Older People's Exercise intervention in Residential and nursing Accommodation (OPERA)

Contents

Background

Untreated depression is a major cause of morbidity in older people, particularly in those who live in residential and nursing homes (RNHs). Up to 40% of RNH residents are depressed.[1;2] In many cases this is not recognised by the RNH staff or by the resident's general practitioner.[3;4] Modest improvements in mental and physical health are likely to produce large relative increases in the number of quality adjusted life years available to this group, which has an extremely poor baseline level of health and life expectancy. Antidepressants are a common first line treatment for depression. In a care home setting, a controlled trial suggested that tricyclic agents are effective but poorly tolerated,[5] whilst more modern drugs are well tolerated but are less well researched in this setting.[6;7] The use of drugs as the primary

approach to managing depression in these patients presents three specific problems: firstly the failure to recognise mild/moderate depression, secondly the absence of evidence for their effectiveness in the very elderly (aged > 80),[8] and thirdly the potential for serious adverse events related to their use, in particular because of the multiple medications commonly taken by RNH residents. Typically RNH residents are on 6-8 different medications, with most receiving at least one psychotropic medication.[9-11] The BNF cautions against the use of tricyclic antidepressants in the elderly because they may cause specific problems with drowsiness, urinary retention and hyponatraemia; and against the use of selective serotonin reuptake inhibitors (SSRIs) in patients with cardiac disease, diabetes, and renal impairment, three conditions which are highly prevalent in RNH residents (32%, 20% & 4% respectively).[12;13] Falls are a major cause of morbidity and mortality in older people.

Antidepressant drugs, both tricyclics and SSRIs are associated with a two-fold increase in falls in care home residents.[14] Reducing the burden of depression in RNH residents by using a conventional medical model of diagnosis and drug treatment are likely to fail, because of poor recognition, low intervention rates and the toxicity of medications. More generally there is a move away from drug treatment for mild/moderate depression. NICE 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.[15] Specifically for the elderly, the guidelines recommend that their poor physical state and social isolation should be addressed. Multiple physical morbidities are expected in RNH residents[16] and even lack of social interaction has been shown to be common in observational research in residential settings.[17] There is good evidence that both functional impairment and loneliness are risk factors for depression in RNH residents.[18]

In RNH residents who are not depressed at baseline, the annual incidence of depression is around 12%, with depression resolving after a year in only about half of them.[19] Looking more widely at interventions to reduce morbidity in the frail elderly, there is a growing recognition that addressing single outcomes such as falls, cardiovascular disease or depression as isolated problems inadequately addresses the needs of this group.[20] Physical health problems are independently associated with mental health outcomes in older people, thus an intervention that addresses both has intuitive appeal. To maximise the impact on the outcome of interest, in this case depression, interventions should ideally address patients' general health. Depression in RNH residents is undoubtedly an important health problem, but it is difficult to obtain new resources for its treatment from Primary Care Trusts given the

competing demands for high-cost, life-saving treatment for younger people. Yet depression is a viable target for public health interventions as physical health and costs of care are significantly higher for older people with depression.[21;22]

Thus, an ideal strategy to reduce the burden of depression in RNH residents should:

- not be based primarily on drug treatment,
- not be dependent on a health professional establishing a clinical diagnosis of depression,
- address both the treatment of established depression and the prevention of incident depression, thus reducing the overall prevalence of depression in RNHs,
- improve social interactions,
- be expected to have beneficial effects on multiple systems,
- be economical to deliver.

Exercise is a promising non-medical approach to the management of depression. Plausible mechanisms for its possible effect include improved social contact, a diversion from negative thoughts, and the physiological effects on neurotransmitters such as monoamines & endorphins.[23] A number of systematic reviews which pooled data from different study designs found that exercise improved depression.[24;25] A review of 14 randomised controlled trials suggested that exercise might be efficacious in reducing symptoms of depression in the short term, although all of these studies had significant limitations. Compared with 'no treatment' (usually including an attentional control), the pooled standardised mean difference in effect size was -1.1 (95% CI -1.5, -0.6), indicating a modest reduction in depressive symptoms in favour of exercise. The samples in these studies were diagnostically heterogeneous, ranging from mild depressive symptoms through dysthymia to major depression. Only six studies compared exercise with standard treatments for depression, of which four included cognitive behaviour therapy and only one included antidepressant medication. None of these studies found a statistically significant effect of exercise. Nearly all of the exercise interventions in studies covered by this review took the form of regular sessions of vigorous aerobic exercise, such as running for 20 minutes two or three times per week, supervised by an exercise therapist or personal trainer either individually or in groups. No statistically significant differences were found between aerobic and anaerobic exercise regimens.[26] NICE guidelines recommend exercise as a first line treatment for mild depression.[27] A recent systematic review of the effects of exercise on depression in older people concluded that it might be efficient at reducing depressive symptoms in the short term but that there were insufficient data on its

long-term effect.[28] It identified five RCTs of exercise regimens in older people, all of which were supervised group exercise programmes (mean number of participants 64, range 14-156). Four of these RCTs reported positive results. However, their methodological standard was poor and the longest duration of intervention was just 16 weeks. None of these studies was performed in residential accommodation; and all of them used 2-3 exercise sessions per week. None of them sought to change participants' approach to exercise throughout the week.

Maximising psychological and physiological effects from an exercise regimen requires that increased exercise is built into residents' usual routine. However active residents may be during brief formal exercise sessions, these will occupy only a small percentage of their time. Engineering a system change within RNHs so that increased exercise is both facilitated and actively encouraged will ensure that residents are regularly exposed to the intervention throughout the week.

In this trial we are testing a pragmatic intervention, reflective of current best practice, consisting of training for RNH staff to support the building of safe physical activity into the RNHs' normal routine; and a twice-weekly formal exercise class led by a specially trained physiotherapist. This is a 'whole RNH' intervention; all residents without an absolute contraindication to exercise will be invited to attend the class and to increase physical activity generally. This will allow depressed residents to benefit from interaction with non-depressed residents; and reflects how such a programme, if effective, might be implemented in RNHs by NHS physiotherapists. Furthermore, it may: avoid the use of drug treatment; demedicalise mild/moderate depression; confer wider health benefits; improve social interactions within RNHs; and have beneficial effects on all residents.

This is a cluster-randomised trial with the RNH as the unit of randomisation and residents as the unit of assessment to assess the impact of a whole RNH intervention to increase exercise on the prevalence of depression and the remission of existing depression.

Research objectives

Our objectives within this cluster-randomised trial are to evaluate the impact of a 'whole home' intervention, consisting of training for residential and nursing home staff backed up with a twice-weekly physiotherapist-led exercise class, on:

- Prevalence of depression in those able to complete assessments twelve months after their homes are randomised (our primary outcome).
- The proportion of residents depressed at baseline that experience remission from their depression six months after their home is randomised.
- Change in the severity of depressive symptoms in depressed residential and nursing home residents twelve months after their home is randomised.

We will also examine the following secondary outcomes:

For all residents participating in assessments

- Health related quality of life
- Mobility & exercise tolerance
- 'Fear of falling'
- Cognitive function
- Chronic pain

For all residents with consent/assent to examine the medical and care home records

- Incidence of injurious falls as indicated by peripheral fractures
- Mortality
- Hospital admissions
- Prescribing costs

In addition, we will assess the cost-effectiveness of the exercise programme from both a societal and an NHS perspective.

