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Translation of questionnaires on quality of life, disability, self-esteem, and stigma into Kinyarwanda (the language of Rwanda)

Submission date	**Recruitment status**	[_] Prospectively registered
02/11/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/11/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/08/2022	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Rwanda has a very high prevalence of epilepsy estimated at 49 per 1000 and an important treatment gap of epilepsy and its comorbidities 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 primordial to drive this research in a low-resource setting. A sound translation process is crucial to ascertain the face validity and content validity before moving to validation studies. This protocol provides a framework for the translation into Kinyarwanda of several validated scales to measure stigma, self-esteem, disability, and (health-related-) quality of life, with a mixed multistep methodology adapted to the COVID pandemic allowing remote collaboration and data collection.

Who can participate?

Rwandan patients with epilepsy, Rwandan healthy volunteers, physicians, linguistic experts, and translators proficient in Kinyarwanda and English

What does the study involve?

A) Panel members:

-role as a full member of a panel with linguistic experts, forward translators, and back translators, which convenes to reach consensus on the translation of scales and signs off on intermediate and final versions.

-content validity assessment using a computer-assisted self-interview.

-attend all panel meetings and participate actively to achieve an optimal translation.

B) healthy volunteer for comparability/similarity assessment of English back-translation:

- participation in a survey on similarity/comparability of the English version of the questionnaires, using an online questionnaire for each item, called computer-assisted self-interview

C) Patient or healthy volunteer for testing of the prefinal version:

- complete prefinal version of the Kinyarwanda translated questionnaires.

- in-depth interview for each item which will be conducted, called computer-assisted personal interview.

D) Healthcare professional for testing of the prefinal version:
-computer-assisted self-interview, which assesses user preference questions.

What are the possible benefits and risks of participating?
The study doesn't require any invasive procedure. We do not anticipate any risks for patients participating in this study.

Where is the study run from?
The study is an international collaboration, coordinated by a Belgian principal investigator at Ghent University Hospital and a Rwandan site lead investigator at CARAES Ndera Hospital.

When is the study starting and how long is it expected to run for?
April 2021 to February 2022

Who is funding the study?
The study is funded by Fracarita Belgium.

Who is the main contact?
Peter Dedeken, MD
peter.dedeken@ugent.be

Contact information

Type(s)
Scientific

Contact name
Dr Peter Dedeken

ORCID ID
http://orcid.org/0000-0001-8493-6276

Contact details
Corneel Heymanslaan 10
Ghent
Belgium
9000
+32 474233896
peter.dedeken@ugent.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A COVID-19 pandemic adapted framework for international collaboration on the cross-cultural translation of questionnaires on quality of life, disability, stigma, self-esteem, and wealth into Kinyarwanda using a mixed multistep approach with early involvement of patients living with epilepsy and healthy volunteers

Study objectives
Validated and reliable scales and questionnaires in the endogenous language are primordial to drive this research in a low-resource setting. Ultimately disentangling the different determinants that affect disability, depression, stigma, and self-esteem, will inform public health interventions to focus on the most impactful factor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2021, CARAES Ndera Hospital Ethical Committee (CARAES Ndera hospital, P.O. Box 423 Kigali - Rwanda; +250 781 447 928; nderaethicscommittee@gmail.com), ref: 025/CNEC /2021

Study design
International collaboration single-center study using a mixed approach

Primary study design
Other

Secondary study design

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Translation of questionnaire on (health-related) quality of life, self-esteem, disability, and stigma for Rwandan patients with epilepsy and volunteers

Interventions
Different samples of study subjects will be recruited during the project.
A) Panel members enrolled in step 1 to 9, participate for the full study and will attend panel meetings and participate actively in a consensus discussion. In step 3, they complete once an

online content validity assessment questionnaire, thorugh a computer-assisted self-interview.
B) Healthy volunteer enrolled in step 6 for comparability/similarity assessment, complete once an online comparability/similarity questionnaire on all items, through a computer-assisted self-interview
C) Patients or healthy volunteer enrolled in step 8 for for prefinal version testing, complete the Kinyarwanda versions of all questionnaires once and are subject to an in-depth interview for each item through a computer-assisted personal interview.
D) Healthcare professional enrolled in step 8 for for prefinal version testing, complete the Kinyarwanda versions of all questionnaires once and and complete a user preference questionnaire thorugh a computer-assisted self-interview.

Step 1: Forward Translation: three forward translators provide translation from English to Kinyarwanda of all items, including response options.
Step 2: Forward translation reconciliation: the expert panel creates a single Kinyarwanda translation based on the forward translations from step 1, reviews and approves the version
Step 3: Content Validity Assessment: the expert panel assesses all items of each questionnaire in terms of relevance both conceptually and culturally, using a content validity questionnaire
Step 4: Final Forward translation: the expert panel reviews the content validity indices by item and by the scale and discusses items that perform weakly, amend as necessary and approve the final forward translation versions after review.
Step 5: Back-translation: two back translators provide translation from Kinyarwanda to English of all items, including response options.
Step 6: comparability/similarity assessment: both English back translations are compared to the original English version for comparability/similarity using a comparability/similarity questionnaire
Step 7: prefinal version creation: the expert panel, including back translators, discuss the results of the back translations and amend the Kinyarwanda versions as needed. In case of major changes, steps 5-7 are repeated.
Step 8: prefinal version testing: early patient, healthy volunteer, and HCP testing to assess problems in understanding of items and response categories, possible pitfalls
Step 9: Final version creation: expert panel review of the prefinal testing with possible amendments. Approval of the final versions after review. Final versions will then proceed in a validation study, defined in a different protocol.

