

What is the translation of HSCL-25 in Bulgarian. A consensus procedure by Delphi-round and Forward-Backward translation

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UNIVERSITÉ DE BREST - BRETAGNE OCCIDENTALE
Faculté de Médecine & des Sciences de la Santé

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What is the translation of HSCL-25 in Bulgarian; A consensus procedure by Delphi-round and Forward-Backward translation.

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Présentée par Mr le Professeur Jean Yves LE RESTE

Titre de la thèse :

What is the translation of HSCL-25 in Bulgarian ;

A consensus procedure by Delphi-round and Forward, Backward translation.

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

En foi de quoi la présente autorisation d'imprimer sa thèse est délivrée à Mr MOINARD Pierre, interne en médecine générale.

Fait à BREST, le 16 1 2014

VISA du Doyen de la faculté

A BREST, le 16/01/2014

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Professeur C. BERTHOU

Le Président du Jury de Thèse,

Professeur J.Y. LE RESTE

Directeur du Département

Département de Médecine Générale

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Je remercie les membres de mon jury :

Monsieur le Professeur Jean Yves LE RESTE
Médecin Généraliste à Lanmeur
Maitre de stage
Professeur à la faculté de médecine de Brest

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Maître de stage
Maître de conférence associé à la faculté de médecine de Brest

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Professeur associé à la faculté de médecine de Brest

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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.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

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.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

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HSCL-25 Forward-Backward translation to Bulgarian by Delphi Procedure. Third Phase of FPDM

Résumé

Introduction : La dépression est une maladie chronique souvent diagnostiquée et traitée en soins primaires. Les patients multi-morbides de plus de 50 ans sont particulièrement à risque. Les variations interindividuelles et interculturelles rendent le diagnostic difficile. Peu d'outils diagnostic sont adaptés et utilisés par les médecins généralistes.
L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) souhaite valider un outil diagnostic de la dépression en médecine générale pour entreprendre des recherches européennes.
Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25-items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie.

Objectif : L'objectif était de traduire la HSCL-25 en Bulgare tout en adaptant son contenu aux particularités culturelles et linguistiques bulgares, sans perte de sens.

Méthode : Une procédure Delphi adaptée avec traduction Aller-Retour a été utilisée. Une traduction de l'Anglais au Bulgare a été soumise par procédure Delphi à un panel d'experts bulgares en soins primaires. La traduction retour a été réalisée en aveugle de l'original.

Résultats : Le panel d'experts répond aux critères d'inclusion. La traduction Bulgare a été validée unanimement au premier tour. La traduction retour en anglais a été produite.

Discussion : Le choix d'une méthode de traduction Aller-Retour par procédure Delphi adaptée avec exigence sur la qualité du panel d'experts, garantit une traduction bulgare de HSCL-25 validée et fiable proche de l'original. Prochainement, une analyse culturelle de la traduction assurera la concordance entre la version originale et la traduction.

Abstract

Introduction: Family physicians (FPs) are the first port of call for depressive patients in developed countries. The multi-morbid patients over 50 years are especially at risk. Symptoms are difficult to identify owing to their interindividual and intercultural variations. Few diagnostic tools are adapted and used by FPs. Family Practice Depression and Multimorbidity (FPDM) study by European General Practice Research Network (EGPRN) aims to find a diagnostic depression tool in primary care and to undertake collaborative research throughout Europe.
Previous steps of FPDM have found that the Hopkins Symptom Checklist in 25-items (HSCL-25) was the most appropriate tool according to the criteria of effectiveness, reproducibility and ergonomics.

Objective: This study aimed to translate HSCL-25 in Bulgarian while adapting its content to the cultural and linguistic characteristics ensuring that original meaning was preserved.

Method: A Delphi method adapted for a Forward-Backward translation was used. The translation from English to Bulgarian was submitted by Delphi procedure to a panel of Bulgarian experts in primary care. Backward translation was performed with a blind back-translation principle.

Results: The inclusion criteria of panel were followed. The Bulgarian translation was confirmed unanimously in one Delphi round. The Backward English translation was produced and agreed by the FPDM's scientific committee.

