**Managing Agitation and Raising QUality of LifE in dementia (MARQUE)**

Feasibility trial of an intervention to improve the management of agitation in severe dementia (workstream 6)

**Statistical and Economic analysis plan**

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Version 1.0, 20/08/2018

Version 0.4, 30/07/2018

Version 0.3, 06/07/2018

Version 0.2, 03/07/2018

Version 0.1, 19/03/2018

**Introduction**

This analysis plan sets out the methods of analysing the predetermined primary, secondary and health economic outcomes of the MARQUE feasibility trial (work stream 6), which will be reported in the National Institute for Health Research/ Economic and Social Research Council report(s) at the end of the trial and also in the main peer review paper(s) to result from this feasibility trial.

It will also follow the appropriate Priment Clinical Trials Unit standard operating procedures. This analysis plan covers the statistical analysis of the clinical outcomes and the health economic analysis. It does not cover the qualitative data collection and analysis.

Further information on this study can be found in the protocol version 4.0 (09/05/2018). The protocol is stored on: S:\FPHS\_PCPH\_Priment\Projects\Current\Non CTIMPS\MARQUE\Protocol\WP6\MARQUE work stream 6\_protocol\_IRAS 226973 v4 09-May-2018 FINAL SIGNED VERSION

**Aims**

To test the feasibility, acceptability and practicality of a pilot manualised staff intervention for severe dementia in three nursing homes.

**Objectives**

1) To assess feasibility of an intervention study (feasible if at least 60% of staff attend at least 3 sessions)

2) To assess acceptability of the intervention (acceptable defined as at least 80% of consenting carers rating the interventions as acceptable or very acceptable on a Likert scale during a focus group.)

3) To describe the consent rate

4) To assess the appropriateness of potential primary and secondary outcomes for a definitive trial to include completeness of data collected on the scales listed below:

1. **Agitation**: Cohen Mansfield Agitation Inventory [CMAI]
2. **Pain**: **Pain Assessment in Advanced Dementia** [PAINAD]
3. **Comfort**: Symptom Management at the End of Life in dementia Scale [SMEOLD]
4. Resident **quality of life**: Dementia Quality of life Proxy scale [DemQoL-Proxy], **Quality of Life in Late Stage Dementia** [QUALID] scale, and EuroQol EQ-5D 5 level [EQ-5D-5L-Proxy]
5. Relatives/Carers **satisfaction with care**: Satisfaction with Care at the End of Life in Dementia Scale [SWCEOLD]
6. **Comfort in those who die** during the study: The Comfort Assessment in Dying with Dementia Scale [CAD-EOLD]
7. **Competence** of paid carers as an outcome: Sense of Competence In Dementia Scale [SCID] as a measure to explore the mechanisms of change for a definitive trial.
8. **Engagement** with residents: the Quality of Interactions Schedule [QUIS]

5) To describe fidelity to the intervention (based on a pre specified checklist)

6) To explore whether it would be feasible to estimate the cost of the intervention

**Study population**

*Inclusion criteria*

Care homes

Dementia registered

Located within 60 minutes’ travel on public transport from Maple House

Will commit to the training being compulsory

Will commit to supporting approaching family carers for individual level data collection

Not planning on closing within the next 12 months

Paid carers (staff)

Permanent care staff

Works at least some day shifts

Residents with dementia

Diagnosis of dementia or a score of two or more on the Noticeable Problems Checklist

A severe rating on the Clinical Dementia Rating Scale

No capacity to consent for themselves

Family carer

Identified as the family carer by the home

The person with dementia is one of the first five in that home to be recruited to the study

*Exclusion criteria*

Care homes

Planned closure in the next 12 months

Paid carers (staff)

Only work night shifts

Bank or agency staff

Residents with dementia

Capacity to consent

No diagnosis of dementia or Noticeable Problems Checklist score less than two

A Clinical Dementia Rating of less than three

**Study design**

A mixed methods study designed to assess a staff level training intervention for feasibility, practicality and acceptability in dementia registered nursing homes with distinct dementia units, sampled to provide diversity in terms of size, ownership, location and residents.

**Intervention**

A four session staff intervention on agitation in severe dementia. Sessions are: understanding and recognising it, common issues in advanced dementia and recognising pain, working with others during advanced dementia and developing an action plan.

**Sample size**

There was no formal sample size calculation. The study aims to recruit three care homes, 60 paid carers, 51 residents with dementia and 15 family carers.

**Data collection**

*Baseline*

Care home

Care home census

Paid carers (about themselves)

Demographics

Sense of Competence in Dementia Care Staff (SCIDS) scale

Resident with dementia (proxy)

Socio-demographic details (age, sex, ethnicity, marital status level of education)

Cohen-Mansfield agitation inventory (CMAI)

EQ-5D-5L

Client Service Receipt Inventory (CSRI) modified for care homes

Medication use

DEMQOL

**Pain Assessment in Advanced Dementia** (PAINAD)

Quality of life in Late-Stage Dementia (QUALID)

Symptoms Management at End-of-Life in Dementia (SM-EOLD)

Family carer

Demographics

Satisfaction with care at the end-of-life in Dementia (SWC-EOLD)

*Follow up (between 11 and 14 weeks)*

Paid carers (about themselves)

Sense of Competence in Dementia Care Staff (SCIDS) scale

Resident with dementia (proxy)

Cohen-Mansfield agitation inventory (CMAI)

EQ-5D-5L

Client Service Receipt Inventory (CSRI) modified for care homes

Medication use

DEMQOL

**Pain Assessment in Advanced Dementia** (PAINAD)

Quality of life in Late-Stage Dementia (QUALID)

Symptoms Management at End-of-Life in Dementia (SM-EOLD)

Family carer

Satisfaction with care at the end-of-life in Dementia (SWC-EOLD)

*If the resident dies*

Family carer

Comfort assessment in dying with dementia (CAD-EOLD)

*At any time*

All

Serious adverse events

Withdrawal

**Standardised measures**

Paid carers (about themselves)

Sense of Competence in Dementia Care Staff (SCIDS) scale1 is a 17 item scale. Items are scored 1=not at all and 4=very much. Scores are added to give an overall score ranging from 17 to 68 with higher scores indicating higher levels of confidence. There are also subscales: Professionalism 7, 8, 9, 10, 12 (scores ranging from 5 to 20); Building Relationships 1, 2, 3, 4 (scores ranging from 4 to 12); Care Challenges 13, 14, 15, 17 (scores ranging from 4 to 12); and Sustaining Personhood 5, 6, 11, 16 (scores ranging from 4 to 12). The overall score will be used, and the subscales explored.

Residents with dementia (proxy)

The Cohen-Mansfield Agitation Inventory (CMAI)2 assesses the frequency of 29 agitated behaviours on a seven point Likert scale; 1=never and 7=several times an hour. The item scores are added to give a total agitation severity score, with a possible range between 29 and 203.

The DEMQOL – proxy3 is a quality of life measure for people with dementia. This proxy version is filled in by people who know the person with dementia well (in MARQUE this will be their main carer in the care home and their main family carer). Items are scored 1=a lot and 4=not at all, with several items being reverse scored (1, 4, 6, 8, 11, 32), so that a higher score equals a better quality of life. If there is less than 50% missing data, the within participant mean is used for each missing item score. The total score is derived by summing the scores of the first 31 items (not item 32), giving a total score ranging from 31 to 124.

**Pain Assessment in Advanced Dementia** (PAINAD)4 has five items (breathing independent of vocalisation, negative vocalisation, facial expression, body language and consolability) which are rated by an observer. Each item is score 0, 1, 2 with 0 being near normal (no pain shown) and 2 being strong indications of pain. The scores from the items are summed to give an overall score between 0 and 10. In the original testing of this measure the score was not Normally distributed.

Quality of life in Late-Stage Dementia (QUALID)5 consists of 11 items, which are scored on five point Likert scales with 1 indicating the best quality of life and 5 indicating worst quality of life. Scores from each item are summed to give a score between 11 (best quality of life) and 55 (worst quality of life).

Symptoms Management at End-of-Life in Dementia (SM-EOLD)6 consists of nine items with scoring options 5=never through to 0=every day, giving a score between 0 and 45, with higher scores indicative of better symptom control.

EQ-5D-5L – proxy7 is a descriptive system that comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The proxy version is for use when patients are mentally or physically incapable of reporting on their health-related quality of life, for instance because of severe intellectual disability or mental health problems. The caregiver (the proxy) is asked to rate the patient’s health-related quality of life in their (the proxy’s) opinion. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient’s health state.

Client Service Receipt Inventory (CSRI)8 is a tool used to collect information on income, accommodation and a record of services that may be used grouped into subsections such as hospital care, primary care, community-based specialist or generic health care, social care, etc. Its primary purpose is to allow resource use patterns to be described and support costs to be estimated using an appropriate unit cost. We will use a modified version for care homes.

Family carers

Comfort assessment in dying with dementia (CAD-EOLD)6 consists of 14 items, each with four response options, giving a total possible scales score between 14 and 42 with a higher score indicating better comfort level.

Satisfaction with care at the end-of-life in Dementia (SWC-EOLD)6 consists of ten items, which are scored from 1 to 4 on a Likert scale. Items 2, 5 and 10 are reverse scored. Possible scores range from 10 to 40, with higher scores indicating more satisfaction.

**Data entry and checking**

Data will be entered using a web based system set up by Sealed Envelope9 by research assistants. This has been set up so that, it mirrors the data collection sheets in order. It also has range checks, consistency checks and for closed questions gives a number of options plus “other” where appropriate. Data will be cleaned by a statistician and health economist (all CSRI and medication data, EQ-5D-5L). If there are any values that are inconsistent and/ or out of range, these will be sent to the Study Manager/ Research Assistants for checking and changing as necessary.

**Statistical analyses**

Analyses will be carried out when database has been cleaned and locked and after the statistical and health economic analysis plan has been finalised.

We will use a consort type diagram to indicate the flow of participants through the study. This will include the numbers eligible, the number consenting and the number available for follow up and will include reasons for non-consent and withdrawal and drop out (objective 3). This will be constructed in conjunction with the Study Manager/ Research Assistants.

The number of intervention sessions attended by the staff will be tabulated and in particular the proportion of staff who attended at least three sessions reported (objective 1).

Fidelity checklist data will be tabulated (objective 5).

Based on data from focus groups % carers who find the intervention acceptable will be reported (objective 2). These data are not stored in the Sealed Envelope database.

We will use descriptive statistics to summarise the care home, staff, family carer and resident characteristics and questionnaire scores at baseline and follow up using mean (SD) or median (IQR) for continuous data and frequency (%) for categorical data and for each report % with missing data (objective 4). We will compare the baseline and follow up questionnaire scores to obtain an estimate of change with 95% confidence interval. We will report correlation coefficients between baseline and follow up measures for all continuous scores.

Care home statistics will be treated with caution as there are only three care homes in the study (therefore a maximum of three data points).

Analyses will be conducted using Stata version 1410 or higher.

**Health economic analyses (objective 6)**

Economic evaluation is recommended in developing and piloting interventions to identify weaknesses and suggest refinements. The aim of this analysis is to assess the feasibility of collecting quality of life and use of health and social care resources information. Findings will be used to refine the methods for a cost-effectiveness analysis as part of a full trial. We will also make an initial assessment of the cost of the intervention (including the cost of training and delivery of the intervention) based on information collected as part of trial monitoring processes and costed using published sources11. Individual use of health and social care resources will be collected using an adapted version of the CSRI. We will assess the best methods for collecting these data as part of the trial including a mixture of resident care home records, staff and hospital records. Descriptive statistics will be reported for missing data, the proportion of residents accessing each type of resource use and the mean number of contacts for the duration of the trial. We will assess the feasibility of collecting information on the impact on relatives/carers including time, financial and quality of life impact and report descriptive statistics for missing data and mean values.

Measuring quality of life at the end of life to calculate cost-effectiveness is fraught with a range of issues including the suitability of outcome measures, appropriate valuation, suitability and reliability of proxy responses and more practical issues related to data collection12. We will explore the feasibility and implications of using the EQ-5D-5L proxy version, DEMQoL proxy version and QUALID to calculate quality of life as part of a cost-effectiveness analysis. This will include descriptive statistics on data completeness, acceptability of measures, ceiling/floor effects, means and standard deviations.

**References**

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