

People with multiple sclerosis help design a tool to measure physical functioning and how it affects their daily lives: a plain language summary

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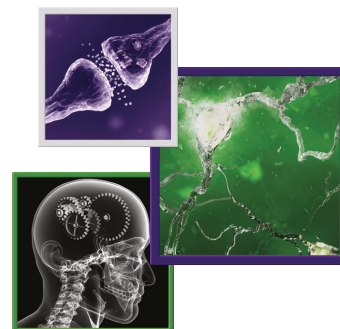


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People with multiple sclerosis help design a tool to measure physical functioning and how it affects their daily lives: a plain language summary



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Where can I find the original article on which this summary is based?

The original article called 'The validity, responsiveness, and score interpretation of the PROMIS[®] Physical Function – Multiple Sclerosis 15a short form in multiple sclerosis', is free to access and can be found here: [www.msard-journal.com/article/S2211-0348\(22\)00268-1/fulltext](http://www.msard-journal.com/article/S2211-0348(22)00268-1/fulltext)

Summary

What is this summary about?

This summary describes how researchers worked with people with multiple sclerosis (MS), neurologists and measurement experts to create an easy-to-use questionnaire to measure the physical function of people with MS. This questionnaire covers topics that are relevant and important to people with MS and their doctors.

The ability to do what you want to do, when you want to do it, is one of the most important concerns for people with MS. This questionnaire could help doctors to record and manage how much MS affects people's lives.

MS can bring a range of challenging symptoms such as '**brain fog**', tiredness, and problems with movement and balance. Many of these symptoms can make day-to-day activities, like working, very difficult for people with MS. Doctors currently use examinations like the **Expanded Disability Status Scale (EDSS)** and the **MS Functional Composite (MSFC)**, but these do not fully consider what is important to people living with MS. A questionnaire that specifically measures **physical functioning** of people with MS could help doctors and people with MS to better understand, communicate and manage the physical effects of MS. In this study, people with MS were asked to help create a questionnaire about physical function that reflects topics that are important to them.

What were the results?

The PROMIS[®] physical function – Multiple Sclerosis 15a (the PROMIS[®] PF MS questionnaire) was successfully created with the help of people with MS. People with MS thought that the PROMIS[®] PF MS questionnaire covered issues important to their physical function. Scores were in line with results of other physical symptom measurement scales like the EDSS.

What do the results mean?

The PROMIS[®] PF MS questionnaire could be used to meaningfully record physical function among people with MS.

How to say (double click sound icon to play sound)...

• **Multiple sclerosis:**
MUHL-tuh-puhl skler-OH-sis



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Brain fog: Used to describe the issues people with MS experience with their thinking processes, such as memory and the ability to plan, make decisions, concentrate, reason, understand and learn. Healthcare professionals may call these cognitive issues.

Expanded Disability Status Scale (EDSS): A method of measuring how MS affects someone physically and monitoring how this changes over time.

MS Functional Composite (MSFC): A method of measuring the physical functioning of a person's arms, hands and legs, as well as their cognition. Problems with cognition (thinking processes) may result in a person experiencing 'brain fog'.

Physical function: The ability to carry out activities, such as work, household chores and self-care, which require strength, endurance and mobility.

Who is this article for?

- People with MS, their friends, families and carers
- Patient representatives
- Healthcare professionals who treat people with MS, e.g., doctors, nurses, nurse practitioners, physician assistants, etc.

Who sponsored this study?

Sponsor: a company or organisation that oversees and pays for a clinical research study. The sponsor also collects and analyses the information that was generated during the study.

This study was **sponsored** by Merck KGaA, Darmstadt, Germany.

What is the purpose of this plain language summary?

The purpose of this plain language summary is to help you to understand the findings from recent research.

The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence.

Why is this study important to people with multiple sclerosis?

- MS is a long-term condition in which the immune system mistakenly attacks the protective layer around the nerves in the eyes, brain and spinal cord.
 - This leads to the symptoms of MS, such as weakness in arms or legs, problems with co-ordination and balance, and 'brain fog'.
- Physical function is the ability to carry out activities, such as work, household chores and self-care, which require strength, endurance and mobility.
 - The wide range of symptoms caused by MS can affect physical function, which can have a big effect on the health-related quality of life in people with MS.
- Measuring a person with MS's ability to carry out daily life activities that require physical function is a meaningful way to measure how much the physical symptoms of MS affect the activities and roles that are important to them.

- Various aspects of physical function can be measured with examinations and tests, such as the MSFC and the EDSS.
 - These are important tools for measuring physical function, but neither fully reflect the experiences of people with MS, nor how they feel about their physical function.
- Patient-reported outcomes are a type of information directly reported by the patients about their health that are becoming an increasingly important way of understanding a patient's point of view about their health.
- To help doctors measure the effect of physical function on the lives of people with MS, researchers worked with people with MS, neurologists and **measurement experts** to research, design, develop and test a user-friendly, modern questionnaire.
- The questionnaire will allow people with MS to share their views on their own physical function.

