Individual cognitive stimulation therapy for dementia: a clinical effectiveness and cost-effectiveness pragmatic, multicentre, randomised controlled trial

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Scientific summary

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Background

There is currently growing recognition and evidence that people with dementia and their family carers can benefit from non-pharmacological interventions, especially those of a psychosocial nature. Increasing attention has been given to cognitive-based interventions, such as cognitive stimulation approaches. A recent Cochrane review has shown that group cognitive stimulation programmes benefit cognition for people with mild to moderate dementia, over and above any medication effects, and may be associated with improvements in quality of life. Cognitive stimulation therapy (CST) is an evidence-based approach, associated with benefits in quality of life and cognition for people with dementia when used in a group setting. This approach is recommended by several organisations such as Alzheimer's Disease International and the National Institute for Health and Care Excellence (NICE) as a useful psychosocial intervention, with proven cost-effectiveness. However, as many people with dementia may be unsuitable or unwilling to participate in groups, investigating the potential utility and effectiveness of this approach when provided at home is likely to be useful in making the intervention more accessible to people with dementia and their family carers.

Objectives

The main objectives of this trial were to develop a home-based individual CST programme and to investigate whether individual cognitive stimulation therapy (iCST) benefits cognition and quality of life for people with dementia compared with treatment as usual (TAU) and to evaluate its cost-effectiveness as a home-based approach.

Methods

Design

This multicentre, single-blind, randomised controlled trial had two arms, an intervention group and a TAU control group. Assessments were blind to treatment and were carried out at baseline, 13 weeks and 26 weeks, with the 26-week assessment being the primary end point. Randomisation was carried out remotely by an accredited clinical trials unit. Researchers, who did not undertake any follow-up assessments, arranged for dyads to receive the treatment and supported them in getting started with the sessions. All follow-up data were collected by researchers who were blind to treatment allocation. Assessors rated their impression of allocation of each dyad and their confidence in that judgement.

Participants

There were 356 community-dwelling participants (mean age 78.2 years) with mild to moderate dementia [meeting *Diagnostic and Statistical Manual of Mental Disorders*-Fourth Edition (DSM-IV) criteria], who had a relative or other unpaid (informal) carer who acted as an informant and was willing and able to deliver the intervention. Most carers were spouses (63%). A total of 273 dyads completed the study. The most frequent diagnosis was Alzheimer's disease (64%), followed by vascular dementia (11%).

The trial was run in London, Bangor, Hull, Manchester, Dorset, Devon, Lincolnshire, and Norfolk and Suffolk. Recruitment to the trial took place in a variety of community settings, including NHS Memory Clinics, Community Mental Health Teams (CMHTs) for older people and associated outpatient clinics. Most people with dementia were recruited through Memory Clinics, referrals from consultant psychiatrists and CMHTs. All research activities, including assessments and intervention sessions, took place in the participants' homes.

Inclusion criteria

All participants were people with dementia who:

- met the DSM-IV criteria for dementia of any type
- scored 10 or above on the Mini Mental State Examination
- had some ability to communicate and understand communication, indicated by scoring either 0 or 1 on the Clifton Assessment Procedures for the Elderly Behaviour Rating Scale items
- could see/hear well enough to participate
- had no major physical illness or disability affecting participation
- lived in the community at baseline and had regular contact with a relative or other informal carer who could act as an informant and could participate in the intervention.

Exclusion criteria

People with dementia not living in the community (i.e. in a care home) and having no available family carer to deliver the sessions and act as an informant.

Participants who met the specified inclusion criteria enrolled in the study only after providing informed consent in accordance with the provisions of the *Mental Capacity Act 2005* [Great Britain. The National Archives. *Mental Capacity Act 2005*. URL: www.legislation.gov.uk/ukpga/2005/9/contents (accessed 14 March 2011)]. Consent was viewed as a continual process, and willingness and capacity to continue participating was continually checked through discussion with participants during the assessments. Ethical approval was obtained through the East London 3 Research Ethics Committee (reference number 10/H0701/71).