Discussion: The quality of the panel of experts FPs ensured a validated and reliable Bulgarian translation. The following step will consist in a cultural check to ensure that HSCL-25 is in total agreement with the Backward translation.

Introduction

Depression is the second most common chronic disorder seen by primary care physicians, first port of call in most European Countries. (1) The multi-morbid patients over 50 years are especially at risk. (2)(3)(4)(5)(6)

Depression is a variable combination of symptoms shared with other mental disorders like contextual distress, anxiety and somatoform disorders. The patient himself experiences difficulties to express his suffering and shows his own illness expression. (7)

The difficulties to diagnose and assess the severity of depression lie in this inter-individual variability. Clinicians can overestimate or underestimate the distress level of their patients. (8)(9) Those difficulties may lead to inappropriate care and causes public health problems.(10) Diagnostic and Statistical Manual of Mental Disorders (DSM-IV/5) is widely considered as gold standard to diagnose depression, but it's rarely used in Family practice.(11)(12) Despite all this, Family Physicians (FPs) seem to be uncomfortable with depression definition and available diagnostic tools.(13)(14) Incidence and prevalence rates of depression differ in Family practice across Europe, related to complex contextual variations with differences in health care system, in concepts, objectives and practices as well as cultural variations in the expression of the disease.(15)(16)(17)(18)

European FPs community needs a better knowledge of usable instruments to diagnose depression in adult patients.(8) There is also a need for a European consensus on a single diagnostic tool for depression to undertake collaborative research in Family practice throughout Europe. (19) It must be validated, reproductive and ergonomic for FPs daily practice.

The family practice depression and multi-morbidity study (FPDM) started in 2011. The first and the second step designated the Hopkins Symptom Checklist-25 (HSCL-25) as the best tool. This screening instrument is easy to implement and was extensively compared to DSM-IV/5. The HSCL-25 was used but there is no official and consensual translation available.

Background

The aim of FPDM study was to select a single tool that could be consensually used by FPs to diagnose adult patient's depression and to make it applicable in the participating European countries. In order to be satisfactory, it had to be validated, reliable and easy to use by FPs throughout Europe; this study consisted of four steps.

The first step was a systematic literature review in order to select the candidate tools. This systematic review investigated all diagnosis 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. (20)

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 and the University of California Los Angeles) procedure.(21) 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.

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

The aim was to translate HSCL-25 in Bulgarian by using a Delphi consensus procedure with a Forward-Backward translation.

Method

Definition

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. It includes 25 items: 10 items about anxiety and 15 about depression. (22)(23)(24) 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".(25)(26) The HSCL-25 was used in family planning services, among refuges and among migrants. (27)(28)(29)

For the translation to retain the same meaning as the original, a Forward-Backward translation was conducted following a formal consensus method: Delphi round. Formal consensus is the most appropriate method when there is a need to reach a solid consensus transparently on a little investigated subject. Delphi procedure, reliable and efficient is used frequently in health care as a rigorous way to reach consensus in defined clinical areas.(30)(31)(32) 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 national investigator (NI)), statistical aggregation of group's responses to allow a quantitative and qualitative analysis of the data.(33)

Consents and anonymity

The NI asked the participants for their signed consent, anonymized the expert responses and delivered an identification number later identification.(21) The name of each expert was not transmitted to other. Only NI's consent was sent to the investigator team. As the study involved no patient, it didn't require an ethics committee's decision.

Participants

Pilot Team (PT): The EGPRN French team was familiar with Delphi methodology. It requested to the national investigator his consent and 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 Investigator (NI): The NI was in charge of recruiting translators and experts. He acted between each phase and between two Delphi rounds. He didn't act when a Delphi round was running.

