ISRCTN23303832 https://doi.org/10.1186/ISRCTN23303832

Validation of Kinyarwanda versions of questionnaires in patients with epilepsy and healthy volunteers

Submission date
07/02/2022

Recruitment status
No longer recruiting

Registration date
09/03/2022

Overall study status
Completed

Last Edited
05/07/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Epilepsy is a common condition that affects the brain and causes frequent seizures. Rwanda has a very high prevalence of epilepsy estimated at 49 cases per 1000 people. An important treatment gap of epilepsy and its associated illnesses has been observed. A more profound understanding of possible influencing factors may provide better guidance to close this gap. Validated and reliable scales and questionnaires in the endogenous language are needed to drive this research in a low-resource setting. This study aims to demonstrate the validity and reliability of the Kinyarwanda versions of the World Health Organization Quality of Life - Brief Version questionnaire (WHOQOL-BREF), the Quality of Life in Epilepsy 10 questionnaire (QOLIE10P), the Washington Group Short Scale (WG-SS) on disability, the Stigma Scale in Epilepsy (SSE), the Rosenberg Self-Esteem questionnaire and the Equitytool.

Who can participate?
500 Rwandan patients with epilepsy and 260 healthy volunteers not affected by epilepsy, aged 15 years and above

What does the study involve?
All participants will complete the Kinyarwanda versions of the questionnaires and the validated Kinyarwandan version of PHQ-9. The study will be conducted in a two-step design. After enrolment of the first sample of 75 patients and 50 volunteers, each individual scale is analysed for construct validity. In case the observed values indicate that some items of the questionnaire do not contribute to the scales, an expert panel will provide recommendations on a possible change of the scale and/or study continuation. A random sample of the participants will complete the same questionnaires again 10 days later.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for participants. The study will deliver long-term value as each individual scale provides data to better understand the impact of epilepsy in Rwanda. In

addition, the combined use of these scales will provide input into models of the complex relationship between epilepsy, resulting disability, depression, stigma, and self-esteem. Disentangling these will inform public health interventions to focus on the most impactful factor.

Where is the study run from?
University Hospital of Ghent (Belgium)

When is the study starting and how long is it expected to run for?
August 2021 to March 2023

Who is funding the study?
Fracarita (Belgium)

Who is the main contact?
Dr Peter Dedeken
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Contact information

Type(s)
Principal investigator

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Dr Peter Dedeken

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Additional identifiers

Protocol serial number
1.2

Study information

Scientific Title
Validation of the Kinyarwanda version of WHO-QOL, QOLIE10P, WG-SS, Rosenberg Self-Esteem Scale, Equitytool and Epilepsy Stigma Scale in patients living with epilepsy and healthy volunteers

Study objectives

Primary:
World Health Organization Quality of Life - Brief Version questionnaire (WHOQOL-BREF), the Quality of Life in Epilepsy 10 questionnaire (QOLIE10P), the Washington Group Short Scale (WG-SS) on disability, the Stigma Scale in Epilepsy (SSE), the Rosenberg Self-Esteem questionnaire and the Equitytool.

1. Demonstrate show good properties related to validity:
1.1. Construct validity by exploratory and confirmatory factor analyses to ensure the questionnaire refers to the same construct model as the initial scale
1.2. Content validity coefficients by item and by domain
1.3. Convergent validity for WHOQOL-BREF, QOLIE-10P, and WG-SS, by domain
1.4. Discriminant validity at questionnaire level
2. Demonstrate good reliability
2.1. Internal consistency (Cronbach's α) coefficients by questionnaire and for multi-domain questionnaires, for each domain
2.2. Test-retest reliability at questionnaire level and for multi-domain questionnaires, for each domain

Secondary:
1. The Kinyarwanda version of the epilepsy stigma scale describes a single factor model
2. There are no ceiling effects for the QOLIE-10P, Washington Group Short Scale and ESS
3. Explorative analysis of the possible relationship between epilepsy, its resulting disability, depression, stigma, and self-esteem using the psychosocial model described by Trani, applied to people with epilepsy (PWE)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/11/2021, Rwandan National Ethics Committee (Ministry of Health, PO Box 84, Kigali, Rwanda; +250 (0)255107884; info@rnecrwanda.org), ref: 925/RNEC/2021

Primary study design
Observational

Study design
Cross-sectional validation study

Study type(s)
Other

Health condition(s) or problem(s) studied
Epilepsy

Interventions
This is a cross-sectional validation study in PwE, with a comparator group of volunteers not affected by epilepsy. The study will be conducted in a staggered design with two phases:

Phase 1. 75 PwE and 50 volunteers will be enrolled.

Interim Analysis
An interim database lock will be performed. Exploratory and confirmatory analyses will be performed on item and construct of the questionnaires in order to early detect poor factor loading. In case of insufficient factor loading, the expert panel that signed off on the final Kinyarwanda version will convene to discuss possible reasons for poor factor loading related to the relevance of the item, inappropriate translation, or incorrect cross-cultural adaptation. The panel will provide any of the following recommendations: remove the item, recruit an additional sample of 50 PwE and 50 HV and reanalyzed or continue the trial.

Phase 2:
Continued recruitment until both cohorts are completed. Retest will be performed in a randomly selected sample of 15% of PwE and volunteers

This study validates multiple questionnaires in a single study. The use of more than one questionnaire will facilitate the process. For example, the WHO-QOL economic domain will correlate with the Equitytool but not with other questionnaires. On the other hand, the Epilepsy Stigma Scale may correlate with the Rosenberg Self-esteem scale. To obtain adequate validity comparisons such as convergent and discriminant validity, we deem all questionnaires needed.

