С | С | С | С | С | С |
| 8 | С | С | С | С | С | С | С | С | С | С |
| 9 | С | С | С | NC | С | С | NC | С | С | С |
| 10 | NC | С | С | NC | С | С | NC | С | С | С |
| 11 | С | С | С | С | С | С | NC | NC | С | С |
| 12 | С | С | С | NC | NC | С | С | С | С | С |
| 13 | С | С | С | С | С | С | С | NC | С | С |
| 14 | C | C | C | NC | C | С | NC | С | C | C |
| 15 | C | C | C | NC | C | C | NC | C | C | C |
| 16 | C | C | C | C | C | C | NC | C | C | C |
| 17 | C | C | C | NC | C | C | NC | C | С | C |
| 18 | C | C | C | C | C | C | C | NC | C | C |
| 19 | С | С | С | NC | С | С | C | C | С | C |
| 20 | С | С | С | NC | С | С | NC | NC | С | С |
| 21 | С | С | С | NC | С | С | NC | NC | С | С |
| 22 | С | С | С | С | С | С | С | С | С | С |
| 23 | С | С | С | NC | С | С | С | NC | С | С |
| 24 | С | С | С | С | С | С | С | NC | С | С |
| 25 | NC | С | С | NC | С | С | С | С | С | С |
| Choose the best answer for how you felt over the past week | С | С | С | NC | С | С | С | С | С | С |
| Not at all | С | С | С | C | NC | С | C | С | С | С |
| A little | С | С | С | NC | С | С | C | С | С | С |
| Quite bit | С | С | С | С | С | С | С | С | С | С |
| Extremely | С | С | С | C | C | С | C | C | С | С |
| The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress. The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ≥ 1,55. | С | С | С | NC | NC | С | С | С | С | С |
| A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL 25 is 5 to 10 minutes | C | С | C | NC | C | С | С | C | C | С |

Table 3: Results of the first Delphi round

C = Consensus

NC = No Consensus

3.4. For each language

3.4.1. Galician

There were two Delphi rounds to validate the Galician Forward of HSCL-25. Three items were not accepted in the first round: item n°6, 10 and 25:

-Item N° 6 (Trembling): the first proposal was "Trema", present indicative of the verb tremar. The average rate was 7.25/9 and seven experts (35% rated strictly less than 7). It was apparently an agreement problem. The second proposal was "Ten tremores". In the second round, every expert rated 7 or above (seven, eleven and two experts rated respectively 7, 8 and 9). The consensus was reached with a high level of agreement for this excerpt. The Backward translation was the same as the original version: « Trembling ».

- Item N° 10 (Feeling restless): the first proposal was "Séntese inquedanza". The average rate was 7.2/9 and seven experts (35%) rated strictly less than 7. The second proposal was: "Séntese inquedo". This second proposal reached consensus with a good level of agreement. The Backward translation was the same as the original version: « Feeling restless ».
- Item N° 25 (Sleep disturbance): the first proposal was "Problemas para durmir". The average rate was 7.45/9 and seven experts (35%) rated strictly less than 7. "Durmir" is a verb which could be translated in « to sleep » and its meaning is closer to « stay asleep » than « fall asleep ». It could produce a confusion or at less a restriction. The second proposal was: "Alteracións do sono". Two experts, who rated 5 and 6 made the same comment: "Durme mal". The Backward translation was « Sleep disorders» which is very close to the original version « Sleep disturbance». Finally, few comments appeared on the new proposals: and they were widely accepted.

NI sent the final Galician version of HSCL-25 to three translators forming the Backward-translation team who translated it back to English. They were knowledgeable about health care terminology. One was a philologist and the two others are FPs. The blind-back translation principle was respected.

Finally, he sent the Backward English version to the PT.

3.4.2. Castilian

All items were accepted in the first round Delphi but several translations required comments, the most discussed items of forward translation were the Final excerpt , the beginning excerpt, item1, 4, 8, 11 12, 14, 16, 18, 19.

The Castilian version obtained was translated in English by four independents translators, which gave us one backward blind translation. They were knowledgeable about health care terminology, and their native language was Castilian. One of them was a Philologist and others were FP researchers. The blind-back translation principle was respected.

3.4.3. Catalan

All items were accepted in the first round Delphi but several translations required comments, items 2, 5, 10, 11, 14, 18 21, 25, the final excerpt.

The Catalan version obtained was translated in English by three independents translators, which gave us one Backward blind translation, one official translator and two FPs. The native language of the translators was Catalan and they were knowledgeable about health care terminology.

| | Original english | Gali | cian | Cata | alan | Castilian | | |
|--------------------------|--|---|--|---|---|---|---|--|
| | version | Forward | Backward | Forward | Backward | Forward | Backward | |
| Introductary sentence | Choose the best answer for how you felt over the past week | Escolla a resposta que mellor describa como se sentiu durante a semana pasada | Choose the best answer to indicate how you felt during the last week | Trii la millor resposta per indicar com s'ha sentit en la derrera setmana | Choose the best answer to indicate how you felt during last week | elija la repuesta que mejor describa como se ha sentido durante la semana passada | Choose the best answer to describe how you felt over the last week | |
| 1 | Being scared for no reason | Asústase sen motivo | Being scared for no reason / Being suddenly scared for no reason | Estar espantat sense motiu aparent | Being scared for no reason | Se asusta sin motivo | Being scared for no reason | |
| 2 | Feeling fearful | Ten medo | Feeling fearful | Sentir por | Feeling fearful | Siente miedo | Feeling afraid/fearful | |
| 3 | Faintness | Debilidade | Weakness | Debilitat | Weakness | Debilidad | Weakness | |
| 4 | Nervousness | Nerviosismo | Nervousness | Nerviosisme | Nervousness | Nerviosismo | Nervousness | |
| 5 | Heart racing | Palpitacións | Heart pounding | Cor accelerat | Racing heart | Palpitaciones | Palpitations | |
| 6 | Trembling | Ten tremores | Trembling | Tremolos | Tremulous | Tiembla | Trembling | |
| 7 | Feeling tense | Séntese tenso | Feeling tense | Sentir-se tens | Feeling tense | Se siente tenso | Feeling tense | |
| 8 | Headache | Dor de cabeza | Headaches | Mal de cap | Headhache | Dolor de cabeza | Headhache | |
| 9 | Feeling panic | Sente pánico | Feeling panic /Having panic attacks | Sensacio de pànic | Sense of panic | Siente panico | Feeling panic | |
| 10 | Feeling restless | Séntese inquedo | Feeling restless | Sensacio de inquietud | Sense of restlessness | Siente inuietud | Feeling restless | |
| 11 | Feeling low in energy | Sente que lle falta enerxía | Feeling low in energy | Sensacio de manca d'energia | A lack of energy | Siente que le falta energia | Feeling a lackof energy | |
| 12 | Blaming oneself | Cúlpase a si mesmo | Blaming yourself for things | Culpar-se un mateix | Blaming your self | Se culpa a si mismo | Blaming oneself | |
| 13 | Crying easily | Chora con facilidade | Crying easily | Plor fàcil | Crying easily | Llora con facilidad | Crying easily | |
| 14 | Losing sexual interest | Perda do apetito sexual | Loss of sexual interest | Pèrdua de l'interès sexual | loss of sexual interest | Pierde el interés sexual | Losing interest in sex | |
| 15 | Feeling lonely | Séntese só/soa | Feeling lonely | Sentir-se sol | Feeling lonely | Se siente solo | Feeling alone | |
| 16 | Feeling hopeless | Séntese sen esperanza | Feeling hopeless | Sentiment de desesperanca | Feeling of hopelessness | Se siente sin esperanza | Feeling of hopeless | |
| 17 | Feeling blue | Séntese triste | Feeling blue | Sentir- se trist | Feeling sad | Se siente triste | Feeling sad | |
| 18 | Thinking of ending one's life | Pensa en acabar coa súa vida | Having thoughts of ending your life | Pensaments de suicidi | Thoughts of suicide | Piensa en acabar a su vida | Thinking of ending your life | |
| 19 | Feeling trapped | Séntese atrapado | Feeling trapped | Sentir-se atrapat | Feeling trapped | Se siente atrapado | Feeling trapped | |
| 20 | Worrying too much | Preocúpase en exceso | Worrying too much about things / Worrying too much | Preocupar-se en excès | Worrying too much | Se preocupa n exceso | Worrying too much | |
| 21 | Feeling no interest | Non sente interese por nada | Feeling no interest in anything / Feeling no interest | Sentiment de manca d'interès | A lack of interest | No siente interés por nada | Not interested in anything | |
| 22 | Feeling that everything is an effort | Sente que todo lle supón un esforzo | Feeling that everything is an effort | Sentir que tot és un esforç | Feeling that everything is an effort | Siente que todo le cuesta un esfuerzo | Feeling that everything is an effort | |
| 23 | Worthless feeling | Séntese inútil | Feeling worthless | Sentir-se inùtil | Feeling useless | Se siente inutil | Feeling useless | |
| 24 | Poor appetite | Falta de apetito | Loss of appetite | Pèrdua de la gana | Loss of appetite | Falta de apetito | Poor appetite | |
| 25 | Sleep disturbance | Alteracións do sono | Sleep disorders | Alteracio de la son | Sleeping disturbance | Problemas para dormir | Problems sleeping | |