Translators: The NI selected four 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 family physician (FP) research group and one official translator. Bulgarian had to be their native language. The Backward translation team involved one (or two) FP(s) and one official Bulgarian/English translator.(34) The two teams should not have involved the same person.(35)

Experts panel : Initially, 20 to 30 experts were recruited in order to keep at least 15 participants until every round's end. The selection criteria for every expert were: being native to Bulgaria and Bulgarian was his native language; being English speaker; being in FP practice. Over half had to have teaching or research activities. In order to assess the representativeness of the panel by its diversity, the experts informed their gender, area of practice, years of practice and publications.(36)

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 Bulgarian aiming to retain the same meaning as the original.

Delphi rounds

At the beginning of the first round, NI sent by mail the original English version and translated version in Bulgarian. FPs experts received records individually. NI didn't use mailing list in order to assure anonymity which increased responses reliability and to avoid contamination (discussion between experts).(37)

Experts expressed their level of agreement on each proposal by using a Likert scale. This Likert scale was an agree/disagree scale of 1 to 9, 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. They were not aware of the following interpretation of data processing. Consensus was defined for an excerpt's translation when it was rated 7 or above by over 70% of the panel, 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, all the experts' commented on this proposal, the new proposal. Experts rated the new proposal in the same way as for the first round. The following rounds rolled out in an identical manner. This process was repeated until all excerpts find a consensual translation. The number of rounds was not limited. (38)

At the Delphi procedure end, there was a consensus on a final Bulgarian version of HSCL-25.

Backward translation

NI sent the final Bulgarian 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.(39)

Results

Forward

The NI submitted the questionnaire to one official translator and one FP researcher. A consensual Forward translation of HSCL-25 was proposed. (Table 2) The native language of translators was Bulgarian and they were knowledgeable about health care terminology.

Panel

The NI had particularly sought to obtain the consents of experts as well as the characteristics of each (Table 1).

Twenty-two FPs were recruited for the Delphi procedure. They were all FPs in family practice. The experts consisted of 40,91 % male and 59,09 % female. Their age was distributed as follows: Between 20-30 (4,55%); 31-40 (13,64%); 41-50 (50%); 51-60 (31,82%).

Experts worked in a city > 5000 (72.73%), in a small city (22,73%) and in a rural city (4,55%).

The expert's level of English was evaluated. Among the 22 FPs, 18,18% were basic users, 59,09% independent and 22,73% proficient.

Clinical experience was analysed by year of activities: 0-10 (4,55%); 11-20 (36,36%); 21-30 (50%); 31-40 (9,09%).

Among the 22 FPs experts, 22,73% were academic researcher and had publications, 36,36 % had teaching activity. In total, 40,91% were academic researcher or had a teaching activity. The others worked in general medical practice.

Delphi Procedure

The Delphi round lasted two weeks. The NI oversaw but didn't take part of the rounds. The NI had also conformed to the procedure of the Delphi round: the proposed translation was sent sentence by sentence to the experts, using a Likert scale in 9 points, in separated mails. There was only one Delphi round to validate the Bulgarian Forward of HSCL-25.

The entire proposals were validated with 7 or above. Seven items of HSCL-25 were rated between 7 and 9 (Items 10, 11, 12, 15, 19, 21, 22).

The most discussed was 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. The second concerned, 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.

Backward

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.

FPs Experts Number	Gender	Age	English speaker	Years of practice activity	Academic researcher (years)	Publication	Teacher (Years)	Area of practice	Lower Rate
	M .male *F .female*		*A.basic user* *B.indepen-dent* *C.proficient*			*Y - Yes* *N - Not*		*1.< 2000* *2.2000-5000* *3. >5000*	
1	M	45	B	18	-	N	-	2	8
2	F	52	B	27	-	N	-	2	9
3	F	57	B	30	-	N	-	1	9
4	F	37	B	14	-	N	-	2	9
5	M	55	B	20	-	N	10	3	8
6	F	44	B	20	-	N	8	3	8
7	M	40	B	15	-	N	-	2	8
8	M	55	C	28	8	Y	12	3	9
9	F	48	B	24	-	N	-	3	8
10	F	51	A	26	-	N	6	3	7
11	F	48	A	22	-	N	-	3	9
12	M	39	B	14	5	Y	8	3	7
13	M	45	B	20	-	N	-	2	9
14	F	42	B	17	-	N	-	3	8
15	M	55	C	35	-	N	12	3	8
16	F	47	C	23	-	N	-	3	9
17	F	39	B	15	-	N	-	3	9
18	M	40	C	16	2	Y	12	3	9
19	M	41	A	15	-	N	-	3	9
20	F	29	C	4	2	Y	-	3	7
21	F	44	A	22	-	N	-	3	9
22	F	51	B	26	10	Y	12	3	9

