**Abstract**

*Background:* Coping in MS refers to cognitive and behavioural efforts to manage stresses imposed by the illness. Existing generic and disease-specific coping scales do not meet modern guidelines for scale development, and/or cannot produce interval-level metrics to allow for change scores.

*Objective:* To develop a brief patient-reported outcome measure for coping in MS, capable of interval-level measurement.

*Methods:* Qualitative work in 43 people with MS lead to a draft scale which was administered to 5,747 participants, with longitudinal collection in 2,290. A calibration sample of 1,000 subjects split into development and validation sets was used to generate three scales consistent with Rasch model expectations.

*Results:* The total Coping Index-MS (CI-MS-T), CI-MS-Internal (CI-MS-I) and CI-MS-External (CI-MS-E) cover total, internal and externally-focused coping. All three scales are capable of interval-level measurement.

Trajectory analysis of 9,000 questionnaires showed two trajectories in CI-MS-T: Group 1 showed a low level of coping with slight decline over 40 months while Group 2 had a better and stable level of coping due to improving CI-MS-Internal which compensated for the deteriorating CI-MS-External over time. CI-MS-Total<30 identified group membership at baseline.

*Conclusion:* The CI-MS-Total, CI-MS-Internal and CI-MS-External, comprising 20 items, provide interval-level measurement and are free-for-use in not-for-profit settings.

Coping in MS refers to cognitive and behavioural efforts to manage stresses imposed by the illness. People with MS (PwMS) have been reported to use a variety of coping strategies, the most common of which are acceptance, active coping, planning, positive reinterpretation and growth.1 Research linking resilience factors to disease adjustment also found that adaptive coping (e.g., problem-focused coping, positive reappraisal) was associated with adjustment.2,3 Use of coping approaches like acceptance, problem-solving and avoidance is associated with better health-related quality of life.4

Coping style has been shown to moderate the relationship between fatigue and cognitive performance in MS.5 Recent work suggests that psychological interventions to target coping strategies may improve perceived physical health.6 With respect to health care interventions, a correlation has also been observed between therapeutic adherence with parenteral disease modifying therapy (DMT) and adaptive coping strategies.7 Failing to engage with commencing DMT has been linked with particular coping styles.8 The capacity of PwMS to maintain employment has been shown to be influenced by their coping approach.9 Intervention programs targeting specific coping strategies with the aim of enhancing psychosocial adjustment for PwMS have been proposed.10-12

Given the evidence, it would seem desirable to be able to measure the coping capability of PwMS. While there are many questionnaires designed to measure coping, both generic and disease specific, they either lack compliance with guidelines for Patient Reported Outcome Measures (PROM’s) development, principally the derivation of items from lived experience through qualitative work, and/or do not meet modern psychometric standards to produce interval-scaled metrics to allow for change scores.13, 14 The current study seeks to redress these omissions by developing a scale for coping ability, compliant with guidelines, and meeting rigorous modern psychometric standards for measurement.

**Methods**

A multi-stage methodology was applied, involving both qualitative and quantitative approaches.

*Qualitative exploration*

The lived experience of PwMS was explored through a series of qualitative face-to-face interviews on coping and quality of life, by a single interviewer who was not part of the clinical care team. Purposive sampling was employed to recruit at least 12 participants in each of the three MS subtypes (relapsing, primary and secondary progressive) and to ensure a range of illness durations and Expanded Disability Status Scale (EDSS) levels. Interviews were usually conducted in the clinic, though a few participants requested telephone. The recorded interviews were transcribed and thematic analysis applied; details on data collection and analysis are described elsewhere 15. Statements related to coping were extracted and used to derive a draft questionnaire.

*Quantitative Analysis*

Participants were recruited into the Trajectories of Outcome in Neurological Conditions (TONiC) study from across the UK (<https://finders-study.org/tonic>). Eligibility criteria included adults with any MS disease subtype and any level of disability providing they could give informed consent and complete questionnaire packs (with the help of a scribe if necessary). The draft coping questionnaire was included in a pack which included a number of other PROM’s measuring the bio-psychosocial model, and included both the Cope-60 (in a subgroup of early respondents) and Hospital Anxiety and Depression Scale-depression subscale (HADS-D) .16, 17 In addition, a Numeric Rating Scale (NRS) of perceived coping was included, scored 0-10 where a high score represented ‘Coping very well’. This draft was subjected to cognitive debriefing to ensure that items were understandable and relevant. Ethical approval was granted from the research committee (reference 11/NW/0743).