Table 4: Forward/backward: Galicia, Catalan, Castiliar

Accepted after two rounds

| | Original english Galician | | cian | Cat | alan | Castilian | | |
|--------------------------|--|--|--|---|--|---|--|--|
| _ | version | Forward | Backward | Forward | Backward | Forward | Backward | |
| e | Not at all | En absoluto | Absolutely not/ Not at all | Gens | Not at all | En absoluto | Not a bit | |
| ctiv | a little | Un pouco | A little | Una mica | A little | Un poco | A little bit | |
| Adjective | quit a bit | Bastante | Quite a lot | Bastant | Quite a bit | Bastante | Quite a bit | |
| ¥ | extremely | Moito | A lot | Molt | A lot | Mucho | A lot | |
| 1st explanatory sentence | The HSCL-25 score is based on pencil- and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1.00 to 4.00 | A puntuación HSCL-25 baséase nun cuestionario autocumplimentado con lapis e papel, de 25 preguntas sobre a presenza e a intensidade de ansiedade e síntomas depresivos na última semana. Os participantes responden unha de catro categorías para cada ítem, nunha escala de catro puntos que van desde 1 a 4. | HSCL-25 scores are based on a 25-item paper-based questionnaire on the presence and severity of anxiety and other depressive symptoms in the last week.Participants answer one of four categories for each item on a 1-to-4 rating scale. | L'escala HSCL-25 es basa en un questionari auto administart de 25 preguntes, sobre la presència i la intensitat de simptomes d'ansietat i depressio en la darrerra setmana, Els participants responen a una de les quatre categories per a cada item en una escala de quatre punts que va de l'1 al 4, | The HSCL-25 scale is based ona self-administred questionnaire of 25 questions about the presence and intensity of anxiety and depression symptoms in the last week. The participants answer to one of the four categories for each item, in a four-point scale ranging from 1.00 to 4.00 | La puntuaion HSCL-25 se basa en un cuestionario autocumplimentado con làpiz y papel, de 25 preguntas sobre la presencia y la intensitad de ansiedad y sintomas depresivos en la ùltima semana. Los participantes responden una de cuatro categorias para cada item, en una escala de cuatro puntos que van desde 1 a 4. | The HSCL-25 score is based on survey that is self-administered with pen and paper. It has 25 questions about the presence and intensity of anxiety and depressive symptoms over the last week. The participants answer one of the four categories for each item on a four-point scale ranging from 1.00 to 4.00 | |
| 2nd explanatory sentence | The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1 and 4). It is often used as the measure of distress. The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ≥ 1.55. A cut-off value of ≥ 1.75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL 25 is 5 to 10 minutes | A puntuación do HSCL-25 calcúlase dividindo a puntuación total (a suma de todas as preguntas) entre o número de respostas (cuxa puntuación oscila entre 1,00 e 4,00). Úsase de forma habitual para medir o nivel de angustia. Considérase que o paciente é un "caso psiquiátrico probable" se o valor medio do HSCL-25 é ≥1,55. Polo xeral, úsase un valor de corte ≥ 1,75 para diagnosticar a depresión maior, definida como "un caso que precisa tratamento". Este valor de corte recoméndase como un predictor válido dun trastorno mental, avaliado independentemente por medio de entrevistas clínicas, aínda que depende en parte do diagnóstico e do xénero. O tempo de realización do HSCL-25 é de 5 a 10 minutos. | HSCL-25 scores are calculated by dividing the total score (sum of all the questions) by the number of answers (scores ranging from 1.00 to 4.00). The questionnaire is frequently used to measure anxiety levels.Patients with mean rating HSCL-25 scores of 1.55 or greater are considered to be likely psychiatric cases In general, a cut-off score of 1.75 is used to diagnose cases of major or chronic depression defined as requiring medical treatment. This cut-off point is recommended as a strong predictor of a mental disorder, independently assessed through clinical interviews, yet partially dependent on the diagnosis and gender. | La puntuacio total de HSCL-25 es calcula dicidint la suma de la puntacio desl diferents items pel nùmero d'items contestats. El resultat total oscilla entre 1,00 i 4,00, Aquesta escala sovint s'utilitza com a mesura de l'angoixa. El pacient és considerat com a "probable cas psiquiatric" si la qualificacio mitjana del HSCL-25 és ≥ 1,55. Generalment s'utilitza un punt de tall≥1,75 per al diagnostic de la depressio major i es defineix com "cas de precisa de tractament", Es recomana aquest punt de tall com un predictor vàlid de trastorn mental com ho seria l'avaluacio independent per entrevista clinica, depenent en part del dignostic i del gènere. El temps d'administracio del HSCL-25 és de 5 a 10 minuts, | The total HSCL-25 score is calculated by dividing the sum of the different items score of items answered. The total score ranges from 1 to 4. This scale is often used as the measure of anxiety. The patient is considered as a "probable psychiatric case" if the HSCL-25 avergae is ≥1.55. Usually, a cut off point off ≥1.75 is used to diagnose major depression and it's defined as "a case, that needs treatment". This cut-off is recommended as a valid predictor of mental disorder as would to be independent evaluation by clinical interview, depending in part on the diagnosis and gender. Administration time of HSCL 25 is from 5 to 10 minutes | La puntuacion del HSCL-25 se calcula dividiendo la puntuacion total (sumando la puntuacion de todos las preguntas) entre el nùmero de respuestas (varia entre 1,00 y 4,00). Se usa habitualmente para medir el malestral pscicologico, El paciente se considera "un probable caso psiquiàtrico" si el valor medio del HSCL-25 es ≥1,55, Por lo general se usa un valor de corte de ≥1,75 para el diagnostico de depression mayor, definida como un "caso que necesita tratamiento". Este valor de corte se considera un predictore vàlido de un trastorno mental, evaluado de forma independiente mediante entrevista clinica, aunque depende en parte del diagnostico y el género. El tiempo de administracion del HSCL-25 es de 5 a 10 minutos. | The HSCL-25 score is calculated dividing the total score (the sum of the score score of all questions) by the number of items answered (ranging between 1 and 4). It is usually used to measure the level of anxiety. The patient is considered as a "probable psychiatric case" if the avergae of the HSCL-25 is ≥ 1.55. A cut-off value of ≥ 1.75 is generally used for diagnosis of major depression defined as "a case, thats needs treatment". This cut-off point is considered a valid predictor of mental disorder, assessed in an independent way by a clinical interview, although it depends , in part, on the diagnosis and gender. The administration time of HSCL 25 is from 5 to 10 minutes. | |

Table 4: Forward/backward: Galicia, Catalan, Castillan

3.4.4. French

There were two Delphi rounds to validate the French Forward of HSCL-25: Nine excerpts entered the second round fourteen translation proposals were accepted by the experts in the first round. Eighteen proposals did not reach this agreement. They had to be reformulated for a second round using the comments collected. Indeed, item 3, 5, 6, 9, 10, 12, 14, 15, 17, 19, 20, 21, 23, 25, adjective « a little », the first and second explanatory sentence.

