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TRANSLATION AND CROSS-CULTURAL ADAPTATION OF THE MANUAL ABILITY QUESTIONNAIRE ABILHAND IN SYSTEMIC SCLEROSIS INTO EUROPEAN PORTUGUESE LANGUAGE

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TITLE: TRANSLATION AND CROSS-CULTURAL ADAPTATION OF THE MANUAL ABILITY QUESTIONNAIRE ABILHAND IN SYSTEMIC SCLEROSIS INTO EUROPEAN PORTUGUESE LANGUAGE

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INDEX

ABSTRACT

Introduction: Manual disability in patients with Systemic Sclerosis (SSc) is a major cause of impairment in everyday life. The ABILHAND questionnaire measures the manual ability and offers the advantage of selecting and hierarchizing manual activities that patients find specifically difficult to realize. Due to language and cultural barriers, the English ABILHAND questionnaire cannot be immediately used in Portuguese patients. The aim of this work was to describe the translation and cross-cultural adaptation of the ABILHAND questionnaire into European Portuguese among people with SSc and test the conceptual equivalence of the translated version in the Portuguese context.

Methods: The ABILHAND questionnaire was translated following 5 steps: Forward translation into European Portuguese by 3 native Portuguese speakers, Synthesis of the three translations, Back translation into English by 2 native English speakers. After the review of the Portuguese version by an expert committee, the field test with cognitive debriefing involved a sample of 10 SSc patients with diverse socio, demographic and disease background.

Results: Minor difficulties arose in translating the ABILHAND questionnaire into Portuguese showing that some concepts may be culture dependent. However, the expert committee review was able to discuss and solve these difficulties. Ten patients with SSc (8 women and 2 men, mean age of 62 (±15.7) years, 6 with limited and 4 with diffuse subset) participated in the field test. The field test combined with the cognitive debriefing showed that the questionnaire was relevant, understandable and easy to complete.

Conclusion: The resulting Portuguese version of the ABILHAND questionnaire showed acceptable linguistic validity. However, before its implementation in clinical practice and research settings, its psychometric properties (validity and reliability) need to be evaluated in future studies.

KEYWORDS: Systemic Sclerosis; ABILHAND; translation; cognitive debriefing; quality of life; outcome research

RESUMO

Introdução: A incapacidade manual em pacientes com esclerose sistémica (ES) é uma causa grave de disfunção na vida quotidiana. O questionário ABILHAND mede a habilidade manual e oferece a vantagem de selecionar e hierarquizar atividades manuais que os pacientes acham especialmente difíceis de realizar. Devido a barreiras linguísticas e culturais, o questionário ABILHAND em inglês não pode ser imediatamente utilizado em pacientes portugueses. O objetivo deste trabalho foi descrever a tradução e adaptação cultural do questionário ABILHAND para Português Europeu em pessoas com ES e testar a equivalência conceptual da versão traduzida no contexto português.

Métodos: O questionário ABILHAND foi traduzido seguindo 5 passos: Tradução direta para o Português Europeu por 3 falantes nativos de português, Síntese das três traduções, Tradução reversa para Inglês por 2 falantes nativos de inglês. Após a revisão da versão portuguesa por um comitê de especialistas, as entrevistas com *debriefing* cognitivo envolveram uma amostra de 10 pacientes com ES com diversas características sociodemográficas e estados de doença.

Resultados: Pequenas dificuldades surgiram na tradução da escala ABILHAND para Português, mostrando que alguns conceitos podem ser culturalmente dependentes. No entanto, a revisão pelo comitê de especialistas foi capaz de discutir e resolver essas dificuldades. Participaram nas entrevistas 10 pacientes com ES (8 mulheres e 2 homens, idade média de 62 (±15,7) anos, 6 de padrão limitado e 4 de padrão difuso). O ensaio de aplicação do questionário juntamente com o *debriefing* cognitivo mostrou que este questionário era relevante, compreensível e de fácil preenchimento.

