

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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Declared competing interests of authors: Clive Ballard reports grants and personal fees from Lundbeck Ltd and ACADIA Pharmaceuticals Inc., and personal fees from Roche, Orion Pharma, GlaxoSmithKline, Otsuka Pharmaceutical, Heptares Therapeutics Ltd and Eli Lilly and Company outside the submitted work. Sube Banerjee reports grants and personal fees from AbbVie, personal fees and non-financial support from Eli Lilly and Company, and personal fees from Eleusis Pharmaceuticals Ltd, Daval International, Boehringer Ingelheim, Axovant Sciences, Lundbeck Ltd and Nutricia outside the submitted work. Sube Banerjee also reports being a member of the Health Technology Assessment (HTA) Mental, Psychological and Occupational Health Panel, and has been involved as the principal investigator in a series of National Institute for Health Research grants that has developed the Dementia Quality of Life measure (DEMQOL) system for the measurement of health-related quality of life in dementia, which is one of the candidate measures in this project. Alistair Burns reports being the editor for the International Journal of Geriatric Psychiatry and being the National Clinical Director for Dementia, NHS England, during the conduct of the study. Peter Garrard reports personal fees from Merck Sharp and Dohme Ltd outside the submitted work. Esme Moniz-Cook reports non-financial support from her contribution to the recent Joint Programme – Neurodegenerative Disease Research Outcome Measures, outside the submitted work. John T O'Brien reports personal fees from GE Healthcare, TauRx Pharmaceuticals, Cytox Ltd and Accera Inc, and grants and personal fees from Avid Radiopharmaceuticals

Inc./Eli Lilly and Company outside the submitted work. James Pickett reports being a full-time employee of the Alzheimer's Society. Rob Howard is a member of the HTA Commissioning Board. Sasha Shepperd is a member of the Health Services and Delivery Research Prioritisation Commissioning Panel.

Published May 2017

DOI: 10.3310/hta21260

Plain English summary

Disease modification trials in mind to moderate dementia

Health Technology Assessment 2017; Vol. 21: No. 26

DOI: 10.3310/hta21260

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 15/62/02. The contractual start date was in December 2015. The draft report began editorial review in June 2016 and was accepted for publication in October 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

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