This pack was provided for postal completion at intervals of at least 8 months to the study participants. Once sufficient data allowed, a calibration sample of 1000 was extracted which covered the first four time points (baseline and first three follow-ups -250 people in each group), in which no single person was repeated. This calibration sample was then randomly divided into two samples each of 500 people, one sample for development, and one for validation to demonstrate the reproducibility of any resulting coping questionnaire. The sample size was consistent with retaining a Type 1 error rate of 5% in the chi-square fit statistics used by the RUMM2030 software for the Rasch analysis.18-20

*Rasch Analysis*

Data from the items were required to be consistent with Rasch model expectations of stochastic ordering, local independence, unidimensionality and group invariance.21-23 Ideal values for these indicators are given in the fit table. For further details of the Rasch model, please see Appendix 1.

Subsequently, the item parameters were exported from the calibration set to the full data set (i.e. 9000+ questionnaires from over 5000 people) in RUMM2030, and the person estimate derived from each scale used for further analysis. In addition, the Standard Error of Measurement (SEM) and resulting Smallest Detectable Difference (SDD) of the new instrument are reported.

*Trajectory Analysis*

The groups should be thought of as latent longitudinal strata in the data, that are composed of individuals following approximately the same development course on the outcome of interest.24For further details of the trajectory analysis, please see Appendix 1. The time metric was months since the baseline questionnaire. The outcome was the level of coping (either in total or for any subscales that emerge) utilising a Rasch-transformed latent estimate assessed at baseline and up to three further follow-ups, and modelled with a censored normal distribution.

A small test-retest analysis was undertaken on those completing the baseline data with a 2-4 week interval. Finally, a logistic regression was used to explore the association between coping and depression.

**Results**

*Qualitative*

Interviews conducted in 2012-13 achieved saturation of themes with 43 people with MS. The sample represented the range of disabilities (EDSS≤4 23.3%, EDSS≥7 27.9%) and spanned durations from diagnosis of 0.5-45 years (Appendix 2: Table A2/1).

Participants felt MS posed a unique stressor as it is incurable, long-term and the future course cannot be predicted. Coping required acceptance, whether to unexpected relapses or inexorable progression. The importance of activity to assist with coping by continuing normal activities and interests was stressed, although that might require pacing, flexibility and a stepwise approach. They sought some aspect of their life they felt they could preserve despite their MS which might be tangible like a hobby or a personal characteristic like religious belief.

The importance of maintaining an optimistic, determined and self-reliant attitude was emphasised. To achieve this, PwMS cited a range of strategies, such as ‘looking on the bright side’, comparing themselves positively to others with MS, reframing, or remembering past successes to boost confidence. Humour was used to defuse the stress of coping with MS. In practical terms, some found social support from family and friends while others from professionals. They occasionally used information-seeking, denial or meditation.

From this, 43 draft items emerged covering the above range of themes including acceptance, planning, help from professionals and significant others, denial, avoidance, substance abuse, and information gathering. Appendix 2 provides a flow chart showing study stages (Figure A2/1) and further information on the themes covered (Table A2/2).

*Quantitative*

5747 baseline questionnaires were returned between 2015 and end of 2019. The mean age was 50.2 years (SD12.1), and mean duration of MS was 11.2 years (SD 9.6). 73.4% were female. Subtypes were RR 66.1%, SP 22.7%, PP 11.3% (Appendix 2: Table A2/1).

By the end of 2019 a further 2290 had entered follow-up and returned the first follow-up questionnaire; 1124 the second questionnaire, and 412 their third follow-up questionnaire. Each of these time points were sampled to give the 1000 cases for the Rasch calibration. The mean age of those in the calibration sample was 53.4 years (SD 11.8), and mean duration 11.5 years (SD10.0). Three-quarters (75.6%) were female.

