Dementia Care Mapping™ to reduce agitation in care home residents with dementia: the EPIC cluster RCT

Claire A Surr,[1]* Ivana Holloway,[2] Rebecca EA Walwyn,[2] Alys W Griffiths,[1] David Meads,[3] Rachael Kelley,[1] Adam Martin,[3] Vicki McLellan,[2] Clive Ballard,[4] Jane Fossey,[5,6] Natasha Burnley,[1] Lynn Chenoweth,[7] Byron Creese,[4] Murna Downs,[8] Lucy Garrod,[5] Elizabeth H Graham,[9] Amanda Lilley-Kelley,[2] Joanne McDermid,[10] Holly Millard,[5] Devon Perfect,[5] Louise Robinson,[11] Olivia Robinson,[1] Emily Shoesmith,[1] Najma Siddiqi,[12,13] Graham Stokes,[14] Daphne Wallace[1] and Amanda J Farrin[2]

[1]Centre for Dementia Research, School of Health and Community Studies, Leeds Beckett University, Leeds, UK
[2]Clinical Trials Research Unit, University of Leeds, Leeds, UK
[3]Leeds Institute of Health Sciences, University of Leeds, Leeds, UK
[4]University of Exeter Medical School, Exeter, UK
[5]Psychological Services, Oxford Health NHS Foundation Trust, Oxford, UK
[6]Department of Psychiatry, University of Oxford, Oxford, UK
[7]University of New South Wales, Sydney, NSW, Australia
[8]Centre for Applied Dementia Studies, University of Bradford, Bradford, UK
[9]Academic Unit of Elderly Care and Rehabilitation, Bradford Teaching Hospitals NHS Foundation Trust, Bradford, UK
[10]Wolfson Centre for Age-Related Diseases, King's College London, London, UK
[11]Institute for Ageing and Health, Newcastle University, Newcastle upon Tyne, UK
[12]Department of Health Sciences, Hull York Medical School, University of York, York, UK
[13]Bradford District Care NHS Foundation Trust, Bradford, UK
[14]HC One, Darlington, UK

*Corresponding author c.a.surr@leedsbeckett.ac.uk

Declared competing interests of authors: Claire A Surr was previously employed by the University of Bradford, which owns the intellectual property (IP) rights to the Dementia Care Mapping™ (DCM) intervention tested in this trial. In this role, she held responsibility for DCM training and method development. She was a technical author on the British Standards Institute's PAS 800 guide on implementing DCM in health and social care provider organisations. She declares personal fees from Hawker Publications Ltd (London, UK) outside the submitted work. Clive Ballard reports grants and personal fees from Acadia Pharmaceuticals (San Diego, CA, USA) and Lundbeck Ltd (Copenhagen, Denmark), personal fees from Hoffman-La Roche Ltd (Basel, Switzerland), Otsuka Pharmaceutical (Tokyo, Japan), Novartis International AG (Basel, Switzerland), Eli Lilly and Company (Indianapolis, IN, USA) and Pfizer Inc. (New York, NY, USA) outside the submitted work. Murna Downs works at the University of Bradford, which holds the IP rights for DCM and runs courses for practitioners and professionals who wish to learn how to use the method. David Meads was a member of the NIHR Health Technology Assessment Elective and Emergency Specialist Care methods panel from February 2013 to June 2017. Louise Robinson was a member of the NIHR Primary Care Themed Call Board until 18 February 2014.

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Scientific summary

EPIC cluster RCT

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Scientific summary

Background

At least 80% of people living in care homes have dementia. Concerns have consistently been raised about care home quality, and improvement in this area has been a UK-wide government research and practice-development priority for over a decade. Poor-quality care is associated with poor outcomes for people with dementia, including an increase in behaviours that staff may find challenging to support (with the most common of these being agitation), reduced resident quality of life and increased prescribing and administration of antipsychotic and other tranquillising medications. Person-centred care is a recommended approach to the delivery of good-quality care.

Dementia Care Mapping™ (DCM) is a whole-home, practice development intervention that has been widely used in health and social care settings, nationally and internationally, to support the embedding of person-centred care in practice. There is good evidence of its use in practice settings as a quality audit and improvement tool. This trial was designed to provide robust evidence on the clinical effectiveness and cost-effectiveness of DCM as an intervention to support care homes in sustainably transferring the learning gained from person-centred care training into care practice. The trial aimed to determine whether or not DCM could provide a solution for achieving widespread implementation of an approach to training and practice development that is practical for use in routine health and social care and that improves care quality and outcomes for people living with dementia.

Objectives

The primary objective of the DCM Enhancing Person-centred care In Care homes (EPIC) trial was to determine whether or not the intervention was more clinically effective in reducing agitation in residents with dementia, as measured by the total Cohen-Mansfield Agitation Inventory score, and more cost-effective than the control (usual care) 16 months after randomisation. The secondary objectives were to determine whether or not the intervention was more clinically effective than the control at reducing behaviours that staff may find challenging to support and the use of antipsychotic and other psychotropic drugs and at improving the mood and quality of life of residents with dementia, care home staff well-being and role efficacy, and the quality of staff–resident interactions at 6 months and at 16 months.