Conclusão: A versão Portuguesa resultante do questionário ABILHAND apresentou validade linguística aceitável. No entanto, antes da sua implementação na prática clínica e ambientes de pesquisa, as suas propriedades psicométricas (validade e confiabilidade) precisam ser avaliadas em estudos futuros.

Palavras-chave: Esclerose sistémica; ABILHAND; tradução; debriefing cognitivo; qualidade de vida; *outcome research*

INTRODUCTION

Systemic sclerosis (SSc) is a chronic multisystemic disease characterized by microangiopathy, immune dysregulation and fibrotic changes affecting skin and internal organs (1, 2). It is a heterogeneous disorder that can lead to a substantial decrease in quality of life (QoL) through physical, emotional and social impacts (3, 4). Importantly, hand involvement in SSc is a cause of major impairment in daily functioning and activities (5, 6). Several disease manifestations may contribute to manual disability in patients with SSc, such as sclerodactyly, scleroedema, Raynaud's phenomenon, digital ulcers, finger calcinosis, and arthritis. Manual ability may be defined as the capacity to manage daily activities requiring the use of the upper extremities, independent of the strategy involved (7). Patients suffering from hand involvement report limitations in activities like object manipulation, doing small manual jobs and writing (8). Manual disability greatly impacts patients' everyday life and should be better assessed and managed to improve quality of life (9).

The ABILHAND self-reported questionnaire is particularly useful for the management of hand function in SSc patients (7). This questionnaire assess manual ability, which is defined as, "the capacity to manage daily activities requiring the use of the upper limbs, whatever the strategies involved" (7). It includes 26 items focusing in a large range of activities, such as dressing, cooking, hygiene, working in an office, and cleaning. It uses a 3-level scale, where 0 is impossible, 1 is difficult, and 2 is easy. Activities not commonly performed in the previous 3 months are not scored, and are recorded as missing responses (10). This questionnaire was originally made in English, consequently a translation for the Portuguese language is necessary to be able to apply the questionnaire in the Portuguese population. In order to use this questionnaire and ensure that the concepts assessed are equivalent in several different countries, with both a different culture and language, a translation and a cross-cultural adaptation of the ABILHAND questionnaire needs to be carried out following a rigorous methodology ensuring conceptual equivalence across languages (11). In this study we follow the methodology proposed by Beaton et al. 2000 (12). This work reports the translation and cross-cultural adaptation of the ABILHAND questionnaire into European Portuguese language among people with SSc.

METHODS

Permission from the author (Dr. Marie Vanthuyne) of the paper with the validation of ABILHAND questionnaire in SSc was requested before starting the adaptation for Portuguese (supplementary material, text 1).

This study received approval from the ethics committee of Coimbra Hospital and University Centre (246/2021) (supplementary material, text 2). Written informed consent was obtained from all participants prior to the start of the study.

The cross-cultural adaptation of the ABILHAND questionnaire in SSc into European Portuguese followed the protocol proposed by the current international recommendations (12). All the process was carried out between September 2021 and March 2022. The translation was done using a forward-backward procedure, which consists in 5 steps: i) Forward translation, ii) synthesis of translation, iii) back translation, iv) expert committee review and, v) field test with cognitive debriefing.

i) Translation

Three bilingual translators (native speakers of Portuguese), V.O., A.R.A and F.F. made independent forward translations of the original English version to Portuguese. Two of the translators were aware of the medical concepts of the questionnaire, but the other one was not aware. Each translator produced an independent written report, and they were also asked to register specific points where they had difficulties translating and what they settled for. Item content, response options and instructions were all translated.

ii) Synthesis of translation

The members of the Portuguese research team (T.S. and M.J.S.) then compared the 3 Portuguese versions, analyzed the items that were more challenging and discussed what would better fit into the Portuguese language. Minor adjustments were made accordingly. At the end, the three versions were synthetized into a single consensual version.

iii) Back translation

Two other bilingual translators (native speakers of English), T.S. and L.P. that were totally blind to both the medical concepts addressed in the questionnaire and the original questionnaire, translated the synthesized version into the original English language.