Fit to the Rasch model of the 43 items within the development sample was poor (Table 1, Analysis 1). The item set was saturated with a breach of the local independence assumption. Items were then removed in an iterative fashion, starting with the worst fitting items, and then removing one of a pair of locally dependant items which showed worst fit on other indicators, and/or where one item was dependent with several others.

<Insert table 1 about here>

Coping Index-MS-Internal (CI-MS-I)

This process resulted in a 10-item scale, the Coping Index-MS-Internal (CI-MS-I) covering ‘internal focus’, which satisfied the Rasch model and showed reproducibility in the validation sample (Table 1, Analyses 2-3). Differential item functioning was occasionally present for age and gender, but never repeated in the validation sample, so no action was taken. The CI-MS-I was invariant for duration, and disease subtype. A bi-factor equivalent solution was obtained in both samples to verify fit by the conditional test of fit and to confirm the unidimensionality of the scale, the absence of DIF at the test level and reproducibility (Table 1, Analyses 4-5). The Standard Error of Measurement (SEM) was 1.58, Smallest Detectable Difference (SDD) 4.39, representing 14.6% of the operational range of the scale. The CI-MS-I displayed a moderate (Spearman >0.4) correlation with the coping NRS, and the COPE-60 domains of positive growth, active coping and planning, with a slightly weaker correlation (>0.3) with acceptance. It also showed a gradient across the coping NRS categories (i.e.0-10)(F=215.2 (df 10); p <0.0001).

Coping Index-MS-External (CI-MS-E)

The remaining items were again fit to the Rasch model, to see if a second scale could emerge. This generated the Coping Index-MS-External (CI-MS-E) covering external focus, with adequate fit to the Rasch model and weak reproducibility (Table 1, Analyses 6-7). A bi-factor equivalent analysis showed adequate fit to the model, unidimensionality and absence of DIF at the test level, and reproducibility (Table 1, Analyses 8-9). The SEM was 1.69, SDD 4.69, representing 15.6% of the operational range of the scale. The CI-MS-E displayed a moderate correlation with the COPE-60 domains of instrumental social support and positive growth, with a slightly weaker correlation (>0.3) with suppression and planning. On this occasion, while the scale showed a significant difference across the coping NRS categories (F=23.9 (df 10); p <0.0001), the actual score discrimination was poor (two points across the entire NRS).

The two scales displayed a slightly different emphasis. CI-MS-I included items such as ‘I have found areas of my life that MS cannot affect’ and ‘I focus on each day as it comes’. It reflects strategies like active coping and restraint. On the other hand, CI-MS-E includes items such as ‘It is helpful to talk to other people with MS’, and ‘I rely on supportive relationships with my friends and family’. It focuses on seeking of support and acceptance. The latent correlation between the two subscales was 0.75, showing some communality, but also some differences in focus.

Coping Index-MS-Total (CI-MS-T)

Further analysis examined whether or not a total score could be derived from all 20 items. The missingness across these 20 items range from 1.3% ‘My sense of humour helps me cope’ to 2.5% 'It is helpful to talk to other people with MS’, with an overall average of 1.6%, A bi-factor equivalent solution was examined by using testlets based upon the two derived subscales above. This showed adequate fit to the model in the full calibration sample, specifically through the conditional test of fit, and absence of DIF at the test level, and unidimensionality (Table 1, Analysis 10). However, with an ECV of 0.86, 14% of the variance had to be discarded to obtain a unidimensional latent estimate of coping from the 20 items in the Coping Index-MS-Total (CI-MS-T), indicating that total raw score cannot be viewed as unidimensional and should always be converted to the interval level CI-MS-T (using Table 2), which has taken account of this reduced variance.

With the bi-factor solution, the CI-MS-T was shown to be invariant across all contextual factors, including time. The SEM was 2.83, and the SDD was 7.8, representing 13% of the operational range of the scale. The distribution of the CI-MS-T is shown in Figure 1. It is almost perfectly targeted, with the mean level of coping at 0.394 logits, whereas the scale in centred on zero logits.

