REMCARE: reminiscence groups for people with dementia and their family caregivers – effectiveness and cost-effectiveness pragmatic multicentre randomised trial

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Executive summary

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Executive summary

Background

The growing number of people with dementia and the increasing cost of care provide a major incentive to develop and test methods of providing effective community support for a longer period of time. Most attention has been given to pharmacological interventions, but there is increasing recognition that psychosocial interventions may be equally effective and even preferable where medication has negative side effects. Reminiscence groups, run by professionals and volunteers, which use photographs, recordings and other objects to trigger personal memories, are probably the most popular therapeutic approach to working with people with dementia. Our Cochrane review prior to this trial showed that there were few studies evaluating their effectiveness and cost-effectiveness. There was, however, informal evidence that the inclusion of family carers in groups with people with dementia, notably in our pilot studies, improved relationships between people with dementia and their carers, and benefited both. A trial platform, with 57 people with dementia and their family carers participating, had enabled a treatment manual to be developed and outcome measures trialled, as well as effect sizes estimated. This had indicated significant improvements in autobiographical memory in people with dementia and depression in family carers, associated with the reminiscence intervention.

Objectives

The objectives of this trial were twofold: first, to explore the effectiveness of joint reminiscence groups for both people with dementia and their carers compared with usual care; and, secondly, to explore the cost-effectiveness of this intervention, paying particular attention to the pattern of health care, social care and voluntary sector service use and associated costs, by people with dementia and their carers.

Methods

Design

This multicentre, pragmatic randomised controlled trial had two parallel arms – an intervention group and a control group, who received care as usual. Assessments, blind to treatment allocation, were carried out at baseline, 3 months and 10 months, with the 10-month assessment being the primary end point. Randomisation was completed using a dynamic allocation method stratifying for spousal or non-spousal relationship of the dyad. Complete list randomisation for each wave of recruitment within each centre was completed. Randomisation was carried out remotely by an accredited Clinical Trials Unit when up to 24 pairs had completed baseline assessments: this was initiated by a local researcher who did not take part in follow-up assessments. The researcher arranged for those pairs (up to 12) randomised to the intervention group to attend sessions, and liaised with the group facilitator. Though participants could not be blinded to their allocated treatment, all follow-up data were gathered by blinded interviewers. In order to reduce the risk of participants occasionally and inadvertently informing researchers of the treatment they were receiving, explicit reminders were given to participants before assessment visits, and self-report measures were used wherever feasible. Assessors were also asked to record their impression of the arm to which each participant belonged, and their confidence in that prediction, so that any bias could be detected.

Participants

There were 488 participants (mean age 77.5 years) with mild to moderate dementia [meeting *Diagnostic and Statistical Manual of Mental Disorders*-Fourth Edition (DSM-IV) criteria], initially living in the community, and who had a relative or other caregiver maintaining regular contact, who could act as an informant and who was willing and able to participate in the intervention. Most carers were spouses (71%). A total of 350 dyads completed the study. Where a specific subtype of dementia was recorded, in the majority of cases this was Alzheimer's, either alone (72%) or mixed with vascular dementia (11%).

The trial took place in Bangor, Bradford, London, Manchester, Newport and Hull. Recruitment to this trial took place through mental health services for older people in each area [especially Memory Clinics, Community Mental Health Teams (CMHTs) for older people and associated professionals, including psychiatrists, occupational therapists and specialist nurses], associated day services and through relevant local voluntary sector agencies such as the Alzheimer's Society and Age Concern. The majority of participants were recruited through NHS Memory Clinics and CMHTs for older people. Recruitment took place in 3–5 waves in each centre. Assessments were usually carried out in the participant's home, and treatment groups held in a variety of community settings.

Inclusion criteria

All participants were people with dementia who:

- met the DSM-IV criteria for dementia of any type, including Alzheimer's, vascular, Lewy body type and mixed
- were in the mild to moderate stage of dementia (Clinical Dementia Rating)
- could communicate and understand communication, shown by a score of 1 or 0 on the relevant items of the Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale
- could engage in group activity
- lived in the community at the time of the baseline assessment and had a relative or other caregiver who maintained regular contact that could act as an informant and was willing and able to participate in the intervention with the person with dementia.

Exclusion criteria

Participants did not have any characteristics which could affect participation, for example:

- major physical illness
- sensory impairment
- disability or
- high level of agitation.

Participants entered the study only after giving signed informed consent in accordance with the provisions of the Mental Capacity Act 2005. In the event of a participant being judged to lose capacity to consent to participate during the trial, the views of a personal consultee (the carer) were sought regarding continuation. General ethical approval was obtained through the Multicentre Research Ethics Committee for Wales (ref. no. 07/MRE09/58). Participants were free to seek additional assistance and support elsewhere at any time after baseline.

Interventions

The intervention consisted of joint reminiscence groups held weekly for 12 consecutive weeks, followed by monthly maintenance sessions for a further 7 months. The sessions followed a treatment manual, and were led by two trained facilitators in each centre, supported by a number of volunteers. Up to 12 dyads were invited to attend each group. Each session lasted 2 hours

and focused on a different theme, including childhood, schooldays, working life, marriage, and holidays and journeys. Dyads were encouraged to contribute with materials brought from home. Subsequent maintenance sessions were held monthly and followed a similar pattern. Each session blended work in large and small groups, and a range of activities including art, cooking, physical re-enactment of memories, singing and oral reminiscence. The inclusion of the person with dementia is considered paramount. In the joint reminiscence groups facilitators and volunteers guided carers to allow the person with dementia to respond and to value their contribution.

Dyads in the control group received usual care which varied between and within centres.

