Supporting good quality, community-based end-of-life care for people living with dementia: the SEED research programme including feasibility RCT

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Scientific summary

The SEED research programme including feasibility RCT

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Scientific summary

Background

Two-thirds of people with dementia die in the community, usually in nursing or residential care settings, and often in receipt of suboptimal end-of-life care compared with the care of cancer patients. Meeting the health-care needs of the majority of people with dementia from diagnosis through to death will usually be the responsibility of the general practitioner and associated community care teams.

Aim and objectives

The overall aim of the Supporting Excellence in End-of-life care in Dementia (SEED) programme was to support professionals to deliver good-quality, community-based care towards, and at, the end of life for people living with dementia and their families. Specific objectives included to:

- identify which aspects of existing care towards, and at, the end of life in dementia are effective and efficient
- develop, implement and evaluate an evidence-based intervention, and associated resources, to support the provision of good-quality care towards, and at, the end of life in dementia
- determine how community-based end-of-life care in dementia should be organised and commissioned.

Programme design

We followed the Medical Research Council framework for the development and evaluation of complex interventions, beginning with systematic reviews of existing evidence and in-depth exploration of current care. The SEED programme comprised six separate and interlinked workstreams:

- workstream 1 – mapping current evidence and identifying quality indicators and outcome measures for end-of-life care in dementia (March 2014 to July 2015)
- workstream 2 – qualitative studies to identify components of good end-of-life care in dementia (October 2013 to January 2016)
- workstream 3 – development of the SEED intervention using data from workstreams 1 and 2 and the Marie Curie Dementia Programme (August 2015 to November 2016)
- workstream 4 – pilot trial of the SEED intervention, with process evaluation, to ascertain feasibility and acceptability (August 2016 to July 2018)
- workstream 5 – economic modelling of the SEED intervention including a willingness-to-pay exercise to explore cost versus consequences (October 2013 to May 2018)
- workstream 6 – commissioning good-quality, community-based end-of-life care in dementia (October 2014 to September 2018).

Patient and public involvement

Patient and public involvement has been pivotal to the creation, development and delivery of the SEED programme. The initial idea for this research originated from Alzheimer's Society's Research Network carer groups. Continuity of patient and public involvement was ensured by (1) a member of the original Alzheimer's Society Research Network carer groups becoming programme patient and public involvement co-lead and (2) some members joining our external patient and public advisory board.

The patient and public advisory board met a total of seven times throughout the programme. A second, locally based, patient and public involvement group was also established to provide more in-depth, ongoing input to individual workstreams; therefore, each workstream benefited from regular insightful feedback grounded in the views and experiences of families living with dementia. Examples of such specific and tailored patient and public involvement included (1) piloting of the Q-sort methods in workstream 1 and (2) providing constructive comments on topic guides in workstreams 2 and 4. The extensive patient and public involvement also strongly influenced the dissemination strategy, for example the patient and public involvement group's recommendation to use the data and key findings to develop practical tools, such as a massive open online learning course for family carers.

Workstream methods and results

Workstreams 1 and 2 addressed the core work required for the development phase of the Medical Research Council complex intervention guidance, identifying the evidence base (workstream 1) and developing an understanding of existing practice and possible mechanisms for change (workstream 2).

Workstream 1: mapping existing guidance/care pathways and identification of quality indicators and/or outcome measures

Methods

This comprised the following:

- a series of updated systematic reviews to identify existing relevant guidelines, quality indicators and/or outcome measures
- an online survey (updated 2008 National Council for Palliative Care survey) to identify national examples of good, and sustainable, practice (to inform workstream 2 sampling)
- a Q-sort study, with 57 participants (14 people with dementia, 21 carers and 22 bereaved carers), to explore which outcomes for end-of-life care were important to people with dementia and their families.

Results and key findings

Examples of national good practice rely on non-commissioned, non-recurrent funding and leadership from an interested clinician. We had previously found a number of existing systematic reviews of outcome measures for end-of-life care for people with dementia; therefore, we did not repeat this work, but instead focused on quality indicators. Existing guidelines recommended that care towards, and at, the end of life for people with dementia be community based for as long as possible. No dementia guidelines included any quality indicators to drive improvement in palliative care. However, current palliative care quality indicators are not entirely suitable, as they do not incorporate key aspects of dementia, such as person-centred care or behaviours that challenge. People with dementia and their families consider compassionate care and informed shared decision-making as important outcomes for end-of-life care.

Workstream 2: qualitative studies to define and determine what constitutes good-quality care towards, and at, end of life in dementia

Methods

The views of national experts, service managers, front-line staff, people with dementia and family carers were explored using a range of qualitative methods (i.e. semistructured interviews, focus groups and observations of routine care). The large data set comprised 119 interviews, 12 focus groups and 256 hours of observation. Each data set was initially analysed thematically, prior to an integrative analysis, which drew out key themes across stakeholder groups.

Results

The integrative analysis identified seven key components required for the delivery of good end-of-life care for people with dementia: timely planning discussions, recognising end of life and providing supportive care, co-ordinating care, effective working with primary care, managing hospitalisation, continuing care after death, and valuing staff and ongoing learning. These factors span the entire illness trajectory, from planning at a relatively early stage in the illness to continuing care after death. Some components were more important to professionals (i.e. national experts, service managers and front-line staff) than to people with dementia and their families, for example future care planning and recognition of the end-of-life phase.

Workstream 3: development of the SEED intervention using data from workstreams 1 and 2 and the Marie Curie Dementia Programme

Methods

Innovative co-design methods, and the theory of change, were employed to synthesise data and key findings from workstreams 1 and 2 and the Marie Curie Dementia Programme. Intervention development took place in two distinct phases. The first phase comprised a series of workshops with the full SEED programme team to generate and prioritise ideas for possible interventions. In the second phase, the broad concept of the intervention was operationalised through small group co-design workshops with key stakeholders (patient and public involvement group members, clinical specialists and service providers), thus enabling continuous, integrated user involvement.

Results

The seven key components identified in workstream 2 were operationalised as a primary care-based, dementia nurse specialist intervention. From a theoretical perspective, we utilised the theory of change as it allows a collaborative and iterative process and focuses on desired outcomes. A training and supervision programme was developed, along with an intervention manual. Findings also indicated the need for a care resource kit to help the dementia nurse specialist deliver the intervention, work more effectively with people with dementia and their families, and improve the knowledge and skills of family and professional carers. As an extensive review of existing resources identified few resources for both family carers and professional carers on advanced dementia, we developed a massive open online course, titled *Dementia Care: Living Well as Dementia Progresses*, to address this gap (this course was winner of the 'outstanding care resource' category at the 10th National Dementia Care Awards, 2019).

Workstream 4: pilot trial of the SEED intervention with process evaluation

Methods

A cluster design was used to assess the feasibility and acceptability of recruitment and retention, the SEED intervention, and the chosen outcome measures. Four general practices were recruited in North East England: two were allocated to receive the intervention and the other two provided usual care. Patients on the general practice dementia register were screened, eligible patients were approached, and a family carer and, for those in care homes, a key informant were identified. Outcome data were collected at baseline and at 4, 8 and 12 months. A process evaluation used interviews, observation and dementia nurse specialist activity logs to collect stakeholder views of the intervention and to capture whether and how the intervention was delivered.

Results

The SEED intervention proved feasible and acceptable to all stakeholders, and being located in general practice was considered particularly beneficial. The intervention was seen as distinct from existing services. Improving the local context for end-of-life care was achieved through, for example, the development of training for care home staff and the implementation of a template for annual dementia reviews. Extending the intervention to all people with dementia, from the point of diagnosis, was widely recommended by stakeholders. Although some issues concerning outcome measurement were resolved, none of the outcome measures used was found to be suitable as the primary outcome measure for a future trial. In the light of these remaining uncertainties, we do not intend to proceed to a definitive trial of the SEED intervention at this stage.

Workstream 5: economic modelling of the SEED intervention, including a willingness-to-pay exercise to explore cost versus consequence

Methods

The economic evaluation compared the SEED intervention with alternative ways of providing care, including an example of current practice. The potential value of the SEED intervention was assessed using a contingent valuation survey of 1002 members of the general public. These data were used in an economic decision model. The economic model describes what happens to a person with dementia over time and how the SEED intervention might change this. The results of the model were presented in terms of the costs and consequences (e.g. hospitalisations) and, using the contingent valuation data, a cost–benefit analysis.

Results

The contingent valuation showed that the SEED intervention was valued, with a wider package of care valued more than selected features in isolation. Individuals with experience of dementia placed a higher value on the SEED intervention than those without such experience, but there was no evidence of a difference in the value by gender, household size or health status. Based on the economic modelling study, the SEED intervention is unlikely to reduce costs, but this may be offset by the value placed on the SEED intervention by the general public. The SEED intervention may benefit people with dementia and carers, but the impact on services is mixed.

Workstream 6: commissioning good-quality, community-based end-of-life care in dementia

Methods

To determine how current care in this area was commissioned and organised, a narrative review of policy and practice literature was undertaken, followed by in-depth interviews with service commissioners ($n = 20$). Owing to an update of the National Institute for Health and Care Excellence dementia care guidance, the development of programme-specific commissioning guidance was postponed. When new National Institute for Health and Care Excellence guidance was released (in 2018), key findings from the programme were compared with this guidance. The results of this analysis were disseminated to commissioners at a national workshop.

Results

Commissioners receive little formal guidance and training. In addition, they work in a context of persistent uncertainty owing to a constantly changing policy and organisational landscape. Dementia care and end-of-life care are usually commissioned separately, and a more integrated, joined-up commissioning approach is urgently required.

Limitations

The biggest challenge to the successful delivery and completion of this research programme was the translation of a theoretical, co-developed complex intervention into practice in a constantly changing organisational landscape of health and social care at both national and local levels. The introduction of new commissioning structures, especially in primary and community care, with a considerable and continuous period of change and reorganisation, led to difficulty identifying and recruiting participants (workstreams 2 and 6) and delays in securing governance approvals. A further major limitation, especially for a future trial, is the lack of valid and relevant primary outcome measures to evaluate the effectiveness of complex interventions to improve care at the end of life in dementia. Such measures need to capture changes in outcomes for individuals (e.g. improved comfort at end of life for a person with dementia) and system-level changes (e.g. introduction of robust systems for discussing and documenting advance care planning). Two of the potential future primary outcome measures performed well: Symptom Management at the End Of Life in Dementia and Comfort Assessment in Dying with Dementia, however, the Satisfaction with Care at the End of Life in Dementia measure was criticised by participants. It may be that, for dementia care in general, new measures for evaluating the success of complex interventions need to be developed that better reflect outcomes that (1) are important to people with dementia and their families and (2) more accurately reflect the complexity of symptoms in advanced dementia.

Conclusions

Extending existing evidence and using new empirical data, we followed the Medical Research Council framework for complex interventions to co-design a primary care-led, dementia nurse specialist intervention to enable community-based professionals to deliver co-ordinated and proactive end-of-life care to people with dementia and their families and pilot it in practice. Seven components of care were key to the dementia nurse specialist role: timely planning discussions, recognising end of life and providing supportive care, co-ordinating care, effective working with primary care, managing hospitalisation, continuing care after death and valuing staff and ongoing learning. The intervention was acceptable, feasible and shown to integrate well with existing care. The dementia nurse specialist was highly valued by all stakeholders, both in real life and hypothetically in the contingent valuation study; however, the economic evaluation (cost–consequence analysis and cost–benefit analysis) showed that it is unlikely to reduce the costs of care.

Future work

Based on the key findings to date, we do not plan to progress to a full randomised trial of the SEED intervention in its current form. In view of the introduction of updated National Institute for Health and Care Excellence dementia guidance, and a steady and unplanned shift of post-diagnostic dementia care to primary care, further research is needed to:

- determine the feasibility of providing the SEED intervention throughout the illness trajectory, that is to all people with dementia from point of diagnosis to death, and if, and how, it would need to be adapted
- identify appropriate, and/or develop, new outcome measures to evaluate the effectiveness of such a complex intervention that has the potential to influence both patient- and carer-reported outcomes and system-level processes, outcomes and structures.

In the absence of a future trial that would incorporate a more accurate and detailed cost-effective analysis, it would be worth exploring whether or not specialist micro- and macro-simulation economic modelling techniques could inform translation of the SEED intervention into an efficient model for practice.

Trial registration

This trial is registered as ISRCTN21390601.

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