Other aspects that the trial sought to explore included the safety profile of the intervention, any differential predictors of the effects of the intervention, and the process, challenges, benefits and impact of implementing the intervention.

Methods

Design

The DCM EPIC study was a pragmatic, multicentre, cluster randomised controlled trial utilising an open-cohort design with embedded cost-effectiveness and process-evaluation analyses.

Setting

Fifty residential, nursing and dementia care homes across West Yorkshire, Oxfordshire and South London, providing care for people with dementia, were recruited using a random sampling method. Homes were eligible if they could recruit a minimum of 10 residents to the trial, had no improvement notices and were not taking part in any conflicting research.

Participants

The residents recruited at baseline were registered after care home recruitment, confirmation of eligibility, informed consent and collection of baseline data, but prior to care home randomisation. At baseline, residents were eligible for the trial if they were a permanent resident in the care home, had a formal diagnosis of dementia or a score of 4+ on the Functional Assessment Staging Test of Alzheimer's Disease and had sufficient proficiency in English to understand what the research involved, if able to do so. Residents were not eligible if they were known to be terminally ill, permanently bed-bound or cared for in bed, or if they were taking part in other conflicting research.

Following a change from a closed-cohort to an open-cohort design, owing to a greater than expected loss to follow-up among residents, further residents were recruited at 16 months. In addition to the baseline eligibility criteria, residents recruited at 16 months were not eligible if they had declined to participate in the trial at baseline or had moved into the home or participating unit less than 3 months prior to screening.

Randomisation

Care homes were randomised on a ratio of 3 : 2 to the intervention or control group. Treatment arms were balanced for home or unit type (i.e. general residential or nursing home vs. specialist dementia care home), size (large $\geq$ 40 beds vs. medium or small $<$ 40 beds), the provision of dementia awareness training by research team (yes or no) and the recruiting hub (West Yorkshire, London or Oxford).

Intervention

The intervention followed standard procedures as set out in the DCM manual and guidance. Two staff members from each intervention care home were trained to use DCM, followed by implementation of three standard DCM cycles (each comprising briefing; observation; data analysis, reporting and feedback; and action-planning). The first cycle was supported by an external DCM expert mapper provided by the research team, who attended the first cycle and provided additional support remotely. This is a higher degree of support than what mappers would usually receive post training, but it was required to support standardised intervention implementation across all intervention care homes. To support intervention fidelity and its measurement, care homes were provided with guidelines that included standardised templates for recording attendance at briefing and feedback sessions and for DCM reporting and action-planning. Additional mechanisms for supporting intervention adherence included sending short message service (SMS) reminders and hard copies of all paperwork to mappers ahead of each cycle and telephone support provided by the DCM intervention lead. Intervention homes were asked to complete DCM alongside usual care.

Control

Control homes were asked to continue with usual care.

Outcome measures

The primary outcome was agitation at 16 months, measured by the Cohen-Mansfield Agitation Inventory. Other resident outcomes included BSC and mood measured by the Neuropsychiatric Inventory (NPI); quality of life measured with the Quality of Life in Late-Stage Dementia (QUALID) scale, Quality of Life Alzheimer's Disease (QOL-AD) measure, Dementia Quality of Life (DEMQOL) measure, DEMQOL-proxy, EuroQol-5 Dimensions, five-level version (EQ-5D-5L), and EQ-5D-5L-proxy; and prescribed and administered medications and safety data (e.g. hospitalisations and deaths). The staff outcomes were the sense of competence gained in caring for people with dementia measured using the Sense of Competence in Dementia Care Staff (SCIDS) scale. The care home outcomes were the quality of staff interactions with residents measured using the Quality of Interactions Schedule (QUIS).

Sample size

The sample size was calculated to detect a moderate standardised effect size of 0.4 on the primary outcome: the between-arm difference in mean Cohen-Mansfield Agitation Inventory scores at 16 months. Fifty care homes, each recruiting 15 participants, provided 90% power at a 5% significance level to detect a clinically

important difference of 3 points (standard deviation 7.5 points), assuming 25% loss to follow-up and an inflation factor of 2.0 (i.e. a cluster size of 11 participants available for analysis after loss to follow-up) and an intracluster correlation coefficient of no greater than 0.1. As the intracluster correlation coefficient was expected to be higher in the intervention arm, an allocation ratio of 3 : 2 was used, giving 30 (450) and 20 (300) care homes (residents) in the intervention and control arms, respectively, equating to 50 (750) care homes (residents) overall.

During the trial, the loss to follow-up was higher than the anticipated maximum of 25%, mainly owing to death rates. To maintain a statistical power close to 90% and to preserve our ability to detect a moderate standardised effect size of 0.4, to maintain validity and to increase the generalisability of the trial, we recruited additional, newly eligible, consenting residents from the randomised care homes 16 months after randomisation and performed a cross-sectional analysis of the data.