Methods

Our focus is on testing an intervention, which if shown to be effective, could be implemented as part of routine health/social care. An exercise intervention as part of routine care in RNHs will be difficult to introduce into normal practice if it is to be available only to those who have been diagnosed with depression because of the need formally to identify those entitled to attend; and it is less likely to be effective if only those who are depressed attend. If a positive approach to increasing exercise in the residents is built into the values of RNH staff, the likelihood of an exercise intervention having a positive effect will be maximised. For these reasons we are testing a whole-home intervention consisting of a training programme for RNH staff, supported by a twice-weekly physiotherapist-led exercise class. Since all residents will be exposed to the intervention its effects, positive or negative, on mental and physical health may affect both those who are depressed and those who are not depressed. It therefore makes sense to seek outcomes for all RNH residents. Indeed, it would be difficult to justify excluding the non-depressed population from an assessment of possible harm from the intervention. With an ongoing intervention these effects, positive and negative, will continue to accrue in the long term. Thus our pragmatic primary outcome of interest is the proportion of RNH residents who are depressed one year after randomisation. Our more explanatory primary outcomes are remission of depression after six months, and reduction in the severity of depressive symptoms after one year, in those who were depressed at randomisation.

Conceptually this is a very simple trial to find out if exercise helps depression. However, we are proposing a complex intervention that involves all residents and staff in participating homes. Thus we need to do additional work to understand how the intervention works in practice and to explore any barriers to implementation; and we need to measure its effect on both depressed and non-depressed residents. Only by measuring its effect on the health related quality of life of all residents can we carry out a robust health economic analysis, and it is essential that we measure any potential harms from the intervention in all those who are exposed to it.

Planned Interventions

Control intervention (Depression awareness programme)

In line with the MRC's Good Clinical Practice Guidelines there is an active control intervention in all participating RNHs to ensure that they are aware of current best care for the identification and management of depression in this population.

- By using current best care as our control, we can ensure that any benefits identified are due specifically to our intervention package rather than to raising awareness of depression within the intervention RNHs.
- We will reduce the risk of 'resentful demoralisation' in the control homes affecting recruitment of new residents after randomisation or even leading to the RNH withdrawing from the study.[29]

We have developed a depression awareness programme for RNH staff. This consists of brief in-service training for RNH staff backed up with a DVD on recognizing depression, information leaflets/posters and regular contact with study team members. As an addition to best usual care we inform the RNHs of all participating residents' GDS-15 scores. In the control homes our research nurses deliver this intervention soon after randomisation and when they visit the homes for recruitment and follow-up.

In the active intervention RNHs the depression awareness training delivered by the research physiotherapists as part of the overall intervention package.

Active intervention package (exercise programme)

There are two inter-linked components to the intervention:

- physical activation programme, and
- group-based exercise

We anticipate that our intervention, as well as improving mood should also improve functional abilities, reduce falls, and improve mobility.

Physical Activation Programme

The physical activation programme promotes a commitment to encouraging safe physical activity for residents of the home. Evidence suggest that for a complex intervention of this nature to be effective it

needs to be 'normalised'; that is, it should be seen as part of the organisation's normal functioning rather than as an optional extra.[30] Although there is no direct evidence to inform the content of our strategy, evidence from other nursing homes projects is informative (see below). The physiotherapists are asked to do the following:

- Implement a depression awareness programme (see above).
- Improve knowledge and awareness of the benefits of physical activity in the staff, residents and relatives.
- Provide an individualised review of mobility safety. Ensure that appropriate and safe walking aids (including grab rails where needed), and footwear are available to each individual, and reinforce the need for use.[31]
- Provide advice on activation strategies for individual clients, including the level/type of assistance/supervision needed, and support the staff and residents in their implementation.
- With the Director of Nursing/Home Manager, review the policies and strategies in place to promote physical activity.
- Where appropriate, involve volunteers and families in the supervision and promotion of physical activity.
- Identify a physical activity 'champion' within the home who will serve as the main point of contact with the therapist and undertake regular review of the organisation's progress. The main activity that will be targeted in the physical activation programme will be safe walking. This is a realistic aim.[32]

Group-based exercise

All residents are invited to attend twice-weekly group exercise sessions in the communal space of the homes. This is a rolling programme; all new residents are encouraged to enter the groups as they enter the home. The groups are led by physiotherapists experienced in managing frail older people. Timing of the sessions seeks to facilitate maximal likelihood of attendance. The sessions use mixed training stimuli, combining aerobic conditioning, progressive strength and balance training. The programme utilises music and rhythmic, simple movement patterns. The group sizes are do not normally exceed eight participants, and last 40 minutes to an hour depending on the tolerance and ability of the group. Prior to the groups, the physiotherapists give each participant a brief risk assessment; determining any absolute contra-indications to exercise[33], and the optimal exercise intensity for each participant. The physiotherapist may have a group with a range of abilities, and thus intensity is set to

ensure safety of all participants. In larger homes, where there may be a need for several groups, physiotherapists will group together participants with similar levels of ability, and set the intensity of exercise accordingly. It is challenging to gain engagement and attendance from depressed individuals, but maximising participation is essential to demonstrating effectiveness of the technology. Consent/assent to study assessments does not indicate consent to participate in the exercise class on any particular day. Best clinical practice for consent to physiotherapy treatment is complied with to obtain agreement from individuals for participation in the exercise class. The physiotherapists work with staff to gain participants' trust and acceptance of the programme. All residents will have an activation prescription in addition to the exercise classes (see below).

Rationale for the programme-The design of the programme has been informed by an extensive literature search and the practical experience of the team. In summary, there are three main hypotheses suggesting how exercise can alleviate depression, and a limited amount of experimental evidence. Aerobic activity may affect circulating corticosterone, or hippocampal brain neurotrophic factors, or correct dysregulated monoaminergic neurotransmission, all of which are implicated in the origins of depression.[34-36] Improved self-esteem and self-efficacy, distraction from negative emotion and behavioural activation are also thought to alleviate depression.[37] Experimental evidence also supports progressive strength training as a method of reducing depression.[38] We have therefore proposed a mixed exercise programme. Therapists attend a two-day course to be trained in the intervention. The intervention is documented and standardised, but allows therapists a range of options to adapt the content to the needs of the groups/settings. This approach has been successful in previous studies we have conducted with physiotherapists; therapists are happy that the approach reflects their practice and, importantly, it is possible to document the concept and method with the precision necessary for replication and dissemination.[39] This approach utilises recognised methods of selecting baseline exercise intensity, and progressing exercise,[40] modified for frail older people. Exercise that utilises rhythmic movement and reflex motor activation is effective in people with cognitive impairment.[41] The intervention seeks to minimise unwanted side-effects including an increase in falls and pain.

We are including non-depressed residents in the exercise programme because:

- Non-depressed adults will stimulate those who are depressed to participate,
- It is difficult to predict who will develop incident depression, or outside the trial situation to identify those with mild/moderate depression; thus an inclusive approach is needed for both prevention and treatment,
- Pragmatically, this is how classes would be/are run. Strength training is important for a range of geriatric syndromes which overlap with depression, and residents are likely to have multiple health problems. It would be inconceivable that multiple classes would be set up to target falls and depression separately.