<Insert figure 1 about here>

The CI-MS-T showed a moderate correlation with Cope-60 domains of ‘positive growth’, ‘active coping’, ‘acceptance’ and ‘planning. It also showed negative correlations with ‘venting’, ‘denial’ and ‘disengagement’. It showed a weak correlation (0.3824) with the coping NRS, but stronger than any other positive domain on the Cope-60, except a negative correlation of the NRS with disengagement (-0.4142). There is a moderate gradient of CI-MS-T across the NRS (F 121.98 (10); p=<0.001), strongest at the upper level of coping, but less so at the lower end, where there are much smaller numbers in each NRS category.

While CI-MS-I and CI-MS-E showed a significant difference in coping levels at baseline for disease subtype, these differences amounted to less than half a point on the scales, and no difference was found for CI-MS-T. Females were found to display a slightly higher level of coping than males (t test p=<0.001), but while this difference was significant, it represented only a small variation in the actual level of coping (< 2 points). No difference was found for the level of coping for those who were married/cohabiting, or not (t test >0.05) across all three scales. Correlations of all three scales with age and disease duration were weak (<0.2).

Test-retest analysis involved 75 individuals, 60 (80%) of whom reported that their coping had remained the same across the test-retest period. Mean age was 48.7 years (SD 12.0) with disease duration 10.8 years (SD 8.8). Three-fifths (60.7%) were female, and subtypes were RR 74.6%, SP 17.6%, PP 7.8%. Test-retest Intra-Class Correlation for the CI-MS-T was 0.841 (95%CI: 0.731-0.906); for the CI-MS-I 0.809 (95%CI: 0.676-0.887) and for the CI-MS-E 0.834 (95%CI: 0.719-0.902).

A transformation from raw score to interval scale estimate for each scale is given in Table 2.

<Insert table 2 about here>

Parameter estimates from the three scales were exported into the main data set to facilitate longitudinal analysis. Trajectory analysis based upon the CI-MS-T, and the fit parameters described above, identified two distinct trajectories showing relatively stable levels of coping (Figure 2). One group (Group 1) showed a low level of coping and remained that way for 40 months of follow-up. For those people in Group 1 who completed the baseline and first two follow-up questionnaires, there was a small decline over the first three years with an effect size of 0.283. The second group (Group 2) had a higher level of coping, and although it showed a significant positive slope indicating a gradual increase in the level of coping, that increase represented a trivial effect size. While the trajectories of CI-MS-I showed a similar pattern, those of CI-MS-E indicated a significant downward slope for both groups, suggesting a reduction in externally-focused coping over time (Figure 3).

<Insert figures 2 and 3 about here>

Inspecting the range of baseline clinical, demographic and health status factors across the trajectories revealed that whilst the majority of factors showed significant differences between trajectory groups, most demonstrated only trivial effect sizes (Table 3). Notably, the baseline health utility score for the CI-MS-I showed a moderate effect size (0.556) while the CI-MS-T showed only a small effect size (0.358). For the CI-MS-E reporting a religious belief showed a small effect size (0.276). No significant effect was found for DMT or educational level. Considering an indication for possible intervention to support those PwMS who are coping poorly, a value of 30 on the CI-MS-T interval scale estimate would appear to discriminate across the trajectory groups (Figure 4).

<Insert table 3 and figure 4 about here>

Finally, the association between CI-MS-T and depression was explored, the latter categorised as ‘none’ or ‘possible/probable’ depression, based upon the HADS-D, with ‘possible/probable’ accounting for almost a third (32.1%) of cases. Adjusted for age, gender, EDSS level (grouped as 0-4 and ≥4.5) and duration, with the CI-MS-T grouped into its interquartile ranges, those in the lower quartile (low coping) had increased odds for depression of 8.15 compared to the those upper quartile (high coping) (95%CI- 6.67-9.98) (Table 4). Cragg & Uhler's R2 (Nagelkerke) was 0.215, which indicates an adequate level of improvement over the null model.

<Insert table 4 about here>

**Discussion**

The CI-MS-T has been developed as a 20-item scale, comprising two subscales, one of which has an internal focus, and the other an external focus, with some overlap. Both subscales and the total scale satisfied Rasch model requirements, and were stable over repeated samples. The two subscales (CI-MS-I and CI-MS-E) had a latent correlation of 0.75, whereas each subscale correlated with the CI-MS-T at >0.8. All three scales, based upon a bi-factor equivalent solution, offered reproducible latent estimates, with minimal discard of variance. Expected correlations were observed with relevant components of the COPE-60, and the scales also showed a gradient across the coping NRS categories (although weak for CI-MS-E).

