An intervention to promote self-management, independence and self-efficacy in people with early-stage dementia: the Journeying through Dementia RCT

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Scientific summary

The Journeying through Dementia RCT

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Scientific summary

Background

The Journeying through Dementia intervention was designed to promote independence, self-management, self-efficacy and continued participation in life among people in the early stages of dementia. The intervention is one of the few interventions that enables a person to take part in sessions without a supporter or carer. This form of intervention is important, as early diagnosis needs to be followed by treatment and support to enable people with dementia to live as well as possible. The Journeying through Dementia intervention was created in consultation with people with a diagnosis of dementia and those who support them. It involves 12 weekly facilitated groups of 8–12 participants with dementia and is delivered in a community venue. Each participant also receives four one-to-one sessions with a facilitator. Groups of participants are facilitated to select topics from the menu of possibilities contained within the manualised intervention. They are encouraged to explore the selected topic through a combination of discussions and activity. An important aspect is enactment of activities within the community, making the intervention relevant to the lives of participants and enabling them to try out new or neglected activities with the support of others. Four one-to-one (1 : 1) sessions with one of the facilitators complement the group sessions by assisting participants to pursue individual goals with or without a supporter.

The primary aim of this pragmatic trial was to determine the clinical effectiveness and cost-effectiveness of the Journeying through Dementia intervention for people in the early stages of dementia.

To meet this aim, the objectives were to:

- conduct an internal pilot randomised controlled trial of the intervention to check the feasibility of rates of recruitment at scale
- undertake a full pragmatic randomised controlled trial evaluating the clinical effectiveness and cost-effectiveness of the intervention
- conduct fidelity checks regarding the delivery of the intervention
- undertake an embedded qualitative substudy to explore issues concerned with intervention delivery
- identify how the intervention might be realistically delivered through services.

Methods

The study design was a pragmatic superiority two-arm parallel-group individually randomised controlled trial. It involved an intention-to-treat comparison of the Journeying through Dementia intervention with usual care. There were also three substudies: (1) an examination of intervention fidelity, (2) a qualitative study of experiences of those who took part and (3) a health economics evaluation of costs of delivering Journeying through Dementia compared with usual care from an NHS and social care perspective.

The Journeying through Dementia Participant and Public Involvement Advisory Group, comprising people living with dementia (i.e. people with a dementia diagnosis and supporters), gave feedback throughout the trial on study materials and presentation of outputs. A person with dementia was a member of the Trial Steering Committee and they attended each meeting and advised on study implementation and interpretation of the findings.

The study was conducted in 13 sites in the Midlands and north of England. To take part, sites had to demonstrate ability to recruit people with dementia within the agreed timeline and provide the workforce to both deliver and supervise delivery of the intervention. Nominated facilitators and supervisors were identified by study sites and trained by the study team. Support for facilitators for delivery at site was provided by supervisors who were, in turn, supervised by identified experts from the study team. Supervision protocols were provided by the study team and attendance was recorded.

The study sample size of 488 people with dementia was based on a 4-point improvement on the primary outcome (i.e. Dementia-Related Quality of Life score) at 8 months post randomisation. This was deemed to be clinically significant. To take part in the study, people with dementia had to be in the mild stages of dementia (as measured by the Mini Mental State Examination), living in the community and have good comprehension of English. Higher scores on the Mini Mental State Examination indicate better cognitive function. The participant could invite supporters to the first, sixth and final group session and to one-to-one sessions, if the person with dementia wanted this involvement. Groups of participants created at sites from those randomised to the intervention were invited to take part over 12 successive weeks. The sustained involvement of all recruited participants (i.e. both intervention and control) was promoted through regular participant newsletters.

The intervention was offered in addition to usual care. Treatment as usual varied across trial sites and could include prescription of medication, assessment of needs, referral to services within the NHS or third sector and provision of educational material. After assessment of needs by NHS memory services, referrals can be made to community health teams, services provided through the third sector or support groups offered by memory services. At the majority of sites, and if there were no complicating factors, the person is then referred back to primary care. Referral back to memory services might occur if there was further deterioration. The types of support group offered within the NHS through memory services included cognitive stimulation therapy (nine sites), memory groups (two sites), Living Well with Dementia groups (three sites) and educational groups (three sites). Although Living Well with Dementia groups can contain some elements that are also in the Journeying through Dementia intervention, at 8 months only one participant reported attending one such group run by the NHS, confirming that attending these groups is uncommon. We have no evidence of other groups that participants attended that were using elements (e.g. mix of one-to-one sessions and group sessions or enactment of skills in the community) of the Journeying through Dementia intervention.