Effecting organisational change- A growing body of evidence on diffusion of innovation and implementation of research/guidelines into clinical practice has highlighted the importance of organisational context as a key factor in effecting change in practice.[42;43] Successful implementation is more likely if the intervention/guideline resonates with the experience of those being asked to embrace it.[44;45] Embedding the exercise intervention within a whole-home strategy that actively engages with the organisational context in which the intervention is delivered should enhance the effectiveness of implementation. There is no guidance for implementation of physical activity programmes in nursing homes, but research on the implementation of clinical practice guidelines has demonstrated that a number of issues need to be addressed. These include:

- Perceived or real workload issues
- Poor communication with nursing/therapy staff
- Insufficient knowledge or education
- Large staff turnover.[46]

We have adopted a range of strategies (see above) based on our knowledge of working with homes and informed by best available evidence.[47;48]

Safety and grade of staff - Several studies have shown that low intensity and poorly implemented physical activation programmes may increase falling[49;50] and pose a threat to the safety of older people living in nursing homes. We consider it essential to the safety of participants that experienced therapists implement the intervention. They need to have the essential awareness of the multiple health problems facing older people in care settings, of exercise prescription in frail older adults, and of promoting safe mobility. If successful, future studies would consider whether fitness instructors could deliver the

intervention, or components of it, and what level of additional training and supervision they would require. We will undertake an assessment of the competencies and skills required to deliver the intervention. In the event that any participants suffer an injury during the exercise class we will do a critical event analysis.

RNH recruitment-We will recruit roughly equal numbers of RNHs in two localities, North East London and the West Midlands. We have agreement from two local NHS Trusts (Barking & Dagenham Primary Care Trust (PCT), NHS Coventry, NHS Warwickshire, and Coventry & Warwickshire Partnership Trust,) to support this project and, in some cases, to host the service delivery components of the study. We will initially approach all RNHs in these Trust's localities and then approach RNHs in neighbouring PCTs' localities. There are over 80 RNHs in Barking & Dagenham and the neighbouring Havering. There are around 135 RNHs in Coventry & Warwickshire Partnership Trust's locality. These two localities have diverse populations that are representative of the social and ethnic mix of the UK as a whole. We decided against recruiting RNHs that cater exclusively for none-white residence as such RNHs are scarce and there would be difficulties in delivering the intervention and measuring outcomes in non-English speakers; there would also be problems appropriately randomising such atypical RNHs. We are seeking to recruit RNHs with a range of characteristics (large / small, independent/chain, local authority / private / charitable, purpose-built / traditional, nursing / residential, dementia specialism / not).

Participant recruitment- Residents may participate in the study in three ways:

a) completing the baseline and follow-up assessments
b) allowing their routine data to be accessed by the study team
c) participating in the exercise programme

We consider 'a' and 'b' here; 'c' will be considered separately under the intervention. Once the RNHs have consented to join the study we will consider all permanent residents for inclusion in the study:

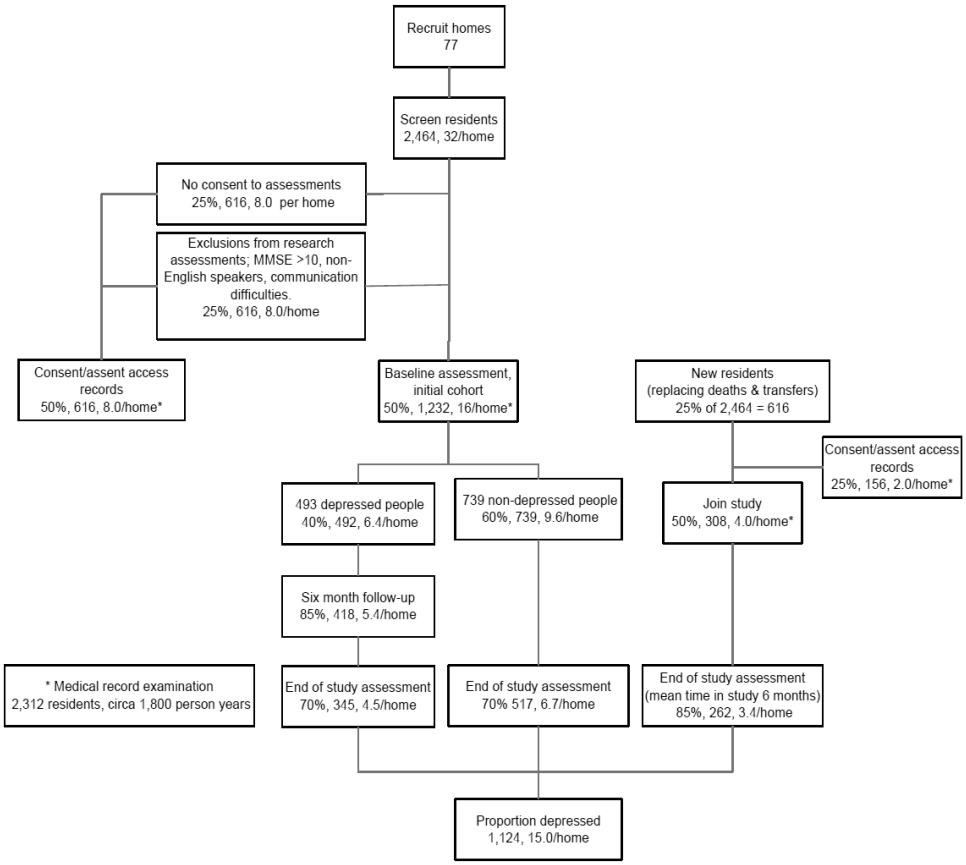
1. The RNH identifies those residents whom it would be inappropriate to approach for consent/assent either directly or via their next of kin, for example those with a very limited life expectancy.
2. A specially trained research nurse briefly assesses each remaining individual to explain the study and to assess his/her competence to give consent and to participate in the research assessments. Residents are given information about the study in a suitable format (e.g. large print or audio). The RNH and research nurse identify those residents who will clearly be unable to participate in any

assessments but who nevertheless may be able to give consent to the use of their routine data. This group might include those unable for any reason to communicate in English sufficiently well to participate in the assessments.

3. Competent residents have the opportunity to reflect on whether they wish to join the study prior to giving consent to the assessments and/or the use of their medical records. At this stage we will also seek consent from residents to contact their next of kin to collect data for the health economic analysis at the end of the study.
4. The next of kin of those deemed not competent to consent to the study assessments are approached for their assent for the resident to take part in the assessments and/or the use of their medical records. If no next of kin can be contacted we will, as suggested by the 2005 Mental Capacity Act s32(3), nominate an appropriate person, e.g. Age Concern Advocate or GP, to give assent (http://www.opsi.gov.uk/acts/acts2005/20050009.htm).

We will repeat this process for any new permanent resident moving into participating RHNs upto nine months following that RNHs randomisation.

Figure 1
Overall study design



Baseline assessments-

The baseline assessment takes place after consent/assent has been obtained. At this assessment, we confirm eligibility, specifically excluding those with severe cognitive impairment who are not able to complete the GDS-15. In the original protocol we specified a that people with a Mini Mental State Score of ≤10 would be excluded.[51] Experience in the pilot study indicated that even people with quite severe cognitive impairment could complete the MMSE, and some whith an MMSE score <10 were unable to complete this. We have therefore removed this entry criterion.