Measurement expert: Someone who helps to identify what needs to be measured and the best way to do it.

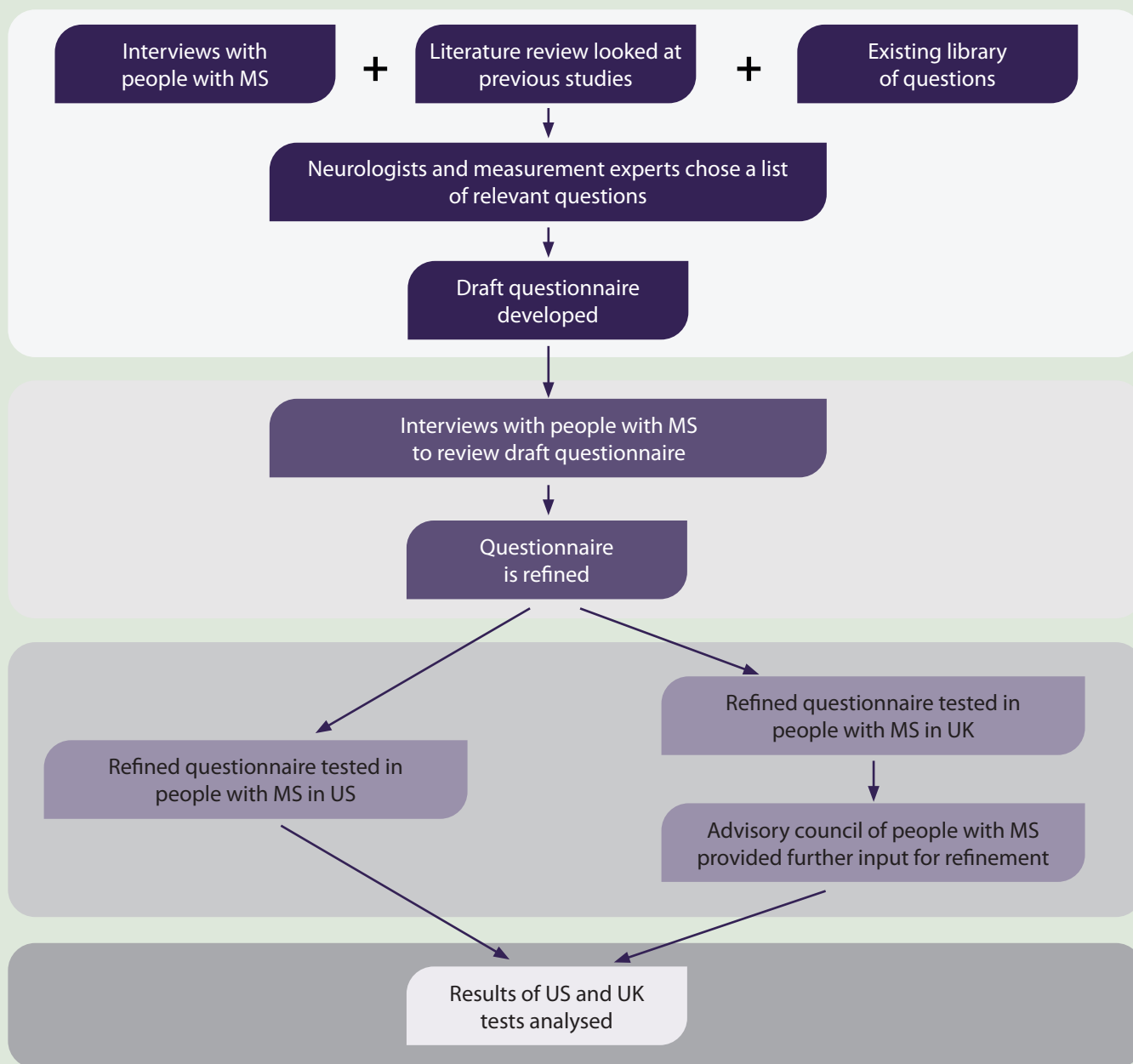
Who took part in this study?

- A range of people with an MS diagnosis from the UK and US took part in this study. In addition to their diagnosis, they were:
 - Aged between 18 and 65 years
 - Had an EDSS score of 6.5 or less, meaning they were able to walk at least 20 meters (65 feet) with or without help
 - Able to use a computer or tablet
 - Able to read and write in English
 - Able to give consent and complete the study questionnaires
- Neurologists and health measurement specialists were also part of this study.

How was the physical function questionnaire developed?

