The electronic person specific outcome measure (ePSOM) programme: Overview and survey results

DOI: 10.1002/alz.041991

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THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

Human: Improving clinical trial methodology

The electronic person-specific outcome measure (ePSOM) development programme: Overall approach

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Abstract

Background: The ePSOM development programme is a collaboration between the University of Edinburgh and Alzheimer's Research UK prompted by the recognition that outcome measures currently used in clinical trials in prodromal and preclinical neurodegenerative diseases do not capture the research participants' views of effectiveness. A better understanding of earlier manifestations of Alzheimer's disease and the drive for relevant outcome measures, allied to technological advances in artificial intelligence, have mediated the electronic Person-Specific Outcome Measure (ePSOM) development programme. The group took the view that 'maintenance of brain health' as opposed to 'avoidance of symptoms' would form the underpinning narrative in the ePSOM programme and ultimately app design.

Method: There are 4 sequential stages in the ePSOM programme (the first three completed): (1) literature review, (2) focus group study, (3) national survey, and (4) development of an app for capturing person-specific outcomes. The survey data was analysed using clustering and natural language programming techniques and the results are presented separately. Here, we report the overall approach to the ePSOM programme.

Result: Our literature review on patient-reported outcome measures in the Alzheimer's disease population showed trials currently do not use any patient-reported outcome measures. Our focus groups with people living with memory problems; healthy volunteers and health care professionals (n=41) yielded five key domains in relation to what matters to people when developing new treatments for Alzheimer's disease: Everyday Functioning; Relationships and Social Connections; Enjoying Life; Sense of Identity; and Alleviating Symptoms. Our online survey, which was created based on the literature review and focus groups, was completed by 5807 individuals. 30 clusters of themes emerged from the survey responses.

Conclusion: The ePSOM development programme is building evidence in order to deliver the methodology for incorporating personally meaningful outcome measures in Alzheimer's disease clinical trials. The completed three stages will underpin the ePSOM app, which will be using natural language processing methodologies, and have good psychometric properties enabling the app to be use in regulatory trials.