BMJ Open

Disease-related knowledge measurement instruments of people affected by multiple sclerosis: protocol for a systematic psychometric review

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To cite: Gonzalez-del-Rio M, Bertran-Noguer C, Ramió-Torrentà L, *et al*. Disease-related knowledge measurement instruments of people affected by multiple sclerosis: protocol for a systematic psychometric review. *BMJ Open* 2021;**11**:e049580. doi:10.1136/bmjopen-2021-049580

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-049580).

Received 27 January 2021
Accepted 13 September 2021

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ABSTRACT

Introduction Disease-related knowledge is a key component of shared decision making and a relevant outcome to measure the effectiveness of information provision interventions. However, no systematic psychometric reviews have been found that assess the measurement instruments aimed at evaluating the disease-related knowledge of people affected by multiple sclerosis. This review aims to systematically assess the quality of the measurement properties of all available disease-related knowledge measurement instruments of people affected by multiple sclerosis.

Methods and analysis A systematic psychometric review will be carried out in accordance with the guidelines proposed by the international 'COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN)' initiative. Studies that meet the following criteria will be selected: (1) those whose aim is to measure disease-related knowledge, (2) those whose study populations are affected by multiple sclerosis and (3) those whose aims are to develop measurement instruments or evaluate one or more of their measurement properties. The information sources will be MEDLINE (via PubMed), CINAHL, PsycINFO and OpenGrey. The methodological quality will be assessed using the 'COSMIN Risk of Bias' checklist. Available evidence will be synthesised and graded using a modified Grading of Recommendations Assessment, Development and Evaluation approach.

Ethics and dissemination As this is a systematic review, no ethics approval is needed. Study findings will be shared with multiple sclerosis patient support groups and in reports to funders. The results will be submitted to a peer-reviewed journal and will be presented at national and international conferences.

PROSPERO registration number CRD42019125417.

Strengths and limitations of this study

- We will use the guidelines developed by the international COsensus-based Standards for the selection of health Measurement INstruments to conduct this review.
- A comprehensive literature search strategy has been planned.
- We will not use language and date restrictions in the search strategy.
- We will evaluate the methodological quality of the included studies, apply criteria of good measurement properties and summarise the evidence and the quality of the evidence for each measurement instrument identified.
- Psychometric reviews are quite complex as they involve multiple reviews, one review for each measurement property; to address this complexity, the review team includes reviewers with knowledge of the construct of interest and experience with the target population and with the field of psychometrics and qualitative research.

INTRODUCTION

Multiple sclerosis (MS) is a chronic inflammatory and degenerative disease that affects the central nervous system (brain, optic nerves and spinal cord), damaging myelin and axons. It is estimated that 2.3 million people worldwide suffer from the disease, with an average prevalence of 33 cases per 100 000 inhabitants, with areas of medium or high prevalence at more than 150 cases per 100 000 inhabitants. MS is considered the most common demyelinating disease and the first cause of non-traumatic neurological disability in young adults.[1]

In recent decades, the review of MS diagnostic criteria, the emergence of new therapies and the identification of some predictive biomarkers for clinical outcomes have enabled early detection of the disease. All these aspects have allowed treatment to be given as soon as possible in appropriate cases and through increasingly tailored therapeutic decisions, thus reducing relapse rates and slowing down disease progression.[2]

Different studies show that aspects addressed from a person-centred healthcare approach, such as therapeutic adherence, weighing risks and benefits before starting a

new treatment and acquiring healthy behaviours, positively impact on quality of life.[3–5] It is precisely in this paradigm of contemplating the preferences, needs, expectations and vital trajectory of people affected by MS that good professional-patient communication and shared decision making can be expected to prevail.[3 5 6] To reach this optimum point, it needs to be taken into account that contributing, ensuring and improving disease-related knowledge of people affected by MS should be the first step on this lifelong path.

Knowledge framed in the context of health education has been defined as the 'factual and interpretive information leading to understanding or usefulness for taking informed action'.[7] As such, disease-related knowledge of people affected by MS can influence their self-management of the disease, coping and adherence to treatment, and, hence, clinical outcomes.[8] Likewise, previous research has established that disease-related knowledge determines how people affected by MS evaluate treatment risks, for example, high rates of treatment discounting based on risks are associated with less disease-related knowledge.[9] Furthermore, disease-related knowledge is a requirement for a key component of patient-centred healthcare, shared decision making, especially important in the case of chronic diseases such as MS where different treatment options are available.[5] In summary, disease-related knowledge enhances the autonomy of people affected by MS and subsequently leads them, through empowerment, to better informed decision making, greater involvement in disease management, richer personal life planning and more conscious self-care.[5 10–12]

For all these reasons, the provision of accurate, clear and valuable information from the moment of diagnosis onwards is a right supported by the European MS Platform Code of Good Practice in order to improve disease-related knowledge of people affected by MS.[13] Similarly, a recent systematic review shows that information provision interventions compared with standard care for people affected by MS have a moderate certainty of evidence to improve disease-related knowledge.[14] In this connection, nurses have been consolidated as key health professionals in the healthcare of people affected by MS, and they play an essential role in delivering information provision interventions.[15 16] The constant evolution and expansion of their role in MS healthcare has placed them at the forefront of patient health education programmes.