The assessment lasts around 30-60 minutes, the research nurse administers our questionnaire instruments (GDS-15, Euroqol MMSE, Barthel Index, fear of falling, current pain) and a brief physical

assessment (SPPB) verbally, and complete on paper whilst with the resident and will then enter the data directly onto a study laptop after the assessment time with the resident.

We collect demographic data (age, sex, ethnicity, social class – age left school) and data on length of residence, fee status and current medication from the RNH records for all those for whom we have consent/assent to access their records.

The diagnosis of depression is commonly overlooked in RNH residents.[52] It would be inappropriate, once we have identified depression, to prevent these residents from accessing appropriate conventional health care. We therefore provide the RNH staff with participants' Geriatric Depression Score (GDS-15) scores, and an interpretation of their meaning, prior to randomisation. If the GDS score is 10 or more we encourage the home to discuss this result with the resident's general practitioner.

Randomisation and protection from bias- Randomisation takes place after we have collected all the baseline data in the individual RNH. This ensures allocation concealment for existing residents at the start of the study. For each location, we will minimise by size and type of home (local authority/voluntary/private/residential/private nursing/dementia specialist (>50% dementia beds)). A statistician separate from the rest of the study team is responsible for the randomisation. For new residents joining the study after randomisation allocation concealment will be impossible because all RNH staff and study staff visiting the RNHs will be aware of the home's allocation. Indeed, one marker of success for the programme will be achieving this obvious level of awareness. Lack of allocation concealment may bias recruitment for this minority of residents joining the study after randomisation.[53;54] We will protect against this by ensuring that we are aware of all new residents and monitoring reasons for exclusion from the study. In the event that there are differences in the baseline characteristics between intervention and control RNHs in those who join the study after randomisation, we will consider basing our analysis of the proportion of residents depressed at the end of the study only on those residents who joined the study before randomisation and who were present at the end of the study. We will have sufficient power for this analysis.

Our primary effectiveness outcome, the GDS-15, and other questionnaire data will be collected by our research nurses, who will be aware of the RNH's randomisation status, directly onto a study laptop. We will use linear regression modelling to explore outcome data for individual data entry bias. More

potential for bias exists in the physical function assessment; this is unavoidable. Our overall mortality data will be not be prone to bias; our interpretation of cause of death data will be blind to allocation.

Table 1, Inclusion/exclusion criteria

Inclusion Criteria	Exclusion criteria
Assessments	
• Permanent resident in RNH • Aged 65 or over • Consent/assent to assessment • Able to participate in baseline assessment • GDS-15 score ≥5 for baseline depression[55]	• Severe cognitive impairment (MMSE <10) • Problems communicating by any means • Terminal or other serious illness • Non-English speakers for who a translator is not available
Record examination	
• Consent/assent to record examination	
Exercise class	
• Able to transfer (with assistance from one person) from a wheelchair to a chair	

Initial phase of study - The intervention is grounded in previous work on group exercise programmes and studies involving RNHs and their residents.[56;56;57] All of the components build on existing work; however these have not been tested together. Informed by the MRC framework for testing complex interventions, and specifically our previous work on modelling a complex intervention for falls prevention, we decided on the final components of the intervention in the pilot stage.[58;59] We will piloted our recruitment processes in three homes during the six months before the main study started. In two of these we piloted the active intervention and in the third we will piloted the control intervention. This will allow us to test all our recruitment, intervention and follow-up processes.

Follow-up- Follow-up assessments for all consenting/assented residents are one year after the home is randomised. In addition those participants who were depressed at baseline have an assessment six months after randomisation. If any of those who were depressed at baseline have moved to another RNH in the locality, or if they are in a local hospital when their assessments are due, we will endeavour to carry out their assessments in these alternative locations.

Sample size

Because few RNH residents move out of residential accommodation we anticipate good follow-up rates. This population has a high mortality, up to 34% per year;[60] additionally, for some, their health will deteriorate so that they are no longer able to complete some, if not all, of the follow-up assessments. However, those residents with the poorest health will be less likely to join the study, so that we can anticipate a smaller attrition rate. The nearest equivalent study collected data on 169/220 depressed residents after 9.5 months (77%)[61], equivalent to 71% at one year. We therefore anticipate a loss to follow-up rate of 30%, made up of those who have died and those no longer willing or able to complete the assessments.

Table 2, Sample size calculations

	A) To show a reduction in the proportion of participating residents depressed (GDS-15 <5) at the end of the study from 40% to 25%	B) To show an increase in the remission rate after six months from 25% to 40% in those depressed at baseline	C). To show a mean reduction in GDS-15 score of 1.2 after twelve months in those depressed at baseline
Power	80%	80%	80%
Significance	5%	5%	5%
Simple sample size	343	343	280
Mean cluster size at follow-up	15.0	5.4	4.5
Inflation factor	1.7	1.22	1.175
Total number required at follow-up	583 with complete assessments	418 with depression at baseline & complete assessments	330
RNHs required	39	77	74

All of our sample size estimates include an inflation factor to account for clustering effects. Few previous studies are available to allow us to estimate the range of likely values for the intra-cluster correlation (ICC) needed to estimate this. We have therefore used a conservative value of 0.05 for the ICCs for the different outcomes, towards the upper end of the range seen in previous primary care studies. The inflation factor also depends on the average cluster size and the variation in cluster size. Our average cluster size is different for our three outcomes relevant for sample size calculations (table 2 and figure 1). Data on variation in cluster size are not available, but we expect any effect on our sample size

to be modest[62] and that our conservative estimate of ICC will to some extent allow for this. To reduce NHS treatment costs we are using an unbalanced randomisation:- 1 intervention home:1.5 control homes. All our estimates are based on this unbalanced randomisation. The mean change in the GDS-15 score in a community sample of people aged over 85 after a major negative life event (death of partner) is 1.2.[63] This is indicative of a clinically important mean difference in GDS-15. The standard deviation of the GDS-15 nursing home residents is in the range 3.2 -3.6.[64-67]; for depressed residents it is 3.5[68] We have used a standard deviation of 3.5 in the sample size calculation for comparison 'C' (table 2). Comparison 'B' needs the largest number of homes. We will therefore recruit 77 RNHs to the study at the rate of 3.5/location/month for 11 months in year two of the study, plus three pilot RNHs in year one of the study.

Power for primary analysis

Our primary analysis will be a comparison of the difference in proportion of depressed residents at the end of the study. Recruiting participants from 77 RNHs gives more than 97% power to detect this at the 5% significance level, even if we need to exclude residents recruited post-randomisation from this comparison. It also means that, for our primary analysis, we have sufficient power to allow for likely variation in cluster sizes even if our ICC is as high as 0.05 (expected increase in sample size required ~15%) and can also allow for physiotherapist effects; a single physiotherapist will carry out the exercise programme in more than one RNH, and clustering effects due to physiotherapist may therefore occur.

Process evaluation of implementing the intervention- To help to optimise our intervention and gain general information on effecting organisational change in RNHs are studying the process of implementation in the pilot RNHs. This evaluation consists of in-depth interviews with RNH managers and a purposive sample of care staff, patients and their carers, to explore their experiences of the programme, their beliefs about the facilitators and barriers to involvement, and their views on the process of consent for participation in the study. Interviews with RNH managers will also cover their reasons for taking part, their feelings about the study, and their beliefs about the potential for long-term changes in the home as a result of the intervention. All interviews are audio-taped and transcribed for analysis using the Framework method.[69] We will use participant observation of the in-home training sessions on depression and the exercise classes, and collect process data including the number of patients enrolled, number of drop-outs, number of patients giving individual consent, and number of patients requiring carer's assent. Data from the interviews, observational work and process data has

been triangulated and fed back to the research team to assist them in optimising the intervention prior to the main trial. Data will also be fed back to the home staff, patients and carers to enable them to participate in the refinement of the intervention. A full protocol for the process evaluation has been developed from the results of pilot work and is available separately.

