
# Process Evaluation Protocol


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# Background

OPERA (the Older People's Exercise intervention in Residential and nursing Accommodation) is a cluster randomised controlled trial that aims to evaluate a physical activity intervention to reduce depression in residential and nursing homes (RNH) The intervention will involve both a whole home intervention to increase activity/mobility and a twice-weekly physiotherapist-led structured exercise sessions. The intervention has been developed in such a way that it could be implemented as part of routine health and social care.

The intervention will be available to all residents in the intervention homes whether or not they are depressed, and whether or not they consent to take part in the trial. Both control and intervention homes will receive a depression awareness training package that will be delivered to all staff by visiting physiotherapists and research nurses.

This protocol describes the planned process evaluation (PE) that will take place consecutively with the main study. Process evaluations are increasingly being used. They aim to explore and understand the implementation of the intervention; including barriers and enhancers of the intervention and unexpected outcomes and will help to place the results of the trial in context (1). A pilot study for OPERA has been carried out and a separate report on the process evaluation of the pilot study has been provided.

## Methodological Considerations

Our evaluation will be grounded by the theory of change posited by Weiss (2-4). Drawn from the literature on program evaluation, a theory of change refers to the causal processes through which change comes about as a result of a program's strategies and action (2). It relates to how practitioners believe individual, intergroup, and social/ systemic change happens and how, specifically, their actions will produce positive results. Additional information regarding the MRC framework and the theory of change model can be found in the appendices (pages 15-16). The PE will be based on the framework proposed by Steckler & Linnan (5) which posits seven key components to good PE, these are: Context, Reach, Dose Delivered, Dose Received, Fidelity, Implementation and Recruitment. This PE will report on all of these.

### *Participant observation*

In many cases the research fellow will act as a non participant observer within the home although there may be times that this is impractical and rather than just being a 'fly-on-the-wall' some participation will be necessary. Cohen and Crabtree (10) state that participant and non participant observation complement each other. Participant observation "combines participation in the lives of the people being studied with maintenance of a professional distance that allows adequate observation and recording of data" (11, pp. 34-35). Whilst Non-participant observation is observation with limited interaction with the people one observes. For example, some observational data can be collected unobtrusively (e.g. the general state of a home). Observation fosters an in-depth and rich understanding of a phenomenon, situation and/or setting and the behaviour of the participants in that setting. Observation is an essential part of gaining an understanding of naturalistic settings and its members' ways of seeing (10). The theoretical underpinning of the observations, in this study, is the theory of change model (2) which sees change over time happening as a series of processes are implemented. The observations will provide a unique insight into the case study homes as OPERA and its processes are implemented and will give the opportunity to record changes over time.

### *Data analysis*

Data will be analysed using the Framework method. This approach is described by Ritchie and Spencer (14) and Pope et al., (15) and is broadly as follows:

- Data familiarisation: reading of complete interview transcripts, listening to original audio-recordings and use of field notes;
- Identifying a thematic framework: key issues, concepts and themes are identified and an index of codes developed;
- Indexing: whereby the index generated through identification of the thematic framework is applied to all data;
- Charting: a summary of each passage of text is transferred into a chart to allow more overall and abstract consideration of index codes across the data set and by each individual;
- Mapping and interpretation: understanding the meaning of key themes, dimensions and broad overall picture of the data and identifying and understanding the typical associations between themes and dimensions.

The charting process provides an opportunity to code data from numerous vantage points, by demographic factors, such as gender or age, by personality characteristics, such as looking specifically at people who are highly anxious compared to those who are not, or by medical aspects, such as those with diabetes compared to those without.

### *Integrating Quantitative and Qualitative Data (Mixed Methods)*

This PE is a mixed methods design employing both quantitative and qualitative methodologies in a single study (6). The use of mixed methods research is increasingly popular in health services research and evaluation (7). This growth in popularity has been driven by the increasing complexity of research problems relating to human health and wellbeing. In the UK a body of knowledge has developed over recent years around the use of mixed methods within randomised controlled trials (RCTs). Researchers are now starting to understand the value of incorporating qualitative methods within a trial and have found that doing so helps to improve the study design and helps to put results into context (e.g. 8). Indeed PE studies are greatly enhanced by the inclusion of mixed methods as they aid the process of exploring apparent discrepancies between findings (1, 9). The integration of the quantitative and qualitative elements of our mixed methods design is described in more detail in the data analysis section below.

Quantitative and qualitative research methods are most often associated with deductive and inductive approaches, respectively. Deductive research begins with known theory and tests it, usually by attempting to provide evidence for or against a pre-specified hypothesis. Inductive research begins by making observations, usually in order to develop a new hypothesis or contribute to new theory (16). Quantitative research is usually linked to the notion of science as objective truth or fact, whereas qualitative research is more often identified with the view that science is lived experience and therefore subjectively determined. Quantitative research usually begins with pre-specified objectives focused on testing preconceived outcomes. Qualitative research usually begins with open-ended observation and analysis, most often looking for patterns and processes that explain "how and why" questions (16).

When applying quantitative methods, numerical estimation and statistical inference from a generalisable sample are often used in relation to a larger "true" population of interest. In qualitative research, narrative description and constant comparison are usually used in order to understand the specific populations or situations being studied. As a result, quantitative research is most often seen as a method trying to demonstrate causal relationships under standardized (controlled) conditions. Conversely, qualitative research is usually seen as a method seeking better understanding of some particular, natural (uncontrolled) phenomenon (17, 18).

The dichotomy of quantitative, deductive analysis under standardised, objective conditions versus qualitative, inductive inquiry aimed at understanding phenomena in uncontrolled, natural contexts remains a barrier between researchers from different analytical disciplines (18). Both qualitative and quantitative methods can be used in the same study. This is variously called 'multi-method', 'mixed methods' or 'multiple methods' research (19). Researchers have pointed to the complexity of health care and the need for a range of methodologies to understand and evaluate these complexities (20-24). There has also been a growing recognition of the importance of understanding the impact of the delivery and organisation of health or care services, with a focus on processes as well as outcomes, and the range of methodological approaches required to do this (25). However, there are many justifications for using mixed methods research, apart from comprehensiveness, including increased confidence in findings, ensuring that disempowered groups in society are heard, and developing or facilitating one method by guiding the sampling, data collection or analysis of the other (26, 27).

Integrating quantitative and qualitative methodologies into a single study requires careful consideration at the outset of the design (28). Considerations include the 'priority' given to a particular method and how the other method will complement this. In other words, the first step is to select a principal data collection method that has the strengths that are most important to the project's goals. The second step is to select a contrasting complementary method that offers a set of strengths that can add to the research design's overall ability to meet the project's goals (28).

In this study the principal data collection method will be the quantitative data as this is being collected from all homes and at all time-points. The qualitative data will complement the quantitative data but of course will only be collected from case-study homes.