Intervention

The intervention consisted of one-to-one, home-based, structured cognitive stimulation sessions for people with dementia, provided by the family carer. Dyads were asked to complete up to three 30-minute sessions per week over 25 weeks. The programme consisted of a total of 75 activity sessions, focusing on different themes, such as being creative, word games and current affairs. Dyads were given resources including a manual, an activity workbook, a carer's diary and a toolkit containing items such as compact discs, dominos and maps. Each dyad worked with an unblinded researcher who provided initial training and ongoing support to carers. Participants in the control group received TAU, which varied within and between centres and changed over time. In general, services offered to this group were also available to those in the treatment group.

Main outcome measures

The primary outcomes were cognition [Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog)] and self-reported quality of life [Quality of Life in Alzheimer's Disease Scale (QoL-AD)] for the person with dementia, and mental and physical health [mental component summary-12 and physical component summary-12 derived from the Short Form questionnaire-12 items (SF-12)] for the family carer. Secondary outcomes for the person with dementia included proxy-rated quality of life, behavioural and psychological symptoms, activities of daily living and self-reported depressive symptoms. Depressive symptoms, anxiety, health-related quality of life ratings [as measured by the European Quality of Life-5 Dimensions (EQ-5D)™], and carer resilience were secondary outcomes for family carers. Perception of relationship quality was also measured for both carers and people with dementia. Units of health and social care service use were measured with an adapted version of the Client Service Receipt Inventory, and their costs established using nationally applicable unit costs. Quality-adjusted life-years (QALYs) were calculated from the European Quality of Life-5 Dimensions-3 level response.

Sample size

The main analysis was based on intention to treat for the primary outcome ADAS-Cog. The trial was initially powered to detect a standardised mean difference (SMD) of 0.35, using a conservative approach and based on previous studies and the Cochrane review. Using a two-group *t*-test with a 0.05 (two-sided) significance level comparing iCST and TAU with 80% power gave a sample size of 260. Assuming 15% attrition, we originally proposed to recruit 306 people with dementia. However, the attrition rate was observed to be closer to 25%; thus, we revised the recruitment target upwards by 50 dyads to accommodate this and so changed the recruitment target to 356 caregiving dyads.

Economic evaluation

The economic evaluation was a cost-effectiveness analysis, conducted first from a health and social care perspective, and then from a societal perspective. The primary outcome measures in the economic evaluation were the ADAS-Cog and QoL-AD for the person with dementia, and the QALY for the carer (derived from the EQ-5D with societal weights). The incremental cost-effectiveness ratio (ICER) for each outcome for the person with dementia, and perspective was calculated as the difference in mean costs between iCST and TAU groups over the period of follow-up, divided by the difference in the mean end point outcome measure between groups. In contrast, for the analysis of QALYs (for the carer), we compared mean QALY over 1 year by carrying the last value carried forward from the final assessment to 12 months post-baseline and we likewise annualised costs by doubling the costs estimated over the full follow-up period. Cost-effectiveness acceptability curves were produced to represent graphically the uncertainty around the point estimate of incremental cost-effectiveness. Seemingly unrelated regressions with bootstrapped standard errors, adjusting for baseline covariates, were estimated to calculate net monetary benefit over a range of willingness-to-pay values for incremental primary outcome measure changes and QALY gains.

Results

The overall attrition rate was 23% at week 26, falling to 21% if deaths are excluded. The intention-to-treat analysis indicated that there were no differences between intervention and control groups on any of the primary outcomes at either the primary or secondary time points [at week 26: cognition mean difference –0.55, 95% confidence interval (CI) –2.00 to 0.90; *p*-value = 0.45; self-reported quality of life mean difference –0.02, 95% CI –1.22 to 0.82; *p*-value = 0.97]. There were no differences between the two groups on carers' mental and physical health (at week 26: mental health mean difference 0.13, 95% CI –1.65 to 1.91; *p*-value = 0.89; physical health mean difference 0.46, 95% CI –1.21 to 2.13; *p*-value = 0.59). The intervention did not improve activities of daily living, depressive symptoms or behavioural and psychological symptoms for people with dementia. People with dementia allocated to iCST reported better relationship quality with their family carer in comparison to those in TAU at the primary end point (week 26: relationship quality mean difference 1.77, 95% CI 0.26 to 3.28; *p*-value = 0.02). There was no impact on carers' mood, resilience or relationship quality with the person with dementia. Carers in the treatment group reported higher health-related quality of life (week 26: health-related quality of life mean difference 0.06, 95% CI 0.02 to 0.10; *p*-value = 0.01) in comparison with those in TAU, at the primary end point.