Patient knowledge is a relevant outcome to measure the effectiveness of strategies for informing, educating and involving patients.[12] However, several studies that evaluate the impact of information provision interventions in disease-related knowledge using measurement instruments (questionnaires or scales) fail to report or assess their validity. There is a need to use instruments, both in research and in practice, with proven validity to evaluate this outcome in a given population and context.[14]

In order to identify the most valid and appropriate measurement instruments for a certain purpose and setting, it is worth pointing out the innovative introduction of systematic psychometric reviews.[17–19] This type of review, conceived as an essential tool for clinical practice, health service planning and research, aims to identify the most suitable measurement instruments to assess a certain construct of interest in a specific population. However, no systematic psychometric reviews have been found in either the literature or in the prospective records of systematic review protocols that assess and summarise the measurement instruments aimed at evaluating the disease-related knowledge of people affected by MS. Therefore, we plan to carry out a systematic psychometric review of these measurement instruments in order to identify valid and reliable disease-related knowledge measurement instruments for people affected by MS.

METHODS AND ANALYSIS

Aim

To critically evaluate, compare and synthesise the quality of the measurement properties of all available disease-related knowledge measurement instruments of people affected by MS. The research question to be answered by this review is: What are the most suitable instruments to measure disease-related knowledge of people affected by MS?

Design

A systematic psychometric review will be carried out in accordance with the guidelines proposed by the international COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative.[17–19] This review protocol adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols statement.[20]

Eligibility criteria

Studies that meet the following criteria will be eligible: (1) the measurement instrument should aim to measure knowledge about MS; (2) the study population should be people over 18 affected by MS and (3) the aim of the study should be the development of a measurement instrument, the evaluation of one or more measurement properties or the evaluation of its interpretability and feasibility. Studies that only use the instrument as an outcome measure (eg, clinical trials) and those that use it to validate another instrument will be excluded.

Search strategy

A comprehensive and wide literature search will be conducted since its purpose is to identify all available measurement instruments. The sources of information will be the following bibliographic databases: MEDLINE (via PubMed), CINAHL and PsycINFO. In addition, grey literature databases such as 'Open Grey' will be consulted. The search strategy will combine an exhaustive selection of terms in controlled language and free text. Likewise, a validated bibliographic filter will be used to identify studies of measurement instruments.[21] This filter

is highly sensitive, and its use is recommended by the COSMIN guidelines. Idiomatic and date restrictions will not be used. The search strategy built for MEDLINE (via PubMed) is described in online supplemental file 1. In order to identify possible studies and measurement instruments that have not been retrieved through the initial search strategies, additional searches will be carried out including the name of the instruments identified. Reference lists of identified studies will be checked to detect potentially relevant studies. In addition, the authors of the selected studies will be contacted in order to retrieve the maximum possible information about the identified measurement instrument.

Study management and selection process

Retrieved references will be imported into the Rayyan QCRI web application programme.[22] This programme facilitates collaboration between reviewers during the study selection process. Two reviewers will independently assess the titles and abstracts of the references retrieved, confronting them with the eligibility criteria. If the title and abstract seem relevant to at least one of the reviewers, the full text of the article will be reviewed by two reviewers independently. Criteria discrepancies between reviewers will be discussed, and a third reviewer will be consulted if a consensus is not reached. If more data are required to resolve questions regarding the selection of a study, the authors will be contacted to request further information.

Data extraction from the studies

The identified studies will be grouped by instrument in order to identify the number of studies and instruments separately. The following information will be collected from each instrument: available studies, type of administration, number of scales and items, response options, range of scores, language and available translations. Similarly, information related to the characteristics of the population of each study will be summarised: sample size, age, percentage of females, disease characteristics, context of administration, country and response rate.

Assessment of the methodological quality of included studies

The methodological quality of the included studies will be assessed using the 'COSMIN Risk of Bias' (available at: https://www.cosmin.nl/wp-content/uploads/COSMIN-RoB-checklist-V2-0-v17_rev3.pdf). This tool is intended as a checklist that allows the design of quality of validation studies that are carried out to be critically and systematically evaluated. It evaluates the methodological quality to analyse content validity, construct validity (structural validity, hypothesis testing, cross-cultural validity), criterion validity, reliability (internal consistency, test–retest or inter-rater reliability, measurement error) and responsiveness. A single paper can provide information about one or more studies carried out to evaluate the different measurement properties of an instrument. The quality of each of these studies will be evaluated separately and will be classified as 'very good', 'adequate', 'doubtful' or 'inadequate'. The evaluation will be carried out by two reviewers independently, and in the case of discrepancies, a third reviewer will participate. Evaluation data will be collected using forms designed by COSMIN (available at https://cosmin.nl/wp-content/uploads/Scoring-form-COSMIN-boxes_april_final.xlsx).

