Exercise for depression in care home residents: a randomised controlled trial with cost-effectiveness analysis (OPERA)

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Executive summary

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Executive summary

Background

The population of Britain, as in other countries, is ageing and the residents of care homes are increasingly frail. Many care home residents have depression. Much of this depression is not recognised either by the care home staff or the resident's general practitioner. There is limited evidence that pharmacological treatments are effective for depression in the very elderly and ample evidence for the high incidence of adverse events. The National Institute for Health and Care Excellence guidelines do not recommend drug treatment for mild depression; they suggest that drugs should be used only as part of a more holistic package of care for those with moderate depression. For the elderly, the guidelines recommend that their poor physical state and social isolation should be addressed. Interventions that may address these multiple requirements are therefore needed.

Exercise is a promising non-drug intervention for depression. Exercise may have a central effect on depression through an increase in the release of ß-endorphins, through an increase in the availability of brain neurotransmitters (such as serotonin, dopamine and noradrenaline), or through increases in brain-derived neurotrophic factor. Engaging in exercise may have the capacity to counteract common symptoms of depression, such as negative thought patterns including low self-esteem and anhedonia through distraction, mastery experience, improvements in self-evaluation and a sense of achievement. Further theoretical underpinning comes from the theories of positive psychology, considering the potential of exercise interventions to build on the 'virtues' and 'character strengths' such as love of learning, bravery and hope (expecting the best and working to achieve it). In addition the increased social interaction involved in a group exercise may have positive effects on mood.

Aims and objectives of OPERA

The overall aim of the OPERA study was to evaluate the impact of a 'whole-home' intervention, consisting of training for care home staff backed up with a twice-weekly, physiotherapist-led exercise class on depressive symptoms in care home residents.

Our primary objective was to compare depression levels between intervention and control homes, addressed via three primary analyses that represent different ways of expressing depression levels.

To compare:

- the prevalence of depression in intervention homes with that in control homes in all residents contributing data 12 months after homes were randomised (cross-sectional comparison)
- the number of depressive symptoms at 6 months between intervention and control homes in residents who were depressed at pre-randomisation baseline assessment (depressed cohort comparison)
- the number of depressive symptoms at 12 months between intervention and control homes in all residents who were present at pre-randomisation baseline assessment (cohort comparison).

In parallel with this effectiveness analysis there was a cost-effectiveness analysis, a process evaluation of the study, an ethics study and a post-study evaluation.

Methods

We recruited care homes from two geographical locations: Coventry and Warwickshire (C&W) and north-east London (NEL).

We approached all apparently eligible care homes within the relevant primary care trust areas with between 16 and 60–70 beds. Interested care homes were visited by a member of the recruitment team to assess their suitability. At this time, homes were excluded if fewer than six residents were likely to be able to take part in the study, more than half of the residents had severe cognitive impairment, the majority of residents were non-English speaking, or after discussion with the study team the home felt they were too busy to participate. In care homes in which the managers consented to join the study we assessed all English-speaking, permanent residents, aged ≥65 years, excluding for potential inclusion in the study those with a terminal illness, those who were too ill to be seen at the time of assessment or who had severe communication problems, or those for whom the care home manager felt the study was not suitable for some other reason. We asked residents to give consent, or their next of kin (NOK) to give agreement, for us to collect data directly from participants, and/or from their care home and National Health Service records. Care homes wrote to the NOK of residents who lacked capacity to consent, seeking agreement for them to take part in the study.

Baseline assessments

At the baseline assessment we collected the Geriatric Depression Scale-15, Mini Mental State Examination, EuroQol 5D (European Quality of Life-5 Dimensions; EQ-5D), fear of falling and current pain, a brief physical assessment, and the Short Physical Performance Battery. We collected demographic data (age, sex, ethnicity, age at leaving full-time education) and data on length of residence and fee status from the care home records. Data on current medication use were obtained directly from residents' Medication Administration Record sheets. The resident's key carer or carer looking after them on the day of data collection was asked to complete a proxy EQ-5D, Barthel Index and Social Engagement Scale.