Converging comments from experts have emerged for innaccepted proposals. For example: the forward of « sleep disturbance » did not accepted and the majority of the comments proposed to replace the translation « vous n'arrivez pas à dormir » by « votre sommeil était perturbé ».

All new proposals from the translation team were accepted during the second round There were differences between the initial version in English and the bacward for many proposals. The meaning of the words, the syntax, the quotations and the strength of the proposals seemed to be different possibly in relation to the French language. The comparison of the two English forms will allow cultural analysis.

3.4.5. Italian

There were two Delphi rounds to validate the Italian Forward of HSCL-25. Almost all proposals were accepted in round one. Five excerpts entered the second round.

Five proposals were not accepted at the first round (3; 6; 12; 27; 28). Indeed, only 61% of the panel agreed with proposal 27 and 67% with proposals 3; 6; 12; 28.

These proposals were accepted at the second round: just one participant made a comment regarding the third item: "sentirsi intimoriti, mi sembrerebbe meglio" that is "sentirsi intimoriti, seems to me better".

The Italian version obtained was translated in English by two independents translators, which gave us one backward blind translation. The native language of the second translator was Italian and he was knowledgeable about health care terminology.

3.4.6. Bulgarian

All items were accepted in the first round Delphi but several translations required comments. The most discussed items were the item 11, 12, 22:

-item 11 and 12 with the two, 7 answers between 7-9. Two comments emerged about these items. The first concerned, item 11 "Feeling low in energy", "Усещане за понижена енергия" in Bulgarian. The FPs experts had commented: липса на / намалена. For the term "low", three words had the same meaning in Bulgarian: понижена, липса на, намалена.

- item 22 "Feeling that everything is an effort", "Чувство, че всичко изисква усилие" in Bulgarian. The FPs experts had commented: се случва с / става с. same for the term « is an ... », three words had the same meaning in Bulgarian: изисква, се случва с, става с.

The Bulgarian version obtained was translated in English by two independents translators, which gave us one backward blind translation. The native language of the second translator was Bulgarian and he was knowledgeable about health care terminology.

| | Original english | Fre | nch | Ita | lian | Bulga | arian |
|-----------------------|---|--|--|--|---|---|--|
| | version | Forward | Backward | Forward | Backward | Forward | Backward |
| Introductary sentence | Choose the best answer for how you felt over the past week | Veuillez choisir la réponse qui décrit le mieux comment globalement vous vous sentiez toute la semaine dernière | Please choose the answer that describes best how you generally felt throughout last week. | Scegliere la risposta più adatta su come ti sei sentito nell'ultima settimana | Choose the answer that best describes how you have been feeling during the past week | Изберете отговора, който най-добре описва как сте се чувствали през изминалата седмица | Choose the answer which describes best how you felt over the past week: |
| 1 | Being scared for no reason | Vous aviez peur sans raison | You felt scared without any reason | Avere paura senza motivo | Being afraid with no reason | Чувство за уплаха без причина | Being scared for no reason |
| 2 | Feeling fearful | Vous vous sentiez effrayé | You felt frightened | Essere timorosi | Feeling fearful | Чувство за страх | Feeling fearful |
| 3 | Faintness | Vous aviez une sensation d'étourdissement | You felt dizzy | Sensazione di mancamento | Faintness | Отпадналост | Faintness |
| 4 | Nervousness | Vous vous sentiez nerveux | You felt nervous | Essere nervoso | Feeling nervous | Нервност | Nervousness |
| 5 | Heart racing | Vous aviez l'impression que votre cœur battait anormalement vite | You felt that your heartbeat was abnormally fast | Avere tachicardia | Tachycardia | Сърцебиене | Heart racing |
| 6 | Trembling | Vous aviez la sensation de tremblement | You had a shaky feeling | Tremore | Trembling | Треперене | Trembling |
| 7 | Feeling tense | Vous vous sentiez tendu | You felt tense | Sensazione de tensione | Feeling tense | Чувство за напрежение | Feeling tense |
| 8 | Headache | Vous aviez des maux de tête | You had headaches | Avere mal di testa | Experiencing headache | Главоболие | Headache |
| 9 | Feeling panic | Vous vous êtes senti paniqué | You felt panicked | Sensazione di panico | Panicky | Чувство за паника | A sense of panic |
| 10 | Feeling restless | Vous vous sentiez agité | You felt agitated | Sensazione de irrequietezza | Feeling restless | Чувство на безпокойство | A sense of anxiety |
| 11 | Feeling low in energy | Vous manquiez d'énergie | You didn't have any energy | Sentirsi stanco | Feeling tired | Усещане за понижена енергия | A sense of low energy |
| 12 | Blaming oneself | Vous ressentiez une sensation de culpabilité | You felt guilty | Avere sensi di colpa | Blaming oneself | Самообвинение | Self-accusation |
| 13 | Crying easily | Vous pleuriez facilement | You cried easily | Piangere facilmente | Often tearful | Плачливост | Tearfulness |
| 14 | Losing sexual interest | Vous ressentiez un désintérêt pour la vie sexuelle | You were not interested in sex | Perdere l'interesse sessuale | Losing sexual interest | Загубата на сексуален интерес | Loss of sexual interest |
| 15 | Feeling lonely | Vous aviez la sensation de solitude | You felt lonely | Sentirsi soli | Feeling lonely | Чувство за самотност | A sense of loneliness |
| 16 | Feeling hopeless | Vous vous sentiez désespéré | You felt hopeless | Sentirsi senza speranza | Without hope | Чувство за безнадежност | A sense of hopelessness |
| 17 | Feeling blue | Vous aviez le cafard | You felt down | Sentirsi tristi | Feeling sad | Чувстам се нещастен | Feeling blue |
| 18 | Thinking of ending one's life | Vous aviez pensé à mettre fin à votre vie | You thought about ending your own life | Avere pensieri di togliersi la vita | Thinking about taking one's life | Мисли за самоубийство | Thoughts of suicide |
| 19 | Feeling trapped | Vous vous êtes senti pris au piège | You felt trapped | Sentirsi intrapollati | Feeling trapped | Чувстам се като в капан | Feeling trapped |
| 20 | Worrying too much | Vous vous inquiétiez trop | You worried too much | Preoccuparsi troppo | Worrying too much | Притеснявам се твърде много | Worrying too much |
| 21 | Feeling no interest | Vous n'étiez plus inté-ressé par quoi que ce soit | You weren't interested in anything any more | Non avere alcun interesse | No interest in anything | Чувство за загуба на интерест | A sense of a loss of interest |
| 22 | Feeling that everything is an effort | Tout était un effort pour vous | Everything was an effort for you | Sentire che tutto è uno sforzo | Feeling that everything is an effort | Чувство, че всичко изисква усилие | A sense that everything needs effort |
| 23 | Worthless feeling | Vous aviez le sentiment d'être nul, bon à rien | You felt rubbish, good for nothing | Sentirsi inutile | Feeling of uselessness | Чувство за безполезност | A sense of worthless |
| 24 | Poor appetite | Vous aviez perdu l'appétit | You lost your appetite | Avere poco appetito | Loss of appetite | Лош апетит | Poor appetite |
| 25 | Sleep disturbance | Votre sommeil était perturbé | Your sleep was disturbed | Disturbu del sonno | Sleep disturbance | Нарушения на съня | Sleep disturbance |

| | 1 oor appente | l'appétit | appetite | Avere poco appento | Loss of appeni | | | | | | |
|---|-------------------|------------------------------|--------------------------|---------------------|----------------|--|--|--|--|--|--|
| | Sleep disturbance | Votre sommeil était perturbé | Your sleep was disturbed | Disturbit del sonno | | | | | | | |
| Table 5: Backward/Forward: Italian, French, Bulgarian | | | | | | | | | | | |
| | Accepted | after two roun | ds | | | | | | | | |
| | | | | | | | | | | | |