Ethical arrangements

This study is a complex intervention within a cluster-randomised trial involving a potentially vulnerable participant population, some of whom will be unable to give consent. Thus raises a number of ethical issues, including consent to cluster randomisation, individual consent to the exercise component of the intervention, participation in research assessments and access to records. Specific measures have been incorporated into the study to address these issues, drawing on recommendations for good practice as well as legal and regulatory frameworks. These include:

- Involvement of local relevant user groups as part of gaining consent for cluster randomisation.[70-73]
- Specific training for research nurses in assessing competence for consent to assessment and access to records*
- Next of kin assent for those residents not competent to consent*
- Best clinical practice protocol for obtaining agreement of residents to participate in exercise classes. We are not aware of any published guidance on this point. We will work with relevant user groups to develop these for use in this study
- Information leaflets available in the home for residents, families and staff providing basic information about the study

(*Compliance with Mental Capacity Act 2005 sections 3, 30-34. http://www.opsi.gov.uk/acts/acts2005/20050009.htm)

To explore these issues further we will, hold two focus groups to explore the views of key informants in the wider community (representatives from local and national user groups) about carrying out this study in nursing and residential homes and the process of consent for such research. This will inform detailed ethical analysis of our proposed approach to recruitment and consent.

Research Governance

This is a relatively high-risk study that will require regular monitoring of peripheral fracture rates and mortality; a well- functioning DMEC and TSC are essential. There would be particular concern if any exercise-related deaths were identified. There is a rigorous programme of quality control. We will employ a second research fellow based at Warwick who will be responsible for the process evaluation and qualitative aspects of the study. Part of his/her duties are to ensure adherence to the study protocols within the RNHs. To achieve this s/he will periodically observe the consent/assent process and baseline and follow-up assessments. In the pilot study a senior member of the study team (ASl) will also observe the consent process in a sample of cases. The clinical research fellow and the process evaluation research fellow based at Warwick will share responsibility for quality control of the interventions. The clinical research fellow will periodically make quality control visits to observe the group exercise sessions; the process evaluator will ensure quality control for the implementation of organisational change and for the control intervention. Quality assurance checks will be undertaken by the WCTU to ensure the integrity of randomisation, study entry procedures and data collection.

Adverse Event Monitoring

We have prepared a protocol for monitoring and reporting adverse events (V1.3_13 10 08). The protocol covers the specific requirements for recording and reporting adverse events in a cluster randomised trial where adverse events are expected to be high due to the age and frailty of the participants. The protocol distinguishes between adverse events that are directly attributable to the study interventions, and the monitoring of peripheral fractures and deaths indirectly attributable to the study.

Data analysis

Outcome measures **-** Because of the poor state of health of many of our study participants. We are using a parsimonious set of outcome assessments. We will collect these at one year on all participants and additionally at six months on those who were depressed at baseline. We have selected six months for our primary analysis of remission of depression. Within drug trials we would expect maximal effect to be seen by four months. If exercise were an effective treatment for depression in this group we would expect a response in a similar time. However, there will be a time lag between randomisation and participants gaining any benefits from the exercise programme because of the time taken to start

changing the attitudes of the RNH staff and to establish the class as a regular routine in the RNH. We anticipate that the intervention should be fully functional two months after randomisation; and our first assessment will be after six months. In addition to the patient-centred outcomes we will run a detailed process evaluation alongside the study to develop an understanding of how to interpret our findings and to inform implementation strategies if we demonstrate a positive treatment effect.

Primary outcome – Depression

The primary outcome measure is the geriatric depression scale 15 (GDS-15).[74] This brief scale/score consists of 15 simple yes/no questions and has been well validated in residential situations. It avoids using potentially somatic features of depression which may be misleading in this age group, focusing more on mood and functional symptoms of depression.[75] It is one of the most widely used measures in this field.[66] It is simple to complete, with 97% of cognitively intact nursing home residents producing analysable data, and it has good internal consistency (0.8) in this population.[66] The GDS-15 can be interpreted as an indication of the presence/absence of depressive mood. A score of five or above appears to give the best sensitivity and specificity.[67;76] The GDS-15 has also been used as a continuous measure in at least one RCT based in a nursing home.[77]

Notwithstanding the good previous validation work on the GDS-15 we will assess its performance in our pilot homes before starting the main study. In particular we will compare the performance of the GDS-15 with the GDS-12R, a infrequently used measure, that excludes some items in the GDS-15 that may be redundant for those in residential care.[67]

Secondary outcomes

1. Quality of life- The EuroQol is a widely-used brief measure of health utility.[78;79] It measures quality of life using questions in five domains, the EQ-5D, plus the EuroQol thermometer. To reduce questionnaire load we will use the EuroQol as our overall measure of health-related quality of life and for our health economic analyses. It has been used satisfactorily in nursing home residents.[80] Previous work suggests that it is better at picking up serious illness and has fewer floor effects in groups like this than other measures, such as the SF-6D.[81;82]

   We have some concerns about the completion of the EQ5-D by some of our cognitively impaired participants. In particular completion of the "Euroqol Thermometer" may be difficult for some residents. Wherever possible we will use participant self report – however for some cognitively

impaired participants this may not be possible and we will use proxy values based on the judgment of their carers within the home. To avoid the possibility of introducing bias if a carer provides a proxy value at follow-up assessment when the participant's health had deteriorated during the study we will collect proxy values for all participants at each time point. When participant self report is not available at all assessments we will use the proxy values for that participant.

2. Mobility - The effect of the programme on mobility is assessed using the Short Physical Performance Battery (SPPB), which incorporates three essential aspects of mobility that should be improved by the exercise programme; balance, chair rise and walking ability. The SPPB has been used extensively in trials and observational studies of older people. Because of the central importance of physical function to the ability to thrive, has well established and surprisingly strong relationships with a range of important public health outcomes, including onset and progression of disability; mortality and nursing home admission.[83;84] The SPPB is particularly well suited to frail elderly populations. Testing procedures are standardised and timed. A change of 0.5/12 points is considered a small but meaningful change, and 1.0/12 points for more substantial changes. Our sample size is more than adequate to detect differences of this magnitude in the context of published estimates of the expected standard deviation of the score.[85]
3. Falls- There is evidence to support the use of multi-factorial interventions in falls prevention in nursing homes.[20] What is less clear is whether all elements of these interventions are needed and whether the interventions reduce injurious falls. Indeed one RCT of a low intensity exercise intervention found an increase in falls in the intervention group (43% vs. 56%),[86] whilst a more intensive intervention succeeded in reducing both falls (OR 0.49, 95%CI 0.37-0.65) and hip fractures (OR 0.23, 95%CI 0.06-0.94)[87]. Whilst we are optimistic that our intervention will reduce both falls and falls injury, there is a justifiable concern that, by encouraging residents to be more active, it might lead to an increase in falls. This is a potential barrier to implementation. Collecting reliable data on actual falls in an RNH environment is problematic, and it is not the primary focus for this study. Furthermore, the cluster randomised nature of this study means that RNH staff may be prone to bias in reporting falls. We will therefore address this outcome in two ways:
   a) We will ask participants about their fear of falling by asking "Are you afraid of falling" requiring only a simple yes/no response from participants.
   b) Rather than measuring falls, most of which do not cause injury, we will measure the rate of peripheral fractures as a marker for injurious falls. We will identify these from the RNH and hospital records. Since all residents will be exposed to the intervention, its positive or negative

effects on fear of falling and injurious falls will affect all residents. It is important that all residents, not just those who are depressed, are included in this outcome assessment. We collect these data on all residents for whom we have permission to examine their medical record.