Table 1: Panel of FPs experts

	ORIGINAL ENGLISH VERSION	FORWARD	BACKWARD
	Choose the best answer for how you felt over 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	Чувство за уплаха без причина	Being scared for no reason
2	Feeling fearful	Чувство за страх	Feeling fearful
3	Faintness	Отпадналост	Faintness
4	Nervousness	Нервност	Nervousness
5	Heart racing	Сърцебиене	Heart racing
6	Trembling	Треперене	Trembling
7	Feeling tense	Чувство за напрежение	Feeling tense
8	Headache	Главоболие	Headache
9	Feeling panic	Чувство за паника	A sense of panic
10	Feeling restless	Чувство на безпокойство	A sense of anxiety
11	Feeling low in energy	Усещане за понижена енергия	A sense of low energy
12	Blaming oneself	Самообвинение	Self-accusation
13	Crying easily	Плачливост	Tearfulness
14	Losing sexual interest	Загубата на сексуален интерес	Loss of sexual interest
15	Feeling lonely	Чувство за самотност	A sense of loneliness
16	Feeling hopeless	Чувство за безнадежност	A sense of hopelessness
17	Feeling blue	Чувстам се нещастен	Feeling blue
18	Thinking of ending one's life	Мисли за самоубийство	Thoughts of suicide
19	Feeling trapped	Чувстам се като в капан	Feeling trapped
20	Worrying too much	Притеснявам се твърде много	Worrying too much
21	Feeling no interest	Чувство за загуба на интерест	A sense of a loss of interest
22	Feeling that everything is an effort	Чувство, че всичко изисква усилие	A sense that everything needs effort
23	Worthless feeling	Чувство за безполезност	A sense of worthless
23	Poor appetite	Лош апетит	Poor appetite
25	Sleep disturbance	Нарушения на съня	Sleep disturbance

ORIGINAL ENGLISH VERSION	Items	1."Not at all"	2."A little"	3."Quite a bit"	4."Extremely"
	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. 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.				
FORWARD	Категория	1."Съвсем не"	2."Незначително	3."Съвсем малко"	4."Извънредно"
	HSCL-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 оценка по HSCL-25 е ≥ 1,55. Гранична стойност от ≥ 1,75 обикновено се използва за диагностициране на тежка депресия и определя случая като "случай, нуждаещ се от лечение". Тази гранична стойност, получена независимо от клиничното интервю и зависеща до определена степен от диагнозата и пола, се препоръчва като валиден предиктор за психично разстройство. Времето за провеждане HSCL-25 е от 5 до 10 минути.				
BACKWARD	Items	1."Not a bit"	2."A little bit"	3."Quite a bit"	4."Extremely"
	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 2: HSCL-25: original version/ Forward version/ Backward version

Discussion

The power of the study was based on its methodology and the selection of FPs experts.(40)(41) The Delphi procedure with FPs experts aimed to evaluate the Bulgarian's translation and integrate idiomatic expressions, colloquial health phrase and emotional terms in common use. The procedure allowed to evaluate a question quickly and cheaply without geographical constraints. The Likert scale is an international validated, qualitative and ordinal scale. The ranking 7 or above guaranteed an adherence to the translation.

Selection bias & Sample's characteristics

The sample's characteristics are always disputable. On one hand they were carefully chosen to ensure a maximum of heterogeneity of the panel. All types of FPs were represented. FPs experts were sufficient (22 FPs) according to Delphi procedure. Experts were native of Bulgaria and Bulgarian was their native language. Each expert was competent in English. The translation's judgment was provided by a mix of academic and non-academic FPs. A consequence of the academic criterion was reflected with a majority in City (>5000) practice. On the other one they were chosen to ensure homogeneity of the Bulgarian translation through Bulgaria, the study had selected FPs experts who came from different geographical locations.