iv) Expert committee review

Finally, the expert committee consisting of rheumatologists (T.S. and M.J.S) and a nurse (R.F.) reviewed all of the translations. The objective of the committee is to reach a consensus on discrepancies and develop a pre-final version. The committee made

decisions in order to ensure equivalence of the translation in four areas: semantic equivalence (i.e. ensuring that the words have the same meaning), idiomatic equivalence (i.e. formulating equivalence expressions for colloquialisms), experiential equivalence (i.e. replacing items that are not experienced in the target country by similar ones experienced in that country) and conceptual equivalence (i.e. ensuring the concepts behind the words are the same between cultures). Then, a Pre-Final European Portuguese ABILHAND questionnaire was made.

v) Field test with cognitive debriefing

The pre-final version was pre-tested in a representation sample of Portuguese patients with SSc. Patients covering a broad spectrum of socio-demographic background (age, gender, disease duration, education) were recruited from the Rheumatology Department of the Coimbra Hospital and University Centre. Patients were recruited according to the following inclusion criteria: (i) fulfilling the 2013 ACR/EULAR Classification criteria for SSc (13), (ii) ability to understand and fill out the questionnaires, (iii) willingness to provide informed signed consent, and (iv) completed all the questionnaires required. Participants were excluded in the presence of severe comorbidities that could affect the completion of the questionnaire.

Ten patients participated in the field test. The patients filled the questionnaires in the presence of a member of the Portuguese research team (R.P.), so that a cognitive debriefing could be done afterwards. The purpose of the cognitive debriefing interview is to assess the cultural relevance, acceptability, comprehensiveness and understandability of the questionnaire items to SSc patients. Patients were asked about the ease to fulfill the questionnaire, to comment on its relevance and which items lead to confusion with an explanation on why they were misleading. The time taken to complete the questionnaire was also recorded for each patient.

In addition, information on age, gender, disease characteristics, including disease subset, autoimmunity, educational level, and working status were collected in a pre-established form.

Patients were also asked to fill in the Health Assessment Questionnaire (HAQ; score ranging from 0 = no disability to 3 = impossible to do) (14) and 2 visual analog scales (VAS; ranging from 0 mm = no limitation to 100 mm = maximal limitation) about the interference of Raynaud's phenomenon and of digital ulcers with their daily activities.

Health related QoL (HR-QoL) was accessed with the EuroQOL five dimension (EQ-5D) questionnaire which includes the dimensions mobility, self-care, usual activities,

pain/discomfort and anxiety/depression (15, 16). Each dimension has three levels: no problems, some problems, and severe problems. The combination of the five scores leads to an index score between -0,59 and 1.00.

RESULTS

The Final Portuguese Version of the ABILHAND questionnaire is shown in the supplementary material text 3 and can be obtained from our department website (http://www.reumatologiachuc.pt)

Translation and back translation of the ABILHAND questionnaire

The translation of the ABILHAND questionnaire into European Portuguese was mostly straightforward. Some small discrepancies arose but they were easily solved, as most of them were just a question of wording. For example: in ITEM #1 “Threading a needle” was translated into “costurar à mão”; “enfiar a linha na agulha” and “enfiar uma agulha” which the portuguese research team discussed and decided that “enfiar a linha na agulha” was the translation that best described this item.

In ITEM #5 “taking the cap off the bottle”, there were also different translations all meaning the same thing e.g. “retirar a rolha duma garrafa”, “tirar a tampa de uma garrafa” and “desenroscar a tampa de uma garrafa”. The Portuguese research team opted for the simplest option that was easier to understand: “tirar a tampa de uma garrafa”.

In ITEM #13 “Opening mail”, there was important discrepancy in meaning as the literal translation was “abrir correio”. However, one of the translator translated it as “abrir um envelope”, i.e. opening a letter, which brought the question of whether this item was too ambiguous and could lead to confusion. This because opening mail could be seen as opening a package or opening the mailbox, activities that don’t require the same level of manual ability that of opening a letter. For that reason, the Portuguese research team decided it was best to use the item opening a letter “abrir um envelope”.