Results

Out of 335 screened care homes, 241 randomly sampled care homes were approached; 94 formally expressed interest and were assessed for eligibility. Of the 63 eligible care homes, 50 consented to take part, were able to recruit a minimum of 10 resident participants and were randomised into the trial: 19 were placed in the control group and 31 in the intervention group.

At baseline, a total of 1564 residents were screened for eligibility; 1069 were eligible, 781 consented, 743 registered for the trial and 726 were registered at the point of care home randomisation. Following the approved design change, a further 1444 residents were screened from 48 care homes 16 months after randomisation. Of those, 421 were eligible, 266 consented and 261 residents were subsequently registered (intervention, $n = 162$; control, $n = 99$).

Overall, at 16 months, a total of 675 residents were included in the cross-sectional sample: 414 residents from the original cohort who reached 16 months and 261 additionally recruited residents.

A primary analysis was conducted on the cross-sectional sample. All 675 residents in the cross-sectional sample at 16 months were included in the primary analysis, 666 of which had complete data. No evidence of a clinical or statistical difference was found between treatment arms in the primary outcome of agitation at 16 months. The adjusted mean difference in total Cohen-Mansfield Agitation Inventory score was –2.11 points, being lower in the intervention arm than in the control (adjusted means: 45.47 points in control, 43.35 points in intervention; 95% confidence interval –4.66 to 0.44 points; $p = 0.104$). The adjusted intracluster correlation coefficient was zero in the control and 0.001 in the intervention arm.

A complier-average causal effect analysis of the cross-sectional sample, comparing care homes in the intervention arm that completed at least one cycle to an acceptable level with care homes that would have completed at least one cycle to an acceptable level had the intervention been offered to them, gave a mean difference in Cohen-Mansfield Agitation Inventory score at 16 months of –2.5 points (95% confidence interval –5.4 to 0.4 points; $p = 0.089$), being lower in 'compliers' than in 'non-compliers'.

The sensitivity analyses and the complier-average causal effect analysis supported the results found in the primary analysis, namely that the intervention is not superior to the control.

Analyses of behaviours that staff may find challenging to support, mood, quality of life, pro re nata/as required (PRN) prescription medications and quality of staff interactions were conducted on a closed cohort at 6 months, and on the cross-sectional sample (primary) and a closed cohort (supportive) at 16 months. No statistically significant differences were found in the closed cohort between arms on any resident-level or care home-level secondary outcome at 6 months. Although no statistically significant differences were found between arms in the primary cross-sectional sample at 16 months, trends in favour of the intervention as regards behaviours that staff may find challenging to support and mood were found in the closed cohort at 16 months.

There were no reported unexpected serious adverse events.

In the health economic base-case cost–utility analysis, the intervention was more costly (by £1479) and more clinically effective (by 0.024 quality-adjusted life-years) than the control. This yielded an incremental cost-effectiveness ratio of £60,627, well above the £20,000 National Institute for Health and Care Excellence threshold, indicating that DCM is not cost-effective. The cost-effectiveness analyses based on improvement in Cohen-Mansfield Agitation Inventory score indicated that, although the intervention was more costly, it was also more clinically effective than the control. The incremental cost per unit improvement in Cohen-Mansfield Agitation Inventory score was £289 for the intervention versus £67 for the control, for the imputed and complete-case samples, respectively. However, all cost-effectiveness plane simulations lie above the willingness-to-pay threshold suggesting that, using the base-case analysis, DCM is unlikely to be cost-effective. The cost-effectiveness acceptability curve confirmed this and indicated that, when λ = £20,000, there is a very low probability that the intervention will be cost-effective.

The process evaluation identified that DCM implementation was poorer than expected, with 22.6% (n = 7) of care homes not completing one full cycle, 51.6% (n = 16) of homes completing only their first cycle supported by an expert mapper, 12.9% (n = 4) completing two full cycles and only 12.9% (n = 4) completing the three full, per-protocol cycles to an acceptable level. The mappers, managers, residents, relatives and staff interviewed were able to identify a range of benefits of using DCM for residents, staff and care home practices, including improved communication, staff being better able to identify resident needs and the provision of more activities. A range of care home-level (context, manager support, staff motivation and engagement, mapper skills and qualities), intervention-level (understanding of tool and process, complexity and time demands) and trial-level (expectations of DCM and the trial, expert mapper support) barriers to and facilitators of implementation were also identified.

Conclusions

This trial indicates that, as an intervention led by care home staff, DCM is not clinically effective or cost-effective at reducing agitation or improving quality of life and other care outcomes for residents with dementia living in care home settings. This outcome may be associated with the poor intervention fidelity we experienced during the trial, despite efforts to support implementation, which went beyond standard DCM practice/implementation structures. This suggests that the majority of care homes may not provide the right conditions for a costly intervention such as DCM and that externally led models may provide a more practical and resource-effective method of implementation. However, further research is needed to evaluate this. Future research should more carefully consider the conditions needed for effective psychosocial intervention implementation and appropriate models for delivering interventions, given the available resources and cultural and organisational challenges of implementing complex interventions in care home settings.

Trial registration

This trial is registered as ISRCTN82288852.

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This report

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