For our cohort analyses, all baseline data were collected prior to randomisation. For the end-of-study cross-sectional analysis we also included participants recruited after randomisation.

Follow-up

We did four cycles of follow-up data collection in each care home over several visits, usually within 1 week, at around 3, 6, 9 and 12 months after the care home was randomised. We collected Geriatric Depression Scale-15, Mini Mental State Examination, EQ-5D, fear of falling, and current pain at 6 and 12 months. We collected Short Physical Performance Battery at 12 months. We collected care home data on medication use, visits by health-care professionals, proxy EQ-5D and the Social Engagement Scale at 3, 6, 9 and 12 months. At these visits we also sought to recruit any new residents to the study.

Primary outcome measure

Our primary outcome measure was the Geriatric Depression Scale-15. This brief instrument consists of 15 yes/no questions and has been well validated in care home populations. It avoids using potentially somatic features of depression that may be misleading in this age group.

Interventions

Any intervention with a care home that is seeking to maximise physical activity and exercise has to be delivered within the existing organisational structures. A 'whole-home' intervention, using an organisational approach to encourage all residents and staff in efforts to increase the residents' level of physical activity, is more likely to achieve the positive effects sought than simply providing group exercise sessions. We used an active control intervention consisting of a package of depression awareness training for care home staff in all participating homes to ensure that they were aware of current best care for the identification and management of depression in this population.

The OPERA intervention was designed to test the effects of exercise and increased physical activity on depression and other important outcomes. We delivered a 'whole-home' exercise intervention, consisting of training for care home staff backed up with twice-weekly physiotherapist-led exercise groups.

The twice-weekly group exercise programme delivered a structured, standardised and replicable programme of exercise targeted at the physiological, biochemical and psychological mechanisms considered responsible for depressive symptoms in older people, which also accounted for the frailty of residents.

Sample size

The sample size was based on showing an increase in the remission rate for depression over 6 months from 25% to 40% at 5% significance level with 80% power. We assumed we would recruit 16 residents per home and that 40% would have depression (6.4 per home). Allowing for 15% loss to follow-up and an intracluster correlation coefficient of 0.05 mean, we needed to recruit 77 care homes (1232 residents) to cohort analyses.

Randomisation

This was a cluster randomised study, with homes as the unit of randomisation. Care homes were first stratified by location (NEL or C&W) and then minimised into intervention and control arms. Allocation concealment was ensured by using a statistician independent of the study.

Economic evaluation

Our primary economic analysis was a cost–utility analysis over 12 months, examining the cost per quality-adjusted life-year gained for all those residents who were assessed for proxy EQ-5D prior to randomisation.

Process evaluation, ethics study and long-term follow-up

Alongside the main study we carried out a process evaluation and long-term follow-up using both qualitative and quantitative methodologies to explore the process of implementing the study in a care home setting to develop a set of transferable principles regarding both the OPERA depression awareness training and the OPERA 'whole-home' exercise intervention to inform its implementation on a wider scale. We did independent observations of the process of obtaining consent from participants. We did focus groups and interviews with key informants about the process of consent in care home studies.

Results

Recruitment

Between January 2009 and March 2010, 78 homes joined the study. Prior to randomisation, we began the assessment process with 907 residents. Six died before randomisation and are not included as study participants, and for a small minority recruitment was complete only after randomisation. We recruited a further 153 participants after randomisation, making a total of 1054 participants. Of the 781 who we assessed prior to randomisation, 765 provided a Geriatric Depression Scale-15 score. Of these, 374 (49%) were depressed and constitute our depressed cohort. We found that older people participating in research may not necessarily welcome the standard informed consent framework of provision of full information and explicit written consent uninfluenced by others.

Follow-up

No care homes dropped out of the OPERA study. For the cohort analyses we obtained 484 Geriatric Depression Scale-15 scores at 12 months: 62% of those assessed at baseline, 79% of survivors and proxy EQ-5D data on 526 participants; 68% of those present at baseline, 86% of survivors. For the depressed cohort analysis we obtained 259 Geriatric Depression Scale-15 scores at 12 months; 69% of those depressed at baseline, 80% of survivors. For the end of study cross-sectional analysis we assessed 631 residents and obtained care home data from 763 residents.