In ITEM #22 “tearing open a package of chips” there was also a discrepancy worthy of mention. One of the translators translated it as “abrir um pacote de batatas fritas com as duas mãos”, i.e. opening a package of chips with both hands, instead of the more literal translation of “abrir um pacote de batatas fritas”. This is because “abrir um pacote de batatas fritas” is not very specific and could be understood as opening the package of chips with scissors or some utensil. Then, to avoid confusion and accurately test manual ability, the portuguese research team choose to use “abrir um pacote de batatas fritas com as mãos”.

ITEM#24 “Fastening a snap-fastener (e.g., bag, jacket)” was also object of different wordings that meant the same e.g., “apertar molas”, “fechar items com botões de mola” and “fechar um fecho de mola”. Ultimately, it was agreed that “fechar um botão de mola” would better describe this item.

A noteworthy commentary arouse in ITEM #25 “Shelling hazelnuts” as the translation of this item is straightforward “descascar avelâs” but it is something rarely performed in the portuguese culture. It was left like this for the back translation with a note to be further discussed in the expert committee review.

Some translators added a bit of extra information in their translations to provide more concrete activities to the person reading, e.g. cutting nails “on yourself”, but it was ruled out as unnecessary by the Portuguese research team and the simpler translation stayed.

The back translations produced by the two native English speakers, T.S. and L.P., had a high accuracy with the original English version. In some items, the selection of words in one of the translation was exactly the same as the original and in the other translation was not, but the meaning was always kept. As expected, some of the Items subjected to change didn’t translate that well into the original language. In ITEM #5 the meaning was the same but the wording was a bit off “removing a lid from a bottle”, instead of “Taking the cap off the bottle”. In ITEM #13, it was translated back to “opening mail”. In ITEM #22, none of back translations used the term “tearing open” as in the original, translating it to “opening a package with the hands”. In ITEM #24 there was also a small discrepancy where it was back translated to “closing press stud” and “closing spring closure”, instead of the original “Fastening a snap-fastener”. ITEM #25 didn’t suffer any changes. Another interesting mention was that the original ITEM #9 “wiping windows” became “cleaning windows” and the original ITEM #19 “cleaning vegetables” became “washing vegetables”. However, this does not affect their meaning and comprehension.

Expert Committee review: The ITEM #25 was subject to discussion, and decided that to maintain experiential equivalence ITEM #25 should be changed to something done more frequently in the Portuguese culture. After intense consideration the committee agreed that the closest experience to shelling hazelnuts in the portuguese culture is peeling chestnuts. Portuguese culture has a tradition to eat chestnuts around November and the level of manual dexterity needed to peel hazelnuts or chestnuts is roughly the same. This way consensus could be achieved and ITEM #25 was changed to “descascar castanhas” i.e. peeling chestnuts. Another item subject to discussion was ITEM#15 “winding up a wristwatch”. Nowadays with the new technologies, it is very rare for people to wind up wristwatches. The committee reflected if the item should stay for the older generation that might still use wristwatches or be adapted. After consensus was decided that this activity left out a big part of the Portuguese population and the item was changed to “Winding up a watch” (dar corda a um relógio). The rest of the questionnaire did not bring more concerns for discussion. The committee considered the

Portuguese version maintained semantic, idiomatic, experiential and conceptual equivalence with the original version and the back translation showed a high rate of accordance.

Field test and cognitive debriefing

Table 1 summarizes the demographic and clinical characteristics of the participants included. Ten patients with SSc (8 women and 2 men, mean age of 62 (±15.7) years; 6 with limited and 4 with diffuse subset) underwent a cognitive debriefing interview.

The mean total score of the HAQ was 0.6375 ± 0.66 (range 0-3, with a higher score indicating a worse health status). The Raynaud's phenomenon and digital ulcers visual analogue scale (VAS) was 40.4 ± 33.4 and 14.5 ± 21.4, respectively (range 0-100 with a higher score indicating a better health status) and ranged from 2 (one participant) to 90 (one participant).