| | Original english | Fre | nch | Ital | lian | Bulga | arian |
|--------------------------|--|--|---|--|--|--|--|
| | version | Forward | Backward | Forward | Backward | Forward | Backward |
| 'e | Not at all | Pas du tout d'accord | Strongly disagree" | Niente | Nothing | Съвсем не | Not a bit |
| adjective | A little | Un peu d'accord | Agree a little | Poco | Slightly | Незначително | A little bit |
| Jec | Quit a bit | Plutôt d'accord | Rather agree | Abbastanza | Significantly | Съвсем малко | Quite a bit |
| ad | Extremely | Complètement d'accord | Completely agree | Moltissimo | Very much | Извънредно | Extremely |
| 1st explanatory sentence | The HSCL-25 score is based on pencil-and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1.00 to 4.00 | La HSCL-25 est un auto-questionnaire en 25 questions relatives à la présence et à l'intensité des symptômes d'anxiété et de dépression durant toute la semaine dernière. Les participants cotent chaque proposition, sur une échelle en quatre points, cotée de 1 à 4. | The HSCL-25 is a self-assessment questionnaire with 25 questions relating to the presence and intensity of anxiety and depression symptoms during the whole of the previous week. The people taking part rate each statement, on a four point scale, ranging from 1 to 4 | Il punteggio dell'HSCL-25 si basa su un'autovalutazione in carta e penna di 25 domande sulla presenza e intensità sui sintomi di ansia e depressione nell'ultima settimana. I partecipanti rispondono a una delle quattro categorie per ogni elemento in una scala di 4 punti che si estende da 1 a 4. | The HSCL-25 score is based on a self - assessment on pen and paper of 25 questions regarding the presence and intensity of the symptoms of anxiety and depression during the last week. The participants reply to one of the four categories for every item on a scale of 4 points which ranges from 1 to 4. | Резултатът от HSCL- 25 се основава на самостоятелно попълнен инструмент на хартиен носител, включващ 25 въпроса за наличието и интензивността на симптоми на тревожност и депресия през последната седмица. Участниците избират една от категориите за всяка позиция по скала от четири точки от 1.00 до 4.00. | The HSCL-25 is based on self-completed instrument on paper, including 25 issue of the presence and intensity of symptoms of anxiety and depression in the last week. Participants choose one of the categories for each item on a scale of four points from 1.00 to 4.00 |
| 2nd explanatory sentence | The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1 and 4). It is often used as the measure of distress. The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ≥ 1.55. A cut-off value of ≥1.75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL 25 is 5 to 10 minutes | Le score du HSCL- 25 se calcule en divisant la somme des cotations des propositions par le nombre de réponses reçues. Le résultat final est compris entre 1,00 à 4,00. Il est couramment utilisé pour mesurer la souffrance psychologique. Le patient est considéré comme « probablement atteint d'une maladie psychiatrique » si le score moyen du HSCL-25 est supérieur ou égal à 1,75 diagnostique généralement une dépression majeure et défini « un patient nécessitant un traitement ». Ce seuil est considéré comme un score prédictif validé des troubles mentaux. Il a été évalué de manière indépendante par des études cliniques. Il varie peu quelles que soient les situations diagnostiques et le sexe. Remplir le questionnaire HSCL-25 prend entre 5 et 10 minutes. | The score of the HSCL-25 is calculated by dividing the sum of the statement ratings by the number of collected answers. The final result ranges from 1,00 to 4,00. It is currently used to measure psychological suffering. The patient is considered to be "probably suffering from a mental illness" if the average score of the HSCL-25 is higher or equal to 1,75 generally reveals a major depression and indicates that "a patient needs treatment". This threshold is considered to be a validated predictive score for mental disorders. It has been assessed by independent clinical studies. It varies little regardless of diagnostic context and gender. Filling in the HSCL-25 questionnaire takes between 5 and 10 minutes. | Il punteggio dell'HSCL-25 si calcola dividendo il punteggio totale (somma dei punteggi degli elementi) con il numero di elementi risposti (che variano da 1,00 a 4,00). Spesso si usa come misura di ansietà. Il paziente è considerato come un "probabile caso psichiatrico" se il punteggio medio dell'HSCL-25 è ≥1,55. Un cut-off che sia ≥ 1,75 è normalmente usato per la diagnosi di depressione maggiore definita come "un caso che necessita di trattamento". Questo cut-off è raccomandato come un valido predittore di disordine mentale come valutato in modo indipendente da un colloquio clinico, dipendente in qualche modo dalla diagnosi e dal genere. Il tempo di somministrazione dell'HSCL-25 è da 5 a 10 minuti. | The HSCL-25 score is calculated by dividing the total score (the sum of the scores of the items) by the number of items replied to (which vary from 1.00 to 4.00). It is often used to measure anxiety. The patient is considered to be a "likely psychiatric case" if the average score of the HSCL-25 is ≥ 1.55. A cut-off point of ≥ 1.75 is normally used for the diagnosis of worse depression defined as "a case that requires treatment". This cut-off is recommended as a reliable predictor of mental disorder as evaluated independently via a clinical discussion, dependent in part on the diagnosis and the type. The HSCL-25 takes between 5 and 10 minutes to complete. | НЅСL-25 резултатът се изчислява, като се раздели общият брой точки (сбор точки по критерий) на броя на отговорените критерии (вариращи между 1,00 и 4,00). Той често се използва като мярка за страдание. Пациентът се приема като "вероятно психиатричен случай", ако средната опенка по НЅСL-25 е ≥ 1,55. Гранична стойност от ≥ 1,75 обикновено се използва за диагностициране на тежка депресия и определя случай, нуждаещ се от лечение". Тази гранична стойност "случай, нуждаещ се от лечение". Тази гранична стойност от телиничното интервю и зависеща до определена степен от диагнозата и пола, се препоръчва като валиден предиктор за психично разстройство. Времето за провеждане НЅСL-25 е от 5 до 10 минути. | The HSCL-25 result is calculated by dividing the total score (total score of items) by the number of the items answered (ranging from 1,00 and 4,00). It is often used as a measure of distress. The patient is considered as "a probable psychiatric case" if the average rating on HSCL-25 is ≥ 1,55. The borderline value of ≥ 1,75 is commonly used for diagnosing major depression defined as "a case, in need of treatment". This borderline point obtained independently by the clinical interview and somewhat depending on diagnosis and gender is recommended as a valid predictor of mental disorder. The administration time of HSCL-25 is 5 to10 minutes |

Table 5: Backward/Forward: Italian, French, Bulgarian

Accepted after two rounds

3.4.7. Croatian

There were two Delphi rounds to validate the Croatia Forward of HSCL-25.

Almost all proposals were accepted in round one. Nine excerpts entered the second round but11 items were problematic.

- 5 items (numbers 2, 3, 9, 10, and 15) were only gender problems about items talking about fear and loneliness and the NI decided not to have a second round in relation to these.
- Item11: Feeling low in energy, the first translation was about feeling of losing power or feeling weak. The participant's comments here were about a lack of energy.
- Item 16: feeling hopeless, the 7 comments were more about desesperation than the loss of hope.
 - Item 17: feeling blue, the 5 comments were more about melancholy than sadness.
- Item 21: feeling no interest, the 5 comments were more about feeling indifference than any interest.
- Item 14: losing sexual interest, the 5 comments were about the loss of interest while the first translation was about the absence of sexual relation.
- Item 20: worrying too much, the 5 comments were about worrying beyond measure unless first translation was just about worrying.

The progression of consensus after the new proposal of the NI and the first translator for these 6 items was highly satisfying. At the end of the second round, the most frequenty rate for all proposal was 9. The average of satisfaction for each rate at the end of the second round is presented in table 5.

The forward translation was done by a second official translator (different from the first one) and blind-knowledge of HSCL-25 and whose mother tongue was Croatian.

3.4.8. Greek

There were two Delphi rounds to validate the Greek Forward of HSCL-25. Almost all proposals were accepted in round one. Nine excerpts entered the second round:

- Item N°1 (Being scared for no reason): the first proposal was "Είμαι τρομοκρατημένος χωρίς αιτία ». Various synonyms were proposed in comments: « ταραγμένος ή φοβισμένος » and « τρομαγμένος ». The second proposal was: « Είμαι τρομαγμένος χωρίς αιτία ». This second proposal reached consensus.
- Item N°3 (Faintness): the first proposal was "Αδυναμία ». Various synonyms were proposed in comments: « λιποθυμική τάση », « ατονία /αίσθημα αδυναμίας« The second proposal was: « Αίσθημα λιποθυμιάς ». This second proposal reached consensus.
- Item N°11 (Feeling low in energy): the first proposal was "Αισθάνομαι κόπωση ". Various synonyms were proposed in comments: "Δεν έχω ενέργεια", "Αισθάνομαι εξαντλημένος", "Αισθάνομαι χωρίς ενέργεια", "Νοιώθω να έχουν πέσει οι μπαταρίες μου". The second proposal was: « Αισθάνομαι ότι δεν έχω ενέργεια ». This second proposal reached consensus.
- Item N°13 (Crying easily): the first proposal was "Κλαιω εύκολα ». The second proposal was: « Εύκολο κλάμα ». This second proposal reached consensus.

