

Creating an international standard for procedures in translating and cross-cultural adapting tinnitus questionnaires: A checklist with extension and elaboration.

COST GRANT: TINNET BM1306

Host TINNET member: Deborah Hall (WG5)

Host organisation: University of Nottingham, UK

Visiting TINNET member: Silvia Zaragoza Domingo

Visitor's affiliation: Neuropsychological Research Organization s.l.(PSYNCRO)

Dates: Monday 16 January to Friday 20 January 2017 (5 days). We also worked over the evenings to maximise the benefit of this opportunity.

Original motivation and purpose of the STSM: As expert on COAs translations in pharma industry, I am committed to support TINNET COST on the international expansion of the work by collaborating on the creation of guidelines for Clinical Outcomes Assessment (COA) tools (inventories, questionnaires) translation, also promoting good translation practices across the TINNET group members.

Based on existing documents describing basic processes for Linguistic Validation of COAs we will create a specific guideline including practical recommendations based on the experience in this activity. The visiting TINNET expert has conducted by herself and thorough outsourcing several cultural adaptations of COAs of different type including but not limited to Quality of Life instruments. This experience and related materials created by Psyncro with this purpose, will serve as a complementary information contributing to the creation of a useful guideline for future translations of instruments in the Tinnitus therapeutic field. During the mission, workshops will be held with the host team members to discuss specific questions and resolve practical issues in this process. The invited member has conducted in the past trainings on this area within the pharma industry and outsourcing companies, therefore all this body of knowledge will be transferred to the hosting organization members.

Background For clinical trials, our activity includes the implementation of clinical trials in different countries in the world, however, the majority of COAs are originally created in English. This instruments require not single translation but full cultural adaptation before to be applied abroad. The process of translation and cultural adaptation is named Linguistic Validation (LV) that includes several steps and different professionals to work in collaboration. In recent conferences, our organization presented the description of challenges emerging from this process even when the main activity is outsourced to specialized vendors.

The different steps included in LV process are well described in the literature but varies depending on the source. Pharma industry use to speed up this process by just doing the minimal steps as requested by regulatory bodies (i.e. FDA or EMA). For academic researchers a specific tailored guidance document based on previous papers can be set, including the solutions to main challenges. We propose to participate in the following pieces of work: i) to summarize the main steps for COAs tools LV process as mentioned in the literature, ii) To elaborate a comprehensive checklist useful to researchers aiming to LV Tinnitus COAs tools, iv) prepare

templates ready to use by researchers aiming to conduct LV of COAs tools and iii) co-writing a paper including all the above information.

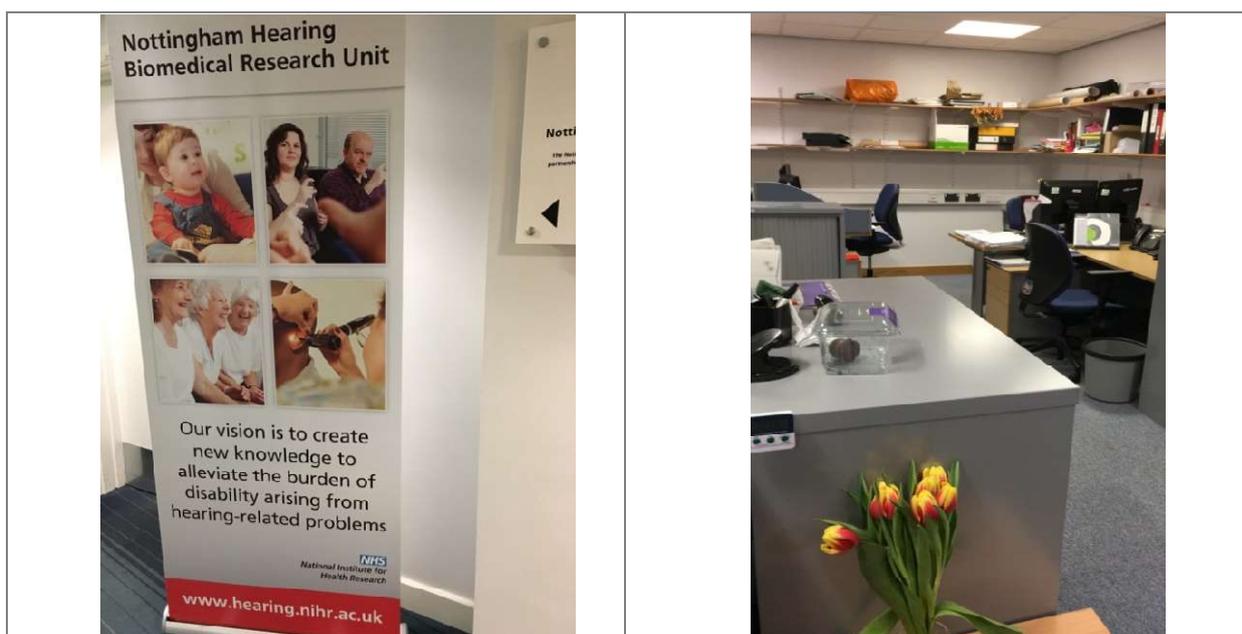
Detailed work plan: i) Summarize LV processes as reported by the literature by creating a specific paper to guide researchers on LV steps ii) Create specific checklists as a tool useful to researchers, iii) Set up templates ready to use for researchers for future LV of COAs tools in the field, iv) Conduct a workshop commenting on main challenges facing LV process in the real practice and across countries/languages, v) Include comments from workshop attendants and solutions proposed, specifically under the paper discussion section, v) Propose ways for improving the process in the future in this field of Tinnitus, as but not limited to the creation of specific glossary of terms with concept definition for the Tinnitus area, define preferred translations in specific languages across countries, creation of a network of tinnitus experts to act as future consultants for review of i.e forward and backward translations.