The mean total score of the EQ5D was 0.56242 ± 0.3 (range -0.59 – 1.0) with a higher score indicating a perceived better health status) and ranged from 0.28 (two participants) to 1 (two participants).

Completion time for the ABILHAND questionnaire was 2.44 ± 2.32 (range 0.48 to 8.39) minutes.

Cognitive debriefing

In general, the patients found the questionnaire easy to comprehend and fill out. Some concerns arose around certain items namely ITEM#10 "Fechar uma torneira" as it wasn't clear which type of tap the questionnaire refers to, a rotating/screwing tap or a lever tap. Patient ID#4 and ID#6 were able to close a lever tap but couldn't close a rotating/screwing tap. Patient ID#1 reported that in the ITEM#19 "lavar vegetais" the season played a major role, as she could easily wash vegetables in the summer but not in the winter due to the Raynaud phenomenon. Aside from that, certain items were not executed in the last 3 months multiple times, for example ITEM#15 "dar corda a um relógio" was reported as not executed by half the patients: ID#1, ID#2, ID#4, ID#7 and ID#9. ITEM#2 "colocar joias em si próprio/a" also was not executed by 3 patients: ID#2, ID#4 and ID#9. Finally, some patients ID#3 and ID#8 had a very mild involvement of the hands by the disease and found that the questions in the questionnaire were not very relevant.

***Table 1* – Individual patient´s characteristics.**

Patient ID	Gender	Age	SSc* Subset	Disease duration (years)**	SSc specific autoantibody	Working Status***	Years of formal education
P1	F	39	Limited	14	Centromere	1	12
P2	F	57	Diffuse	4	Anti-Scl 70 +	3	12
P3	F	52	Limited	11	Centromere	1	9
P4	F	65	Diffuse	2	Anti-Scl 70+	3	6
P5	F	74	Limited	22	None	4	4
P6	F	61	Limited	14	Centromere	1	12
P7	F	27	Diffuse	2	None	1	16
P8	F	79	Limited	22	Centromere	4	4
P9	M	63	Limited	23	Centromere	3	4
P10	M	67	Diffuse	15	None	4	12

Legend – *systemic sclerosis; **since the first Raynaud phenomenon; ***working status: 1= full-time, 2= part-time, 3= work disability due to health, 4= retired due to age, 5= homemaker, 6= student, 7= job-seeking

DISCUSSION AND CONCLUSION

This study succeeded in formulating an European Portuguese Version of the ABILHAND questionnaire for people with SSc. Also, it followed the current international guidelines for translation and cross-cultural adaptation of self-report measures, allowing for the creation of a validated questionnaire adapted into the Portuguese culture (12). During the translation process, some cultural differences were noted and adjustments were required.

A strength of this questionnaire is that is clear, comprehensive and has good acceptability independent of the level of education or degree of hand involvement and progression of the disease. Furthermore, it allows a focused evaluation of the progress of manual ability in people with SSc. For this reason, this Portuguese version of the ABILHAND questionnaire can be useful for future studies in Portugal. These studies will be able to use this new version to evaluate and monitoring the effect of pharmacological and non-pharmacological treatment in manual ability of people with SSc. For example, it can help comparing the patients' status before and after a treatment or just allow to observe more accurately the progression of the disease. Another advantage of the

Portuguese ABILHAND questionnaire is the fact that the completion time is about 3 minutes long and doesn't require an interviewer as it is a self-report measure.

This present work is an important step for the implementation of the ABILHAND questionnaire into clinical practice and research. However, before its implementation it is recommended to confirm the validity, discriminative ability and responsiveness of the questionnaire in a larger group of SSc patients. These aspects will be evaluated by our research team in a near future.