Intervention delivery

Both the control and active interventions were well received by the care homes. The activities of the physiotherapists in the homes were appreciated by both staff and residents. However, there was little evidence that we were able to change activity patterns within the intervention homes or to effect long-term changes after the intervention was withdrawn. We delivered 3191 group exercise sessions with 31,705 resident attendances and an average group size of 9.9 (5.3 study participants). On average, our participants attended around half of the possible sessions. No serious adverse events occurred during the group exercise sessions.

Clinical outcomes

There was no evidence of a positive effect from the intervention in any of our primary or secondary analyses. In the end-of-study cross-sectional analysis the odds for being depressed were 0.76 [95% confidence interval (CI) 0.53 to 1.09] lower in the intervention group. The point estimates for benefit from the OPERA intervention on the Geriatric Depression Scale-15 in both the cohort analysis (0.13, 95% CI –0.33 to 0.60) and depressed cohort (0.22, 95% CI –0.52 to 0.95) favoured the control intervention. There was no difference in fractures incidence rate ratio 1.14, 95% CI 0.60 to 1.63 or mortality [odds ratio (OR) 1.07, 95% CI 0.78 to 1.48] between the two groups. There was no evidence of a difference in the other outcomes between the two groups.

Economic analysis

Resource use and quality-adjusted life-year data, based on proxy EQ-5D, were available for 798 residents recruited prior to randomisation. In the base-case analysis, the additional National Health Service cost of the OPERA intervention was £374 (95% CI –£655 to £1404). The mean difference in quality-adjusted life-years was negligible (0.0014) (95% CI –0.0728 to 0.0699) and favoured the control arm. The probability of the intervention being cost-effective at a willingness-to-pay threshold of £20,000 per quality-adjusted life-year was 33% and at a threshold of £30,000 was 37%.

Discussion

The OPERA study was complex and multifaceted. The nature of both the intervention and population being studied means that a simpler study design would not capture all of the active intervention's possible effects (positive or negative) on care home residents. In addition to obtaining data on the effects of the intervention, we have also been able to investigate, in detail, both the process of running the study within care homes and of implementing a complex intervention within care homes. This has generated high-quality data on both how to do research in this environment and how to implement change in this environment.

The overall findings of the study are clear and conclusive. We developed a high-quality intervention that was extremely well received both by staff and residents within the care homes. Uptake of the intervention was very good and was maintained throughout the 12-month intervention period. There was not, however, any benefit on any of our primary or secondary outcome measures. The limit of the 95% confidence for possible benefit from the OPERA intervention (0.33 points on Geriatric Depression Scale-15) is around one-quarter of the minimally clinically important change for an individual and equates to a standardised mean difference of 0.1, effectively excluding any possibility of a beneficial effect on depressive symptoms, as measured on the Geriatric Depression Scale-15, from the OPERA intervention. Furthermore, in our health economic evaluation the OPERA intervention was dominated by the control intervention, i.e. the OPERA intervention cost more and had worse outcomes. These results are particularly disappointing, as nearly half of our residents were depressed and they are still in need of an effective approach to treating their depression.

That there was no difference in the prevalence of depressive symptoms between baseline and follow-up in the control group (mean Geriatric Depression Scale-15 at baseline and follow-up 4.7 and 4.6, respectively)

suggested that the control intervention was also ineffective and it is not the success of depression awareness training that means we failed to find a beneficial effect from the OPERA intervention.

Overall, this is a very robust study, which has obtained a clear answer to the research question set and has helped to develop our understanding both of how to do research in a care home environment and how care is delivered in this environment.

Conclusions

The results of this study do not support the use of a 'whole-home' physical activity and moderate intensity exercise programme, such as the OPERA intervention, to reduce depression in care home residents. Future research should consider evaluating a multifactorial intervention targeted specifically at care home residents with depression.

Trial registration

This trial is registered as ISRCTN43769277.

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