

Community Occupational Therapy in Dementia intervention for people with mild to moderate dementia and their family carers in the UK: the VALID research programme including RCT

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Scientific summary

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Scientific summary

Background

People with dementia find it increasingly difficult to carry out activities, and require increasing support from their family carers, who often experience stress. Occupational therapists support people to improve their health and well-being by enabling them to participate in activities that are meaningful to them. Researchers in the Netherlands developed the Community Occupational Therapy in Dementia (COTiD) intervention, in which occupational therapists delivered in 10 1-hour sessions over 5 weeks to people with mild to moderate dementia and their family carers at home. The Dutch researchers found that COTiD improved the person with dementia's ability to perform daily living activities [activities of daily living (ADL)], quality of life and mood; improved their family carer's sense of competence, quality of life and mood; and was cost-effective.

Aims and objectives

The aim of this applied research programme funded by the National Institute for Health and Care Research (NIHR) was to translate, adapt, evaluate and implement this community occupational therapy intervention designed to promote independence, meaningful activity and quality of life for people with mild to moderate dementia, and thus to benefit their family carers.

Objectives

- To translate and adapt COTiD into the Community Occupational Therapy in Dementia – UK version (COTiD-UK) intervention and training programme and optimise it for UK use.
- To test the feasibility of implementing COTiD within UK health and social care services.
- To field test the proposed outcome measures through an internal pilot trial of COTiD-UK compared with treatment as usual (TAU).
- To estimate the effectiveness of COTiD-UK in improving the functional independence of people with mild to moderate dementia through a multicentre, pragmatic, single-blind, randomised controlled trial (RCT).
- To evaluate cost-effectiveness of COTiD-UK compared with TAU.
- To assess the implementation of COTiD-UK through monitoring and budget impact analysis.
- To widely disseminate the findings of the Valuing Active Life in Dementia (VALID) research programme.

The programme consisted of three phases, including five work packages (WPs): development (WP1 and WP2), piloting and evaluation (WP3 and WP4), and implementation (WP5).

Development phase (work packages 1 and 2)

Aim

To translate and adapt the COTiD guideline and training package to optimise its suitability for use within the UK and, therefore, develop the COTiD-UK intervention ready for evaluation in WP3 and WP4.

Method

We used a mixed-methods approach, including the following activities.

Work package 1: translation and adaptation

This WP included the translation, expert review and adaptation of the manual and training materials used to train occupational therapists to deliver COTiD sessions to 'pairs' or dyads, comprising a person with mild to moderate dementia and their family carer; focus groups with occupational therapists who delivered COTiD, people with dementia and family carers who had not received COTiD; and semistructured interviews with pairs who had taken part in COTiD, managers of occupational therapists who delivered COTiD, and professionals who had referred pairs to receive COTiD. Finally, a consensus conference was held to finalise the content of the UK version of the intervention, COTiD-UK, with people with dementia and family carers, some of whom had participated in COTiD; occupational therapists who had received the training and delivered COTiD; and managers and other team members.

Work package 2: survey of current practice

This WP comprised an online survey collecting both quantitative and qualitative data from occupational therapists to scope current UK occupational therapy practice for people with dementia and their carers.

Results

Work package 1: translation and adaptation

We established a reference group of UK occupational therapists with experience of working with people with dementia and their family carers in practice. They provided expert opinion and guidance throughout the programme independent of the research team. This Occupational Therapy Reference Group reviewed the translated intervention and training materials, which were then adapted in consultation with the original author. We trained 44 occupational therapists from 10 organisations to deliver COTiD, of whom 28 took part in one of five focus groups. A total of 130 pairs took part in the COTiD sessions. We conducted semistructured interviews with nine pairs: four managers and five referrers. Thirty-nine people who had not received COTiD took part in one of six focus groups. Thirty-one people attended the consensus conference.

Work package 2: survey of current practice

A total of 230 occupational therapists consented to take part, of whom 197 (86%) provided quantitative data and 138 (60%) provided qualitative data also. Over half of the respondents undertook primarily profession-specific work. Occupational therapy-specific assessments were the most common profession-specific task, and the median time spent per person with dementia was 2.5 hours.

Conclusion

This phase took twice as long to complete as planned, partly because we underestimated the time needed to complete translation and partly because several organisational and governance issues delayed the occupational therapists delivering the intervention in practice, which in turn delayed the remainder of the data collection activities.

We developed the COTiD-UK intervention ready for evaluation in WP3 and WP4. COTiD-UK retains the same aim and principles as COTiD, in that it aims to enable the person with dementia and family carer to carry out meaningful activities. This is achieved through adapting the environment and activity and coaching the family carer in problem-solving and supervision skills. It is similar to COTiD in that it comprises 10 hours of face-to-face intervention provided at home but is more flexible in content and delivery. For example, occupational therapists can use a wider range of assessment and intervention tools that are already in regular use within UK practice, and the time span for delivery is extended from 5 to 10 weeks to better meet the needs of pairs and be more feasible for service delivery.

