Communication, Coordination, and Security for People with Multiple Sclerosis

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Background and Hypothesis

• Persons with multiple sclerosis (PwMS) who are severely affected by the disease may have complex needs that range from organizing one’s everyday life to measures of disease-specific therapy monitoring and palliative care.
• This subgroup of PwMS is likely to depend on multiple healthcare providers and various authorities, which are often difficult to coordinate. Thus, these PwMS are likely to benefit from a comprehensive cross-sectoral coordination of services provided by a care and case management (CCM).
• The CCM may improve quality of life (QoL, Hamburg Quality of Life Questionnaire (HALEMS)), functional status and may reduce service use, thus far not studied for PwMS.
• In this explorative phase II clinical trial, we evaluated a CCM with long-term, cross-sectoral and outreaching services.

Outcomes

• Primary outcome: the effects of the CCM intervention on HALEMS total score.
• Key secondary outcomes (selection): anxiety and depression (Hospital Anxiety and Depression Scale (HADS)), palliative care needs (Integrated Palliative Outcome Scale Neuro S8 (IPOS-Neuro S8))
• Qualitative assessments: individual semi-structured in-depth interviews and focus groups in a subset of patients and caregivers.

Study design
Results 1: patient recruitment and compliance with the protocol

Results 2: patient characteristics at baseline

<table>
<thead>
<tr>
<th></th>
<th>total n=80</th>
<th>control, n=40</th>
<th>intervention, n=40</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>age (y), mean (SD)</td>
<td>55.7 (10.99)</td>
<td>57.9 (11.04)</td>
<td>53.5 (10.62)</td>
<td>0.076</td>
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<tr>
<td>female gender (n, %)</td>
<td>52 (65)</td>
<td>30 (75)</td>
<td>22 (55)</td>
<td>0.061</td>
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<tr>
<td>EDSS, mean (SD)</td>
<td>6.68 (1.06)</td>
<td>6.66 (1.02)</td>
<td>6.71 (1.12)</td>
<td>0.835</td>
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<tr>
<td>disease duration (y), mean (SD)</td>
<td>18.04 (11.45)</td>
<td>17.53 (12.17)</td>
<td>18.13 (10.84)</td>
<td>0.669</td>
</tr>
</tbody>
</table>

Results 3: outcomes

A: Primary outcome: Total HALEMS: The change from baseline (T1) to year 1 (T4) indicates improvement in both groups, with a significant change in the intervention group only (p=0.044).

B: Key secondary outcome: TOTAL HADS: The change from baseline (T1) to year 1 (T4) indicates improvement in both groups, with a significant change in the intervention group only (p=0.044).

C: Key secondary outcome: IPOS Neuro S8: while the total score is unchanged (not shown), an improvement is noted for subitems 2-9 in the intervention group only (p=0.014).

Conclusions

- The study demonstrates an unmet need in PwMS in advanced stages of their disease (mean EDSS >6, mean age >55), and study feasibility (easy recruitment, ideal compliance to protocol).
- In a rather small exploratory cohort of a phase II clinical trial (total n=80), the results indicate that the CCM intervention may assist to improve the QoL in the patient population. The CCM could reduce scores of depression and anxiety.
- The study group will continue to work on the transfer of an adapted CCM intervention into clinical routine.