Sample was defined according to gender, age and area of practice. Long years of practice ensured the relevance of evaluations. The years of practice activity had to be commented. In 1999, Bulgaria began overall reform of its health system. Before, most Bulgarians relied on communist-era public clinics. Since, the private medical practice was expanded. FPs Experts' experience in primary care was about 13 years. There were no selection bias according to sample's characteristics.

Information bias

As the NI organized the Delphi round according to protocol: the proposed translation was sent sentence by sentence to the experts. No information bias was possible as every participants had a full access to the whole data.

Confusion bias

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 Bulgarian. A specific attention was paid to choose FP researcher and certified bilingual translator knowledgeable about health care terminology. To ensure homogeneity, a Backward translation was necessary. The back translator was working blind and was an academic official translator. (42,43)

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, which is, however, never null with this type of method.

Comments

Only two comments about synonyms emerged. No other translation problem has been reported.

Although proposals have all been completed, it was interesting to analyze the items discussed by FPs experts. Among these items, one concerned anxiety items and six concerned depression items. As explained before, the problem for Item 11 and 22 has fallen under the synonymous. The majority of questions was within the terms used for the items in depression. The terms expressing anxiety seemed more commonly accepted and more rational. While the terms expressing depression were more subjective and required more thinking.

The choice of words was essential to keep the meaning of items. There were differences in words and syntax between original English version of HSCL-25 and Backward translation. A cultural check will examine these changes. (44)(45)(46)

Conclusion

The third phase of FPDM, using a Delphi procedure and Forward-Backward translation, allowed the translation of HSCL-25 in Bulgarian. The translation realized in Bulgaria obtained a consensus with one round Delphi unanimously approved. The translation analysis was performed by official translators and a panel of FPs experts. A mix of FPs experts were selected according to specific criteria (language skills, academic activities, teaching activities, experience, area of practice, gender and age). The result is a fully translated HSCL-25 in Bulgarian language.

The cross-cultural approach is complex. The reliability of HSCL-25's using depended to a reliable translation. It must integrate understanding of a cultural, linguistic and ethnic background. This methodological approach was focused on translation, adaptation and cross-validation of HSCL-25 in Bulgarian. A cultural check will verify their validity, ensuring that the meaning of every translation remains the same compared to the original English version.

With all translations, collaborative research in primary care in Bulgaria and throughout Europe will be undertaken. This will allow a reliable comparison of the diagnostic assessment of depression and treatment practices between different European countries. The FPs can exchange more objectively with healthcare authorities and psychiatrists on the prevalence, incidence and treatment of depression in primary care.

The fourth step of FPDM will consist in testing the HSCL-25 in each language in order to assess the feasibility, practicability and efficiency of the tool in practice.

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Annexes

Annex 1: Results Panel for the 25 items of HSCL-25

	Items HSCL-25	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
FPs Experts																										
1		9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	8	9	9	9	9
2		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
3		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
4		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
5		9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	8	9	9	8	9	9	9
6		9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	8	9	9	9	9
7		9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	8	9	9	9	9
8		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
9		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9
10		9	9	9	9	9	9	9	9	9	9	7	9	9	9	7	9	9	9	9	9	8	7	9	9	9
11		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
12		9	9	9	9	9	9	9	9	9	9	7	9	9	9	8	9	9	9	8	9	7	7	9	9	9
13		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
14		9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	8	9	9	9
15		9	9	9	9	9	9	9	9	9	8	8	9	9	9	9	9	9	9	8	9	9	8	9	9	9
16		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
17		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
18		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
19		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
20		9	9	9	9	9	9	9	9	9	8	7	9	9	9	8	9	9	9	8	9	9	7	9	9	9
21		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
22		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
Average 1-9		**9**	**9**	**9**	**9**	**9**	**9**	**9**	**9**	**9**	**8.86**	**8.55**	**8.95**	**9**	**9**	**8.82**	**9**	**9**	**9**	**8.82**	**9**	**8.73**	**8.55**	**9**	**9**	**9**

Annex 2: HSCL-25 Hopkins Symptom Checklist

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

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 $\geq$ 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". 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 to10 minutes.