Finally, treatment strategies in SSc should not only target disease control but also consider distinct interventions to mitigate all domains of perceived disease impact (3). This work represents an effort to widen the assessment of manual disability impact and a relevant contribution towards the ethical imperative of promoting person-centered care. We need to gain a better understanding of hand incapacity in SSc and to capture the treatment response of health-care interventions (e.g., hand exercises) from the patient perspective. We must pay more considerate and committed attention to the impact of manual disability and develop better and novel ways of measuring it. This Portuguese version provides a measure of the manual dexterity and manual capability to perform daily activities across SSc patients. Further studies are underway to test the psychometric properties of this new questionnaire.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication.

Rodrigo Patrício (R.P.) and Tânia Santiago (T.S.) had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design: Rodrigo Patrício (RP), Tânia Santiago (TS), José António Pereira da Silva (JAPS); Maria João Salvador Daniel dos Santos Henriques (MJS)

Acquisition of data: Rodrigo Patrício (RP), Tânia Santiago (TS), Maria João Salvador Daniel dos Santos Henriques (MJS)

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REFERENCES

1. Knobler R, Moinzadeh P, Hunzelmann N, Kreuter A, Cozzio A, Mouthon L, et al. European Dermatology Forum S1-guideline on the diagnosis and treatment of sclerosing diseases of the skin, Part 1: localized scleroderma, systemic sclerosis and overlap syndromes. J Eur Acad Dermatol Venereol. 2017;31(9):1401-24.

2. Smith V, Scirè CA, Talarico R, Airo P, Alexander T, Allanore Y, et al. Systemic sclerosis: state of the art on clinical practice guidelines. RMD Open. 2018;4(Suppl 1):e000782.

3. Santiago T, Santos E, Duarte AC, Martins P, Sousa M, Guimarães F, et al. Happiness, quality of life and their determinants among people with systemic sclerosis: a structural equation modelling approach. Rheumatology (Oxford). 2021;60(10):4717-27.

4. Hudson M, Thombs BD, Steele R, Panopalis P, Newton E, Baron M. Health-related quality of life in systemic sclerosis: a systematic review. Arthritis Rheum. 2009;61(8):1112-20.

5. Waszczykowski M, Dziankowska-Bartkowiak B, Podgórski M, Fabiś J, Waszczykowska A. Role and effectiveness of complex and supervised rehabilitation on overall and hand function in systemic sclerosis patients-one-year follow-up study. Sci Rep. 2021;11(1):15174.

6. Sandler RD, Matucci-Cerinic M, Hughes M. Musculoskeletal hand involvement in systemic sclerosis. Semin Arthritis Rheum. 2020;50(2):329-34.

7. Vanthuyne M, Smith V, Arat S, Westhovens R, de Keyser F, Houssiau FA, et al. Validation of a manual ability questionnaire in patients with systemic sclerosis. Arthritis Rheum. 2009;61(5):695-703.

8. Galetti I, Nunzio SD, Brogelli L, Mirisola V, Garbagnati C. How do systemic sclerosis manifestations influence patients' lives? Results from a survey on patients and caregivers. Curr Med Res Opin. 2021;37(sup2):5-15.

9. Frantz C, Avouac J, Distler O, Amrouche F, Godard D, Kennedy AT, et al. Impaired quality of life in systemic sclerosis and patient perception of the disease: A large international survey. Semin Arthritis Rheum. 2016;46(1):115-23.

10. Penta M, Tesio L, Arnould C, Zancan A, Thonnard JL. The ABILHAND questionnaire as a measure of manual ability in chronic stroke patients: Rasch-based validation and relationship to upper limb impairment. Stroke. 2001;32(7):1627-34.

11. Cruz EB, Ramiro S, Machado P, Sousa S, Aguiar R, Sepriano A, et al. Translation and cross-cultural adaptation of the ASAS Health Index and ASAS Environmental Factors Item Set into European Portuguese Language. Acta Reumatol Port. 2017;42(3):256-62.

12. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976). 2000;25(24):3186-91.

13. van den Hoogen F, Khanna D, Fransen J, Johnson SR, Baron M, Tyndall A, et al. 2013 classification criteria for systemic sclerosis: an American college of rheumatology/European league against rheumatism collaborative initiative. Ann Rheum Dis. 2013;72(11):1747-55.