- Item N°18 (Thinking of ending one's life): the first proposal was "Σκέψεις να δώσει (ω) τέλος στη ζωή ». Various synonyms were proposed in comments: « έχω σκεφτεί να δώσω τέλος στη ζωή (μου)». The second proposal was: « Σκέφτομαι να δώσω τέλος στη ζωή ». This second proposal reached consensus.
- Item N°20 (Worrying too much): the first proposal was "Ανησυχώ πάρα πολύ ». Various synonyms were proposed in comments: « ανησυχώ πάρα πολύ ». The second proposal was: « Ανησυχώ υπερβολικά ». This second proposal reached consensus.
- Item N°21 (Feeling trapped): the first proposal was "Αισθάνομαι να μην έχω ενδιαφέροντα ». Various synonyms were proposed in comments: « αισθάνομαι ότι δεν έχω ενδιαφέροντα », « αισθάνομαι πως δε με ενδιαφέρει τίποτε ». The second proposal was: « Αισθάνομαι ότι τίποτε δεν είναι ενδιαφέρον ». This second proposal reached consensus.
- Item N°23 (Worthless feeling): the first proposal was « Αισθάνομαι αναξιότητα ». Various synonyms were proposed in comments: « αισθάνομαι ανάξιος », « αίσθημα αναξιότητας », « αισθάνομαι άχρηστος », « έχω την αίσθηση ότι δεν αξίζω τίποτε », « αισθάνομαι ότι δεν έχω καμιά αξία ». The second proposal was: « Αισθάνομαι ότι δεν αξίζω τίποτε ». This second proposal reached consensus.
- Item N°24 (Poor appetite): the first proposal was "Ανορεξία ». Various synonyms were proposed in comments: « μειωμένη όρεξη για φαγητό », « δεν έχω όρεξη », « μειωμένη όρεξη ». The second proposal was: « Μείωση της όρεξης ». This second proposal reached consensus.

NI sent the final Greek version of HSCL-25 to two translators forming the backward translation team who translated it back to English. They were knowledgeable about health care terminology. They were both GPs. The blind-back translation principle was respected.

3.4.9. Polish

There was only one round Delphi to validate the polish translation. All the proposal were ranked 7 or above at 90% for one sentence, 93,3% for five sentences, 96,6% for six sentences, and 100% for the 20 remaining sentences.

The Polish version was then translated back to English by two independent translators; therefore we have two different backward translations.

| | Original english | Croa | tian | Gı | eek | Polish | | |
|--|--|---|--|---|--|--|---|--|
| į————————————————————————————————————— | version | Forward | Backward | Forward | Backward | Forward | Backward | |
| Introductary sentence | Choose the best answer for how you felt over the past week | Izaberite jedan odgovor koji naj+P4:Q14bolje opisuje kako ste se osjećali tijekom prošlog tjedna | Choose one answer that best describes how you have been feeling in the past week | Επιλέξτε την καλύτερη απάντηση για το πώς αισθανθήκατε την τελευταία εβδομάδα | Choose the best answer for how you have been feeling over the past week | Wybierz najlepszą odpowiedź dotyczącą Pana/Pani samopoczucia w ciągu ostatniego tygodnia | Please select the answer best describing your physical and mental state during last week. | |
| 1 | Being scared for no reason | Bili ste bezrazložno uplašeni | You have been scared for no reason | Είμαι τρομαγμένος χωρίς αιτία | Being scared for no reason | Bać się bez powodu | Ungrounded fears | |
| 2 | Feeling fearful | Bojali ste se | You have been afraid | Αισθάνομαι φοβισμένος | Feeling fearful | Poczucie strachu | Fear | |
| 3 | Faintness | Bili ste slabiYou have been weak | You have been weak | Αίσθημα λιποθυμιάς | Faintness | Omdlenia | Fainting | |
| 4 | Nervousness | Bili ste nervozni | You have been nervous | Nerviosismo | Nervousness | Nerwowość | Nervousness | |
| 5 | Heart racing | Ubrzano vam je lupalo srce | Your heart has been racing | Ταχυπαλμία | Heart racing | Kołatanie serca | Palpitations | |
| 6 | Trembling | Drhtali ste | You have been trembling | Τρεμούλα | Trembling | Drżenia | Tremors | |
| 7 | Feeling tense | Bili ste napeti | You have been tense | Αισθάνομαι υπερένταση | Feeling tense | Uczucie napięcia | Emotional tension | |
| 8 | Headache | Boljela vas glava | You have had a headache | Πονοκέφαλος | Headache | Bóle głowy | Headaches | |
| 9 | Feeling panic | Bili ste u panici | You have been in panic | Αισθάνομαι πανικό | Feeling panic | Uczucie paniki | panic attack | |
| 10 | Feeling restless | Bili ste uznemireni | You have been upset | Αισθάνομαι ταραχή | Feeling restless | Uczucie niepokoju | Anxiety | |
| 11 | Feeling low in energy | Niste imali dovoljno energije | You haven't had enough energy | Αισθάνομαι ότι δεν έχω ενέργεια | Feeling low in energy | Poczucie braku energii | lacking energy | |
| 12 | Blaming oneself | Okrivljavali ste se | You have blamed yourself | Κατηγορώ τον εαυτό μου | Blaming (myself) oneself | Obwinianie samego siebie | Self blame | |
| 13 | Crying easily | Bili ste plačljivi | You have felt like crying | Εύκολο κλάμα | Crying easily | Płaczliwość | Excessive weeping | |
| 14 | Losing sexual interest | Niste bili zainteresirani za spolni odnos | You have not been interested in sexual intercourse | Απώλεια σεξουαλικού ενδιαφέροντος | Losing sexual interest | Utrata popędu seksualnego | Loss of sexual drive | |
| 15 | Feeling lonely | Bili ste usamljem | You have felt lonely | Αισθάνομαι μοναξιά | Feeling lonely | Poczucie osamotnienia | Feeling of loneliness | |
| 16 | Feeling hopeless | Osjećali ste sebeznadno | You have felt hopeless | Αισθάνομαι απελπισμένος | Feeling hopeless | Poczucie beznadziejności | Feeling of hopelessness | |
| 17 | Feeling blue | Bili ste sjetni | You have been melancholic | Νοιώθω πεσμένος | Feeling blue | Poczucie przygnębienia | Feeling of depression | |
| 18 | Thinking of ending one's life | Razmišljali ste da si oduzmete život | You have been thinking about taking your life | Σκέφτομαι να δώσω τέλος στη ζωή | Thinking of ending one's (my) life | Myśli samobójcze | Suicidal thoughts | |
| 19 | Feeling trapped | Osjećali ste sekao da ste u klopci | You have felt as if trapped | Αισθάνομαι παγιδευμένος | Feeling trapped | Poczucie uwięzienia | Feeling of entrapment | |
| 20 | Worrying too much | Bili ste previše zabrinuti | You have worried too much | Αισθάνομαι παγιδευμένος | Worrying too much | Zamartwianie się | Excessive worrying | |
| 21 | Feeling no interest | Bez interesa za bilo što | Without interest in anything | Αισθάνομαι ότι τίποτε δεν είναι ενδιαφέρον | Feeling no interest | Poczucie braku zainteresowań | Feeling of lack of interests | |
| 22 | Feeling that everything is an effort | Sve vam je bilo naporno | Everything seemed too hard for you | Αισθάνομαι ότι για το καθετί χρειάζεται να κάνω προσπάθεια | Feeling that everything requires an effort | Uczucie, że wszystko jest ciężarem | Feeling that everything is a burden | |
| 23 | Worthless feeling | Osjećali ste se bezvrijedno | You have felt worthless | Αισθάνομαι ότι δεν αξίζω τίποτε | Worthless feeling | Poczucie, że jest się bezwartościowym | Feeling of low self- esteem | |
| 24 | Poor appetite | Imali ste slab apetit | You have had poor appetite | Μείωση της όρεξης | Poor appetite | Słaby apetyt | poor appetite | |
| 25 | Sleep disturbance | Imali ste problema sa spavanjem | You had problem sleeping | Διαταραχές ύπνου | Sleep disturbance | Zaburzenia snu | Sleep disorder | |
|] | Table 6: Forward/ba | ckward: Croat | ian, Greek, P | <u>olish</u> | | | | |