4. Cognitive function - We will measure this using the mini Mental State Examination.[89] This scale, which measures the key domains of cognition, is easily the most widely used measure of cognitive impairment worldwide. It is quick, validated in relevant populations, sensitive to change and allows comparisons to be made with other studies. There is a suggestion that exercise may have a direct effect on preventing cognitive decline.[90] This is therefore an important secondary outcome. One issue that may arise is the possibility of people initially screening positive for depression (on GDS-15) and cognitive impairment (on MMSE). It is well known that some older people, when treated for depression improve cognitively; in the most marked case this can unveil a misdiagnosis often known as 'pseudodementia'. Initial interest in this situation was stimulated by reports that it was common.[91] Subsequent careful neuropsychological evaluation of people with depressive symptoms indicates that cognitive dysfunction found in depression tends not to normalize after treatment of depression and may in fact be a marker of high risk of development of dementia.[92-94] Co-morbidity between dementia and depression is very common in the care home population and both depressive symptoms and cognition are outcomes in this study. Irrespective of significant cognitive improvement (likely to be rare), the primary analysis will be of resolution of depressive 'caseness' (GDS-15 >5); cognitive improvement will be an independent secondary outcome. Such cases will not require reclassification in statistical analyses.
5. Pain - The association between pain and depression in older people is well recognised.[95;96]Exercise may have a beneficial effect on pain in this population, independent of the beneficial effects it may have on depression.[97] We will ask participants to rate their current level of pain, i.e. pain today, on a ten-point numerical rating scale at each follow-up.
6. Social Engagement We have included a social engagement measure to allow us to measure interactions with other residents, staff and family and friends. Increased social interactions could be an important benefit both from changing the homes approach to exercise and from the group exercise sessions. The social Engagement Scale designed for use in nursing and residential home care gives an indication of the involvement of a resident in activities within a nursing or residential home. The Social Engagement Scale uses six items from the Minimum Data Set residential assessment instrument (MDS-RAI).

7. Medication use- We will estimate participants' medication use over the follow-up period using data on their regular medications collected at baseline line, three, six, and nine months after randomisation/study entry, and at the end of the study. We will use these data to estimate their total use of medication over the study period. For anti-depressants, other psychoactive drugs, analgesics and NSAIDs we will convert these into the number of defined daily doses used over one year (http://www.whocc.no). We will estimate total cost of prescription medication using the prescribing and cost analysis database (http://www.ic.nhs.uk/pubs/prescostanalysis2005). We have used this general approach successfully in a previous HTA-funded study. We will collect these data on all of those from whom we obtain consent/assent to examine their records.
8. Hospital admissions -We will extract data on cause and duration of any hospital admissions during the study period from participants' hospital records. We will code these admissions into Diagnosis Related Groups to identify any fractures and for the economic analysis. Since our participating RNHs are in defined localities we will need to visit only a small number of hospitals. Because of the large health service cost associated with hospital admission we will collect these data on all of those from whom we obtain consent/assent to examine their records.
9. Death - Records of all those from whom we obtain consent/assent to examine their records to be flagged at NHS central registry. This will allow us to identify any differences in mortality between the two groups at an early stage. For those who die within the RNH we will ask the home for a brief description of how they died; for those who die in hospital we will extract this information from their hospital records. Medical members of the study team, blind to participants' allocation, will assess these reports. In the event that any death is deemed to be exercise- related on the basis of these brief reports, we will make a detailed assessment as to whether it was related to our programme.

Statistical analysis

To assess the adequacy of our randomisation process in achieving balanced groups we will compare the characteristics of RNHs (location, type and size of home) and individuals (age, sex, baseline assessment scores) in our intervention and control arms using simple descriptive statistics. To assess whether there is clustering by physiotherapist we will summarise outcome measures by RNH and, in the intervention arm, physiotherapist, and use computer software that can measure the extent of clustering at two levels to estimate clustering parameters. To assess the difference in proportions depressed at 12 months between intervention and control homes we will initially use generalised estimating equations (to account for clustering by RNH) with a logit link (to allow for a binary outcome) in Stata. We will

include co-variates in our analysis. Ideally these should be chosen on the basis of predictive value. As far as possible we will assess evidence from the previous literature to identify potential co-variates. However, the strategy of choosing co-variates based on predictive value arises from work pertaining to individually randomised trials and application to cluster randomised trials is more complicated, particularly for individual level co-variates and binary outcomes.[98-100] In addition, the previous literature from which we can identify cluster-level co-variates is not extensive. We therefore propose the following strategies for co-variate identification:

For our primary outcome, the proportion of residents depressed at the end of the study, we will consider the following cluster-level variables for incorporation as co-variates in our models:

(1) location of home (our stratification variable).
(2) measurable characteristics of care homes and residents identified from previous literature as related to the prevalence of depression;
(3) baseline level of depression in care home (based on empirical evidence that baseline levels of outcome are often important co-variates);
(4) other measurable characteristics of care homes or residents within care homes hypothesised by the study team as being related to outcome.

The co-variates to be included will be finalised in a statistical analysis plan prior to analysts becoming unblinded to randomisation group.

For other outcomes which indicate a change in severity of depression for those depressed at baseline, remission rate and geriatric depression score-15 score we will use a similar strategy, but for these outcomes measurements at baseline and outcome will be of the same individual. We will therefore introduce baseline levels of depression severity as co-variates at the individual, rather than the cluster, level.

If our preliminary analyses indicate the presence of additional clustering by physiotherapist, we will need to incorporate this in our analyses of outcomes. This will be done using WinBUGs software which allows the building of flexible mixed-effect models such as that needed to incorporate clustering by physiotherapist which, if it exists, will exist in only one arm of our trial.

Health economic analysis

We will perform two health economic analyses. Our primary analysis will be a cost utility analysis examining the cost per quality adjusted life year gained for all those residents we have assessed. This is a more meaningful analysis than the alternative analysis that just examines those who were depressed at baseline since the costs, and any potential benefits, will be related to all of those exposed to the intervention. However we will not have health utility data on those who did not participate in the assessments. These residents will also have been exposed to the intervention. We will therefore do a secondary costs and consequences analysis to assess the impact of our programme on the prescribing and other health care costs for all residents where we have consent/assent to examine their records.

The variations around the 'average' resource used in the different homes will be used to inform the sensitivity analysis around the results, to check whether the cost utility result will be drastically altered under different estimates. Building on our previous work modelling the impact of implementing falls guidelines[59] during the pilot phase, we will monitor the recruitment and retention of the exercise programme and take note of how these change over time. This will allow us to assess the impacts these may have upon the cost-effectiveness of the programme and to discover whether there are ways of optimising the cost-effectiveness of the intervention for the main study, and of implementation strategies if the intervention is shown to be effective.

