Evaluating the effectiveness and cost effectiveness of Dementia Care Mapping (DCM) to enable person-centred Care for people with dementia and their carers: A UK cluster randomised controlled trial in care homes (DCM EPIC trial)

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Evaluating the effectiveness and cost effectiveness of Dementia Care Mapping (DCM) to enable person-centred Care for people with dementia and their carers: A UK cluster randomised controlled trial in care homes (DCM EPIC trial)

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Alzheimer's disease & other dementias

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Research Abstract

DESIGN Cluster randomised controlled trial (RCT) (follow-up over 16-months), cost-effectiveness analysis and process evaluation, including cohort collection of data at 6 months, and cross-sectional collection of outcomes at 16 months post randomisation. SETTING Residential, nursing and dementia care homes in the UK. TARGET POPULATION Care home residents with dementia, their relatives and care home staff. HEALTH TECHNOLOGY Dementia Care Mapping (DCM) is an established care home intervention used to support the implementation of person-centred care . DCM is an observational tool, within a practice development cycle. A trained observer records the care experience of up to eight people with dementia for up to six consecutive hours. Findings are fed back to staff, who develop individual and group action plans. This is repeated every 4-6 months. Whilst DCM has been used in dementia care for nearly 20 years, there is limited robust evidence of its efficacy in relation to clinical outcomes such as reduction of behaviours staff find challenging (BSC). Reported practice implementation benefits include improvement of resident well-being and increased staff skills. However, there is very limited robust evidence for effectiveness and no examination of its cost-effectiveness as a UK intervention. Therefore, a definitive pragmatic RCT of DCM in the UK is urgently needed. MEASUREMENT OF COST AND OUTCOMES The primary endpoint is the resident-level agitation measured by the Cohen-Mansfield Agitation Inventory (CMAI) at 16 months after randomisation rated by staff members who know the residents well. The CMAI captures the type, nature and range of agitated behaviours and has good psychometric properties. The Pittsburgh Agitation Scale (PAS) rated by independent researchers will provide concurrent validity. Secondary outcome measures (Neuropsychiatric Inventory (NPI), use of antipsychotic and/or other psychotropic drugs, resident quality of life, staff well-being and role efficacy, care quality and the quality of staff/ resident interactions) will be assessed at 6 and 16 months following randomisation. For the economic evaluation, health status will be captured using the EQ-5D and DEMQOL (and proxy versions) and resource use will be captured using a questionnaire designed especially for the study. Other measures were chosen for their good psychometric properties within this population. SAMPLE SIZE 50 (750) care homes (residents) with 31 (465) and 19 (285) in the intervention and control arms respectively, providing 90% power at 5% significance level. Assuming a SD of CMAI scores of 7.5, a difference between arms of 3 points at 16 months, 25% loss to follow-up and an ICC no greater than 0.1. As provision of care is a further source of clustering an allocation ratio of 3:2 is used. Additional residents will be recruited at 16 months post-randomisation from each care home to maintain power and minimise bias (due to higher than anticipated loss to follow-up and ensure the validity of the trial. (Details of the power calculations undertaken will be published as an appendix to the Statistical Analysis Plan) STATISTICAL ANALYSIS The primary analysis will depend on the rate of loss to follow-up at 16 months. If loss to follow-up is = 35% (in line with original expectations the resident-level primary outcome of agitation (CMAI score) at 16 months post-randomisation will be analysed using a linear two-level heteroscedastic regression model adjusting for design factors, with a contrast for intervention and control. Here, however, data from residents

registered at care home randomisation and 16 months post randomisation will be used. The model will be adjusted for the following fixed effects (all care home characteristics using baseline data): type and size, provision of dementia awareness training and recruiting hub, average residents' dementia severity, and average residents' baseline CMAI score. Unadjusted and adjusted estimates and corresponding 95% confidence intervals will be presented. Additional supportive analysis, dependent upon the rate of loss to follow-up, will be undertake and presented in the main results paper. Secondary outcome measures will be analysed using a similar modelling strategy. The economic evaluation will follow the NICE reference case, presenting (where appropriate) incremental cost-effectiveness ratios (ICERs) with the main outcome being cost-per incremental quality-adjusted life year (QALY). Results will be presented on a cost-effectiveness acceptability curve (CEAC). Net benefit regression will also be conducted. TIMETABLE The study will take place over 52 months , with an average of 4 homes recruited per month and each home participating in data collection for 16 months from baseline to final follow-up. EXPERTISE The team includes expertise on DCM, care homes, designing and conducting clinical trials in care homes, statistical analysis, trial management, health economic evaluation and service user involvement.

Lay Summary
Further information available at:

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