We restructured the training programme into 2 consecutive days followed by a third day once the therapists had delivered COTiD-UK in practice. We also used audio-recording rather than video-recording for the competence assessment process to better meet the needs of UK occupational therapists, many of whom had extensive experience of working with people living with dementia and their family carers or in the community.

Piloting and evaluation phase (work packages 3 and 4)

Aims

Work package 3: internal pilot trial

The aim of WP3 was to field test the outcome measures and trial procedures, and finalise the COTiD-UK intervention training, mode of delivery and supervision.

Work package 4: full randomised controlled trial

To estimate the clinical effectiveness and cost-effectiveness of COTiD-UK compared with TAU.

Method

We designed WP3 as an internal pilot trial with the intention of progressing to WP4, the full RCT, if it met predefined success criteria.

The study design was a multicentre, two-arm, parallel-group, single-blind individually randomised pragmatic trial with an internal pilot. We allocated pairs at random between COTiD-UK and TAU, which may or may not include standard occupational therapy. The primary outcome was the Bristol Activities of Daily Living Scale (BADLS) score at 26 weeks. Secondary outcome measures were as follows:

- for person with dementia – cognition (Mini Mental State Examination), ADL performance (Interview of Deterioration in Daily activities of Dementia), quality of life [Dementia Quality of Life (DEMQOL) scale] and mood (Cornell Scale for Depression in Dementia)
- for the family carer – sense of competence (Sense of Competence Questionnaire), quality of life (DEMQOL scale) and mood (Hospital Anxiety and Depressions Scale)
- for all participants – social contacts, leisure activities and serious adverse events.

These outcomes were selected to reflect those measured in the previous trials of COTiD.

We undertook a cost-utility analysis of the COTiD-UK intervention relative to TAU using costs and outcome data from the trial. Our analysis adopted the perspective of the NHS and Personal Social Services, as well as a societal perspective. The time horizon was 26 weeks, reflecting the trial's primary end point. We assessed the effectiveness of the intervention in quality-adjusted life-years (QALYs) estimated from mortality and health-related quality-of-life data collected using the DEMQOL scale for carers, DEMQOL-Proxy for people with dementia and EuroQol-5 Dimensions, five-level version, and health and social care services used for both.

We embedded two qualitative studies within the trial:

- We explored the experience of undertaking the COTiD-UK intervention from the perspective of people with dementia, family carers and occupational therapists. We conducted semistructured interviews over the telephone with occupational therapists and face to face with pairs. We audio recorded and transcribed all interviews, checked them for accuracy, anonymised them and used inductive thematic analysis.

- We explored why pairs declined to take part in the trial. We interviewed a convenience sample of carers identified during the screening process as being eligible but who subsequently declined to take part. We approached them only if we judged that it was unlikely to cause distress. We audio recorded and transcribed the telephone interviews, checked them for accuracy, anonymised them and used inductive thematic analysis.

Results

The independent Programme Steering Committee reviewed the internal pilot trial and agreed that we should carry the data collected to date forward to the main trial data set.

We recruited 15 NHS trusts; however, one trust did not proceed to recruiting pairs owing to unforeseen service reorganisation that resulted in the occupational therapists whom we had trained no longer being available to take part. We trained 44 occupational therapists to deliver COTiD-UK, of whom 32 proceeded to the RCT and were allocated at least one pair each, although one was subsequently unavailable to provide the intervention as planned owing to ill health.

We randomised 468 pairs: 249 to COTiD-UK and 219 to TAU. As we expected, the demographic and clinical characteristics of both groups were very similar at baseline. People with dementia ranged in age from 55 to 97 years, with a mean age of 78.6 years, and family carers ranged in age from 29 to 94 years, with a mean age of 69.1 years. The majority of people with dementia (74.8%) were married; 19.2% lived alone. Most family carers (72.6%) were spouses but 22.2% were adult children. At 26 weeks, 406 (87%) pairs remained in the trial. We collected and analysed outcome data from 368 (79%) pairs: 207 (83%) allocated to COTiD-UK and 161 (74%) allocated to TAU. At 26 weeks, there was no evidence to suggest a difference between the COTiD-UK and TAU groups in the primary outcome (BADLS score) or in any secondary outcome. Further analysis of BADLS scores and secondary outcomes at 52 and 78 weeks also showed no difference between the COTiD-UK and TAU groups.

The non-adherence rate was 4.64%, compared with the target of 5%. The number of goals set per pair ranged from one to thirteen, with a mean of 4.09 goals. The total number of goals set was 920, of which 729 (79.24%) were achieved, 107 (11.63%) were partially achieved and 84 (9.13%) were not achieved.

A total of 239 serious adverse events were recorded over the course of the trial, but none was assessed as being related to the COTiD intervention or trial participation.

If decision-makers were willing to pay £20,000 (or £30,000) for a QALY, the probability that COTiD-UK is cost-effective would be 0.02% (or 0.04%). None of these statistical or economic findings changed when we re-ran analyses without adjustment or restricted to complete cases.