Sandelelowski (29) states that mixed methods writers have to decide how best to delineate the temporal, analytical and interpretive relationships between the qualitative and quantitative entities in their studies. The report for this study will include a results section that brings together results from both the quantitative and qualitative data sets and the similarities and differences from these findings will be discussed in these sections. Below (see Table 1) are several examples of how the data may be presented to complement each other and answer different aspects of the research questions.



| Table 1. Examples of how data may be integrated | |
|---|---|
| **Quantitative** | **Qualitative** |
| Recruitment logs and registers will tell us how many people attended or did not attend (training or classes) | Interviews and field notes will explore why people attended or did not attend |
| Observation of 'activity' in the homes will be quantified from the 'sweeps' carried out | Field notes and interviews will explore if the people in the home have felt these changes and how have they impacted |
| Data presented in tables, graphs and text | Quotations used to exemplify themes |

## Aims of the Process Evaluation:

- To provide findings that would assist in the interpretation of the clinical trial results;

- To develop a set of transferable principles regarding the whole-home intervention to inform its implementation on a wider scale.

# Objectives:

- To carry out in-depth interviews with care mangers, care staff, patients and carers in a purposive sample of the study sites;
- To observe the consent process, the exercise programme delivery and the depression awareness training;
- To document the RNH environment in case study homes and document any changes observed;
- To collect quantitative data on number of patient/residents approached to take part in the exercise programme and the attendance at each session. Data will also be collected about the physiotherapists used and the number of sessions and homes that they work within;
- Collate and interpret all results and provide descriptive and statistical information;
- Produce a PE report (as a separate report and a report for inclusion in the main study report) and academic papers.

# Methods

## Participants

Seventy-seven homes across two geographical areas (i.e. Coventry and Warwickshire and North East London) will be recruited. Quantitative process evaluation data will be collected from all homes. A purposive sample of eight (six intervention and two control), homes will be examined in more detail and will act as case studies. The main sampling criterion will be ownership of the homes (see figure 1 below) and a secondary criteria in the intervention homes will be to sample homes being served by different physiotherapists. .

**Figure 1.** Case study home inclusion matrix (number of homes to be recruited in each category)

| | Type of homes | | | |
|---|---|---|---|---|
| **Area** | **A** | **B** | **C** | **D** |
| Coventry and Warwickshire | 1 | 1 | 1 | 1 |
| North East London | 1 | 1 | 1 | 1 |

A = Independent homes (< 6 homes in chain), B = Charity (non-profit) C = Group/Chain homes (6 homes in chain or above), D = Control Homes

Recruitment of case study homes will take place after randomisation, and will be staggered through the first six months of recruitment into the study. All homes at the point of recruitment will be informed about the process evaluation and the possibility that they will be asked to take part in it. No more than two homes and no more than one intervention home will be recruited in any four week period.

Individual participants from each of the case study homes will be invited to participate in the qualitative aspects of the PE. This will include interviews with:

- Care Home Manager (plus Group manager if appropriate)
- Care Home Staff (up to three per home)
- Care home Residents (up to three per home)
- Residents relatives/next-of-kin (up to two per home)
- Physiotherapist (involved in the intervention in that home)

### *Inclusion Criteria - resident*

- Ability to understand and communicate in spoken English (In particular residents);
- A consented participant into the OPERA main study;

- Informed consent (for PE).

***Exclusion Criteria - resident***

- Severe cognitive impairment (i.e. not competent to consent);
- Severe problems communicating.

## Case Study Homes

The case studies will be predominantly qualitative in nature and consist of semi-structured interviews and observations. Some quantitative data based on a validated observation tool will be included to measure 'activity' within the case study homes. Data will be collected on three occasions; baseline (immediately after randomisation, during period of physical assessment, but before any training or exercise sessions), at six months and at the end of the study (12-months). To establish changes that happen within the home during the lifetime of OPERA the PE research fellow will gather data that explores the homes environment in terms of observed changes that occur during the lifetime of the program in intervention and control homes (e.g. the level of resident activity).

In each case study home the PE Research Fellow will set up a timetable of visits (to carry out the base-line data collection) in collaboration with the home manager and taking account of local requirements. Four days are planned for each home to complete a baseline assessment including the interviews and observations; these days may be spread over several weeks.

## Interviews

Face-to-face or telephone interviews will be carried out soon after recruitment to the study and before OPERA interventions are implemented (baseline). Formal follow-up interviews with a few of the key informants who were interviewed at baseline will be scheduled for six-months after implementation and at the end of the study.

Participants will be invited to take part in interviews at a time and place that suits them. Interviews with next of kin or relatives may be carried out via telephone for the convenience of the respondents Interviews should last no longer than 30 minutes. Semi structured interviews will be used and at baseline will explore life in the home and the current levels of activity, staff/resident interactions and the process of consent to the OPERA trial (see topic guides, Appendix pages 17-18).

Additional information will be sought from the care home managers/group managers about their reasons for taking part, their feelings about the whole home study and their beliefs about the potential long-term changes in the home as a result of the intervention.

Follow-up interviews will explore in more depth perceptions about the home and its levels of activity and, in intervention homes, perceptions of the activity programme and its impact. Interviews will also explore feelings about the programme being withdrawn at the end of the study.

Where appropriate, interviews will be digitally recorded and transcribed verbatim. All personal information will be removed from transcriptions and no participant will be identified in any written material. However, as care managers will be invited to take part and there will only be a small number of homes it may be possible to identify a particular home/manager. A copy of the transcript will be forwarded to each manager for their approval of its content. Indeed, where possible all transcripts will be verified with interviewees as a form of validation. (Topic Guides for interviews are included in Appendix).

## Observations

Observations will be made in the case study homes by the PE Research Fellow. This will form a substantial part of the evaluation and involves observation of the home environment, levels of

activity and staff/resident interactions. In intervention homes this will also include how OPERA 'exercise sessions' fit in and how these are received/perceived. In addition, there will be observation of the 'processes' and procedures of the OPERA whole-home intervention. Observations will include:

- Observation of the home environment;
- Observation of the consent/assent process;
- Delivery of the Depression awareness training in control homes and Depression awareness/activity training in intervention homes;
- Delivery of the exercise sessions;
- 'Activity'.

## Home environment

On each visit to a home the PE Research Fellow will make field notes, as appropriate, with regard to the current environment of the home. This will include noting time of day, what residents are doing, any activities, staff interactions, general ethos and any contacts made whilst there. Formal observation of activity and well-being within the homes are outlined later.

## Consent

The process of consenting participants will be observed on a number of occasions in each of the homes (up to three participants on each site). This will include observing the process of consent when this is being given by a third party due to the cognitive impairment of the participant. Questions from participants will be noted as will any areas of concern raised by the participant or the person carrying out the consenting. An observation checklist is provided in the appendices (pages 19-21)

## Depression awareness training

Staff in all of the homes (intervention and control) will receive a short training session on depression awareness. Intervention homes will receive additional information about activity. At least one of these training sessions will be observed in each of the case study homes. Key elements that will be noted include:

- Staff response to these sessions;
- How confident the presenter is in engaging/adapting to participants needs;
- The environment used for the training (room, noise, time to participate, distractions);
- Timing (how-long);
- Level of interest (questions?).

Feedback on the usefulness and quality of the training package will be sought from all attendees via an evaluation form (see Appendices page 26). A follow-up questionnaire will be mailed to staff four-weeks after the training. This questionnaire will explore how useful the training has been and if it has been used in practice (see Appendices pages 27-29). A return envelope will be provided.

## Exercise sessions

The researcher will observe several sessions in each case study home in the early stages of their introduction, at about the mid-point and at the end of the 12-months. Observation at these times will include for example:

- Ambiance/atmosphere
    - Does it feel relaxed and easy?
    - How does the session fit into the day
        - e.g. is it close to lunch or tea-time
- How are participants reacting

    - Are they joining in?
    - Are they happy?
    - Are they dissenting?
    - Interaction with session leader
- How are the session leaders performing
    - With confidence?
    - Adapting to audience?
    - Listening?
    - Working within defined manual?
- Setting
    - Setting up
    - Getting to classes (residents)
    - Getting away from the class (residents)
    - Room?
    - Distractions?
    - Involvement of care home staff?
- Timing, how long was the session?
    - What happens when the class ends?

## Activity

The observational instrument of activity and well-being Behaviour Category Codes (BCC) (12, 13) will be used in structured observation sweeps of all case study homes at baseline and follow-ups. This will involve the PE Research Fellow completing a checklist of where residents are what they are doing and what care-staff are doing at regular intervals in the day. More information on the method of assessment and the instrument can be found in the appendices (pages 22-24). 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).

Sweeps will only register 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 describe statistical patterns and trends.

## Focus Groups (user groups): Consent and CRCT

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 it 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. Whilst some of these issues are being explored during observations and interviews for the OPERA process evaluation, these will only include OPERA participants.

Therefore, in order to explore these issues further we will hold two focus groups exploring 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.

## Quantitative data

Quantitative data will be collected from all homes and will complement the qualitative data. Data will be collected via pre-designed Case Report Forms (CRF) and from other sources (e.g. CSCI

reports and physiotherapists records) data will be entered onto the study database. The PE team will monitor these data collection measures to ensure that data that is required is collected and that CRF are fit for purpose.

There are two interlinked strands of the quantitative data these are:

1. The Care homes;
2. The people involved.

### *1. Care Homes*

| **Data collected from all care homes will include:** | |
|---|---|
| **Data** | **Measure used** |
| Number of homes overall; | Home Recruitment log (number approached, declined) |
| Size of home (including number beds and actual occupancy); | Initial CRF, CSCI report |
| Type of home in terms of specialty (e.g. Specialist or not); | Initial CRF, CSCI report |
| Type of home in terms of funding (e.g. independent, charity, group or council/PCT run); | Initial CRF, CSCI report |
| Level of activity already within home (classes, trips?) | Initial CRF |
| Facilities available within the home – accessible garden, exercise studio, ballroom, rooms for communal activities? | Initial CRF, CSCI report, physiotherapist data |

Much of this data will be collected at the outset of the study by the recruiting nurse and recorded on a CRF and entered into the trial database. Additional information will be available from the CSCI website and will be extracted and entered into the database.

### *2. People*

Residents

| **Data** | **Measure** |
|---|---|
| Numbers approached; | Recorded by recruiting nurse |
| Type of consent (personal or third party); | Recorded by recruiting nurse |
| Numbers agreeing to take part ; | Recorded by recruiting nurse and in study folders |
| Drop-outs, adverse events or other attrition; | Collected three-monthly via CRF by recruiting nurse |
| Attendance on the exercise programme. | Attendance register |

The recruiting nurse will record numbers self-consenting or assented by a third party on a trial CRF and numbers recruited into the trial will be updated at least weekly on trial database. The number of residents who take part in the exercise sessions will be recorded on a ‘session’ register.

Care Staff

| **Data** | **Measure** |
|---|---|
| Number (Day/Night), grade, vacancies, qualifications and number/type of ancillary staff | Initial home data CRF |
| Numbers trained (depression awareness/activity awareness), Attendance; | Attendance register (number only) |
| Number of training sessions run; | Attendance register (number only) |
| Satisfaction (with training/programme). | Evaluation form |

The physiotherapist/research nurse that is delivering the depression awareness session will record the number of staff trained and any additional training or training needs. Session evaluation forms will be handed to all participants who will be asked to rate the session (anonymously) for delivery, understanding and usefulness (See Appendices, page 25). These will be collected together at the end of the session placed in a reply-paid envelope and returned to the OPERA office. A second individualised questionnaire (their name added from register of training) will be despatched to staff via the homes (one package containing all individual envelopes) approximately 4-weeks after the training to assess usefulness of information given. Each questionnaire will include a short letter and a reply-paid envelope to return questionnaire. Some additional quantitative information will be available from the observation checklists as these will note the number of occurrences of a particular activity during that period of observation.

# Data Analysis

## Qualitative Data Analysis

Interviews will be digitally recorded, subject to permission of each participant, and where appropriate, will be transcribed verbatim. The recordings will be stored in a secure digital environment and only members of the research team will have access to them. Participants will not be identified and a code number will identify transcripts. Subsequent written material will use pseudonyms, for participants. Transcripts and recordings will be archived and securely stored for a period of five years after the end of the trial after which time they will be destroyed.

The software package NVivo 7 will be used to facilitate this process. Researcher bias will be minimised through regular crosschecking of data and findings by the members of Research Team. In addition, transcripts will be returned to participants (where appropriate) providing them with the opportunity to check the transcripts for accuracy and authenticity and to offer any subsequent reflections. Quotes will be used as exemplars of key points in the writing up of these data.

## Quantitative Data Analysis

All quantitative data collected will be entered into the study database and will be analysed using the statistical package Stata. Descriptive statistics will be generated and comparisons made between homes or types of homes (i.e. charity run etc).

Data analyses will be ongoing throughout the period of the PE. PE data will be analyzed independent of the main study. Data will be extracted and descriptive statistics fed back to the PE team at regular intervals. This will ensure that data are being captured and that the quality of the data is good. Themes emerging from qualitative data will also be discussed and refined by the PE team. A sample of 10% of transcripts will be coded by another member of the team to ensure reliability and validity.

# Summary of PE data to be collected mapped against the key elements of a process evaluation

Outlined below are the 'key' elements of PE proposed by Steckler & Linnan (5) with the data collection measures mapped against them.

*Context*

***"Aspects of the larger social political and economic environment that may influence implementation"***

| | |
|---|---|
| **Homes** | |

| | |
|---|---|
| Location and Size (beds) | CRF and CSCI |
| Type | CRF and CSCI |
| Ownership | CRF and CSCI |
| Number of staff (day/night) | CRF |
| Qualifications/Level (seniors or care staff) | CRF |
| Vacancies | CRF |
| Ancillary staff (numbers/type) | CRF |

*Reach*

***"The proportion of intended target audience that participates in intervention"***

| | |
|---|---|
| Homes (numbers approached, including refused) | Recruitment Log |
| Proportion of residents who are able to participate in initial assessment and activity assessment | Participant recruitment log and physiotherapist record |
| Number of staff trained/ number of sessions | Attendance register (number only) |
| Number of residents attending exercise sessions | Attendance register (need to see serial attendees or non-attendees and reasons for non-attendance) |

*Dose Delivered*

***"The number or amount of intended units of each intervention or each component delivered or provided"***

| | |
|---|---|
| Staff (number of classes) | Training register |
| Residents; Number, level, time/date and duration of exercise sessions | Register & Observations |

*Dose Received*

***"The extent to which participants actively engage with, interact with the recommended resources"***

| | |
|---|---|
| Staff (number attending) | Training register |
| Number of residents attending and taking an active part in exercise sessions | Register & Observations |

*Fidelity*

***"The extent to which the intervention was delivered as planned"***

This will be achieved with reference to interviews with key stake holders in the development and implementation of the program and from observations the case study homes.

*Recruitment*

***"Procedures used to approach and attract participants"***

This will be achieved by reviewing all of the recruitment data including recruitment of homes and participants. Data for this will be gathered via CRF and through observations.

*Implementation*

***"A composite score that indicates the extent to which the intervention has been implemented as planned"***

This will be an overall impression of the implementation of the programme that will comprise elements of all the data collected.

### Summary of PE key components, data collection tools and data gathering timings

| PE Component | Data Collection Point | Data collection and monitoring |
|---|---|---|
| | | |
| **Context** | Home Data Collection CRF | Monthly |
| | CSCI Report (Downloaded) | At recruitment |
| | | |
| **Reach** | Home Recruitment Log | Monthly |
| | Number initial assessments | 3-monthly |
| | Number of Physiotherapist assessments | 3-monthly |
| | | |
| **Dose Delivered** | Number of training sessions (registers) | 3-monthly |
| | Number exercise sessions (registers) | 3-monthly |
| | | |
| **Dose Received** | Attendance registers (training and classes) | 3-monthly |
| | | |
| **Fidelity** | Interview transcripts | ongoing |
| | Observation data (qualitative) | ongoing |
| | Observation data (quantitative) | Monthly |
| | | |
| **Recruitment** | Home recruitment log | Monthly |
| | Observations | ongoing |
| | Interview transcripts | ongoing |
| | | |
| **Implementation** | Composite of all of above | ongoing |
| | | |

## Timetable of the Process Evaluation

The PE Research Fellow will dedicate four days to each home to gather baseline and follow-up data, and four days to each home at the end of the study (a total of 11 person/days per home; 88 person/days in total for data collection). The time required for analysis and interpretation will equate to approximately twice the time spent gathering data. The Gantt chart below shows the planned sequence of activities.

# GANTT Chart for Process Evaluation

| | 2009 | | | | | | | | | | | | 2010 | | | | | | | | | | | | 2011 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 |
| Homes Recruited | | 1 | 1 | 2 | 1 | 2 | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Baseline visits | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follow-up | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Final Visits | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Transcribing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Data interpretation and analysis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Date monitoring | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Feedback PE team | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Report writing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

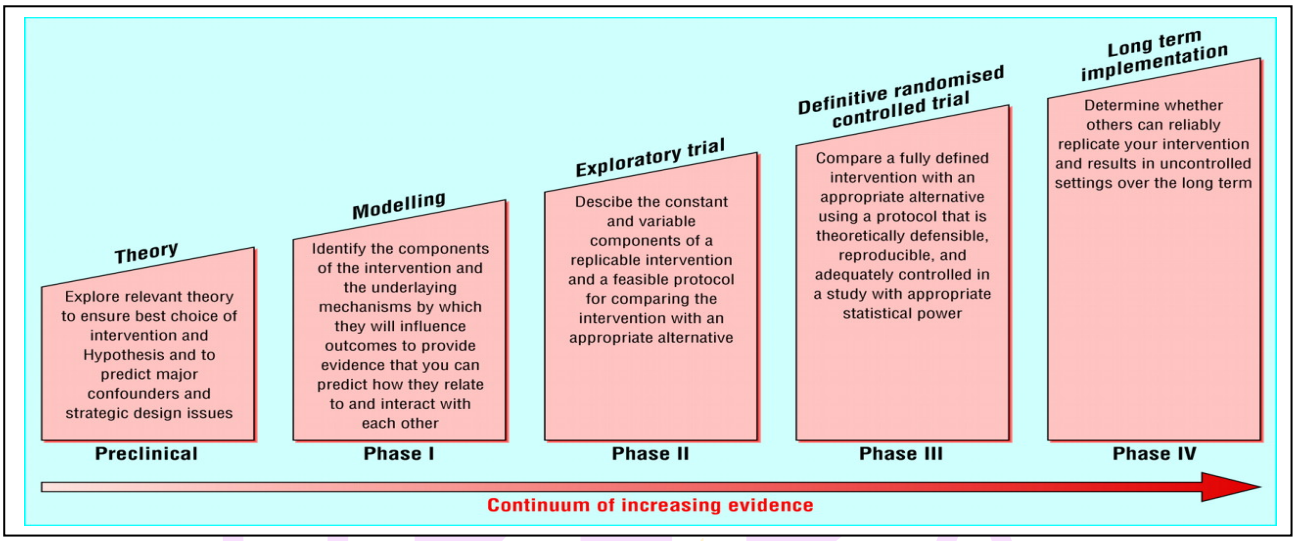
# Appendices

1. **Theory Driven Intervention**
2. **Topic Guides for interviews**
3. **Observation checklists**
4. **Resident Activity and Well-being**
5. **Depression Awareness Training Evaluation form**
6. **References**

## Theory Driven Intervention

The need to base the evaluation in and around a theoretical basis is well founded and highly recommended (5). The pilot provides the opportunity to test the theoretical framework and to ensure that the measures and tools used provide the information required. The whole OPERA study has been developed within the framework proposed by the Medical Research Council (30). This Framework provides a systematic approach to the conception, development, refinement, implementation and evaluation of complex interventions to improve health (See Figure 1). The theoretical perspectives are an important part of this process. Below we outline the theory behind the process evaluation.

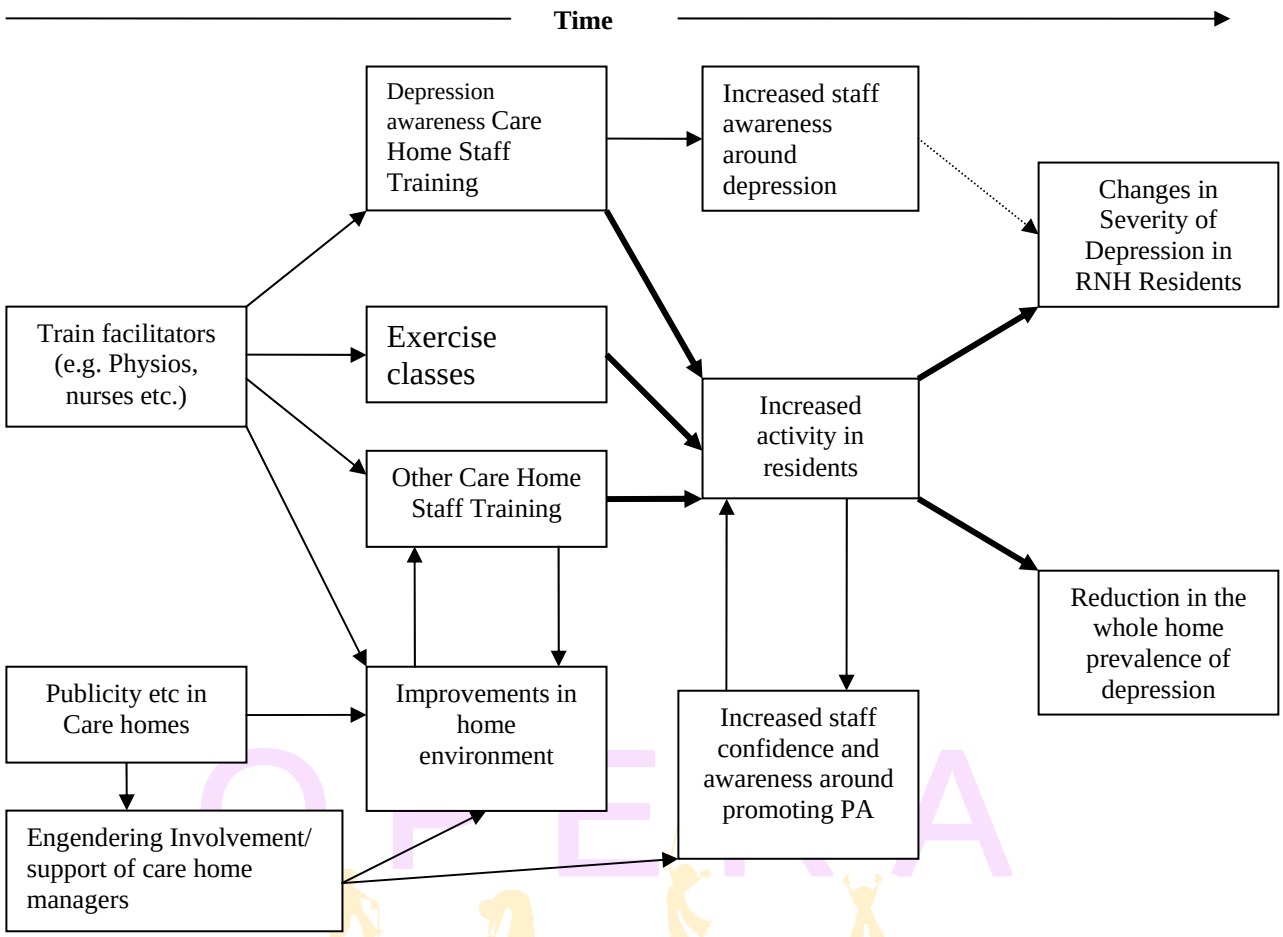
**Figure 1. MRC Complex interventions Framework (30)**




Two interrelated theories strengthen this process evaluation. The first of these is the theory that underpins the intervention itself, this is the Theory of Change Model (TOC) posited by Weiss (2-4). Drawn from the literature on program evaluation, a theory of change refers to the causal processes through which change comes about as a result of a program's strategies and action (2). It relates to how practitioners believe individual, intergroup, and social/ systemic change happens and how, specifically, their actions will produce positive results.

Figure 2 is a very simple representation of the TOC in relation to the ‘active’ whole-home intervention in the OPERA study. The primary outcomes (on the far right) are brought about by a series of ‘changes’ as a result of introducing the intervention into the RNH. Our process evaluation monitors these steps and will be able to identify areas and will be able to draw out the moderators and mediators that may influence the programmes outcomes.

**Figure 2. Theory of Change model for OPERA 'Active' Intervention**



## Topic Guides for Interviews

### *Care home manager - baseline*

(Could use a description of the programme as a stimulus for these interviews)

- Ask about the home and what activities are currently available
- Experiences of being approached by the trial team e.g. initial approach, information provided by research team about the study
- Influences on the decision to take part
- Process of consent (home, individuals and assent)
- Beliefs about the benefits of taking part
- Explore current home practices (activities, games)
- Expectations of what the programme can achieve within the home
- Beliefs about the feasibility of introducing the programme into their home - likely facilitators and likely challenges to this (what aspects do they think will work or not work?)
- Beliefs about acceptability of the programme to care home staff and to residents
- Beliefs about the likely impact on the home of taking part, e.g. in terms of how the home runs, and on individual staff and residents
- Beliefs about the usefulness of the programme to them, to staff and to residents

### *Care home manager follow up*

- Experiences of the various elements of the programme e.g. depression awareness training, exercise sessions, whole home intervention
- Challenges to implementing the programme into the home
- Beliefs about the acceptability of the programme to care home staff and to residents
- Beliefs about the extent to which the programme fits into the overall work of the home
- Beliefs about the impact of the programme on the home overall , on care home staff and on care home residents - short term and long term impacts of the programme
- Beliefs about the sustainability of the intervention without being part of a research project
- Suggestions about how the programme might be improved to make it easier to introduce

### *Care home staff - baseline*

(Could use a description of the programme as a stimulus for these interviews)

- Experience as a care assistant - length of time worked as a care assistant overall, length of time worked in particular home
- Impressions of life in the home (interactions with residents, activities, workload)

In intervention homes will explore the implementation of the OPERA programme:

- Experiences of having the programme explained to them and their role (if any) within helping the implement the programme
- Beliefs about the feasibility of introducing the programme into their home - likely facilitators and likely challenges to this
- Beliefs about the impact on the intervention on the home overall, on fellow care staff and residents
- Beliefs about the usefulness of the programme received, to them and to residents

### *Care home staff - follow up*

- Experiences of the various elements of the programmes- depression awareness training , exercise sessions, whole home intervention (control homes just the DA training)
- Usefulness of training, did they learn anything that they have been able to use in their everyday work
- Ease of attending training, did they have enough time off to attend the training, attitudes of other members of staff to the training
- Beliefs about the impact of the training on the home overall and on residents (if any), potential short and long term impacts
- Have staff acted on information received during training;

Within intervention homes will also explore how the exercise sessions have been received:

- Beliefs about the sustainability of such a programme
- Suggestions about how the programme might be improved

### *Care home residents – baseline*

(Adapted slightly for NOK e.g. what are your experiences of the home in which you have a relative?)

- Discuss life within the home, what they do, activities, staff interactions
- Explore recollections of consenting to be part of main study
    - did they feel that they had enough information given to them about the study

In intervention homes will also discuss:

- Expectations of the programme - benefits and challenges of taking part
- Beliefs about the impact of the programme on residents



### *Care home residents - follow up*

(Adapted slightly for NOK e.g. have you noticed any changes? If intervention has your relative talked about the classes)

- Discuss life within the home, what they do, activities, staff interactions, any recent changes

In intervention homes will also discuss:

- Experiences of taking part in the programme - experiences of attending the activity class
- Impact of the programme on usual life in the home
- Ease of getting to classes - enough support to take part
- Beliefs about the likely impact of the programme on them
- Beliefs about how to make the class better

### *Physiotherapists (base-line and follow-up)*

- Experiences of learning about OPERA
- Experiences of visiting homes
- Thoughts on training given to deliver OPERA
- Experiences of recruiting participants and doing base-line assessments
- Expectations (and later realities) of carrying out a programme like this
- Likes and dislikes (possible changes)
- Delivering the depression awareness and exercise interventions
- Beliefs about the impact of the programme on residents
- Practicalities of collecting and reporting (OPERA forms)
- Impact on homes (follow-up)
- Any changes noticed (follow-up)

## Observation Checklists

| ***Consent Process Checklist*** | | | |
|---|---|---|---|
| Home ID: | | | |
| Researcher: | | | |
| Date: | | | |
| Time: | | | |
| Person taking consent/assent: | | | |
| | | | |
| Location: | Where in Home? | | |
| | | | |
| Type of Consent | | Self | |
| | | Assent | |
| | | | |
| Others present | | NOK/relative | |
| | | Social worker/other | |
| | | Care staff | |
| | | Home Manager | |
| | | No one | |
| | | Other | |
| | | | |
| Consent process | Fully explained (PIS etc.) | Yes/No | |
| | Right to withdraw | Yes/No | |
| | Opportunity to ask questions | Yes/No | |
| | Questions asked | | |
| | Responses to questions | | |
| | | | |
| Observer notes | Consent given | Yes/No | |
| | Reason for non consent | | |
| | | | |
| | | | |

| ***Depression Awareness Training Checklist*** | | | |
|---|---|---|---|
| Home ID: | | | |
| Researcher: | | | |
| Date: | | | |
| Time: | | | |
| Facilitator: | | | |
| | | | |
| Location: | Where is training taking place? | | |
| | Noise | | |
| | Distractions | | |
| | | | |
| Participants | Number attending? | | |
| | Have staff been given time to attend? | | |
| | Other comments about attendees? | | |
| | | | |
| | Reaction to session | | |
| | | | |
| | Comments about DVD | | |
| | | | |
| | Level of interest | | |
| | | | |
| | Questions asked | | |
| | | | |
| | | | |
| Facilitator | Delivery | | |
| | Confidence | | |
| | Adapting to audience | | |
| | Responses to questions | | |
| | | | |
| Timing | How long | | |
| | | | |
| | | | |

| ***Activity Class Checklist*** | | | |
|---|---|---|---|
| Home ID: | | | |
| Researcher: | | | |
| Date: | | | |
| Time: | | | |
| Facilitator: | | | |
| | | | |
| Location: | Where is training taking place? | | |
| | Noise | | |
| | Distractions | | |
| | | | |
| Setting-up | When and how is the room/space prepared? | | |
| | How do the residents get to class? | | |
| | Role of Care staff | | |
| | | | |
| Participants | Number attending? | | |
| | Others near by? | | |
| | Others joining in? | | |
| | Drop outs? | | |
| | Dementia or none? | | |
| | | | |
| Facilitator | Delivery | | |
| | Confidence | | |
| | Adapting to audience | | |
| | Responses to questions | | |
| | Working within manual framework | | |
| | Recording required data | | |
| | | | |
| During class | Levels of engagement | | |
| | Interest | | |
| | Issues | | |
| | Other comments | | |
| | Timing | | |
| | | | |
| After Class | What happens at end | | |
| | Involvement of staff | | |
| | | | |
| General comments | | | |
| | | | |

## Resident wellbeing & activity

***Please note we are ONLY collecting BCC and not AARS***

Guidelines for observational assessment of:

a) Resident wellbeing/activity and
b) b) Staff-resident interaction.

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)

Commencing observation:

4. Enter identifying label for all residents (maintain separate list of identifying label matched with residents actual name/identifying triggers)
5. Enter time of observation on time sheet and start time of each observational sweep
6. Start at same point and end at same point for each observational data sweep
7. Walk through all public/communal areas
8. Record from left to right of visual field
9. Code location, behaviour category (BCC)*, and observed affect (AARS)* on first sighting of resident (see separate sheets, but note * and ** below).
10. Code all residents as observed – if resident leaves location before information for that resident has been coded, do not enter information.
11. At end of each observation sweep, if time available, make field-notes; otherwise wait until end of observation period
12. Code U (Unavailable for observation) for all residents not observed during an observation sweep; leave AARS code blank; code location if this is known

* Additional coding for BCC: If coding A (Active social interaction), or P (Passive social interaction), in parentheses after the code, write ST, RE or OT to indicate whether the interaction was primarily with a STaff member or REsident, or OTher (e.g., relative). If coding E (Engaged in recreational activity), in parentheses after the code, write ST, RE, OT or AL to indicate whether the interaction was primarily with a STaff member, REsident, OTher person, or carried out ALone.

** Additional coding for AARS: use code N for neutral if there are no signs of observable affect (12, 13).

**Continued Overleaf**

***Resident wellbeing & activity (continued) (Please note ONLY BCC will be observed in OPERA)***

| Behaviour Category Codes (BCC) | |
|---|---|
| A | Active Social Interaction<br>Interacting with others, verbally or otherwise |
| A(st) | With staff |
| A(re) | With resident |
| A(ot) | With other |
| | |
| C | Communicating with no response |
| | |
| D | Eating/Drinking |
| | |
| E | Engaging in Recreational Activity<br>Participating in a game<br>Craft Activity<br>Using intellectual abilities<br>Performing work or pseudowork<br>Engaging with media<br>Exercise, physical sport<br>Participating in religious activity |
| E(st) | With staff |
| E(re) | With resident |
| E(ot) | With other |
| E(al) | Engaging alone |
| | |
| O | Other (specify) |
| | |
| P | Passive social interaction<br>Being socially involved, but passively |
| P(st) | With staff |
| P(re) | With resident |
| P(ot) | With other |
| | |
| R | Receiving Care |
| | |
| S | Socially Inactive<br>Being socially uninvolved, withdrawn<br>Sleeping, dozing<br>Independently engaging in self care |
| | |
| U | Unavailable for observation |
| | |
| W | Walking/Wandering |

| Assessment of Observed Effect (AARS) | |
|---|---|
| P | Signs of Pleasure<br>Smiling, laughing<br>Stroking<br>Nodding<br>Singing<br>Arm or hand outstretched<br>Open arm gesture |
| | |
| S | Signs of Anger<br>Clench teeth, Grimace<br>Shout, curse, berate<br>Physical aggression |
| | |
| AX | Signs of Anxiety<br>Furrowed brow<br>Motor restlessness<br>Repeated or agitated motions<br>Facial expression of fear or worry<br>Sigh<br>Withdraw from others<br>Tremor<br>Tight facial muscles<br>Call repetitively |
| | |
| N | Neutral<br>No observable effect |
| | |
| D | Signs of Depression<br>Cry, tears,<br>Moan<br>Mouth turned down |
| | |
| I | Signs of interest<br>Eyes follow object<br>Intent fixation on object or person<br>Visual scanning<br>Facial, motor or verbal feedback<br>Eye contact maintained<br>Body or vocal response to music<br>Talk wide angle subtended by gaze<br>Turn body or move towards person |
| | |
| C | Signs of Contentment<br>Comfortable posture<br>Sitting or lying down<br>Smooth facial muscles<br>Lack of tension in limbs, neck<br>Slow movements<br>Relaxed body stance<br>Lightening of frown or worry line |

| | | | |
|---|---|---|---|
| **1** | Day Area / Lounge | **6** | Kitchen |
| **2** | Dining Room / Area | **7** | Public Area / Foyer |
| **3** | Bedroom / Personal Room | **8** | Garden / External Area |
| **4** | Corridor | **9** | Games / Activity Room |
| **5** | Bathroom / Toilet | **10** | Other |

Draft example of Resident wellbeing & activity observation data collection form (modified). Data will be entered as number of residents in a public area (location) observed in a particular behaviour pattern during a sweep of the home.

## *Observation Schedule*

| | | | | | |
|---|---|---|---|---|---|
| | | | | | |
| Home ID | | | date | obs | period |

| | | Locations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
| | **BCC** | | | | | | | | | | |
| A | Active Social Interaction | | | | | | | | | | |
| | Interacting with others, verbally or otherwise | | | | | | | | | | |
| A(st) | With staff | | | | | | | | | | |
| A(re) | With resident | | | | | | | | | | |
| A(ot) | With other | | | | | | | | | | |
| | | | | | | | | | | | |
| C | Communicating with no response | | | | | | | | | | |
| | | | | | | | | | | | |
| D | Eating/Drinking | | | | | | | | | | |
| | | | | | | | | | | | |
| E | Engaging in Recreational Activity<br>Participating in a game<br>Craft Activity<br>Using intellectual abilities<br>Performing work or pseudo work<br>Engaging with media<br>Exercise, physical sport<br>Participating in religious activity | | | | | | | | | | |
| | | | | | | | | | | | |
| E(st) | With staff | | | | | | | | | | |
| E(re) | With resident | | | | | | | | | | |
| E(ot) | With other | | | | | | | | | | |
| E(al) | Engaging alone | | | | | | | | | | |
| | | | | | | | | | | | |
| O | Other (specify) | | | | | | | | | | |
| | | | | | | | | | | | |
| P | Passive social interaction<br>Being socially involved, but passively | | | | | | | | | | |
| | | | | | | | | | | | |
| P(st) | With staff | | | | | | | | | | |
| P(re) | With resident | | | | | | | | | | |
| P(ot) | With other | | | | | | | | | | |
| | | | | | | | | | | | |
| R | Receiving Care | | | | | | | | | | |
| | | | | | | | | | | | |
| S | Socially Inactive<br>Being socially uninvolved, withdrawn<br>Sleeping, dozing<br>Independently engaging in self care | | | | | | | | | | |
| | | | | | | | | | | | |
| U | Unavailable for observation | | | | | | | | | | |
| | | | | | | | | | | | |
| W | Walking/Wandering | | | | | | | | | | |



| | | | |
|---|---|---|---|
| **1** | Day Area / Lounge | **6** | Kitchen |
| **2** | Dining Room / Area | **7** | Public Area / Foyer |
| **3** | Bedroom / Personal Room | **8** | Garden / External Area |
| **4** | Corridor | **9** | Games / Activity Room |
| **5** | Bathroom / Toilet | **10** | Other |

## Depression Awareness Training Evaluation

Home ID:

Date:

Time:

**Your thoughts on this training are important to us. Your answers are anonymous and will be used to ensure that the training is working for everyone.**

**Please answer the questions below and return the form to us by placing in the envelope provided.**

| | Less than a Year | 1-2 Years | 3 – 5 Years | Over 5 Years |
|---|---|---|---|---|
| How Long have you worked in a Care Home setting? (please **tick** one box) | ☐ | ☐ | ☐ | ☐ |

**Read the following statements and CIRCLE the number that represents your level of agreement with the statement.**

| | Strongly Disagree | | | | Strongly Agree |
|---|---|---|---|---|---|
| The session was relevant to my job | 1 | 2 | 3 | 4 | 5 |
| I learned something new from this session | 1 | 2 | 3 | 4 | 5 |
| I am glad I attended this session | 1 | 2 | 3 | 4 | 5 |
| The session was just the right length | 1 | 2 | 3 | 4 | 5 |



**Comments or Suggestion** (Continue overleaf if required):

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## Thank you for you time

## Training follow-up (Control homes)

Home ID:

Date:

Time:

**Several weeks ago now you attended a training session hosted by researchers involved in the OPERA trial. We are interested in learning if this training was useful to you and how you have applied what you have learned**

**Please complete this questionnaire as honestly as you can and return to us in the envelope provided. Your responses are anonymous.**