Baseline data collection involved collection of all outcome measures, taken face to face from participants following consent to take part. The primary outcome was quality of life, measured by the Dementia-Related Quality of Life measure. This self-report instrument contains 28 items and covers aspects such as daily activities and looking after yourself, health and well-being, cognitive functioning, social relationships and self-concept. A higher score indicates a better health-related quality of life. There were eight secondary outcome measures:

1. Health and social care resource use was measured using the Health and Social Care Resource Use Questionnaire.
2. Psychological well-being was measured using the General Self-Efficacy Scale, with higher scores indicating greater self-efficacy.
3. Psychological well-being was measured using Diener's Flourishing Scale, with higher scores indicating greater psychological resources and strengths.
4. Self-management was measured using the Self Management Assessment Scale, with higher scores corresponding to higher levels of ability to self-manage.
5. Instrumental activities of daily living, with higher scores indicating better functional ability and greater independence.
6. Anxiety was measured using the Generalised Anxiety Disorder-7, with higher scores indicating greater anxiety.

7. Depression was measured using the Patient Health Questionnaire-9 items, with higher scores indicating more depressive symptoms.
8. Health-related quality of life was measured using the EuroQol-5 Dimensions, five-level version, with higher scores indicating better health. A visual analogue scale also measures health state from 0 to 100, with 100 being the best imaginable state of health.

Recruited participating supporters were asked to complete the EuroQol-5 Dimensions, five-level version and the Sense of Competence Questionnaire (where higher scores indicate a better sense of competence).

Following baseline measurement, participants were randomised to the intervention or usual care by the central trial team, using a computerised randomisation system. Outcome measurement was conducted face to face with all consented participants at 8 and 12 months post randomisation. Analyses of data were undertaken on an intention-to-treat basis, with the treatment effect adjusted for the baseline value, stratification site and the clustering effect of the Journeying through Dementia intervention groups.

Registers were maintained by facilitators at all sites of participant attendance (i.e. the 12 group sessions and four 1 : 1 sessions) and analysed for attendance rates. All facilitators were asked to keep records of the content of every session they delivered, which were shared with participants. Copies of these records were sent to the research team and the content analysed to describe the extent to which intervention delivery across all 13 sites adhered to the manualised intervention.

The fidelity substudy involved assessment of the training received by facilitators and assessment of delivery of the group aspect of the intervention at four delivery sites. Facilitator training was observed and recorded by two raters using a bespoke assessment form of key activities/learning outcomes. Delivery of the group was observed and rated in a convenience sample of 4 of the 13 study sites. It was not considered viable to observe one-to-one sessions for fidelity assessment. Two group sessions were observed at each site and rated by two raters using a bespoke assessment form of expected activities/behaviours. The data were analysed for frequency or absence of key activities/behaviours and for inter-rater reliability.

Qualitative semistructured interviews were conducted with a purposefully identified sample of participants randomised to receive the intervention, intervention facilitators and intervention supervisors from the four sites that participated in the fidelity assessment. Fifteen people with dementia (who were representative of the overall trial population), 10 participating supporters, 10 facilitators and four supervisors took part in these interviews. The data were analysed using framework analysis. Members of the Study Advisory Group contributed towards validation of researcher analyses of interviews with study participants. Data from interviews with participants, participating supporters, facilitators and supervisors were analysed separately and then triangulated to identify common and divergent themes.

The health economics evaluation involved analysis of data collected from participants through application of the Dementia-Related Quality of Life measure, the EuroQol-5 Dimensions, five-level version, and from the Health and Social Care Resource Use Questionnaire. Information on intervention training and delivery costs was also collected.

Results

Recruitment and retention

Between November 2016 and August 2018 a total of 480 people with dementia were recruited and randomised, with 350 having participating supporters. Primary outcome data at 8 months was obtained from 388 people with dementia, matching predicted numbers (i.e. taking attrition into account).

Adherence

There were 28 intervention groups across the 13 sites. The median number of participants attending each group session was five. Of the 241 participants randomised to the intervention, 165 attended at least 10 of the 16 available sessions (the per-protocol treatment threshold). Therefore, intervention attendance was good. Most of those attending ≥ 10 sessions were male with a co-resident participating supporter. Analysis of records of intervention delivery confirmed that intervention delivery reflected the manualised intervention for the majority of sessions, but there were instances of non-compliance.