14. Johnson SR, Hawker GA, Davis AM. The health assessment questionnaire disability index and scleroderma health assessment questionnaire in scleroderma trials: an evaluation of their measurement properties. Arthritis Rheum. 2005;53(2):256-62.

15. Ferreira LN, Ferreira PL, Pereira LN, Oppe M. EQ-5D Portuguese population norms. Qual Life Res. 2014;23(2):425-30.

16. Gualtierotti R, Ingegnoli F, Scalone L, Cortesi P, Bruschi E, Gerosa M, et al. Feasibility, acceptability and construct validity of EQ-5D in systemic sclerosis. Swiss Med Wkly. 2016;146:w14394.

SUPPLEMENTARY MATERIAL, TEXT 1

We would like to start this project ASAP.

Please let us know if you agree with this proposal. I thank you in advance for your consideration.

Sincerely,

Tânia Santiago, Maria João Salvador, Rodrigo Patrício

De: Tânia Santiago <tlousasantiago@hotmail.com>
Enviado: terça-feira, 29 de junho de 2021 09:33
Para: marie.vanthuyne@uclouvain.be <marie.vanthuyne@uclouvain.be>
Cc: Dra Maria João Salvador <mjsalvadorhenriques@gmail.com>; Rodrigo Patricio <rodrigo.a.patricio@gmail.com>
Assunto: Permission to Translation and Cross-cultural adaptation to Portugal - Manual ability questionnaire in patients with systemic sclerosis

[Citação ocultada]

Vanessa Smith <Vanessa.Smith@ugent.be> 3 de setembro de 2021 às 20:15
Para: Tânia Santiago <tlousasantiago@hotmail.com>, "marie.vanthuyne@uclouvain.be" <marie.vanthuyne@uclouvain.be>
Cc: Dra Maria João Salvador <mjsalvadorhenriques@gmail.com>, Rodrigo Patricio <rodrigo.a.patricio@gmail.com>

Dear Tania,

This is fine with me.

If Dr. Vanthuyne, first author also agrees , then she will send you all that you have requested.

Kindest

Vanessa

[Citação ocultada]

VANTHUYNE Marie <marie.vanthuyne@saintluc.uclouvain.be> 13 de setembro de 2021 às 20:52
Para: Tânia Santiago <tlousasantiago@hotmail.com>, "vanessa.smith@ugent.be" <vanessa.smith@ugent.be>
Cc: Dra Maria João Salvador <mjsalvadorhenriques@gmail.com>, Rodrigo Patricio <rodrigo.a.patricio@gmail.com>

Dear Tania,
No problem for me, you have the permission to perform the Translation and Cross-cultural adaptation of the ABILHAND scale to european portuguese patients.
Sincerely,
Marie Vanthuyne

De : Tânia Santiago [tlousasantiago@hotmail.com]
Envoyé : vendredi 3 septembre 2021 11:15
À : VANTHUYNE Marie; vanessa.smith@ugent.be
Cc : Dra Maria João Salvador; Rodrigo Patricio
Objet : RE: Permission to Translation and Cross-cultural adaptation to Portugal - Manual ability questionnaire in patients with systemic sclerosis

[Citação ocultada]

Tânia Santiago <tlousasantiago@hotmail.com> 13 de setembro de 2021 às 22:48
Para: VANTHUYNE Marie <marie.vanthuyne@saintluc.uclouvain.be>
Cc: "vanessa.smith@ugent.be" <vanessa.smith@ugent.be>, Dra Maria João Salvador <mjsalvadorhenriques@gmail.com>, Rodrigo Patricio <rodrigo.a.patricio@gmail.com>