**Information Folders**

Did you find the information useful? Yes ☐ No ☐

| |
|---|
| Which parts did you find the most useful? |
| Which parts the least useful? |
| Can you give an example of how you have applied the information on depression in your work since the training session? |
| Since attending the training have you become more or less aware of the levels of depression in the residents? (if possible give an example) |
| Do you require more information about depression Yes ☐* No ☐<br>If yes what type of information would you like (tick all boxes that apply):<br>More training ☐, Leaflets ☐, Useful websites ☐, Video or Multimedia packages ☐, Other ☐ (please state) |

**Thank you for you time**

## Training follow-up (Intervention Homes)

Home ID:

Date:

Time:

**Several weeks ago now you attended a training session hosted by researchers involved in the OPERA trial. We are interested in learning if this training was useful to you and how you have applied what you have learned**

**Please complete this questionnaire as honestly as you can and return to us in the envelope provided. Your responses are anonymous.**

**Information Folders**

Did you find the information useful? Yes ☐ No ☐

| |
|---|
| Which parts did you find the most useful? |
| Which parts the least useful? |
| Can you give an example of how you have applied the information on depression in your work since the training session? |
| Since attending the training have you become more or less aware of the levels of depression in the residents? (if possible give an example) |
| Do you require more information about depression Yes ☐* No ☐<br>If yes what type of information would you like (tick all boxes that apply):<br>More training ☐, Leaflets ☐, Useful websites ☐, Video or Multimedia packages ☐, Other ☐ (please state) |

**Mobility Safety Advice Pages**

Yes ☐ No ☐

| |
|---|
| |
| Which parts the least useful? |
| Any comments or suggestions about the mobility safety advice pages? (please write below) |

| |
|---|
| **Posters**<br>Did You find the OPERA mobility posters useful? Yes ☐ No ☐ |
| Which parts did you find the most useful? |
| Which parts the least useful? |
| Do you require more information about Mobility Safety? Yes ☐* No ☐<br>If yes what type of information would you like (tick all boxes that apply):<br>More training ☐, Leaflets ☐, Posters ☐, Useful websites ☐, Video or Multimedia packages ☐, Other ☐ (please state) |

## Thank you for you time

# References


1. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. BMJ. 2006 Feb 18;332(7538):413-6.
2. Weiss CH. Evaluation research. Englewood Cliffs: Prentice Hall; 1972.
3. Weiss CH. Nothing as Practical as a Good Theory: Exploring Theory-based Evaluation in Complex Community Initiatives for Children and Families. In: Connell J, Kubish A, Schorr L, Weiss CH, editors. New Approaches to Evaluating Community Initiatives. Washington, DC Aspen Institute; 1995.
4. Weiss CH. How can theory-based evaluation make greater headway? Evaluation Review. 1997 Aug;21(4):501-24.
5. Steckler A, Linnan L, editors. Process Evaluation for Public Health Interventions and Research. San Francisco: Jossey-Bass; 2002.
6. Bryman A. Integrating quantitative and qualitative research: how is it done? Qualitative Research. 2006 February 1, 2006;6(1):97-113.
7. Pope C, Mays N. Qualitative Research: Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. BMJ. 1995 July 1, 1995;311(6996):42-5.
8. Donovan J, Mills N, Smith M, Brindle L, Jacoby A, Peters T, et al. Quality improvement report: Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study * Commentary: presenting unbiased information to patients can be difficult. BMJ. 2002 October 5, 2002;325(7367):766-70.
9. Oakley A, Strange V, Stephenson J, Forrest S, Monteiro H. Evaluating Processes: A Case Study of a Randomized Controlled Trial of Sex Education. Evaluation. 2004 October 1, 2004;10(4):440-62.
10. Cohen D, Crabtree B. Qualitative Research Guidelines Project. Journal [serial on the Internet]. 2006 Date: Available from: http://www.qualres.org/HomeObse-3594.html
11. Fetterman DM. Ethnography Step by Step (2nd Edition). Thousand Oaks, CA: Sage Publications; 1998.
12. McKee KJ, Houston DM, Barnes S. Methods for Assessing Quality of Life and Well-Being in Frail Older People. Psychology and Health. 2002;17:737-51.
13. PARKER C, BARNES S, MCKEE K, MORGAN K, TORRINGTON J, TREGENZA P. Quality of life and building design in residential and nursing homes for older people. Ageing & Society. 2004;24:941–62.
14. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. . In: Bryman A, Burgess R, editors. Analysing Qualitative Data London.
: Routledge,; 1994.
15. Pope C, Ziebland S, Mays N. Qualitative research in health care: Analysing qualitative data. BMJ. 2000 January 8, 2000;320(7227):114-6.
16. Casebeer AL, Verhoef MJ. Combining Qualitative and Quantitative Research Methods: Considering the Possibilities for Enhancing the Study of Chronic Diseases. Chronic Diseases in Canada. 1997;18(3).
17. Bryman A. Integrating quantitative and qualitative research: how is it done? Qualitative Research. 2006;6:97 - 113.
18. Creswell JW, Clark VLP, Gutmann ML, Hanson WE. Advanced mixed methods research designs. Handbook of mixed methods in social and behavioural research. 2003:209 - 40.
19. Stecher B, Borko H. Integrating findings from surveys and case studies: examples from a study of standards-based educational reform. Journal of Educational Policy. 2002;17(5):547 - 69.
20. Bradley F, Wiles R, Kinmonth AL, Mant D, Gantley M. Development and evaluation of complex interventions in health services research: case study of the Southampton heart integrated care project (SHIP). British Medical Journal. 1999;318:711 - 5.

21. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. British Medical Journal. 2000;321:694 - 6.
22. McDowell I, MacLean L. Blending qualitative and quantitative study methods in health services research. Health Informatics Journal. 1998;4:15 - 22.
23. Ong BN. London: Chapman and Hall; 1993.
24. Pope C, Mays N. Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. British Medical Journal. 1995;311:42 - 5.
25. Fulop N, Allen P, Clarke A, Black N. Issues in studying the organisation and delivery of health services. Studying the organisation and delivery of health services Research methods. 2001.
26. O'Cathain A, Murphy E, Nicholl J. Integration and publications as indicators of 'yield' from mixed methods studies. Journal of Mixed Methods Research. 2007;1(2):147 - 63.
27. O'Cathain A, Thomas K. Combining qualitative and quantitative methods. Qualitative Research in Health Care. 2006:102 - 11.
28. Morgan DL. Practical Strategies for Combining Qualitative and Quantitative Methods: Applications to Health Research. Qual Health Res. 1998 May 1, 1998;8(3):362-76.
29. Sandelowski M. Tables or Tableaux?: The Challenge of Wrting and Reading Mixed Methods Studies. In: Tashakkori A, Teddlie C, editors. Handbook of mixed methods in social and behavioral research
London
Sage; 2003.
30. MRC. A Framework for development and Evaluation of RCTs for Complex Interventions to improve Health. London: Medical Research Council; 2000.