Compliance analyses were conducted by taking into account the total number of sessions completed. Overall, 22% of participants did not complete any sessions, whereas 51% of dyads completed more than 30 sessions. Adherence analyses indicated that people with dementia completing more sessions showed improved quality in the caregiving relationship at 26 weeks, whereas carers reported lower depressive symptoms at the primary end point.

The intervention costs were approximately £481 per person for paid staff to deliver, or £652 if the costs of carer time were also taken into account. Adjusted mean health and social care costs looked higher, and adjusted societal costs looked lower in the intervention than in the control group (£4740 iCST vs. £4670 TAU and £9770 iCST vs. £10,630 TAU, respectively); however, from either perspective, costs were not significantly different between the groups (£70, 95% CI –£1050 to £1190 greater in the intervention group for health and social care costs only; £860, 95% CI –£2750 to £1040 less in the intervention group for societal costs). Cost-effectiveness analyses from the health and social care perspective yielded an ICER of £300 for achieving a SMD on the ADAS-Cog and £600 for achieving a SMD on the QoL-AD. Incremental cost-effectiveness ratios from the societal cost perspective were negative (where the intervention was dominant, costs were lower and effectiveness greater).

The incremental health and social care cost associated with a QALY gain for carers was £3100. The probability of iCST being cost-effective from the health and social care perspective was 72% at a willingness to pay (WTP) per QALY of £20,000 and 81% at a WTP per QALY of £30,000; the probability of iCST being cost-effective from the societal perspective was 90% at a WTP per QALY of £20,000 and 93% at a WTP per QALY of £30,000. A probability of cost-effectiveness greater than 97.5% was reached at a WTP of £84,200 per QALY (health and social care costs) or £47,300 per QALY (societal costs), and we can be confident that the intervention is cost-effective above these upper limits. The intervention can be considered to be cost-effective in improving unpaid carers' health-related quality of life at a societal WTP well above the NICE threshold of £20,000 to £30,000.

Conclusions

This trial showed that iCST does not improve cognition or quality of life for people with dementia. There was no impact on activities of daily living, behavioural and psychological symptoms, or depression for people with dementia. There was no benefit for carers' mental and physical health. People with dementia participating in iCST perceived the relationship with their carer as more positive compared with those in TAU. Carers' reported levels of utility were significantly higher at the 5% level (on the EQ-5D index); however, physical and mental health scores (on the SF-12) did not differ. The costs of providing the intervention appeared to be offset by some reductions in social care and other services, although the cost difference was not significant at the 5% level. The overall compliance rates were much lower than expected. This trial suggests that in contrast to group approaches, carer-led cognitive stimulation interventions do not improve cognition and quality of life for people with dementia.

Implications for dementia care

The trial provides important information about the use of carer-led cognitive stimulation approaches. Although carers and people with dementia initially expressed interest in taking part, only 65% of the sample allocated to treatment completed more than 10 sessions, with 22% completing no sessions, indicating that for some people with dementia and their carers this type of intervention will not be feasible and that methods for compliance need to be improved. Despite overall negative findings, there was some improvement in terms of the caregiving relationship and carers' health-related quality of life. However, our study suggests that carer-led cognitive stimulation interventions are unlikely to lead to a clinical benefit for cognition and quality of life for people with dementia, limiting the wider implementation of individual approaches.

Recommendations for further research

Future research will be useful in identifying whether or not the mode of intervention provision, such as a group-versus home-based setting, is key to the effectiveness of cognitive stimulation approaches, given the lack of results of benefit in cognition and quality of life for people with dementia. Future studies should investigate factors such as compliance in carer-led cognitive stimulation interventions alongside clinical effectiveness.

Trial registration

This trial is registered as ISRCTN65945963.

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