SUPPLEMENTARY MATERIAL, TEXT 2

REPÚBLICA PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL DE SAÚDE

CHUC CENTRO HOSPITALAR E UNIVERSITÁRIO DE COIMBRA

Comissão de Ética para a Saúde

4/3/22
Dr. Nuno Deveza
Diretor Clínico
C.H.U.C. - EPE

Exmo. Senhor
Dr. Nuno Deveza
Digmº Diretor Clínico do CHUC

SUA REFERÊNCIA	SUA COMUNICAÇÃO DE	NOSSA REFERÊNCIA	DATA
		Nº 102/CES	28-02-2022
		Proc.Nº **OBS.SF.246-2021**	

PI OBS.SF.246-2021 *"TRADUÇÃO E ADAPTAÇÃO CULTURAL DA ESCALA DE AVALIAÇÃO MANUAL ABILHAND NA ESCLEROSE SISTÉMICA"*
Entrada na UID: 22-12-2021
Entrada na CES: 13-01-2022
Investigador/a/es: Rodrigo Alexandre Marques Patrício – Aluno do 6 ano do Mestrado Integrado em Medicina
Coordenador/a/es: Tânia Louza Santiago
Co-Investigador/a/es: José António Pereira da Silva, Maria João Henriques Salvador
Promotor: Não se aplica
Serviço de Realização: Serviço de Reumatologia do Centro Hospitalar e Universitário de Coimbra (CHUC)

Cumpre informar Vossa Ex.ª que a CES - Comissão de Ética para a Saúde do Centro Hospitalar e Universitário de Coimbra, reunida em 16 de Fevereiro de 2022, após reapreciação do projeto de investigação supra identificado, emitiu o seguinte parecer:

"A Comissão considera que se encontram respeitados os requisitos éticos adequados à realização do estudo, pelo que emite parecer favorável ao seu desenvolvimento no CHUC. Contudo, solicita: 1) a clarificação quanto à existência de um promotor, e a sua identificação, caso exista; 2) seja retirado o nome do participante da escala; 3) sugere-se que o responsável pelo tratamento de dados seja o investigador coordenador; 4) a ponderação de se o prazo para a conservação de dados, de 10 anos, não será excessivo; 5) que a versão final dos documentos, depois de corrigida, seja enviada, com as alterações efetuadas devidamente assinaladas".

Mais informa que a CES do CHUC deverá ser semestralmente atualizada em relação ao desenvolvimento dos estudos favoravelmente analisados e informada da data da conclusão dos mesmos, que deverá ser acompanhada de relatório final.

Com os melhores cumprimentos,

A Comissão de Ética para a Saúde do CHUC, E.P.E.

Prof. Doutora Margarida Silvestre
Presidente

CES do CHUC: Prof. Doutora Margarida Silvestre, Enfº Adélio Tinoco Mendes, Dra. Cláudia Santos, Dra. Isabel Gomes, Dra. Isabel Ventura, Rev. Pe. Doutor Nuno dos Santos, Dr. Pedro Lopes, Doutora Teresa Lopa, Dra. Teresa Monteiro

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SUPPLEMENTARY MATERIAL, TEXT 3

ABILHAND – Avaliação da habilidade manual

Qual o seu grau de dificuldade nas seguintes atividades?	Impossível	Díficil	Fácil	OBS
1. Enfiar uma linha na agulha				
2. Colocar joias em si próprio/a				
3. Cortar carne				
4. Usar uma tesoura				
5. Tirar uma tampa de uma garrafa				
6. Tirar uma moeda do bolso				
7. Cortar as unhas				
8. Desembrulhar um chocolate				
9. Limpar as janelas				
10. Fechar uma torneira				
11. Apertar os atacadores dos sapatos				
12. Usar um agrafador				
13. Abrir um envelope				
14. Descascar cebolas				
15. Dar corda a um relógio				
16. Descascar batatas com uma faca				
17. Desenroscar a tampa dum frasco				
18. Fechar o fecho de um casaco				
19. Lavar vegetais				
20. Barrar manteiga numa fatia de pão				
21. Espalhar creme no corpo				
22. Abrir um pacote de batatas fritas com as mãos				
23. Pentear o cabelo				
24. Fechar um botão de mola (por exemplo, de um saco, blusão)				
25. Descascar castanhas				
26. Abotoar as calças				