Development of a core outcome set for disease modification trials in mild to moderate dementia: a systematic review, patient and public consultation and consensus recommendations

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Plain English summary

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Plain English summary

In the UK, around 850,000 people have dementia. If a treatment can change the underlying pathology of dementia this is called disease modification, although no trials have yet found effective disease-modifying treatments. Trials have used differing outcome measures to evaluate if a treatment works, making it difficult to compare and contrast results. To address this issue we aimed, in collaboration with the UK dementia research community and the Alzheimer’s Society’s Research Network, to develop a core set of outcome measures for use in future disease-modifying trials for mild to moderate dementia.

We looked at the outcomes used across completed and ongoing disease modification trials and found measures in six test areas: cognition, biological, behaviour, quality of life, activities of daily living and global. We used these findings to conduct a small consultation with people living with dementia and family carers. We presented all results at our consensus conference and discussed them to reach our conclusions.

We recommend that the core set of outcome measures should include a cognitive measure, namely the Mini Mental State Examination or the Alzheimer’s Disease Assessment Scale – Cognitive subscale, and an optional magnetic resonance imaging scan looking at brain structure as a biological measure. We have specified measures for the other areas that are important but not core. The recommendations may change as new measures are developed, and, as most of the trials included participants with Alzheimer’s disease only, recommendations need to be developed for different dementias. They apply only to mild to moderate stages of dementia.
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