| | Original english version | Croatian | | Greek | | Polish | |
|--------------------------|---|---|---|---|--|---|---|
| | | Forward | Backward | Forward | Backward | Forward | Backward |
| Adjective | Not at all | Nimalo | Not at all | Καθόλου | Not a bit | Brak | None |
| | A little | Malo | A little | Λίγο | A little | Trochę | Some |
| | Quit a bit | Dosta | Quite a bit | Αρκετά | Quite | W dużym stopniu | Considerable |
| | Extremely | Jako | A lot | Πάρα πολύ | Very much | Bardzo mocno | Very strong |
| 1st explanatory sentence | The HSCL-25 score is based on pencil-and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1.00 to 4.00 | HSCL-25 skor sastoji se od 25 pitanja koja se rješavaju jednostavno olovkom i papirom, a temelji se na samoprocjeni prisutnosti i intenzitetu ansksioznih i depresivnih simptoma tijekom prošlog tjedna. Ispitanici odgovaraju jednom od četiri kategorija za svako pitanje na skali od 1-4 | HSCL-25 score consists of 25 items easily completed with pencil and paper, and is based on self-assessment of presence and on intensity of anxiety and depression symptoms in the past week. The respondents answer by one out of four categories for each item on a 1-4 scale | Η βαθμολογία του HSCL-25 βασίζεται σε γραπτό ερφτηματολόγιο αυτοαξιολόγησης 25 ερφτήσεων σχετικά με την παρουσία και την ένταση των συμπτωμάτων άγχους και κατάθλιψης κατά την τελευταία εβδομάδα. Οι συμμετέχοντες απαντούν σε μία από τις τέσσερις κατηγορίες για κάθε ερώτημα σε μια κλίμακα εύρους τεσσάρων βαθμών με τιμές από 1 μέχρι 4 | The HSCL-25 score is based on a written self-assessment questionnaire of 25 questions about the presence and intensity of anxiety and depression symptoms during the last week. Participants answer to one of four categories for each question on a scale of four points which ranges from 1 to 4 | Ocena testu HSCL-25 oparta jest na kwetionariuszu 25 pytań, w którym zakreśla się na papierze obecność i nasilenie objawów lęku i depresji w ciągu ostatniego tygodnia. Badani odpowiadają na jedno z czterech możliwych opcji na skali mierzącej wartości od 1 do 4 | The evaluation of the HSCL-25 test is based on a questionnaire consisting of 25 questions where the respondents mark on paper the presence and intentisty of the symptoms of fear and depression during last week. Respondents choose one of the four options on the scale from 1 through 4 |
| 2nd explanatory sentence | The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1 and 4). It is often used as the measure of distress. The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is 3 1.55. A cut-off value of 3 1.75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL 25 is 5 to 10 minutes | Skor HSCL-25 se izračunava dijeljenjem ukupnog zbroja (zbroj skora pojedinih pitanja) s brojem odgovorenih pitanja (raspon od 1,00 do 4,00). Obično se koristi za mjerenje distresa.Pacijent se smatra « vjerojatno psihijatrijskim slučajem » ako je srednja vrijednost na HSCL-25 ≥ 1,55. Razdjelna točka (cutoff) ≥1,75 se koristi za dijagnozu velikog depresivnog poremećaja i to kao "slučaj koji zahtjeva liječenje". Razdjelna točka se preporuča kao validni prediktor mentalnog poremećaja podjednako kao i sama procjena neovisnim kliničkim intervjuom, dijelom ovisan o dijagnozi i spolu. Vrijeme za ispunjavanje HSCL-25 je 5-10 minuta. | HSCL-25 score is calculated by dividing the total sum (sum of scores of individual items) by the number of answered items (range from 1.00 to 4.00). It is usually used for distress measurement. The patient is considered 'a probable psychiatric case' if the middle value at HSCL-25 ≥ 1.55. The cut off point ≥ 1.75 is used for diagnosis of major depressive disorder as 'a case requiring treatment. The cut off point is recommended as a valid predictor of mental disorder roughly the same as the assessment by independent clinical interview itself, partly dependent on diagnosis and gender. HSCL-25 completion time is 5-10 minutes. | Η βαθμολογία του HSCL-25 υπολογίζεται διαιρώντας τη συνολική βαθμολογία των ερωτημάτων), διά του αριθμού των ερωτημάτων που Ο χρόνος χορήγησης του HSCL 25 είναι 5 έως 10 λεπτά.απαντήθηκαν (κυμαινόμενο μεταξύ του 1,00 έως 4,00). Συχνά χρησιμοποιείται για τη μέτρηση της δυσφορίας. Ο ασθενής θεωρείται σαν "πιθανό ψυχιατρικό περιστατικό" εάν η μέση βαθμολογία του HSCL-25 είναι >=1,55. Το όριο του >= 1,75 γενικώς χρησιμοποιείται για τη διάγνωση της μείζονος κατάθλιψης που ορίζεται ως "περίπτωση που χρήζει θεραπείας". Αυτό το όριο συνίσταται σαν ένας έγκυρος προγνωστικός δείκτης ψυχικής διαταραχής, όπως εκτιμάται ανεξάρτητα από την κλινική εικόνα, η οποία εξαρτάται κάπως από τη διάγνωση και το φύλο | The HSCL-25 score is calculated by dividing the total score (the sum of the score of the questions) by the number of the answered questions (ranging between 1.00 and 4.00). The patient is considered as a "probable psychiatric case" if the mean score of the HSCL-25 is >=1.55. A cut-off of >= 1.75 is generally used for the diagnosis of major depression, which is defined as "a case requiring treatment". This cut-off point is recommended as a valid predictor of mental disorder, as evaluated independently by the clinical overview, which depends on the diagnosis and the gender a bit. The administration time of HSCL-25 is between 5 and 10 minutes. Often it is used to measure stress. | Wynik testu HSCL-25 jest obliczany poprzez podzielenie całkowitej liczby punktów (suma punktów z każdej pozycji testu) przez liczbę pozycji tas ttóre udzielono odpowiedzi (w skali od 1 do 4). Często służy on do pomiaru dystresu. Pacjenta uważamy za "prawdopodobny przypadek psychiatryczny" jeśli średnia ocena w teście HSCL-25 jest >/ (większa lub równa) 1,55. Wartość graniczną>/ (większa, lub równą) 1,75 ogólnie przyjmuje się w diagnozowaniu ciężkiej depresji, definiowanej jako "przypadek wymagający leczenia." Wartość ta jest zalecana jako istotny czynnik w przewidywaniu obecności choroby psychicznej, wymagającej jednak niezależnego wywiadu klinicznego i w pewnym sensie zależy od rozpoznania i plci. Czas na wykonanie testu HSCL 25 wynosi od 5 do 10 minut | The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress. The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ³ 1,55. The HSCL 25 test lasts from 5 to 10 minutes. A cut-off value of ³ 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. |

Table 6: Forward/backward: Croatian, Greek, Polish

3.4.10. German

All items were accepted in the first round Delphi but several translations required comments the most discussed items were the second explanatory sentence, item 1, 7, 10, 11, 16, 21 and 25.

Seven (15%) of the 46 items ranked below 7 are not commented and 22 (36%) of the 61 comments concern items ranked above 6.

The NIs sent the final German version of HSCL-25 to two independent translators who translated it back to English. The translator from Hannovers team translated the items and the one from Göttingens team the instructions. Their native language was German and they were knowledgeable about health care terminology, so the blind backward translation principle was respected.

4. Discussion

4.1. Main results

HSCL-25 was translated in 3 languages family: Romance (Galician, Castilian, Catalan, French, Italian), Slavic (Croatian, Bulgarian, Polish) and Greek., a german version already existed.