Description of the work carried out during the STSM

The following report provides a day-by-day account of progress in meeting the STSM aims, as well as a number of secondary aim to finalize several disseminations about the translation in this fields, and to participate remotely in a seminar that will take place in the unit in a couple of weeks.

Monday 16 to Tuesday 17 January:

Deborah Hall organized all settings in order to integrate my activity within the Research Unit and within the IT facilities during the STSM duration. I had a nice place to work among researchers, PhD students and research assistants. I had the capacity access to the research unit servers, and had my own pass code to access to main areas where I was going to work. Jade McCune and Sandra Smith helped me to cover all needs that I had during my stage at the unit.



Upon start I had the opportunity to learn from Deborah Hall, about the role of the Psychology as a Science and of Psychologist within the Audiology field. It was very interesting to get introduced in such interesting area where psychology has a great path to grow. Also I learned that, in terms of Clinical Trials, the area is quite new and this opens a lot of opportunities for them to learn from past experiences in more mature fields.

During our start up conversation, it was highlighted that people suffering from hearing disorders have an impact on social development and social life. In this line, psychologist are important to evaluate this impact and develop strategies to mitigate this effect. From the COS outstanding points instruments are usually addressed to patients (PROs) and to caregivers or relatives (ProxyROs).

Literature Review Regarding Cultural Adaptation Following a review of the literature done by Deborah Hall's team, I analyzed a set of 13 papers aiming to translate common used COAs instruments in Audiology into other languages.

I reviewed the methodology described on each paper and I created a summary table to capture: the methods followed, main references that guided the methodology and gaps on the process descriptions. This resulted in a nice summary table that was the basis for a new checklist for Good Translation Report practices.

This checklist was included in the main paper as an appendix will be useful to guide the description of translations for future researchers, and therefore improve reporting practices in publications.

We also worked in a main table useful to capture all the process. Deborah also started to select an example to populate the table. For this, a scale free of use was selected and from the scale a single item. This was translated into French by two colleagues and backtranslated by a third collaborator based in Quebec. The main table and this example will be also part of the templates at the Appendices.

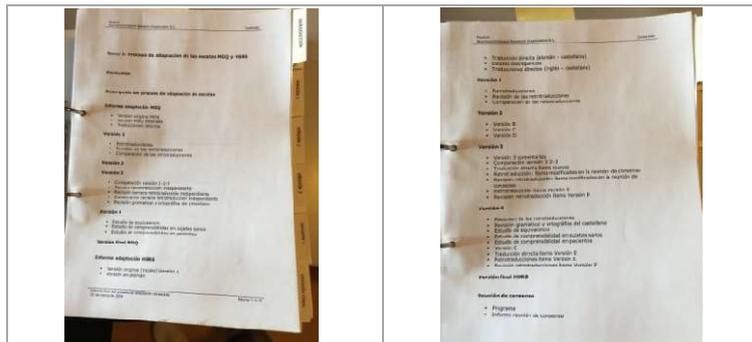
Wednesday 18 January: From the review done we identified new published guidelines to be included cite in the document as references and an existing manual created in another field (Palliative care) that was similar in format to the one that we were creating.

Also from the papers identified conducting translation, we proceed to select examples for each step within the translation process to illustrate real cases published in the literature. We also reviewed previous work done by my company during the adaptation of a couple of instruments into Spanish (MDQ to screen for Bipolar Disorders and SPI diagnostic instruments). Thorough this materials we completed the whole process and we identified all steps. This allowed to update the main step checklist covering all necessary steps. This checklist was serve as the guide to produce the main paper that will be a description step by step.

