Moving to a new level:

A new patient-reported outcome (PRO) walking scale for Multiple Sclerosis clinical trials

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ABSTRACT

Background

Developments in MS clinical trials, regulatory requirements and measurement science indicate more advanced rating scales are needed. A key emphasis is measurement clarity: PROs must prove they measure clearly defined concepts in specific contexts. For MS, the concepts of interest PROs measure should demonstrate suitability for relapsing, secondary and primary progressive MS (RMS; SPMS; PPMS). No walking PROs we identified met advanced criteria.

Objective

To develop a Walking PRO satisfying scientific and regulatory requirements for MS clinical trials and compare its performance with existing scales.

Methods

There were four phases: 1) Literature reviews to identify studies conceptualising walking and existing walking scales; 2) conceptual framework developed, refined and finalised using qualitative interviews and expert input; 3) item content generated, refined and finalised using iterations of mixed qualitative and quantitative methods and cognitive debriefing; 4) measurement performance tested and compared against two existing scales (12-item MS Walking Scale; NeuroQol Lower Extremity, LE) in postal survey data using two psychometric paradigms (Classical Test and Rasch Measurement Theories: CTT, RMT).

Results

We identified no literature conceptualising walking in MS or definitions of walking related variables. Qualitative interviews in MSers (n=59; 20 RMS, 20 SPMS, 19 PPMS) and expert opinion (2 therapist focus groups) produced a conceptual framework with 4 primary areas. We selected one domain, activities people do specific to walking, for scale development. Saturation analyses demonstrated content validity consistency across RMS, SPMS and PPMS. Mixed methods, including independent

postal surveys (n=337; n=526), produced a 32-item PRO. Evaluation in independent MSers (n=611) showed excellent CTT and RMT performance and advantages over MSWS-12 and NeuroQol LE.

Conclusions

MSWS-32 was designed to quantify walking ability and be fit-for-purpose as a primary endpoint measure in RMS, SPMS and PMS contexts of use.