About Romances language: the French was the language which the most that (18) were not accepted during the first round delphi, it was, most of the time, the tense used in common language, the present, which led to several modifications on the final translation, compared to the forward version that used the past tense. The meaning of the words, the syntax, the quotations and the strength of the proposals seemed to be different possibly in relation to the French language For the Hispanic languages (i.e Castilian, Catalan and Galician) and Italian, the translation had to be adapted on the gender, and more precisely on the male plural form for the Italian scale, which was the usual way of speaking in that country. Two round was necessary in Italy (5 items unaccepted) and Galicia (3 items unaccepted).

For the German, all items were accepted in the first round Delphi. Unfortunately, it was not possible to ensure the linguistic stability of the German version of the HSCL-25 in general practice, as a German translation already existed. Moreover, the number of experts at the end of the first Delphi round was insufficient (14).

About Slavics languages: for Croatia, 11 items were not accepted during the first round, most of the time it was used the present perfect, which is a tense of state and not of action. Regarding Polish and Bulgarian all items were accepted after the first round.

For the Greek 9 items were unaccepted after the first round, the HSCL-25 translation was mainly based on an adaptation according to the gender.

HSCL-25 was achieved. All translations were linguistic relaible of the original version. Previous translations of other forms of HSCL (HSCL-37) had failed to maintain this linguistic stability by their mode of translation (69, 70). This work was a real novelty, by the assured reproducibility of the translation result.

There was not need lot of round Delphi, in fact, only two rounds Delphi was necessary in Galicia, France, Italy, Croatia, Greece and only one in the rest of the countries. This low number of rounds is due to Hopkins Syndrom Check List which is very stable and a alpha of Cronbach very high (it is used as a lowerbound estimate of the reliability of a psychometric test like HSCL-25).

This study (under the auspices of EGPRN) proved that HSCL 25 is the best possible tool, in terms of efficiency, reliability and ergonomics, to diagnose depression in European Primary Care medicine in a research perspective; they used a RAND/UCLA methodology, based on an SRL (71) and a Rapid Review (72). HSCL-25 allowed collaborative research, subject to validate outpatients in primary care daily practice.

4.2. Teaching, research and practice future applications

The ergonomics of HSCL-25 will reassure students of the feasibility of such tests in Primary Care Medicine. Teachers could use this validated tool as the basis of their courses for depression diagnosis in FM. They could have enough confidence in the reliability and efficiency data to teach it to their students.

Translation in ten European language of HSCL-25 allows collaborative research, multicentered in daily practice throughout Europe. This cross-sectional tool could allow transversal research between psychiatry and primary care.

The comparison between the backward and forward translation will allow: on the one hand, the ultimate control of the linguistic quality translation work of the whole process and on the other hand, to identify the differences between the two English versions which are not reducible despite the quality control.

Currently, migration is increasing in Europe (due to the complex geopolitical context, globalization...), HSCL-25 has already been used in clinical settings both for refugee and general populations (69, 70). These translations can help doctors in primary care to diagnose depression while not speaking the patient's language.

HSCL-25 will allow homogenization of diagnoses and can be the treatment of depressive patients later.

4.3. Strenght and limits

4.3.1. Strenght

The strength of the study is based on its methodology and the selection of GPs experts.

Quality of methodology:

The entire initial protocol was respected throughout the study. The translation of HSCL-25 was obtained using known and reputed tools for maintaining this stability, a Delphi process and a Likert scale (60, 61, 73, 74).

The scientific committee of the study choose the Delphi procedure because of its capacity to be conducted quickly and cheaply. Because the Delphi procedure does not require any face-to-face meeting, it preserves anonymity, limits leadership effect and conflicts of interest and allows a rich panel of experts without any geographical constraints (75-77).

Delphi process with FPs experts performed an expert consensus on Galician, Catalan, Castillan, French, Bulgarian, German, Croatian, Italian, Greek, Polish translation of the HSCL-25. It must integrate idiomatic expressions, colloquial health phrase and emotional terms in common use in order to be easy to use in GP practice and research.

The Likert scale is an international validated, qualitative and ordinal scale. The ranking 7 or above guaranteed an adherence to the translation (50, 64, 78, 79).

The HSCL-25 seems to be a very stable questionnaire because almost all excerpts translations were accepted in one round. Half of the countries needed two Delphi round: Greece, France, Galicia, Croatia, and Italy. All proposals were accepted in the second round.

The Delphi procedure was adapted to evaluate an issue quickly, with low cost and without geographical constraints.

It allowed a convergent tendency to be obtained from various subjective elements. It was also a reproducible consensus of opinion (47).

Quality of the panel

In this study, 11 Nationals leaders, 224 experts and 23 independants translators participed. The panel is very heterogeneous, cosmopolitan, it's a great strength of this linguistic translation This very high proficiency guaranteed the Delphi procedure's high quality.

The average of international publications for national leaders was 13.8, for a total of 152 publications. The average of years of practice was 21.3 years, and 12.4 in terms of years of research. All leaders were research and 72,7% were teachers. Leaders were instrumental in selecting a varied and heterogeneous panel of experts.

The experts were 81,4% teaching and/or researching activity in a Family Medicine Training Unit. Their clinical experience was very high. They were all english fluent. This very high proficiency guaranteed the Delphi procedure's high quality.

The translators were specialized in the linguistics of their country and spoke very well English, they were selected by the national leaders.

The choice of a panel of general practitioners is made to have a vision of the primary care specialist useful in everyday practice. The Delphi protocol required that they be qualitatively representative and varied (60, 74).

Collaborative research work

This work was included in a European cooperative study responding to the need of general practitioners in Europe (35).

The repetition of translations in all the different languages strengthened the overall value of the results obtained.

One of the aims of this research was to create a diagnostic tool that can be used in different European countries in primary care research (80).

4.3.2. Selection bias

In order to constitute the panel, experts were chosen to ensure a maximum of heterogeneity and to increase its representativeness (56). According to Delphi procedure, GPs experts were sufficient and selection criteria were strictly followed: they were native of the country and it was their native language, they were English speaking and were in GP practice.

The experts were 81,4% teaching and/or researching activity in a Family Medicine Training Unit.

To constitute the panel, experts were chosen to ensure a maximum of heterogeneity, to increase its representativeness (56).

Males were more represented with 51, 6%.

About geographical heterogeneity, GPs experts were working in different locations. For example in Spain (Catalonia, Castille, Galice), no GPs' experts were working in a city <2000 habitants. It can be explained by the high proportion of academic researchers and by Spain health organization. In Spain there is at least one health center in each municipality but GPs' work in larger health centers, with usually 4-10 GPs for 6000-15000 patients. On the contrary, in Greece, 38.4% of GPs' work in cities <2000, a majority of GPs' were working in a rural environment.

So the number of experts, their geographical heterogeneity, their different ways of working, their experience reduced the selection bias.

4.3.3. Information bias

NIs' organized the Delphi round according to protocol: they sent the same documents to each expert, and they all received the whole protocol. No information bias was possible as every participant had a full access to the whole data. The proposed translation and the rules of procedure were clearly written. Furthermore, the short delay imposed by the Delphi process was respected, therefore avoiding information bias.

4.3.4 Confounding factors

Forward-Backward is an international consensual process of translation and adaptation of instruments. The Forward translation process aimed to respect the faithfulness of meaning in English and in ten European languages. A specific attention was paid to choose GP researcher and certified bilingual translator knowledgeable about health care terminology. To ensure homogeneity, a backward translation was necessary. The backward translator was working blind and was an academic official translator (47, 81). Each expert expressed his judgment individually and anonymously. The lack of face-to-face meeting avoided the "opinion leader" effect and limits conflicts of interest. All those arguments reduced the confusion bias.

Differences between the Original and the Back-translation appeared. Even if the linguistic translation was reliable, the meaning of some items could be not completely similar. Possible confounding bias could exist, related to the cultural differences. Those aspects will be analysed with a cultural check (82, 83, 84). The next step is a cultural analysis of the translation which will ensure the semantic reproducibility between the original version and the translation.