The two subscales are demonstrably statistically independent, however inspection of the items reveals that they do not easily align with a single theoretical construct. Other qualitative work has confirmed that MS coping behaviours have a broad basis.23 Coping behaviours “internal” and “external” seemed reasonable. In fact, the items within each scale appear to reflect a range of coping strategies relying on behavioural and cognitive approaches, as well as active coping. The fact that the items do not appear to be precisely grouped according to theoretical coping constructs demonstrates the strength of the qualitative methodology and patient-centred focus of our work, capturing authentic patient experience. It has previously been suggested that problem-focused coping is more closely linked to mental quality of life, as opposed to physical quality of life.24 It is possible that our two subscales reflect this distinction, with the “internal” scale relating to coping measures that impact mental quality of life and the “external” scale including coping items that relate to physical quality of life. Inspection of the items offers some support for this speculation, which would warrant further investigation.

Females were found to have a slightly higher level of coping than males, which was statistically significant but showed marginal difference in actual estimates. There was no difference in coping by disease subtype, and low correlations with age and disease duration. On balance, people were more likely to engage with an internal as opposed to an external perspective for coping, furthermore the use of external coping decreased over follow-up.

Within the context of the Wilson and Cleary model and the International Classification of Functioning, Disability and Health, coping is a person factor.25, 26 Trajectory analysis showed that there were two distinct groups with different levels of coping and very distinct trajectories. Within this sample of over 2000 PwMS followed longitudinally, almost a third showed consistently low levels of coping, whereas by contrast the remaining participants showed better and slightly increasing coping ability. A CI-MS-T interval score of 30 at baseline appears to discriminate between those two groups.

The current study found a strong relationship between coping and depression. One previous study found a protective effect of adaptive coping style against the experience of negative emotion among PwMS.27 Another study found that positive coping strategies improved psychological health as well as quality of life perception.28 Thus the strong relationship between coping and depression is worth further investigation, including a review of MS-specific interventions to improve coping strategies. Services should ensure that people are provided with information about their illness progression, and emotional support concerning coping strategies, social networks, and physical activity, as these are key determinants of successful adjustment.29The current study provides a feasible 20-item patient-reported scale to monitor coping capability and screen for those who are at greater risk of poor coping over time, with a baseline CI-MS-T interval score <30.

There are some limitations to the study. The transformation table should only be used if the respondent has answered all 20 items. Furthermore, the CI-MS-T can only be used with the transformation table, given some of its variance was discarded to give a unidimensional latent estimate. The strengths of the study relate to the foundation of the scales in qualitative analysis, the use of the Rasch model to construct a scale of coping, and the use of its transformed score in trajectory analysis to identify different groups following different trajectories over time.

The CI-MS offers certain advantages compared to COPE-60 or NRS of coping. First, the Cope-60 and the NRS are ordinal scales, and cannot be used to calculate change scores or easily used in parametric analysis, except by grouping in some fashion. Secondly, the CI-MS-T provides a score for total coping but also measures internal and external coping, whereas the NRS provides only the participant’s estimate of total coping, for which previous work suggests responses will cluster in the mid-range.30 Thirdly, the 60-item length of the Cope-60 inhibits routine use. Fourthly, in the qualitative work participants reported MS to be a unique stressor which required them to explore different coping strategies than their normal ones, suggesting a need for a disease-specific scale. Finally, in the cognitive debriefing, many respondents reported disliking the repetition of the items on alcohol and drug use in the Cope-60.

In conclusion, the CI-MS-T is a 20-item coping scale for PwMS, which has been developed with a mixed qualitative and quantitative approach. There are two subscales with internal and external focus. Satisfying strict Rasch measurement theory requirements, the scales have been shown to be capable of interval-level measurement and invariant for key contextual factors. They are free-for-use in all not-for-profit settings, after registration with the research team.

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**Declaration of Conflicting Interests**

The Authors declare that there is no conflict of interest.

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