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German translation, cultural adaption and validation of the Unidimensional Self-Efficacy scale for Multiple Sclerosis and validation of the Neurological Fatigue Index for Multiple Sclerosis

Submission date
28/11/2018

Recruitment status
No longer recruiting

Registration date
02/01/2019

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is an inflammatory disease of the central nervous system (the brain and spinal cord). In most cases, young people aged 20 to 40 are diagnosed with MS, with women being around three times as often affected as men. Damage to the nerve sheaths leads to a variety of symptoms in MS. Specific treatment of these symptoms and improvement in everyday activities are important goals for people with MS. To be able to measure the present health status of individuals and assess the effects of treatment, suitable measurement tools are necessary. These tools need to be precise, valid and reliable. This refers also to subjective instruments such as questionnaires. These tools can be used to measure patients' perception of their health status or disease-related health problems. Certainly, the questions in any questionnaire need to be in the respective language of the people under investigation. These translated questionnaires are required to be validated, too. In their next study, the researchers are interested in the effects of a physiotherapy intervention on physical functioning and self-efficacy. Self-efficacy is a person’s belief in his or her ability to achieve goals. Studies have shown that high self-efficacy levels are related to better health outcomes in people with MS. So far, the researchers are not aware of any validated German questionnaire for measuring self-efficacy in people with MS. Therefore, they plan to translate the original English Unidimensional Self-Efficacy Scale for MS (USE-MS) into German and to validate the German version for people with MS living in Austria.

Who can participate?
People with MS who are 18 or older who do not have another neurological or psychiatric disorder or any severe disease

What does the study involve?
The study consists of two phases. Phase 1 is used to translate the USE-MS into German and to pre-test the German version. Participants with MS are asked to complete the 12-item USE-MS questionnaire. After that, they are asked for an interview (20-45 minutes) to learn about their

opinions regarding the translated scale. Phase 2 of the study involves two tests within 2-14 days. Participants are asked to complete six questionnaires including the USE-MS. All participants receive the same questionnaires and are asked the same questions during the interview.

What are the possible benefits and risks of participating?
It is expected that there are no risks related with this study as there is no intervention. Moreover, it is expected that there is an indirect benefit associated with the study participation because the study is used to make a validated self-efficacy scale for people with MS accessible for German-speaking people with MS. Study participants will influence the wording of the scale, which is of value for people with MS in the clinical practice and research.

Where is the study run from?
The study is run from the Medical University of Innsbruck, Clinical Department of Neurology, Austria, in collaboration with the Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Centre Muenster, Austria.

When is the study starting and how long is it expected to run for?
August 2018 to October 2022

Who is funding the study?
Austrian MS Research Society. All other costs will be paid by the MS Task Group of the Medical University of Innsbruck, Department of Neurology, Austria and the Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Centre Muenster, Austria.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number

ECS 1260/2018

Study information

Scientific Title
German translation, cultural adaption and validation of the Unidimensional Self-Efficacy scale for Multiple Sclerosis and validation of the Neurological Fatigue Index for Multiple Sclerosis

Acronym
German USE-MS NFI-MS

Study objectives
Current study hypothesis as of 21/04/2020:

Phase 1 of the study:
H1: The German version of the 12-item Unidimensional Self-Efficacy scale for Multiple Sclerosis (USE-MS) does not show adequate face and content validity, evaluated by an expert committee and people with multiple sclerosis.
H2: The German version of the USE-MS cannot be adequately adapted for German speaking people with multiple sclerosis, evaluated by qualitative semi-structured interviews of people with multiple sclerosis.
Phase 2 of the study:
H1: The German version of the 12-item Unidimensional Self-Efficacy scale for Multiple Sclerosis (USE-MS) does not show acceptable internal consistency reliability, represented by Cronbach's alpha >0.7.
H2: The German version of the USE-MS does not show good test-retest reliability, represented by intraclass-correlation coefficients >0.75.
H3: The German version of the USE-MS does not show strong positive correlations with scales measuring conceptually similar constructs, such as the General Self-Efficacy Scale and the short version of the Resilience Scale (convergent validity), represented by Spearman's Rank correlation coefficients >0.7.
H4: The German version of the USE-MS does not show moderate positive correlations with MS specific health-related quality of life questionnaires, such as the Multiple Sclerosis International Quality of Life questionnaire (convergent validity), represented by Spearman's Rank correlation coefficients >0.5.
H5: The German version of the USE-MS does not show strong negative correlations with scales measuring conceptually contrasting constructs such as the Hospital Anxiety and Depression Scale (divergent validity), represented by Spearman's Rank correlation coefficients >-0.7.
H6: The German version of the USE-MS does not show moderate negative correlations with a fatigue scale validated in its original English version for people with MS, such as the Neurological Fatigue Index for Multiple Sclerosis (divergent validity), represented by Spearman's Rank correlation coefficients >-0.5. (Note: an appropriate forward-backward translation and cultural adaption for Austria has been made for the German NFI-MS, but not a subsequent quantitative validation. Please see below for further information.)
H7: The German version of the USE-MS does not show ordered thresholds between response categories with similar response probabilities, represented by evenly spaced categories and step difficulties (please replace calibration by difficulties) advances by at least 1.4 logits and by less than 5 logits, as assessed by the Partial Credit Model (Masters, 1982).
H8: The German version of the USE-MS does not show local independence, as represented by non-significant Pearson's correlations of <0.3 of the item standardised residuals.
H9: The German version of the USE-MS does not show unidimensionality, represented by non-

correlated and normally distributed standardised item residuals, evaluated by a Principal Component Analysis; eigenvalue of the first contrast <2; variance explained by each contrast <5% (<5% of t-tests significant (or the lower bound of the binomial confidence interval overlapping 5%); and ≥60% of the variance explained by the Rasch Factor.
H10: The German version of the USE-MS does not show invariance across groups (gender, age, , disease duration, language (English, German)), but demonstrates differential item functioning, represented by a significant Analysis of Variance of the residuals (5% alpha with Bonferroni correction) where the group is the main effect.
H11: The German version of the USE-MS does not show probabilistic ordering of items and does not fit the Rasch model, represented by a non-significant Bonferroni adjusted item-trait interaction Chi-square test (5% alpha), individual item and person fit residuals ranging between -2.5 and 2.5 (99% confidence interval), an expected mean of approximately 0 and a standard deviation near 1.
H12: The German version of the USE-MS does not show sufficient measurement precision to distinguish between different disability groups, represented by a person separation reliability (PSR) of ≥0.80 or a person separation index (PSI) of ≥ 2.00.

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Previous study hypothesis:

Phase 1 of the study:
H01: The German version of the 12-item Unidimensional Self-Efficacy scale for Multiple Sclerosis (USE-MS) does not show adequate face and content validity, evaluated by an expert committee and people with multiple sclerosis.
H02: The German version of the USE-MS cannot be adequately adapted for German speaking people with multiple sclerosis, evaluated by qualitative semi-structured interviews of people with multiple sclerosis.

Phase 2 of the study:
H01: The German version of the 12-item Unidimensional Self-Efficacy scale for Multiple Sclerosis (USE-MS) does not show acceptable internal consistency reliability, represented by Cronbach's alpha >0.7.
H02: The German version of the USE-MS does not show good test-retest reliability, represented by intraclass-correlation coefficients >0.75.
H03: The German version of the USE-MS does not show strong positive correlations with scales measuring conceptually similar constructs, such as the General Self-Efficacy Scale and the short version of the Resilience Scale (convergent validity), represented by Spearman's Rank correlation coefficients >0.7.
H04: The German version of the USE-MS does not show moderate positive correlations with MS specific health-related quality of life questionnaires, such as the Multiple Sclerosis International Quality of Life questionnaire (convergent validity), represented by Spearman's Rank correlation coefficients >0.5.
H05: The German version of the USE-MS does not show strong negative correlations with scales measuring conceptually contrasting constructs such as the Hospital Anxiety and Depression Scale (divergent validity), represented by Spearman's Rank correlation coefficients >-0.7.
H06: The German version of the USE-MS does not show moderate negative correlations with a fatigue scale validated for people with MS, such as the Neurological Fatigue Index (divergent validity), represented by Spearman's Rank correlation coefficients >-0.5.
H07: The German version of the USE-MS does not show ordered thresholds between response categories with similar response probabilities, represented by evenly spaced categories and step difficulties (please replace calibration by difficulties) advances by at least 1.4 logits and by less