Annex 3: 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 P.MOINARD. (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.

5. **Obtaining complementary informations**

If desired, Patrice Nabbe or local national investigator (phone number), who can be reached at telephone number: 00 33 298 835 131 or 00 33 607 631 490 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.

6. **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 4: 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 5: 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 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 investigator: Name, first name of the interviewee:

Signature:

MOINARD Pierre - What is the translation of HSCL-25 in Bulgarian ; A consensus procedure by Delphi-round and Forward-Backward translation. 34 pages, tables, annexes, Thèse Médecine: Brest 02/2014

RESUME / ABSTRACT

Introduction : La dépression est une maladie chronique souvent diagnostiquée et traitée en soins primaires. Les patients multi-morbides de plus de 50 ans sont particulièrement à risque. Les symptômes sont difficiles à identifier de part leurs variations interindividuelles et interculturelles. Peu d'outils diagnostic sont adaptés et utilisés par les médecins généralistes.L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) souhaite valider un outil diagnostic de la dépression en médecine générale et entreprendre des recherches européennes.Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25-items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie.
Objectif : L'objectif était de traduire la HSCL-25 en Bulgare tout en adaptant son contenu aux particularités culturelles et linguistiques bulgares, sans perte de sens.
Méthode : Une procédure Delphi adaptée avec traduction Aller-Retour a été utilisée. Une traduction de l'Anglais au Bulgare a été soumise par procédure Delphi à un panel d'experts bulgares en soins primaires. La traduction retour a été réalisée en aveugle de l'original.
Résultats : Le panel d'experts répond aux critères d'inclusion. La traduction Bulgare a été validée unanimement au premier tour. La traduction retour en anglais a été produite.
Discussion : Le choix d'une méthode de traduction Aller-Retour par procédure Delphi adaptée avec exigence sur la qualité du panel d'experts, garantit une traduction bulgare de HSCL-25 validée et fiable proche de l'original. Prochainement, une analyse culturelle de la traduction assurera la concordance entre la version originale et la traduction retour.

Introduction: Family physicians (FPs) are the first port of call for depressive patients in developed countries. The multi-morbid patients over 50 years are especially at risk. Symptoms are difficult to identify owing to their interindividual and intercultural variations. Few diagnostic tools are adapted and used by FPs. Family Practice Depression and Multimorbidity (FPDM) study by European General Practice Research Network (EGPRN) aims to find a diagnostic tool for depression in primary care and to undertake collaborative research throughout Europe. Previous steps of FPDM have found that the Hopkins Symptom Checklist in 25-items (HSCL-25) was the most appropriate tool according to the criteria of effectiveness, reproducibility and ergonomics.
Objective: This study aimed to translate HSCL-25 in Bulgarian while adapting its content to the cultural and linguistic characteristics ensuring that original meaning was preserved.
Method: A Delphi method adapted for a Forward-Backward translation was used. The translation from English to Bulgarian was submitted by Delphi procedure to a panel of Bulgarian experts in primary care. Backward translation was performed with a blind back-translation principle.
Results: The inclusion criteria of panel were followed. The Bulgarian translation was confirmed unanimously in one Delphi round. The Backward English translation was produced and agreed by the FPDM's scientific committee.
Discussion: The quality of the panel of experts FPs ensured a validated and reliable Bulgarian translation. The following step will consist in a cultural check to ensure that HSCL-25 is in total agreement with the Backward translation.

MOTS CLES :

Depression / Translation / HSCL-25 / Delphi / Bulgarian

JURY :

PRÉSIDENT DU JURY Pr. JY LE RESTE

MEMBRES DU JURY Dr. P NABBE
Pr. B LE FLOC'H

DATE DE SOUTENANCE :

Jeudi 27 Février 2014

ADRESSE DE L'AUTEUR

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