Intervention Type
Other

Primary outcome measure
Content Validity is measured using the item content validity index (I-CVI), Scale-CVI, proportional index and unanimity agreement score, at a single time point (step 3)

Secondary outcome measures
1. Comparability and similarity is measured once in step 6 using a 7-point Likert scale, ranging from 'extremely comparable' to 'not at all comparable' and 'extremely similar to 'not at all similar'
2. User preference for healthcare professionals is measured once in step 8 using a 4-point Likert scale in a non validated, study-specific user preference questionnaire
3. Patient and volunteer testing assesses difficulty, emotional barriers, and understanding of all items for all questionnaires using a 4-item Likert scale completed by the interviewer and using the yes/no items completed by the interviewer from his/her observation at the end of the study

Overall study start date

01/04/2021

Completion date
01/02/2022

Eligibility

Key inclusion criteria
A) Patients with epilepsy (N=2) included in panel discussions
1. Definite clinical diagnosis of epilepsy, defined as two epileptic seizures, unprovoked, with a minimum interval of 24 hours
2. Able to read self-administered questionnaires and able to write
3. Bilingual English and Kinyarwanda, preferably trilingual French, English, Kinyarwanda
4. Able to attend/complete computer-assisted personal interviewing
5. Willing to attend video conferencing and CASI
6. ≥ 18y of age
7. Providing signed informed consent

B) Healthy volunteers (N=2) included in panel discussions
1. Able to read
2. ≥ 18y of age
3. Willing to attend video conferencing and CASI
4. Provide signed informed consent

C) Volunteers (N=30) enrolled for assessment of similarity/comparability of the original version (OV) and Back translation (BT)
1. Fluent in English
2. Able to attend/complete CASI
3. ≥ 18y of age
4. Providing signed informed consent

D) Patients (N=5) for testing of prefinal version
1. Definite clinical diagnosis of epilepsy, defined as two epileptic seizures, unprovoked, with a minimum interval of 24 hours
2. Able to understand and respond to the questionnaire
3. ≥ 18y of age
4. Provide signed informed consent

E) Healthy Volunteers (N=5) for testing of prefinal version
1. Able to understand and respond to the questionnaire
2. ≥ 18y of age
3. Provide signed informed consent

F) Healthcare Professional (N=5) for testing of prefinal version
1. ≥ 18y of age
2. Board-certified healthcare professional in Rwanda
3. Fluent in Kinyarwanda
4. Provide signed informed consent

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
55

Total final enrolment
70

Key exclusion criteria
A) PwE (N=2) included in panel discussions
1. Presence of cognitive deficit hampering interview, comprehension of questions
2. Presence of neurological deficit that hinders answering of questions, reading, or understanding
3. Presence of hallucinations, psychosis

B) HVs (N=2) included in panel discussions
1. Presence of any medical condition unless treatment provides total symptom control for at least 6 months or unless judged healthy by the enrolling investigator
2. Presence of cognitive deficit, possibly hampering participation or reading, understanding or answering of questions,
3. Presence of hallucinations, psychosis

C) volunteers (N=30) enrolled for assessment of similarity/comparability of the original version (OV) and Back translation (BT)
1. Presence of physical condition hampering reading, understanding or answering
2. Presence of hallucinations, psychosis

D) Patients (N=5) for testing of prefinal version
1. Presence of cognitive deficit hampering interview, comprehension of questions
2. Presence of neurological deficit that hinders answering of questions, reading or understanding
3. Presence of hallucinations, psychosis

E) Healthy Volunteers (N=5) for testing of prefinal version
1. Presence of any medical condition unless treatment provides total symptom control for at least 6 months or unless judged healthy by the enrolling investigator
2. Presence of cognitive deficit, possibly hampering participation or reading, understanding or answering of questions,
3. Presence of hallucinations, psychosis

F) Healthcare Profession (N=5) for testing of prefinal version
1. Presence of any medical condition unless treatment provides total symptom control for at least 6 months or unless judged healthy by the enrolling investigator
2. Presence of cognitive deficit, possibly hampering participation or reading, understanding or answering of questions

Date of first enrolment
06/07/2021

Date of final enrolment
10/01/2022

Locations

Countries of recruitment
Rwanda

Study participating centre
CARAES Ndera Hospital
P.O. Box 423
Kigali
Rwanda
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Sponsor information

Organisation
Ghent University Hospital

Sponsor details
Corneel Heymanslaan 10
Ghent
Belgium
9000
+32 9 332 45 39
Naomi.VanKeymeulen@uzgent.be

Sponsor type
University/education

Website
https://www.ugent.be/en

ROR
https://ror.org/00xmkp704

Funder(s)

Funder type

Charity

Funder Name
Fracarita Belgium

Results and Publications

Publication and dissemination plan
The study protocol is planned to be published in Trials, BMC, Springer Nature
The final versions of the questionnaires will be made available on the website of the CARAES Neuropsychiatric Hospital after an additional validation study.
Manuscript on the results of different steps as learning for cross-cultural translation and adaptation is planned in a methodology journal.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
Requests for full protocol and anonimised participant data, need to be submitted to the principal investigator, Peter Dedeken, MD (peter.dedeken@ugent.be), and will only be disclosed after approval by the study team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		11/06/2021	08/11/2021	No	Yes
Protocol file	version 2.2	29/11/2021	16/08/2022	No	No