Main outcome measures

The primary outcome measures were self-reported quality of life for the person with dementia (QoL-AD), and psychological distress for the carer [General Health Questionnaire-28 item version (GHQ-28)]. Secondary outcome measures for the person with dementia included autobiographical memory, depression, anxiety and activities of daily living. The carer reported their stress related to caregiving and their levels of anxiety and depression. Both the carer and the person with dementia rated the quality of the relationship between them. Data on service use and costs were collected for both parties. To enable exploratory cost–utility analysis, the European Quality of Life-5 Dimensions (EQ-5D) instrument was administered to both people with dementia and their family carers. Family carers were also asked to complete a proxy EQ-5D for the person with dementia.

Sample size

The trial was initially powered to detect a standardised difference of 0.38 in the QoL-AD rated by the person with dementia and 0.28 in the GHQ-28 or carer-rated QoL-AD, requiring 200 dyads in each arm to complete the 10-month assessment. This allowed for clustering effects within groups. Taking into account predicted attrition, the initial target sample size was, accordingly, 576 dyads.

During the course of the trial, this target was revised in the light of lower clustering effects and slightly better retention rates at 10 months. The revised recruitment target of 508 provided a potential sample size of 366 at 10 months' follow-up, assuming 72% retention across the 10-month period. This provided 80% power to detect a standardised difference of 0.30 in the GHQ-28 or carer-rated QoL-AD at the 5% significance level, and 80% power to detect a standardised difference of 0.31 in the patient-rated QoL-AD. The slight loss in power to detect a difference in the carer-rated measures was more than compensated for by the increased power to detect a difference on the patient-rated primary outcome measure.

Economic evaluation

From a public sector, multiagency perspective we aimed to undertake a primary cost-effectiveness analysis, using QoL-AD and the GHQ-28, separately for people with dementia and family carers in the trial. We planned to undertake exploratory secondary cost–utility analysis. A micro-costing of reminiscence groups and maintenance therapy was undertaken. Patterns of health care, social care and voluntary sector service use and associated costs by participants with dementia and their carers were evaluated, including patterns of dementia drug use and associated costs, and comparisons made between the intervention and control conditions.

Results

The final sample size of 350 dyads completing the 10-month end point assessment represents 95% of the revised target sample size. The overall attrition rate was 28% at 10 months, falling to 22% if deaths are excluded.

The intention-to-treat analysis indicated there were no differences in outcome between the intervention and control conditions on primary or secondary outcomes at the 10-month end point [self-reported QoL-AD mean difference 0.07, standard error (SE) 0.65; $F = 0.48$; $p = 0.53$] or at the assessment carried out at 3 months. Carers of people with dementia allocated to the reminiscence intervention reported a significant increase in anxiety on a subscale of the GHQ-28 at the 10-month end point (mean difference 1.25, SE 0.5; $F = 8.28$; $p = 0.04$). People with dementia in the intervention group made more use of local authority and NHS day care than those in the treatment as usual group. Economic analyses from a public sector, multiagency perspective indicated that joint reminiscence groups are unlikely to be cost-effective.

Compliance analyses were undertaken as specified in the analysis plan. Taking attendance at six or more of the 12 weekly sessions as an index of compliance, on the basis of clinical consensus, 70% of those allocated to the intervention received it as planned. This fell to 57% when considering those dyads who additionally attended three or more of the monthly maintenance sessions. The compliance analyses, which should be viewed as exploratory, suggested that people with dementia attending more reminiscence sessions showed improved autobiographical memory at 3 months, and an improvement in self-reported relationship quality and quality of life at 10 months. However, carers showed increased stress related to caregiving associated with more sessions attended at this point.

Conclusions

This trial does not provide support for the effectiveness or cost-effectiveness of joint reminiscence groups for people with dementia and their carers. Although there may perhaps be some beneficial effects for people with dementia who attend sessions as planned, this must be viewed in the context of raised anxiety and stress in their carers. The reasons for these discrepant outcomes need to be explored further, and may necessitate reappraisal of the movement towards joint interventions.

Implications for dementia services

The results of this trial do raise a number of issues for dementia care services. First, one-fifth of those offered the opportunity to participate in the groups declined to do so (attending only one session or none at all). Given that all these participants had agreed to enter a trial evaluating reminiscence groups, this suggests that there will be many more for whom group-based approaches of this type may not be favoured. Second, the greater use of services, such as day care, in the intervention group may signal the effects of carers meeting together and sharing experiences regarding services that might not otherwise be taken up. Third, the results of the current trial suggest that other approaches to enhancing relationships between people with dementia and their carers need to be explored, and that more work may be needed to address the anxieties and stresses that arise for carers from these relationships and the changes they observe in the person with dementia.

Recommendations for further research

1. The conventional approach, of conducting reminiscence groups with people with dementia without carers participating, was considered as a potential control comparison group in our preparatory work for this trial, but appeared at that stage to be associated with similar outcomes. Following the results of the full trial there remains uncertainty regarding the effects, on either people with dementia or their carers, of people with dementia participating in reminiscence groups with other people with dementia. Within-group and other proximal outcomes for people with dementia associated with reminiscence work would be the focus, following the lack of longer-term benefit identified in the current trial.
2. The effects of interventions that involve people with dementia and family carers together would benefit from further review. Are the negative effects on carers noted in this report a function of the specific intervention, or the joint group approach? How does this approach compare with other carer interventions? Would a mixed-methods approach provide insights as to the factors raising anxiety and stress in family carers participating in joint reminiscence groups?

Trial registration

This trial is registered as ISRCTN42430123.

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Publication

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