than 5 logits, as assessed by the Partial Credit Model (Masters, 1982).
H08: The German version of the USE-MS does not show local independence, as represented by non-significant Pearson's correlations of <0.3 of the item standardised residuals.
H09: The German version of the USE-MS does not show unidimensionality, represented by non-correlated and normally distributed standardised item residuals, evaluated by a Principal Component Analysis; eigenvalue of the first contrast <2; variance explained by each contrast <5% (<5% of t-tests significant (or the lower bound of the binomial confidence interval overlapping 5%); and ≥60% of the variance explained by the Rasch Factor.
H10: The German version of the USE-MS does not show invariance across groups (gender, age, disability, MS phenotype, disease duration, immunomodulatory drugs), but demonstrates differential item functioning, represented by a significant Analysis Of Variance of the residuals (5% alpha with Bonferroni correction) where the group is the main effect.
H11: The German version of the USE-MS does not show probabilistic ordering of items and does not fit the Rasch model, represented by a non-significant Bonferroni adjusted item-trait interaction Chi-square test (5% alpha), individual item and person fit residuals ranging between -2.5 and 2.5 (99% confidence interval), an expected mean of approximately 0 and a standard deviation near 1.
H12: The German version of the USE-MS does not show sufficient measurement precision to distinguish between different disability groups, represented by a person separation reliability (PSR) of ≥0.80 or a person separation index (PSI) of ≥ 2.00.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of the Medical University of Innsbruck, 13/12/2018, ref. EK1260/2018

Study design
Bicentre survey (validation study with repeated measurement)

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
This study will consist of two phases and will take place at Innsbruck Medical University, Clinical Department of Neurology, Austria and the Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Centre Muenster, Austria.

Phase 1:
The original English USE-MS (Young et al., 2012) will be translated into German using a forward-backward translation process and expert committee involvement applying international recommendations concerning questionnaire translation (Beaton et al., 2007). Employing a patient-led process, the pre-final German USE-MS version will be completed by a sample of 30 people with MS with minimal to severe disability, followed by cognitive debriefing and individual semi-structured interviews. The aims of phase 1 are to evaluate face and content validity of the

German USE-MS and to culturally adapt the scale for German speaking people with MS living in Austria.

Phase 2:
The German USE-MS will be validated using methods based on Classical Test Theory and Item Response Theory. A sample of 292 people with MS with minimal to severe disability will be asked to complete the USE-MS and questionnaires measuring a similar or diverging conceptual construct or assessing a construct where the relationship with self-efficacy is already known. Reliability and criterion related validity will be evaluated. In addition, Rasch analysis will be employed on the German USE-MS to evaluate construct validity.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 21/04/2020:

Phase 1 (data collected at one timepoint [baseline]):
Face validity and content validity of the German 12-item Unidimensional Self-Efficacy scale for Multiple Sclerosis (USE-MS) measured by a semi-structured interview (Qualitative Content Analysis) at baseline
Phase 2 (data collected at two timepoints: test 1 [T1] and test 2 [T2] 2-14 days after T1):
1. Internal consistency reliability of the German USE-MS assessed by Cronbach's alpha at T1 and T2
2. Test-retest reliability of the German USE-MS assessed by intraclass-correlation coefficients at T1 and T2
3. Convergent validity of the German USE-MS measured by correlations with the General Self-Efficacy Scale and the short version of the Resilience Scale at T1 and T2
4. Convergent validity of the German USE-MS measured by correlations with the Multiple Sclerosis International Quality of Life questionnaire at T1 and T2
5. Divergent validity of the German USE-MS measured by correlations with the Hospital Anxiety and Depression Scale at T1 and T2
6. Divergent validity of the German USE-MS measured by correlations with the Neurological Fatigue Index at T1 and T2. These correlational analyses will be performed not before the validation of the NFI-MS using Rasch analysis has been completed. For the Rasch analysis of the NFI-MS, the same criteria will apply as for the USE-MS. Should the fatigue scale not be found sufficiently valid, the results will be deleted and changes to the study record will be made.
7. Category threshold order of the German USE-MS assessed by the Partial Credit Polytomous Model at T1 and T2
8. Local independence of the German USE-MS assessed by correlations of the item standardised residuals at T1 and T2
9. Unidimensionality of the German USE-MS evaluated by Principal Component Analysis at T1 and T2
10. Invariance across groups (gender, age, disability, disease duration, immunomodulatory drugs) , that is absence of differential item functioning of the German USE-MS, evaluated using a Two-Way Analysis of Variance of residuals within the Polytomous Rasch Model at T1 and T2
11. Probabilistic ordering of items of the German USE-MS and fit to the Rasch model evaluated by an item-trait interaction Chi-square test with Bonferroni correction for the number of items at T1 and T2

Previous primary outcome measure:

Phase 1 (data collected at one timepoint [baseline]):
Face validity and content validity of the German 12-item Unidimensional Self-Efficacy scale for Multiple Sclerosis (USE-MS) measured by a semi-structured interview (Qualitative Content Analysis) at baseline

Phase 2 (data collected at two timepoints: test 1 [T1] and test 2 [T2] 2-14 days after T1):
1. Internal consistency reliability of the German USE-MS assessed by Cronbach's alpha at T1 and T2
2. Test-retest reliability of the German USE-MS assessed by intraclass-correlation coefficients at T1 and T2
3. Convergent validity of the German USE-MS measured by correlations with the General Self-Efficacy Scale and the short version of the Resilience Scale at T1 and T2
4. Convergent validity of the German USE-MS measured by correlations with the Multiple Sclerosis International Quality of Life questionnaire at T1 and T2
5. Divergent validity of the German USE-MS measured by correlations with the Hospital Anxiety and Depression Scale at T1 and T2
6. Divergent validity of the German USE-MS measured by correlations with the Neurological Fatigue Index at T1 and T2
7. Category threshold order of the German USE-MS assessed by the Partial Credit Polytomous Model at T1 and T2
8. Local independence of the German USE-MS assessed by correlations of the item standardised residuals at T1 and T2
9. Unidimensionality of the German USE-MS evaluated by Principal Component Analysis at T1 and T2
10. Invariance across groups (gender, age, disability, disease duration, immunomodulatory drugs), that is absence of differential item functioning of the German USE-MS, evaluatedusing a Two-Way Analysis of Variance of residuals within the Polytomous Rasch Model at T1 and T2
11. Probabilistic ordering of items of the German USE-MS and fit to the Rasch model evaluated by an item-trait interaction Chi-square test with Bonferroni correction for the number of items at T1 and T2
12. Measurement precision of the German USE-MS evaluated by the Person Separation Reliability and Person Separation Index at T1 and T2

Key secondary outcome(s))

Phase 1 (data collected at one timepoint [baseline]):
Cultural adaption of the German USE-MS for German speaking people with multiple sclerosis living in Austria, measured by a semi-structured interview (Qualitative Content Analysis)

Phases 1 and 2 (data collected at baseline [phase 1] and at T1 [phase 2] by four members of the research team (three neurologists and one physiotherapist) from patients' charts):
1. Demographic data (gender: female, male; age)
2. MS disease specific data (Expanded Disability Status Scale (EDSS) (Kurtzke, 1983) (0-4.0; 4.5-6.5; 7.0; 7.5; 8.0-9.0)
3. Disease duration
4. MS phenotype:
4.1. Relapsing-remitting
4.2. Primary progressive
4.3. Secondary progressive (Lublin and Reingold, 1996)
5. Use of disease modifying treatment (DMT):
5.1. No DMTs