Primary analysis

A total of 480 people (intervention, $n = 241$; usual care, $n = 239$) were randomised. Of these, 92 provided no valid primary outcome data, leaving 388 participants (intervention, $n = 191$; usual care, $n = 197$) in the intention-to-treat analysis. The mean score on the primary outcome (i.e. Dementia-Related Quality of Life score) at 8 months was 93.3 (standard deviation 13.0) in the intervention arm and 91.9 (standard deviation 14.6) in the usual-care arm, therefore providing a difference in means of 0.9 (95% confidence interval −1.2 to 3.0) after adjustment for covariates. The estimated mean difference was small (0.9) and the 95% confidence interval for this difference was below the 4-point target difference defined as being clinically meaningful, as specified in the sample size calculation. Of the other eight secondary outcomes, the only difference was found in psychological well-being (measured by the Diener's Flourishing Scale), which was statistically significant in favour of the intervention group (adjusted mean difference 1.2, 95% confidence interval 0.1 to 2.3). At 12 months, the mean Dementia-Related Quality of Life score was 92.3 (standard deviation 14.3) in the intervention group and 91.7 (standard deviation 13.9) in the usual-care arm, therefore providing a difference in means of 0.4 (95% confidence interval −1.6 to 2.5) after adjustment.

The serious adverse event rate was similar across both groups, with 17% (40/241) of participants in the intervention arm and 15% (35/239) of participants in the control arm experiencing at least one serious adverse event. All serious adverse events were considered as either unrelated or unlikely to be related to the intervention.

Fidelity assessment

The facilitator training was assessed as having excellent fidelity. Assessment of the group aspect of the intervention in four sites found good intervention attendance [25 out of 35 (71%) participants attended ≥ 10 sessions and five (14%) participants attended all 16 sessions]. The facilitators maintained very good fidelity to the intervention during the observed group sessions.

Health economic evaluation

In this analysis we explored the cost-effectiveness of the Journeying through Dementia intervention compared with the usual care arm. The observed difference in quality-adjusted life-years between the Journeying through Dementia group and those receiving usual care was small (and non-significant) and favoured the control group (–0.003, 95% confidence interval –0.044 to 0.038). In addition, the Journeying through Dementia intervention cost, on average, approximately £600 per patient (95% confidence interval £105 to £1179) more than usual care. Overall, owing to the small effect size, the Journeying through Dementia intervention was dominated by usual care (i.e. the intervention was more costly and less effective), with an incremental cost per quality-adjusted life-year of −£202,857 (95% confidence interval −£534,733 to £483,739) and results that covered all four quadrants of the cost-effectiveness plane.

Qualitative findings

The majority of interviewed participants said that they did not feel the need to make lifestyle changes yet or were already employing strategies. Participating supporters wanted to meet people in the same situation as themselves and learn from each other. The training for intervention delivery was well received by facilitators and supervisors. However, analysis suggested that around half of the interviewed interventionists found that the recruited participants did not match their expectations in that they were more impaired than they had expected, with this affecting their ability to deliver the intervention.

Views on all aspects of the intervention varied across all those interviewed. The manualised format and content of the intervention was found to be helpful by facilitators for session planning and delivery but participant ability to achieve what the intervention promotes was questioned by some staff. Several participants and facilitators expressed lack of clarity regarding the purpose of the one-to-one sessions, whereas these sessions were highly valued by others. Group dynamics were reported as being challenging in some cases, but were reported as positive in others. Out-of-venue activities were considered to be beneficial, but also caused anxiety for some facilitators and supervisors. The use of community venues for delivery of the group aspect of the intervention was positively viewed by the majority, but transportation difficulties were frequently described. Whether or not participants would continue to meet beyond the intervention was questioned.

Conclusions

The Journeying through Dementia intervention, as described in the manualised intervention, is not clinically effective or cost-effective and therefore cannot be recommended for use in NHS services in its existing format.

The study involved a robust study design and was executed to the highest standards, achieving and retaining the target numbers of participants. Thirteen sites were involved in delivery of a complex intervention. Lack of effectiveness can be attributed to a number of factors. Significantly, the recruited participants had good quality of life at baseline and some of those interviewed did not perceive the need to make lifestyle changes.

The intervention proved challenging for some facilitators to deliver in practice because of the demands it presented to them and their perceptions of the anticipated user group, which did not match the expectations of some.

Attendance and adherence were higher than is usual in service delivery and assessed fidelity was good. Positive experiences of taking part were described by the majority of participants in the qualitative substudy, but negative aspects were also raised by a minority.

Recommendations for future research

- Further consideration of how to support independence and well-being of people with early-stage dementia and, in particular, those who live alone.
- Creation of a method of measuring well-being while living with dementia.
- An appraisal of how to reach those in most need of this form of intervention. (This study recruited well, but it did not necessarily reach those who might benefit.)
- Further robust feasibility and piloting work prior to a full trial and experimentation with different trial designs.

Trial registration

This trial is registered as ISRCTN17993825.

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This report

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