Costs will be obtained at a micro-level by recording units of resources used in intervention and control groups; local and/or national cost tariffs will be applied to the resources used. Care will be taken to measure the variations around the 'average' resource used, to allow for sensitivity analysis around the results. The intervention home costs will include physiotherapists' time for organising and running the exercise class, the training of RNH staff to implement the exercise regime, and the RNH staff time to set up and monitor the exercise programme for individual residents. In the control homes we will record the time spent by the research nurse implementing 'best practice' for diagnosis and management of depression. The costs of the exercise programme to RNHs, in terms of time taken to set up and monitor the exercise routines, or to implement the control intervention, will be estimated from data provided by participating RNHs. Other important resource units to capture are prescription costs; GP and, for residential homes, community nurse consultations; attendance at hospital A&E and outpatients; and hospital bed-days. These health service usage data will be collected from RNH and hospital medical records.

Where possible any data on further costs to the residents, or there next of kin, will be collected from participants at the end of study assessment; these may include additional travel and medications. Many of our participants will be unable to provide these data themselves, in which case we will collect them from their next of kin. In both cases we will seek to validate these data against the RNH records. We will explore developing a tariff for the 'opportunity cost' for the elderly participants' time used taking part in the exercise class based on the views of a subset of participants using techniques such as contingent valuation or conjoint analysis.

We assign a value to the EuroQol states using the tariff of values developed by Dolan et al and use these values as our benefit measure in the cost utility analyses. Where there are incomplete (censored) benefit or cost data due to loss to follow-up we will use non-parametric methods to infer cumulative costs and benefits.[101;102] We will calculate the incremental cost effectiveness ratio (ICER) of the programme by dividing the additional costs of the intervention by the additional benefits of the programme. Given the unknown nature of the ICER sampling distribution, we will use a non-parametric bootstrapping approach to estimate the confidence interval around the incremental cost effectiveness ratio.

Process evaluation - In tandem with the main study we will conduct a process evaluation using both qualitative methods and quantitative data collection to explore the process of implementing a whole-home intervention across a range of nursing and residential homes in the main study. The ultimate outcome of the process evaluation will be to develop a set of transferable principles regarding the whole-home intervention to inform its implementation on a wider scale. We will do case studies in a purposive sample of up to eight RNHs, informed by home size, whether local authority or privately run, and client base. Homes will be sampled from those who begin participating during the initial six months of the main study. A mixture of interviews and observational work will be undertaken, to explore the process of implementing the intervention across a range of homes. Purposive samples of home care managers and staff, patients and their carers will be interviewed just after randomisation, in the middle of the intervention period and at the end of the intervention period, to explore their beliefs about the programme and its effectiveness, their experiences of taking part, and the barriers and facilitators to their involvement. The final interviews will focus particularly on the impact of the programme on the home and of the programme being withdrawn at the end of the study. The data will be managed in the

first instance by mapping key concepts (charting) and extracting emergent themes from the transcripts. Transcripts will be analysed iteratively and emergent themes and concepts will be revisited and refined. Particular attention will be paid to discordant voices or dissonant cases, i.e. elements of the transcript that do not readily accommodate a theme but which are notable for future analysis. The emergent themes will form the basis of the analytical interpretation.[69]

We will collect quantitative process data in all of the study homes. These data will include: number of care staff trained, number of repeat care staff training sessions required, number of patients approached, number of patients agreeing to take part, number of drop-outs, number of physiotherapists involved in delivering the programme, number of falls/injuries sustained during classes.

Follow-up Study (Six-months post OPERA)

Background

The OPERA trial aims to establish whether exercise is effective in reducing the prevalence of depression among older residential and nursing home residents. Intervention homes in OPERA receive twice weekly exercise groups for 1 year, plus a whole-home activity programme. The trial objectives include bringing about a change in the 'culture' of the homes over the one-year intervention period, this change aims to safely increase mobility and activity among residents. Recruitment of homes to OPERA has been very successful; we randomised our 78th and final home on 5th May 2010; 35 of which are intervention homes. OPERA includes two interventions. An experimental condition that includes staff training in depression awareness and how increasing activity/mobility (DA&AC) can help to reduce depression and twice weekly exercise groups for a year. There is also a control intervention that included staff training in depression awareness (DA). It would be wrong in any follow-up to ignore the control condition homes for a number of reasons. An active intervention was delivered in these homes and whilst it was a one-off training session it is important to know if the information provided and the training given is still being used by the staff in the homes and what impact this training has had on the homes if at all. The OPERA research team (physiotherapists and research nurses) have delivered DA&AC training to 377 staff in the 35 intervention homes. They have also delivered DA training (the control intervention) to 497 staff in the 43 control homes. To date the physiotherapists have delivered over 1,400 exercise groups across the 35 intervention homes with an average attendance at each group of ten residents. By the end of the study we will have delivered over 3000 groups.

As part of the project we have an existing process evaluation which aims, among other things, to evaluate the extent to which a culture change has been achieved. The protocol for the process evaluation has been submitted for publication. The aim of this follow-up is to establish to what extent the culture changes brought about by the OPERA intervention persists after the 12 month intervention period.

Culture within an organisation is constructed from commonly-held and relatively stable beliefs and attitudes and is realised through behaviours and working practices. In OPERA we are providing the opportunity for homes to adopt practices (i.e. increasing activity and safe mobility of residents) that it is hoped will become embedded in the culture of the home and be sustained over time. It is the longer term effects of the OPERA intervention on the culture in the homes which is the subject of this extension proposal.

Our process evaluation, so far, indicates that the OPERA intervention is popular in the homes and that we are producing the desired culture change. Results from the primary efficacy analyses will be available in late 2011. The care homes randomised earliest to the OPERA intervention are now finishing the 12 month intervention; withdrawal of study staff raises the question of subsequent persistence of culture change within the homes.

The intervention costs £12,000 per home, per year, to deliver to one home - £400 per resident. Rolling out this intervention nationwide will have substantial resource implications It is therefore important to know whether the OPERA intervention has generated a sustained change in culture within the participating homes. This follow up study will explore OPERA homes 6 months after the end of the intervention period of the trial.

Research questions

Primary question

- Do any beneficial changes brought about by having participated in the OPERA intervention appear to be persistent?

Secondary questions

- What factors support sustained beneficial changes?
- Are there any sustained effects from having participated in the research in control homes?

Sample

We will recruit all of the OPERA intervention homes and a purposive sample of control intervention homes (Total 53 homes, 35 intervention homes & 18 control homes). During the main OPERA process evaluation eight homes were invited to provide more information about their involvement with OPERA. In these 'case-study' homes the process evaluation research fellow carried out interviews with staff and residents and observations of 'activity' within the home. We will invite all eight case study homes (6 intervention homes and 2 Control), the last of which was randomised in February 2010, to take part in both the interview and the observational parts of this follow-up.

A package of information will be sent to the manager of the homes as they near the six-month post OPERA milestone. The package will include an invitation letter outlining briefly the follow up study, information sheet/s, consent form/s and a reply paid envelope. There are two slightly different sets of information to be sent out. Firstly, for non case study homes, the package will include information sheets and consent forms about the interviews. At least two interviews from each home are planned, which are: the home manager or a delegate of the manager who was working at the home at the time of the OPERA trial and either an activities coordinator or carer who was also working at the home at the time of the OPERA trial. The information will ask the manager to identify these potential participants and to pass the information to them.