5.2. Low effective DMTs: interferon-b 1a, interferon-b 1a, interferon-b 1b, pegylated interferon-b 1a, glatiramer acetate, dimethyl fumarate, teriflunomide, azathioprin, intravenous immunoglobulins
5.3. High effective DMTs: alemtuzumab, cladribine, fingolimod, natalizumab, ocrelizumab, cyclophosphamide, mitoxantrone, rituximab (Montalban et al., 2018, Diener and Weimar, 2012 /2017))

Phase 2 (data collected at two timepoints: test 1 [T1] and test 2 [T2] 2-14 days after T1):
1. MS specific self-efficacy measured by the newly translated German version of the USE-MS
2. General self-efficacy measured by the validated German version (Schwarzer and Jerusalem, 1999) of the 10-item General Self-Efficacy Scale (GSE) (Schwarzer and Jerusalem, 1995)
3. Resilience measured by the validated German version (Schumacher et al., 2004) of the 13-item Resilience Scale (RS-13) (Leppert et al., 2008), which is based on the original English 25-item Resilience Scale (Wagnild and Young, 1993)
4. MS specific health-related quality of life measured by the validated German version (Flachenecker et al., 2011) of the 31-item Multiple Sclerosis International Quality of Life (MusiQol) questionnaire (Simeoni et al., 2008)
5. Anxiety and depression measured by the validated German version (Petermann, 2011) of the 14-item Hospital Anxiety Depression Scale (HADS) (Zigmond and Snaith, 1983)
6. Fatiguemeasured by the validated German version (© The University of Liverpool, Liverpool, United Kingdom, 2010. NFI-MS Austria/German - Version of 30 Sep 13 - Mapi. ID7555 / NFI-MS_AU1.0_deu-AT.doc) of the 23-item Neurological Fatigue Index (NFI-MS) (Mills et al., 2010)

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. People with any MS phenotype according to the currently valid version of the McDonald's criteria (Thompson et al., 2018, Polman et al., 2011) at the time of diagnosis
2. Aged 18 years or over
3. Any ethnicity
4. Disability score on the Expanded Disability Status Scale (EDSS (Kurtzke, 1983)) 0 to 9.0
5. Very good German language skills

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
322

Key exclusion criteria
1. Concomitant diseases which may affect subjective self-efficacy ratings (e.g. malignant diseases, other neurological or psychiatric disorders, depression, bipolar disorder, dementia etc)
2. Known pregnancy
3. Relapse of MS within the last two months
4. Any change of medication within the last four weeks prior to the study
5. A relapse between testings 1 and 2 during phase 2 would lead to the exclusion from the study

Date of first enrolment
01/02/2019

Date of final enrolment
15/06/2020

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Innsbruck
Clinical Department of Neurology
Anichstrasse 35
Innsbruck
Austria
6020

Study participating centre
Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Centre Muenster
Groeben 700
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6232

Sponsor information

Organisation
Medical University of Innsbruck

ROR

https://ror.org/03pt86f80

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Austrian MS Research Society

Funder Name
Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Centre, Muenster, Austria

Funder Name
Medizinische Universität Innsbruck

Results and Publications

Individual participant data (IPD) sharing plan
As of 03/01/2019:
Data generated by this research that support any publications will be made available upon reasonable request as soon as possible. In addition, meaningful data from this research will be made available publically as soon as possible, wherever legally and ethically possible.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Barbara Seebacher (barbara.seebacher@i-med.ac.at). Categorical data will be stored and available after the analysis has been completed and the data have been published. The data can be requested for at least 10 years. For that, informed consent from participants will be obtained. Personal data will be completely anonymised using a participant ID. The copyright for the German USE-MS will belong to the University of Leeds, UK.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	USE-MS results	17/04/2021	19/04/2021	Yes	No
Results article	in German	14/12/2022	13/02/2024	Yes	No
Protocol article	protocol	20/08/2019	23/08/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes