Support at Home: Interventions to Enhance Life in Dementia (SHIELD) – evidence, development and evaluation of complex interventions

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Scientific summary

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Scientific summary

Background

In the UK > 850,000 older people have dementia resulting in progressive cognitive deterioration, increasing disability and social exclusion. There are many psychosocial interventions for dementia but often these have not been standardised, adequately evaluated or systematically implemented. Cognitive stimulation therapy (CST) has been shown to be beneficial for cognition and quality of life, and is cost-effective. There is less evidence for the effects of CST over an extended period. A recent pilot study found that one-third of people who attend CST training go on to run CST groups, but staff identified a lack of support as a key reason for the lack of implementation of CST in practice. The evidence for the potential benefits of reminiscence is limited, but involving people with dementia and their carers may be more effective than working with carers only.

Our experience from the Befriending and Costs of Caring (BECCA) programme showed that many ex-carers are motivated to support others in family carer roles through mentoring and teaching. There is growing evidence that carer well-being may be enhanced through interventions that engage both the primary carer and the person with dementia. A recent review observed a lack of evidence for alternative interventions to acute psychiatric admissions for older people. There is some evidence that home treatment teams (HTTs) may reduce hospital admissions for people with dementia; local data suggest that admissions reduced by 30% and that early discharge can be facilitated. This research programme aims to help to support people at home and improve the quality of life of people with dementia and their carers.

Objectives

1. To develop the maintenance CST (MCST) programme for people with dementia, to conduct a randomised controlled trial (RCT) [with a pilot study of the effectiveness of MCST with acetylcholinesterase inhibitors (AChEIs)] and to conduct an implementation study of MCST.
2. To develop the Carer Supporter Programme (CSP) for the carers of people with dementia and conduct a RCT (with an internal pilot) of the CSP and the Remembering Yesterday, Caring Today (RYCT) reminiscence intervention, separately and in combination, compared with usual care.
3. To develop a model including the most promising interventions and components for an effective home treatment package (HTP) for dementia by systematically reviewing the literature and qualitative studies, using consensus approaches to develop a feasible HTP and conducting in-depth field testing of the HTP for dementia in practice.

Methods

1. MCST study (two projects).
   MCST trial The MCST programme was developed by a systematic review of the literature including a Cochrane Review; adaptation of the CST programme and the original maintenance programme; and qualitative work including focus groups with people with dementia, carers and staff to tailor the sessions to people's preferences and interests. The multicentre, pragmatic RCT assessed the effectiveness and cost-effectiveness of MCST groups for dementia. All participants were initially included in CST groups for 7 weeks and were then randomised either to continue in the intervention group with 24 weekly MCST sessions or to continue with treatment as usual (TAU). Data were collected at baseline and at 12 and 24 weeks (primary end point). The primary outcome measures were quality of life of people with dementia and cognition. The secondary outcomes included the person with dementia's mood, behaviour, activities

of daily living (ADLs), ability to communicate and costs, and carer health-related quality of life. The cost-effectiveness analysis is from a public sector perspective.

MCST implementation study This comprised three projects: (i) a pragmatic multicentre RCT of staff training, comparing CST training and outreach support with CST training only; (ii) a phase IV monitoring and outreach trial that evaluates the implementation of CST in practice by staff members who have previously had the CST manual or attended training; and (iii) implementation in practice study monitoring centres running groups in their usual practice and looking at basic outcomes of cognition and quality of life of the person with dementia. For studies (i) and (ii), centres were randomised to receive outreach support or usual care, with the primary outcome being the number of CST and MCST sessions run for people with dementia. The secondary outcomes included the number of attenders at sessions, staff job satisfaction, dementia knowledge and attitudes, competency, barriers to change, approach to learning and a controllability of beliefs and the level of adherence. Focus groups assessed staff members' perceptions of running CST groups and receiving outreach support.

2. CSP/RYCT study.

   The trial was a factorial, single-blind, four-arm RCT, comparing CSP alone, RYCT alone, CSP and RYCT combined, and usual care, in community settings, addressing both clinical effectiveness and cost-effectiveness. The CSP intervention and supporting related documentation was developed in consultation with service users and carers. Former family carers also had involvement as direct providers of the CSP element of the trial. The carer supporter co-ordinators for each centre recruited and screened the carer supporter. Before being matched with a family carer participant, carer supporter volunteers attended a mandatory 'Being a Carer Supporter' orientation and awareness course and were supported by a carer supporter co-ordinator throughout the study.

   The RYCT group intervention followed the RYCT programme for people with dementia and their family carers with 12 weekly sessions. Each group session was led by two experienced facilitators, supported by a team of volunteers and staff. All members of the RYCT team attended a training day. After the 12 initial sessions, monthly reunion sessions took place over a further 7 months. To ensure enough participants to run viable RYCT groups, we randomised between TAU, RYCT, CSP and CSP/RYCT combined in the proportions 1 : 2 : 1 : 2. Data were collected at baseline, 5 and 12 months (primary end point). After randomisation, all participants also continued to receive usual care from services in their locality. We conducted a feasibility study before the full RCT in accordance with Medical Research Council guidance on complex interventions guidance. All participants were adult English-speaking carers for a relative or close friend with dementia living at home in the community.

3. HTP.

   The first phase of this study comprised systematic reviews on case management in dementia, risk factors for admission in dementia and crisis resolution approaches aimed at maintaining people with dementia at home. The second phase involved focus groups, consensus approaches and a scoping exercise, using the evidence from the literature reviews to develop the HTP. This process involved professionals, academics, care workers, the voluntary sector, carers and people with dementia, and was used to identify and understand risk factors for admission, factors helping to maintain people with dementia at home, optimal approaches to managing crises, and key structural and organisational features associated with good outcomes.

   The consensus conference worked through a range of 'high-risk' case examples using a draft of the HTP to articulate best practice care packages. The HTP functioned as an advisory protocol/care pathway and included a combined risk assessment/care-planning tool, a manual and a training package. The manual was based on a needs assessment using the Camberwell Assessment of Need for the Elderly and included a glossary of preferred interventions in relation to various problems (e.g. challenging behaviour). HTTs for older people benchtested the home treatment manual by working through a number of example cases. People with dementia living in the community were referred for home treatment because of a high or very high risk of requiring institutional or hospital admission. Field testing of the home treatment manual was carried out with 21 clinical cases in practice using HTTs in Lancashire and London. The implementation of the HTP for each person with dementia was managed by an identified HTT key worker. After feedback, the home treatment manual was further revised to produce the final definitive version.

Results

1. MCST study (two projects).
   MCST trial The Cochrane review of cognitive stimulation for dementia meta-analysis provided strong evidence of the benefits on cognitive function and quality of life, over and above any benefits of antidementia medication. The focus group work found agreement for 14 themes and suggestions for improvement for the five remaining themes. These results were used to revise the manual for the MCST programme. The RCT results showed that at 6 months there were significant benefits for self-rated quality of life for the MCST group, and at 3 months there were improvements for proxy-rated quality of life and ADLs. The MCST subgroup taking AChEIs showed cognitive benefits at 3 and 6 months. Although outcome gains were modest, MCST appeared cost-effective for self-rated quality of life, cognition measured on the Mini-Mental State Examination and proxy-rated quality-adjusted life-years (QALYs). MCST plus AChEIs offered cost-effectiveness gains for cognition.
   MCST implementation study Outreach support was rarely accessed. There was no difference in the delivery of the CST programme between the outreach support intervention and the usual care group, but centres with outreach support were more likely to go on to run MCST. More groups were run in the staff recruited for the phase IV study and these staff had prior experience in delivering CST groups. At follow-up, staff in the outreach support group felt more competent in dementia care. For the observational study there was no deterioration in scores for quality of life or cognition at final follow-up.
2. CSP/RYCT study.
   Developing the CSP package, we followed consensus methods involving principles of good practice and meaningful involvement. People with dementia and their family carers were involved in the development via a modified Delphi process and consensus conference to develop the content of the intervention, and in a consultation to develop and refine information and consent documents. In the RCT there was no evidence of effectiveness for family carers for either CSP or RYCT, and no indication of a significant interaction between the interventions. For people with dementia allocated to CSP or RYCT there were significant benefits to quality of life. For the person with dementia, significant interactions between RYCT/CSP for quality of life, anxiety and ADLs indicated that the interventions were not independent. The health economic analysis suggested that, for quality of life, RYCT may be cost-effective for people with dementia.
3. HTP.
   The systematic review of risk factors found that falls/fractures and infections were more common causes of general admission for people with dementia than for other older people. For people with dementia, behaviour problems were likely to precipitate a psychiatric admission. The Cochrane review found evidence for the benefits of case management in terms of reduced admissions to long-term care and hospital length of stay, reduced behaviour disturbance and reduced carer burden. Although case management involved higher use of community services, this was offset by a lower use of acute services and hospitalisations. There was limited evidence that home treatment reduced admissions. In terms of crises, people with dementia focused on risks and hazards in their home, family carers emphasised carer stress and staff were concerned about problems with service co-ordination. In developing the HTP, we that found health-care professionals often emphasised more costly and intensive interventions (extended-hours services and multidisciplinary interventions), whereas carers valued education and support, and people with dementia preferred family support, technology and home adaptations to reduce risks. Five case review workshops were held with 45 staff using the HTP package. Following further revision, 17 staff from crisis teams used the HTP, with 21 cases finding it to be feasible and useful in practice.

Conclusion

There is an urgent need for useful and effective interventions to help to reduce the impact of dementia on patients, carers and society. Continuing MCST improved quality of life, improved cognition for those taking AChEIs and was cost-effective. Moreover, our results support other work indicating that drug and psychosocial interventions may potentially work better together than either alone. Our CST implementation

studies indicated that many staff will run CST groups following a 1-day training course, but that outreach support helps staff go on to run maintenance groups and may also improve staff sense of competence in dementia care. Although the observational study of CST in practice did not find a noticeable improvement in cognition or quality of life at follow-up 8 months later, it is encouraging that neither declined over time. The CSP/RYCT study did not find any particular benefits for family carers. However, both CSP and RYCT appeared to improve the quality of life of people with dementia. RYCT has the potential to be both effective and cost-effective in maintaining the quality of life of people with dementia, but the cost per QALY would be far beyond the National Institute for Health and Care Excellence-accepted price window. Using a factorial design assumes that interventions are independent of each other but for people with dementia we found there were significant interactions. The finding that case management for people with dementia reduces admission to long-term care is consistent with related literature. Case management also reduced behavioural problems in people with dementia. On the evidence available it is not clear how it may affect overall health-care costs. People with dementia and family carers have much to offer in their understanding of the causes and best interventions in times of crisis. Staff suggested more costly and intensive interventions, whereas carers liked education and support, and people with dementia appreciated support from family, and home adaptations and technology to reduce risks. The consensus methods and field testing enabled the production of an easy-to-use HTP to help staff working in crisis teams prevent admissions for people with dementia. The HTP requires evaluation in a full-scale multicentre trial.

The new wave of complex interventions shows great potential for benefit for people with dementia. Alongside this research into psychosocial interventions, further advances in methodology will be required, particularly in relation to process evaluations and implementation. Recent funding rounds by the National Institute for Health Research (NIHR) and the Economic and Social Research Council should help the UK to remain at the forefront of dementia care research with the potential to improve the lives of millions of people with dementia across the world.

Trial registrations

These trials are registered as ISRCTN26286067 (MCST), ISRCTN28793457 (MCST implementation) and ISRCTN37956201 (CSP/RYCT).

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