Qualitative study 1

We interviewed seven occupational therapists and 22 pairs. We identified six themes from the occupational therapist interviews: (1) valuing the occupational focus of COTiD-UK, (2) timing and relationships, (3) achieving goals, (4) developing COTiD-UK knowledge and skills, (5) delivering COTiD-UK within current organisational models, and (6) delivering COTiD-UK in the future. We identified four themes from the interviews with people with dementia and their family carers: (1) achieving goals, (2) working together, (3) effect of dementia and (4) COTiD-UK outcomes.

Qualitative study 2

We interviewed 10 family carers and identified two themes: (1) protectiveness and (2) 'It's not for us'.

Conclusion

This trial recruited 97.5% of the target sample, and attrition and non-adherence rates were low. Sites had fewer available occupational therapists than expected, and drop-out rates were higher than

expected; therefore, we recruited more sites than originally planned, which took longer than expected. Our design required sites to access researchers, often from the local Clinical Research Network, to recruit participants and collect data, and occupational therapists to deliver the COTiD-UK intervention. Only 2 of the 15 trial sites acquired 'excess treatment costs', namely the additional funding that is required within the UK to deliver the clinical intervention being evaluated, as the research grant funding does not cover this. This inevitably reduced capacity to deliver the intervention in some sites because the occupational therapists' availability was dependent on the goodwill of their managers, who had to balance their support for the study with the need to continue providing the usual service being commissioned. Hence, recruitment rates varied across sites, with some sites exceeding their recruitment target and more not achieving it.

The trial statistical results showed no evidence that COTiD-UK was better than the usual care being provided, nor did the economic evaluation provide support for COTiD-UK. By contrast, many people with dementia and family carers described the intervention and its impact in very positive terms, providing examples of how they had resumed old activities and felt empowered to continue participation in future.

Implementation phase (work package 5)

This phase was amended in response to the cumulative delays outlined above, and the number of data already collected, taking into account the lack of statistically significant results and the growing body of implementation science knowledge.

Aim

The aims of this WP were to assess the intervention fidelity and to explore why the intervention was, or was not, delivered as planned.

Methods

We used a longitudinal observational design nested within the trial to assess fidelity to the COTiD-UK intervention. We audio-recorded as many COTiD-UK sessions as was feasible. We developed, piloted and refined fidelity checklists and coding until we achieved good agreement between coders. We purposively sampled 10% of sessions, and estimated percentages of components delivered for each session, occupational therapist and site.

We reviewed data collected during the earlier development, piloting and evaluation phases using the theoretical domains framework to identify factors that enabled or hindered intervention delivery.

Results

A reliable measure of intervention fidelity was developed. Application of this measure found that COTiD-UK was delivered with moderate fidelity overall, although the mean range varied across sites and occupational therapists. The key domains affecting COTiD-UK implementation in practice were knowledge, skills (capability), environmental context and resources (opportunity) and beliefs about capabilities (motivation).

Recommendations for future research

Traditionally, psychosocial intervention research has focused on assessing outcomes such as cognition, daily living abilities and quality of life as core domains potentially impacted by dementia, using measures of deterioration and impairment. We noted that, in the main, pairs set goals relating to a wider range of activities than those covered within the BADLS, for example leisure, creative, social and community based. Given that over 90% of goals set by the dyads taking part in COTiD-UK were fully

or partially achieved, further analysis of the goals set and met could inform the future selection and development of more meaningful occupational outcome measures, tools and processes. It is important to develop ways of measuring the outcomes of complex interventions, such as COTiD-UK, and to measure what is meaningful and prioritised by people with dementia and their family carers. There is also a need to develop such patient-related outcome measures in formats that make them suitable for self-report, to enable data to be collected directly from people with dementia themselves, in turn meaning researchers do not have to rely on proxy data.

Implications for practice

The trial statistical results did not indicate any benefit of the COTiD-UK intervention as delivered in this trial compared with usual care in the outcomes measured. However, the qualitative findings provided positive examples of dyads resuming or establishing meaningful activities. There is no evidence to suggest that occupational therapy input in general does not continue to be a highly valued and important part of multiprofessional teamworking and service provision. We therefore suggest that occupational therapists do not change their practice, but continue to contribute to community teamwork and memory service provision for people with cognitive problems and their families.

Conclusion

This applied research programme used a rigorous and thorough process to translate and adapt the original Dutch intervention to the UK version.

We found no statistical evidence for clinical effectiveness or cost-effectiveness of COTiD-UK compared with the usual care provided. By contrast, people with dementia, family carers and occupational therapists provided positive examples of meaningful activities being resumed or established.

We have shown that it is possible to conduct and effectively deliver a well-designed, high-quality, highly complex clinical trial of occupational therapy across 15 sites and requiring intervention delivery by experienced occupational therapists.

Trial registration

This trial was registered as ISRCTN10748953 (WP3 and WP4).

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