5- Conclusion

The third phase of FPDM, using a Delphi procedure and Forward-Backward translation, allowed the translation of HSCL-25 in Galicia, Catalan, Castilian, French, Italian, Bulgarian, Croatian, Greek and Polish. We performed a consensual translation of HSCL-25 in several European languages using a Delphi procedure adapted for a Forward-Backward translation. This procedure aimed to produce the best translation, taking into account cultural differences and special features. Delphi process was extensively used in many domains because it does not require any face-to-face meeting and preserve anonymity, so it limits domination effect and conflicts of interest effects.

The GPs' can exchange more objectively with healthcare authorities and psychiatrists on the prevalence, incidence and treatment of depression in primary care. The interest of HSCL-25 is in research, practice and teaching.

A cultural check will verify their validity, ensuring that the meaning of every translation remains the same compared to the original English version.

During the next step (fourth phase), every national team will test HSCL-25 to ensure its ergonomics in a general practice setting.

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7- Annex

Annex 1: HSCL-25 Hopkins Symptom Checklist



<u>Département Universitaire de Médecine Générale</u> 22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3

Tél: 02 98 01 65 52 – fax: 02 98 01 64 74

Choose the best answer for how you felt over the past week:

| Items | | 1: "Not at all" | 2:"A little" | 3:Quite a bit": | 4: "Extremely" |
|-------|----------------------------|-----------------|--------------|-----------------|----------------|
| 1 | Being scared for no reason | | | | |
| 2 | Feeling fearful | | | | |
| 3 | Faintness | | | | |
| 4 | Nervousness | | | | |
| 5 | Heart racing | | | | |
| 6 | Trembling | | | | |
| 7 | Feeling tense | | | | |
| 8 | Headache | | | | |
| 9 | Feeling panic | | | | |
| 10 | Feeling restless | | | | |
| 11 | Feeling low in energy | | | | |
| 12 | Blaming oneself | | | | |
| 13 | Crying easily | | | | |
| 14 | Losing sexual interest | | | | |
| 15 | Feeling lonely | | | | |

| 16 | Feeling hopeless | | |
|----|--------------------------------------|--|--|
| 17 | Feeling blue | | |
| 18 | Thinking of ending one's life | | |
| 19 | Feeling trapped | | |
| 20 | Worrying too much | | |
| 21 | Feeling no interest | | |
| 22 | Feeling that everything is an effort | | |
| 23 | Worthless feeling | | |
| 23 | Poor appetite | | |
| 25 | Sleep disturbance | | |

The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress.

The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ³ 1,55.

A cut-off value of ³ 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender.

The administration time of HSCL 25 is 5 to 10 minutes.

Annex 2: informed consent (to translate in your language)

Département Universitaire de Médecine Générale

22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3

Tél: 02 98 01 65 52 – fax : 02 98 01 64 74

INFORMATION NOTICE

International Investigator Senior Coordinator

Name: Nabbe Patrice

Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3

International Developer

Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3

National investigator senior coordinator:

Name:

Address:

National developer:

Dear Madam or Sir

You are invited to participate in a survey by A.AUGUSTIN (trainee in general practice, GP...). The department of general practice from BREST. is the national developer of that survey. He is responsible for it and assumes its organization.

Mrs/Mr will explain his/her work to you. If you decide to participate you will be asked to sign a consent form. This signature will confirm that you did agree to participate.

1. Course of study

A Delphi procedure. This Delphi procedure will be fully anonymized and it will be impossible for a study reader to identify you.

2. Potential risk of study

There are no risks associated with your participation in this study

3. Potential benefits of the study

There is no potential benefit to this study

4. Voluntary participation

Your participation to this study is entirely voluntary.

You are free to refuse to participate and to terminate your participation in the study at any time and without incurring any liability or any injury of this fact and without causing consequences.

In this case you must inform the investigator of your decision

In the event that you withdraw your consent, we will conduct a computer processing of your personal data unless written objection on your part.

During the study, your investigator will notify you, if new facts might affect your willingness to participate in the study.

<u>5.</u> <u>Obtaining complementary informations</u>

If desired, Patrice Nabbe or local national investigator (phone number), who can be reached at telephone number: 00 33 674 36 43 22 at any time can answer all your questions about the study.

At the end of the study, and at your request, your investigator will inform you of the overall results of this research.

<u>6.</u> Confidentiality and use of medical or personal data

As part of biomedical research in which the DUMG Brest, Patrice Nabbe and your national investigator offer to participate, a treatment of your personal data will be used to analyse the results of research in light of the objective of that study which was presented to you.

To this end, the data collected, including any survey and the data on your lifestyle will be forwarded to the promoter of the research where the data will be processed in this study.

Those data will be anonymized and their identification will be held with a code number.

Staff involved in the study is subject to professional secrecy.

These data may also, under conditions ensuring their confidentiality be transmitted to the national or European health authorities.

Under the provisions of Law you have the right to access and modify. You also have the right to object to the transmission of data covered by professional secrecy.

If you agree to participate in this study, thank you to complete and sign the consent form. You will keep a copy of it.

Annex 3: Consent Form for each leader

Consent Form (for each leader with department of general practice, Brest, France Promoter : Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex Dr: NABBE Patrice.... Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3, FRANCE National leader investigator name Address: University: Asked me to participate in a Forward-Backward translation. I had time to reflect on my involvement in this study. I am aware that my participation is completely voluntary and that the study will entail no additional cost to my charge. I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences. I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter. I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me. My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law. Done in two originals at..... the dd/mm/yyyy Name, first name of national leader: Name, first name of the interviewee: Signature:

Annex 4: Consent Form for each national team

Consent Form (for each national leader with each member of local national team)

| Promoter: Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3 | | | | |
|---|--|--|--|--|
| Dr | | | | |
| Address: | | | | |
| Local investigator name | | | | |
| Address: | | | | |
| University: | | | | |
| Asked me to participate in a Delphi consensus. | | | | |
| I had time to reflect on my involvement in this study. I am aware that my participation ompletely voluntary and that the study will entail no additional cost to my charge. | | | | |
| I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences. | | | | |
| I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter. | | | | |
| I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me. | | | | |
| My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law. | | | | |
| Done in two originals | | | | |
| at, the dd/mm/yyyy | | | | |
| Name, first name of investigator: Name, first name of the interviewee: | | | | |

LE BRIS Tanguy - THE HOPKINS SYMPTOMS CHECKLIST IN 25 ITEMS: TRANSLATIONS IN CASTILIAN, GALICIAN, CATALAN, FRENCH, GREEK, ITALIAN, POLISH, BULGARIAN AND CROATIAN SYNTHESIS

54 pages, tables, annexes, Thèse Médecine: Brest 06/2017

RESUME / ABSTRACT

<u>Introduction:</u> Depression is the second most common chronic disorder in primary care. Inter-individual and cross-cultural variations can alter the expression of symptoms. The 25-item Hopkins Symptom Checklist (HSCL-25) was selected by the Family Practice Depression and Multimorbidity (FPDM) study of the European General Practice Research Network (EGPRN) as the most appropriate to diagnose depression according to criteria efficiency, reproducibility and ergonomics versus DSM. The objective was to synthesize the linguistic translations previously produced in Galician, Castilian, Catalan, French, Italian, Greek, Croatian, Bulgarian, German, Polish.

<u>Method:</u> Backward-forward translation by Delphi rounds was used to make consensus. A panel of general practitioners (Gp) experts was recruited by a national investigator (NI) in each country. The quantitative data was made with a Likert scale. Consents and anonymity were guaranteed by NI. The backward translation was carried out blind from the original.

<u>Results</u>: The panel complies with the inclusion criteria. A single round delphi was needed in Poland, Bulgaria, Germany, Castile and Catalonia, a German version already existed, items were accepted with commantaries. Two were necessary in France, Croatia, Greece, Galicia, Italy after experts disagreed on few items. No more rounds

MOTS CLES:

Depression Primary health care / Backward-Forward translation by Delphi process / Hopkins Symptom Checklist in 25-items/ Castilian, Galician, Catalan, Italian, Bulgarian, French, German, Greek, Polish, Croatian translations / synthesis

JURY:

PRÉSIDENT DU JURY Pr. JY LE REST

MEMBRES DU JURY Dr. NABBE

Pr LE FLOC'H

DATE DE SOUTENANCE:

Jeudi 8 juin 2017