The PHQ9 is a screening tool for depression. As depression is common in PwE, the presence of depression may influence self-esteem and stigma scores. The PHQ9 was translated and validated into Kinyarwanda with good construct validity, internal and external validity (Cronbach alfa 0.87).

The WHOQOL-BREF 2004 version is a self-administered questionnaire comprising 26 questions on the individual's perceptions of their health and well-being over the previous four weeks. The WHOQOL-BREF covers four domains each with specific facets: physical health, psychological, social relationships, and environment. Responses to questions are on a 1-5 Likert scale where 1 represents "disagree" or "not at all" and 5 represents "completely agree" or "extremely".

The Rosenberg Self-esteem questionnaire is a 10-item, unidimensional scale that measures global self-worth by measuring both positive and negative feelings about the self. All items are answered using a 4-point Likert scale format ranging from strongly agree to strongly disagree.

The QOLIE-10-P is a brief survey of health-related quality of life for adults with epilepsy. There are 10 questions about health and daily activities, one question about how much distress a PwE feels about problems and worries related to epilepsy, and a review of what bothers a PwE most.

The Washington Group Short Set on Functioning (WG–SS) contains six questions covering six basic functioning domains (seeing, hearing, mobility, cognition, communication, and self-care) and can be self-administered to PwE and healthy persons

Stigma Scale of Epilepsy (SSE), originally developed in Brazil), has been used to evaluate epilepsy-related stigma in the general population and in PwE. The original version did not report the model construct. A validation in Zambia pointed toward a 2-factor model construct related to internalized and enacted stigma.

The Equitytool is a simple and easy-to-use 15 item tool to measure relative wealth. Using a short survey, the Equity Tool allows you to compare the wealth of your respondents to the national or urban populations.

Intervention Type

Other

Primary outcome(s)
Primary outcome measures will be recorded at a single timepoint (i.e. at baseline) for all subjects and at 10 days after baseline in a randomized retest sample:

Construct validity:
1. Model parameters measured by factor loading range, and the Average Variance Extracted, the latter with a cut-off >0.5
2. Confirmatory fit analyses analyzed with Chi-square fit (x2 and p-value; p<0.05), Root Mean Square Error of Approximation (<0.05), Tucker–Lewis's index (>0.95)
3. Criterion validity analyzed by Pearson's correlation; coefficients between item and its domain and among all domains (no cut-off)
4. Discriminatory validity measured by comparing patients with epilepsy to volunteers and by comparing high/low seizure frequency at baseline, presence of depression
5. External validity performed through comparison between scales

Reliability:
1. Internal consistency measured by Cronbach's alpha (>0.7), and Composite Reliability (>0.7)
2. Temporal stability measured by intra-class correlation (ICC) between the scores at two timepoints separated by 10 days (0,8 [good]; 0,9 [exceptional])

Key secondary outcome(s)
1. SSE factor model will be analyzed using model parameters and confirmatory fit analyses on a single timepoint measurement (i.e. at baseline)
2. Ceiling effects will be measured by analysis of variance (ANOVA) on a single timepoint measurement (i.e. at baseline)
3. The possible relationship between epilepsy, its resulting disability, depression, stigma, and self-esteem using the psychosocial model described by Trani, applied to PwE and healthy volunteers, will be based on a single timepoint measurement (i.e. at baseline) and analyzed using:
3.1. Propensity score matching to correct for differences between subjects with and without disability
3.2. Structural equation models using the maximum likelihood procedure x2 test as well as the comparative fit index (CFI significant for >0.95), the root mean square error of approximation (RMSEA significant at <0.05) and the Tucker-Lewis Index (TLI >0.95)

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Aged 15 years and above
2. Signed informed consent
3. Able to understand and respond to questionnaires
4. For PwE: definite clinical diagnosis of epilepsy established by treating physician
5. For volunteers: in case of the presence of a chronic condition such as asthma or hypertension, adequate treatment is actively used with complete control of the condition
6. Willing to perform a retest assessment if randomly selected

Participant type(s)

Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Presence of a condition leading to the inability to write or speak
2. Subject currently enrolled in a clinical trial involving the use of an investigational drug or device, or concurrently enrolled in any other type of medical research judged not to be scientifically or medically compatible with this study, or in an exclusion period following recent trial involvement
3. For volunteers: the presence of any acute infectious disease or the sequelae thereof
4. For volunteers: the presence of any chronic condition resulting in current disability or presence of a neoplastic disorder
5. For volunteers: the presence of any previous trauma resulting in a current disability

Date of first enrolment
09/02/2022

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Rwanda

Saint Helena, Ascension and Tristan da Cunha

Study participating centre
CARAES Ndera Hospital
PO Box 423
Kigali
Saint Helena, Ascension and Tristan da Cunha
-

Study participating centre
King Faisal Hospital
KG 544 Street

Kigali
Rwanda
-

Sponsor information

Organisation
Ghent University Hospital

ROR
https://ror.org/00xmkp704

Funder(s)

Funder type
Charity

Funder Name
Fracarita Belgium

Results and Publications

Individual participant data (IPD) sharing plan
Requests for anonymised participant data should be submitted to the principal investigator, Peter Dedeken, MD (peter.dedeken@ugent.be), and will only be disclosed after approval by the study team, a compliance check with Rwandan regulations and ethical considerations and the intended use of the data. Anonymized data will be provided in an Excel database format.

IPD sharing plan summary
Available on request