Criteria for the evaluation of measurement properties

The results of the psychometric properties will be evaluated using specific criteria developed and agreed by experts.[18] Each property will be classified as 'sufficient', 'insufficient' and 'undetermined'.

Synthesis of the available evidence and its degree of quality

At this point, different studies and instruments will be available. One instrument may have been evaluated in different studies, while other instruments will only have been evaluated in a single study. The evidence for each of the instruments identified will be summarised at this stage. The available evidence on each psychometric property will be classified as 'sufficient', 'insufficient', 'inconsistent' or 'undetermined'. This assessment will be carried out based on the number of studies available per instrument and the consistency of their results. If the results are consistent between the studies, the possibility of carrying out a meta-analysis of the results will be assessed. Once this assessment is carried out, the quality of the evidence will be graded using a 'Grading of Recommendations Assessment, Development and Evaluation' approach modified by COSMIN.[18] This approach uses four factors to determine the quality of the evidence: (1) risk of bias (quality of the studies), (2) inconsistency of the results of the studies, (3) inaccuracy (eg, that a population sample size is excessively small), and, finally, (4) indirect evidence (evidence that comes from different populations not strictly related to the study population, in our case, for example, people with similar neurological diseases). Based on these criteria, the quality of the evidence of each instrument will be classified into four groups: 'high', 'moderate', 'low' and 'very low'. This classification will be carried out by two reviewers independently, and in case of disagreement, a third reviewer will participate.

Interpretability and feasibility description

Interpretability and feasibility are not considered psychometric properties, but they are essential aspects when selecting a measurement instrument. Therefore, they will be described but not evaluated. The following details will be recorded in specific tables: distribution of scores in the study population, percentages of unanswered items, floor and ceiling effects, scores and change scores available for relevant groups, information on the ease of understanding of the instrument by the patient and/or the professional, type of administration, extension of the instrument, minimum time needed to complete it, skills required to respond, cost of the instrument, copyright, availability for different contexts,and necessary equipment.

Making recommendations

Based on the available evidence and its quality, recommendations for use will be made for each of the measurement instruments identified. These recommendations will be classified into three categories:

A. Measurement instruments with evidence for sufficient content validity (any level) together with at least low quality evidence for sufficient internal consistency.
B. Measurement instruments not falling into categories A or C.
C. Measurement instruments with high-quality evidence for an insufficient measurement property.

Measurement instruments classified as A will be those recommended for use. Those classified as B will have the potential to be recommended for use, but further studies will be needed to assess their quality. Measurement instruments classified as C will not be recommended for use.

Strengths and limitations

Comprehensive database searches, the use of a rigorous and up-to-date psychometric review methodology will be the key strengths of this review. However, psychometric reviews are quite complex as they involve multiple reviews, one review for each measurement property. Accordingly, the review team includes reviewers with knowledge of the construct of interest and experience with the target population and with the field of psychometrics and qualitative research.

Patient and public involvement

Patients were not invited to contribute to the writing or editing of this protocol for readability or accuracy. At this time, this systematic psychometric review will be done without patient involvement.

Ethics and dissemination

Ethical approval and participant consent will not be necessary as it is a review based on published studies. The review will be carried out using the best practices in systematic psychometric reviews.[17–19] This review will identify the most suitable instruments for measuring disease-related knowledge of people affected by MS. This can benefit patients by identifying essential knowledge for self-managing their health and health professionals and the healthcare system by providing information on which measurement instruments are most appropriate for planning and evaluating information provision interventions and health education programmes. The results will be reported in accordance with COSMIN guidelines[18] and the 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses of Studies' checklist.[23] Study findings will be shared with MS patient support groups and in reports to funders. The results will be submitted to a peer-reviewed journal and will be presented at national and international conferences.

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Contributors MG-d-R and EZ-d-O contributed to the conception and design of the review, drafted the protocol and designed the search strategy. CB-N and LR-T provided critical insights and revised the protocol. MG-d-R registered the protocol review in the PROSPERO database. All authors have read and approved the final submitted version of this protocol. MG-d-R is the guarantor of this systematic psychometric review.

Funding This work was supported by the Col·legi d'Infermeres/rs de Girona (Official College of Nursing of Girona) grant number (ID:COIGI-B01-2020), by the International Organisation of Multiple Sclerosis Nurses with the International Nightingale Award 2020 and by the Sociedad Española de Neurología (Spanish Society of Neurology) with the Neurovation Award in multiple sclerosis 2020.

Disclaimer These funding sources have had no role in the design of the study and will not have any role during its execution, analyses, interpretation of the data, and decision to submit results.

Competing interests None declared.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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