

Embedding a Validation Study into a Clinical Trial

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Background

- The Beck Depression Inventory (BDI) is a self-report instrument that assesses the presence and severity of depressive symptoms in adolescents and adults [1].
- The second edition (BDI-II) consists of 21 items assessing attitudes and symptoms of depression.
- Ratings from the 21 items are summed to calculate an individual's total BDI-II score and this is a very commonly used indicator of the severity of current depressive symptoms in both clinical practice [2] and research settings [3].
- Although the BDI-II has been translated into numerous languages and has been proved to be psychometrically robust and appropriate for use in countries across the world, there is no Welsh language version of the BDI available.
- This may hinder language choice for Welsh speakers and thus be in breach of clinical and research governance requirements in Wales [4-5].
- Moreover, the absence of a Welsh version of the BDI-II may jeopardize the reliability and validity of the measure administered to bilingual speakers [6].
- One specific aim of LLAIS, the Language Awareness Infrastructure Support Service for CRC Cymru, implemented through its research development group, *Mesur Iechyd Cymru*, is to support the use of Welsh medium health outcome measures and advance methods of translation and validation at a national and international level.
- This paper reports on a study to establish a rigorously translated and validated Welsh language version of the BDI-II.
- This study explores an innovative and cost-effective approach in the development of Welsh language health outcome measures by embedding a validation study into a clinical trial.

Study Aims and Objectives

Aim

- This study aims to provide a rigorously translated and validated Welsh language version of the BDI-II for use by health service researchers and clinicians in Wales and to demonstrate the feasibility of embedding validation studies into clinical trials in Wales for future development of Welsh language health measures

Objectives

- To produce a rigorously translated Welsh language version of the BDI-II
- To validate the BDI-II with a sample of patients with depression, through embedding the study in a clinical trial
- To validate the BDI-II with a sample of members of the general public.

References

- [1] Beck A., Steer R., & Gardin M. (1988) Psychometric properties of the Beck Depression Inventory: Twenty-five years of evaluation. *Clinical Psychology Reviews* 8, 77-100. [2] National Institute for Clinical Excellence (2004) *Depression: Management of Depression in Primary and Secondary Care. Clinical Guideline 23*. National Institute for Clinical Excellence, London. [3] Brantley P., Dutton G. & Wood K. (2004) The Beck Depression Inventory-II (BDI-II) and the Beck Depression Inventory –Primary Care (BDI-PC). IN Maruish M. (2004) *The Use of Psychological Testing for Treatment Planning and Outcomes Assessment: Instruments for Adults*, pg 313-326. Routledge, New York. [4] Welsh Assembly Government (2001) *National Research Governance Framework for Health and Social Care*. Welsh Assembly Government, Cardiff. [5] Welsh Assembly Government (2006) *Welsh Language Scheme*. Welsh Assembly Government, Cardiff. [6] Fitzpatrick R., Davey C., Buxton M. & Jones D. (1988) Evaluating patient-based outcome measures for use in clinical trials. *Health Technology Assessment* 2, 14. [7] Wild D., Grove A., Martin M., Eremenco S., McElroy S., Verjee-Lorenz A. & Erikson P. (2005) Principles of good practice for the translation and cultural adaptation process for patient-reported outcome (PRO) measures; Report of the ISPOR task force for translation and cultural adaptation. *Value in Health* 8, 2, 94-104.

Design and Methods

Translation Study

- Following permission from the publisher and in line with ISPOR guidelines [7], the Welsh language version of the BDI-II was developed between June and September 2008.
- This process involved a number of key stages, including forward and back translation; reconciliation; and cognitive debriefing.

Validation Study

The Welsh language version of the BDI-II will be validated with a clinical population sample and a general population sample, as follows:

(a) Clinical population sample

- The validation study will be embedded within the FoIATED clinical trial which is currently recruiting patients from three centres across Wales.
- 30 Welsh-speaking trial participants will be invited to complete the BDI-II, which is the primary outcome measure in this trial. Data from other related depression and quality of life measures collected in trial will also be used in the validation process.

(b) General population sample

- The validation study will be conducted with a self-selecting sample of Welsh speaking university students who will be invited to complete the Welsh language BDI-II along with a series of other related measures

Data analysis

- A series of statistical tests will be performed on the data to determine the reliability and validity of the measure with the two population samples.
- Reliability will be determined by assessing the internal consistency and item homogeneity of the Welsh BDI-II using Cronbach's alpha coefficient and the mean inter item correlation coefficient (MIC).
- Validity will be assessed by comparing the factor structure of the Welsh BDI-II with the original measure through principal component factor analysis; and examining Pearson correlation coefficients between the Welsh BDI-II and the additional depression measures to ascertain if they correlate adequately in a positive direction, and correlate adequately in a negative direction with the quality of life scales.

Findings and Conclusions to Date

Translation study

- Evaluation of the ISPOR guidelines [7] revealed that the procedure of commissioning two translations, a back translation, and then creating a synthesis translation for trialling, offered a rigorous approach in achieving a clear and accurate rendering of the original measure in Welsh.
- This study provided a valuable opportunity to evaluate consensus guidelines for the translation of PRO measures, the findings of which will now be transferred to other language contexts and outcome measures, thus providing scope for the advancement of methods of translation at a national and international level.

Validation study

- 100% recruitment achieved for the general population sample. Recruitment to the clinical population sample is ongoing.
- Given the range of measures that need to be developed for the Welsh language, this study suggests that embedding a validation study into a clinical trial offers a novel and effective approach for researchers to develop Welsh health outcome measures for the future.
- Moreover, the study offers added value for building evidence for health care.