In addition, the review of materials also suggested the creation of a checklist of documentation that needs to be created when translating instruments. We also identified other materials to be created as templates to help researchers on this activity. One of this templates is the Certification of Translation, and we specified all information that needs to be included on it.

We agreed that my contribution to this project was important in order to identify and clarify based on my past experience all the preparatory steps required to start a new cultural adaptation. It was also important to decide and state in the paper, the minimal requirements to include on each step.

Before my arrival I sent papers published by my company regarding the cultural adaptation of questionnaires in Bipolar Disorders and Restless Legs Syndrome into Spanish for Spain. I also offered my company templates to enrich the guideline with already tested materials. A picture of my archives was also provided to illustrate the volume of documentation generated by a single questionnaire translation.



All checklists and templates selected will be Appendices of the main guideline.

Thursday 19 January: We did continue working in the main paper completing different sections. Sections from papers written in Spanish related to translations conducted by my company, were translated from Spanish to English in order to be included in specific sections of the guideline. This sections were the ones related to instructions given to translators for Forward and Backward translations steps.

As planned, at the afternoon, I give the seminar to the unit with the aim to introduce the team to the world of the translations. The seminar was very active, and participants could make interesting questions.

Questions were about:

- Creation of a Concept Definition document,
- Copyright of newly created scales and for translations of this scales by other researchers, Copyright in case that the journal publish the scale, Copyright in case that the author does not exist anymore
- Translatability of Likert anchor points across languages and distance between them (like Never to Always),
- Versioning of the scales created from scratch, importance to keep track of changes and versions,
- Materials to be developed by the scale developer in order to facilitate future translation activity

It was suggested that the unit as a leader in Hearing research, could start proactively the following materials:

- A COAs instrument library with those instruments more commonly used in audiology, including its with related materials (validation papers) and information about copyright.
- Versions ready to use of COAs instruments whose authors are not available anymore. It was discussed whether the unit could take the initiative to set the version and keep all related information for this instruments
- Glossary of terms and proposed translations in other languages working with country leads in the field.
- Creation of an Item bank specific to Hearing Disorders to be used by researchers in future COAs or educational materials development.

Also some slides from the presentation were considered useful to be included in the guideline as the one showing a figure comparing Linguistic versus Psychometric Validation.

Following the Seminar, I had a meeting with Melanie Ferguson and Eithne Heffernan to discuss the process to adequately translate Educational materials into other languages. We watched educational videos at C2Hear created by both researchers aiming to train patients on the use of different types of hearing devices. Based on my experience I suggested the method of Single FT and single BT in order to check the content of the translated material. Initially they could start with subtitles and then adding sound. One of the languages to translate is from English to Chinese, also to other British languages as the one spoken in Wales.

For scales developed by Eithne I suggested to start writing Concept Definitions for each item. Also I showed her some useful tables that she can use to record translations already done in Swedish by researchers in that country.

For educational or instrument related materials, I suggested the creation of the following materials that can be useful when training trainers to ensure the method is well applied:

1	Practice Scoring Response Form Mock Up
2	Power Point Presentation
3	Video
4	Scripts
5	Vignettes
6	Practice Scoring Workbook

Friday 20 January: We worked on the final steps of the process, clarifying the differences between Pilot Testing and Cognitive Debriefing, as quantitative and qualitative validation steps, respectively, necessary before conducting a full validation with real subject samples.

Future collaboration with the host institution

The STSM has strengthened the relationship between Nottingham and Barcelona to further the TINNET objectives. My experience in clinical research at Pharma and CROs can serve as a starting point for this new emerging area of efficacy studies in hearing. Even we might consider to be partners in future projects if there is the opportunity.

My experience in the translation field can serve as a guidance to all Unit members when trying to translate their research production to other languages.

We had enjoyed very much to work together, although it was the first time we got the feeling that we could make it work easily. Deborah is a high organized manager and this helps a lot to be efficient during the work.



My network with the Universitat Aut3noma de Barcelona (UAB), Psychology and Speech Therapy Schools can be useful for future strategic alliances that can be of mutual interest. My main contact is Olga Soler Vilageliu, PhD that is part of the Transmedia Group <http://grupsderecerca.uab.cat/transmedia/>

Also regarding Psychometric validation of Translations/Cultural Adaptations, my contacts with University of Barcelona (UB) and Universitat Aut3noma de Barcelona (UAB) at Psychometric Statistics Department can be as well as useful to guide this processes in the future.

Nottingham is a beautiful and welcoming city, with a number of international restaurants to enjoy evening life! We also enjoyed sharing our kitchen secrets to maximize the effectiveness of our mission.



Foreseen publications/articles resulting from the STSM

1. Peer-review journal article reporting the guideline for translations and cultural adaptations of COAs instruments in Audiology.

Useful references

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