- The PROMIS® PF MS questionnaire was developed in four steps.
- Firstly, researchers looked at previous studies and interviewed 14 people with MS to understand how MS affected their ability to do physical tasks.
 - Based on this information, 6 neurologists and 4 measurement experts chose a list of relevant questions from an existing library of physical function questions to help draft the PROMIS® PF MS questionnaire.
- Then, researchers interviewed 43 people with MS to find out if the questionnaire was easy to understand and if it included all the important ways that MS affects their physical function. The questionnaire was improved based on the results.
- This final questionnaire was then tested in two groups:
 - 269 people with MS in the US
 - 558 people with MS in the UK

Overview of the questionnaire development steps.



Example questions from the PROMIS® PF MS questionnaire, adapted from Kamudoni. P, et al. 2022. For more information about using PROMIS® PF MS please see [HealthMeasures.net](https://www.healthmeasures.net)

Are you able to hold a full plate of food?				
Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to dress yourself, including tying shoelaces and buttoning your clothes?				
Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors, or carrying groceries?				
Not at all	Very little	Somewhat	Quite a lot	Cannot do
Are you able to stand without losing your balance for several minutes (i.e., without any support)?				
Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do

What were the results of the study?

- Based on these results, the number of questions was reduced from 23 to 15 to make sure only the most relevant questions were included and that they represented different aspects of physical function well.
- A group of people with MS also provided further input to help improve the questionnaire.
- The results from both the UK and US were analysed to determine how well this questionnaire could measure physical function in people with MS in a way that is meaningful to those living with the disease.
- People with MS thought that the PROMIS® PF MS questionnaire covered issues important to them about their physical function.
- People with MS found that the PROMIS® PF MS questionnaire was clear and easy to understand, and the responses were well suited to the questions.
- Scores were in line with results of other physical symptom measurement scales like the EDSS.
- The PROMIS® PF MS questionnaire was able to identify if physical functioning had changed when the test was repeated almost a year later.

What can this study tell us about the PROMIS® PF questionnaire?

- The research suggests that the PROMIS® PF MS questionnaire can help doctors and people with MS keep track of changes in physical function over time.
- The PROMIS® PF MS questionnaire may help people with MS to better explain challenges with their day-to-day physical abilities to their doctors and get the support they need.
- Using a questionnaire that accurately reflects the experience of people with MS can help doctors better measure and manage the symptoms of MS that affect physical function.
- This research shows that it is useful to involve people with MS in the development of new resources and tools, such as questionnaires.
- A limitation of the study was that it did not include people with MS who were under 18 years old, older than 65 years, or those who were unable to walk more than 20 meters (65 feet).
 - This means more research is needed to see how well the PROMIS® PF MS questionnaire would measure physical function in these groups.

Based on this research, the following questions may be helpful to discuss with your doctor or nurse about your MS care

- What does this information mean for me?
- How can we use this information to make decisions about the best way to measure my physical functioning?

Further information

The full title of the article that this summary is based on is: Kamudoni P, Amtmann D, Johns J, Cook KF, Salem R, Salek S, Raab J, Middleton R, Repovic P, Alschuler KN and von Geldern G, 2022. The validity, responsiveness, and score interpretation of the PROMIS[®] Physical Function – Multiple Sclerosis 15a short form in multiple sclerosis. *Multiple Sclerosis and Related Disorders*, 62, p.103753 (2022). [www.msard-journal.com/article/S2211-0348\(22\)00268-1/fulltext](http://www.msard-journal.com/article/S2211-0348(22)00268-1/fulltext)
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There were two observational studies which contributed towards the development of the PROMIS[®] Physical Function – Multiple Sclerosis 15a short form. The start and end dates for these are as follows: the UK based study started in September 2018 and ended in October 2020 and the US based study began in July 2019 and ended in January 2020. There are currently no plans for additional studies.

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Competing interests disclosure

Paul Kamudoni, Christian Henke and Jana Raab are employees of Merck Healthcare KGaA, Darmstadt, Germany. Karon Cook has provided consultancy to Merck Healthcare KGaA, Darmstadt, Germany. Sam Salek has a consultancy contract with Merck Healthcare KGaA, Darmstadt, Germany. Pavle Repovic has acted as a consultant or speaker for Alexion, Biogen, Celgene, EMD Serono Research & Development Institute, Inc., and an affiliate of Merck KGaA, Darmstadt, Germany, Medison, Novartis, Roche, Sanofi Genzyme and Viela Bio. Annette Wundes provided consultancy for AbbVie. Jeffrey Johns, Kevin N. Alschuler, Gloria von Geldern and Rod Middleton have nothing to disclose. The authors have no other competing interests or relevant affiliations with any organisation or entity with the subject matter or materials discussed in the manuscript apart from those disclosed.

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