Secondly, the package for case study homes will include an information sheet and consent form about the observations within the homes. This includes information about approaching key staff and inviting them for an interview during the observation visits.

Approximately one week after this mail shot the study researcher will contact the home and ask if the information was received and answer any questions. The researcher will establish if the home is interested in participating in the follow up study. In non-case study homes it will be established if there are two potential interviewees; if so they will be asked to return the signed consent forms in the envelope provided. Once these are received further contact will establish times and dates for interviews. These will generally be via telephone but can be arranged face-to-face. In case study homes the manager will asked if they consent to the observation visits; if so they will be asked to return a signed copy of the consent form in the envelope provided. Times and days for observation visits will be agreed once consent is returned. Payments of £25 will be made to the home amenity fund for completing the interview study and an addition £25 will be paid to case study homes for the observations.

Interviews – all participating homes

We will do recorded interviews with home managers or their delegates plus a member of staff who was working in the home at the time of the OPERA intervention (this may be a carer or an activities coordinator). Our interview schedule will be developed through discussions with the OPERA management team, research staff (research fellows, recruitment staff and physiotherapists) and lay representative. Questions will be designed to explore reflection on the homes' experiences of OPERA (e.g. interaction with OPERA team, depression awareness training, exercise groups, what went well and what we could have done differently/better), the impact of OPERA interventions on the home during the period of the trial and since its end (e.g. awareness of depression, continued use of information, continuation of OPERA type exercise interventions or other activities), and the impact of the withdrawal of the physiotherapist and the exercise intervention (intervention homes only). Much of the interview will be based on pre-defined questions (i.e. a form of questionnaire) although some free responses will also be possible where further information is volunteered our where clarification is requested. Analysis will be grounded on contemporaneous notes taken during interviews with transcripts and original recordings available, when needed, for clarification.

In the eight case study homes interviews will be arranged with key staff during the observation visits. Potential participants (e.g. home manager care worker or activities coordinator) will be provided with an information sheet and invited to give an interview. Interviews will only take place with written consent from participants.

Observations – OPERA case study homes

We will repeat the ethnographic observations we have carried out in our eight case study homes during the OPERA intervention period (subject to the consent of homes). In ethnographic terms the research fellow will take an etic (outsider's) view of the homes providing a unique opportunity to become immersed in the 'cultural' norms of the individual homes and observe similarities and differences in culture across the sample. Although commonly thought of as cultural research, ethnography seeks an improved understanding of a unique group of people.[103] Observations will mirror those undertaken in the main OPERA process evaluation and are described briefly below.

The research fellow will arrange suitable days to visit the home where he will act as both a participant (interacting with residents and staff) and non-participant observer (observing activity, interactions and the environment). A minimum of three visits will be undertaken in each home and **will**

cover the period from rising in the morning to retiring in the evening. Visits will include the research fellow carrying out both participant and non-participant observations.

Observations will also include the level of 'activity' in the homes (e.g. movement around the home and other activities), staff/resident interactions and the ambience of the home. These will be recorded in field notes. Structured activity sweeps using the observational instrument of activity and well-being Behaviour Category Codes (BCC) [104-105] will be used in observation sweeps of all homes as used in the main OPERA process evaluation. Briefly, the observations will be carried out in the following way:

1. Observational data sweeps should occur every fifteen minutes, for a 90 minute period;
2. No more than three hours of observation should occur in any one day;
3. Observation periods should reflect the daily life in the home: Recommended time periods: 10am-11.30am, 12pm-1.30pm, 2pm-3.30pm, 4pm-5.30pm, 6pm-7.30pm (7.5 hours total). During the 3 days of visits all of these time periods will be covered.

Sweeps will only register the ratio of residents within each public area exhibiting a particular behaviour; no individuals will be identified. Data from this measure will be analysed quantitatively and used descriptively. A comparison with the same data analysis conducted for OPERA will provide a unique opportunity to explore how enduring the patterns of activity seen are and the similarities and differences between homes.

Data Analysis

Qualitative data (open responses from interviews and field notes from observations) will be subjected to thematic content analysis. Anonymised quotations will be used to exemplify themes. Data from the telephone questionnaire questions will provide the opportunity to generate some descriptive statistics and these will be presented in appropriate tables or graphs.

Funding

Funding for this follow-up study was agreed by the HTA on 26th August 2010.

Project timetable and milestones:

The project will take three-and-a-half years. Our proposed study milestones are:

- Month 9 Complete participant recruitment in three pilot homes
- Month 12 Fully functioning exercise programme running in two pilot homes
- Month 12 Agreement from majority of main study homes to participate
- Months 14 - 24 Recruit individual participants and randomise main study homes at rate of seven per month
- Month 18 Submit protocol, and description of the intervention for publication
- Month 24 All main study homes randomised
- Month 36 End of follow-up
- Month 39 Closure of all databases
- Month 42 Submission of draft report and draft papers

Table 2 Project timetable

	Year 1				Year 2				Year 3				Year 4	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Set-up & recruit homes	■	■	■	■										
Start pilot homes			■											
Follow up pilot homes				■	■	■	■							
Start main study homes					■	■	■	■						
Follow up main study						■	■	■	■	■	■	■		
6-month post OPERA follow-up										■	■	■	■	
Analysis and write-up											■	■	■	■

Role of Service Users

By the nature of this study, user involvement is essential. As detailed in our method, we will convene user group meetings in each locality as part of our consent process for the cluster-randomised trials and, during the pilot study, we will organise separate focus groups to explore attitudes to our consent processes. During the pilot phase we will consult with RNH staff, residents and their next of kin to ensure that the intervention has been optimised. Apart from PCT commitments, we already have a commitment from a panel of users/experts including older people's social services, trainers of care home staff, those involved in exercise delivery in care homes and those with experience of relative/residents charities facilitating resident/relative groups in RNHs. We will, of course, have RNH and lay representation on the TSC. An important theme of this work is obtaining user views on the implementation of the project. We will in addition convene a user group, with representatives from relevant charities and RNH organisations that will meet periodically during the study to advise on its conduct. Towards the end of

the study, when the provisional results are available, we will use the expertise and contacts of our panel of commissioners/trainers/users' representatives to form focus groups to assist in the understanding and dissemination of findings.

Research staff

This is a joint project between the University of Warwick, Warwick Medical School Clinical Trials Unit (Warwick) and The Centre for Health Sciences at Barts and the London School of Medicine and Dentistry (Barts). Staff for this study will be split between Warwick and Bart and the London. The Warwick team will be responsible for overall study management, delivering the interventions, process management and analysis.. Each institution will be responsible for recruitment on its own locality. At Warwick we will employ a study manager who will be responsible for overall management of the study and London recruitment; plus a second research fellow who will be responsible for the process evaluation and qualitative aspects of the study. In addition, this second research fellow will assist in observational data collection and assist in extracting health and social care record information, and be responsible for running our user groups, as part of our quality control processes we will also tape record a number of participants assessment. At Warwick we have a full-time clinical research fellow (physiotherapist) who will be responsible for development and quality control of the intervention packages. This individual will also be responsible for delivering the intervention in the pilot phase.

We have R&D agreement from Barking and Dagenham PCT, Redbridge PCT, Havering PCT, Waltham Forest PCT, Barts and The London School of Medicine and Dentistry and Coventry & Warwickshire Partnership Trust to host this work.

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