The Better Health in Residents in Care Homes study (BHiRCH)

**Statistical and Economic analysis plan**

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**Introduction**

This analysis plan sets out the methods of analysing the predetermined primary, secondary and health economic outcomes of BHiRCH, which will be reported in the National Institute for Health Research report at the end of the trial and also in the main peer review paper to result from this randomised controlled trial.

The analysis of this cluster randomised trial will follow the CONSORT statement guidelines and the associated extension for cluster randomised trials1, 2 and ICH E93. It will also follow the appropriate standard operating procedures written by Priment Clinical Trials Unit. This analysis plan covers the statistical analysis of the clinical outcomes as well as the health economics analysis. It does not cover any qualitative data collection and analysis which may be undertaken as part of this trial.

Further information on this trial can be found in the protocol version draft 2 (27/07/2017). The protocol is stored on: S:\FPHS\_PCPH\_Priment\Projects\Current\Non CTIMPS\BHIRCH\Pilot Trial\170142 BHiRCH signed protocol clean V3 11.10.17

**Trial summary**

**Aim**

To determine whether a full trial would be viable in terms of recruitment, retention and quantification of potential primary outcomes.

**Objectives**

To determine if recruitment and retention are sufficient to carry out a full trial

To evaluate whether hospital admissions for respiratory infections, urinary tract infections, dehydration and exacerbation of chronic heart failure are lower in the intervention group than the treatment as usual group

To assess whether activities of daily living differ between randomised groups (Barthel Index)

To evaluate whether person centred care differs between randomised groups (Organisational support for person centred care P-CAT).

To collect cost and outcome data for use in an economic evaluation

Estimate the probability that the intervention is cost-effective

Establish the key cost components through economic analysis and the expected value of perfect information (EVPI)

**Study population**

*Inclusion criteria*

Care homes

Expression of interest in the trial

Have adequate staffing for the intervention

Have the capacity to implement the components of the intervention

Individuals

All English speaking staff, residents and their care partners will be invited to be involved in the collection of individual level data.

*Exclusion criteria*

Care homes

Placed into special measures by the Care Quality Commission (CQC)

Individuals

Residents receiving end of life treatment or palliative care

Those who have stated they do not wish to be involved in research.

Under 65 years old

**Trial design**

This is a pilot cluster randomised trial, where the care home is the unit of randomisation, and the intervention is aimed at the care home staff to reduce the rate of hospital admissions for respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure by ensuring early detection and intervention.

**Randomised treatments**

*Intervention*

The BHiRCH programme is a complex intervention, with four key components. These are:

* Early Warning Tool (Stop and Watch Early Warning Tool)
* Care Pathway (clinical guidance and decision support system)
* Structured method for communicating with primary care (SBAR)
* Implementation support from practice development champions and practice development support groups

These elements of the intervention are explained further in the protocol.

*Treatment as usual*

This is treatment as usual. This may vary between care homes.

**Sample size**

This is a pilot trial and as such a sample size calculation is not relevant.

**Randomisation**

Fourteen care homes will be recruited; eight in West Yorkshire and six in London. They will be randomised to the intervention or usual care with a ratio of 1:1. Recruitment and consent of a given care home and its residents will take place prior to randomisation. Randomisation will be carried out using SAS. Further details on this can be found in the randomisation protocol. There will be stratification by area (West Yorkshire or London).

**Blinding**

It may not be possible to blind the researchers visiting the care homes to allocation. The care home staff cannot be blinded to allocation. However, the residents and the care partners may not be aware whether their care home is in the intervention or treatment as usual group. The statistician and health economists will analyse the data blind to allocation. Allocation will only be revealed when analyses have been checked.

**Outcomes**

*Primary outcome*

Acute hospital admissions for respiratory infections, urinary tract infections, dehydration and exacerbation of chronic heart failure over the study period. This will be a count for each resident in the study of number of times they have been admitted overall.

*Secondary outcomes*

Acute hospital admissions for respiratory infections, urinary tract infections, dehydration and exacerbation of chronic heart failure separately (4 outcomes) over the study period. These will be a count for each resident in the study of number of times they have been admitted

Activities of daily living measured by the Barthel Index4. This is scored in increments of five, though there is not equal weighting for each item such that some items are scored to a maximum of 5 while others are scored to a maximum of 15. There are ten items, and the total score ranges from 0 to 100.

Organisational support for giving person centred care using the Person-centered Care Assessment Tool (P-CAT)5. This consists of 13-items formulated as statements about the extent of personalising care, degree of environmental accessibility, and amount of organisational support. A total score is calculated; higher scores indicate a higher degree of person-centredness. Scores range from 13 to 65.

Nurse-physician communication in the long-term care setting was assessed using the Nurse ratings of communication with primary care questionnaire6. It is an 18-item questionnaire. Questions address aspects of communication described in the literature, including openness, mutual understanding and language comprehension, frustration with the interaction and professional respect, nurse preparedness, time burden and logistical barriers to communication. Questions are rated on a 5-point Likert scale with 1= almost never and 5= almost always. These will be dichotomised to 1 to 3= no and 4 and 5= yes

The perceived knowledge and skills for early detection of changes in health questionnaire was developed after the feasibility study by the BHiRCH team. Each statement refers to the key knowledge and skills which are needed for nurses to effectively carry out the BHiRCH intervention. This questionnaire will provide a measure of knowledge and skills before, during and after the intervention. Questions are rated on a 5-point Likert scale (1=disagree completely to 5=agree completely). Each question will be described separately.

*Process outcomes*

To establish whether resident consent procedures allow the collection of sufficient individual level data

Assess fidelity to the intervention

Assess the level of nursing home staff engagement with the intervention

Measure the completeness of data collection, completion of documentation and return rate of questionnaires.

*Safety outcome*

Serious adverse events

*Health economic outcomes*

Incremental costs per quality-adjusted life years (QALYs) of the intervention compared to treatment as usual, from the perspective of the NHS and personal social services (PSS).

**Data collection**

*Baseline (pre-intervention)*

Care home

Care home characteristics

Number of residents, staff and care partners approached and number consenting

Number of hospital admissions

Number of ambulances called

Number of unscheduled (out of hours) GP visits or telephone contacts

Number of Accident and Emergency attendances

Staff turnover

Number of beds available to new residents in the last month

Length of hospital admissions

Deaths

Resident

Demographics

EQ-5D-5L8

Care partner

Demographics

Preferred role re involvement in health care of their relative

EQ-5D-5L

Staff

Demographics

P-Cat5

Nurse ratings of communication with primary care6

Core competencies for early detection in changes in health

Staff on behalf of residents

Barthel Index4

EQ-5D-5L proxy for resident8

Resident medication from records

Resident CSRI from records9

Resident number of acute hospital admissions from respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure

Resident number of hospital admissions

Resident number of ambulances called

Resident number of unscheduled (out of hours) GP visits or telephone contacts

Resident number of Accident and Emergency attendances

Resident length of hospital admissions

Resident death

Months 1 to 6

Care home

Number of hospital admissions

Number of ambulances called

Number of unscheduled (out of hours) GP visits or telephone contacts

Number of Accident and Emergency attendances

Staff turnover

Number of beds available to new residents in the last month

Length of hospital admissions

Deaths

Staff on behalf of residents

Resident medication from records

Resident CSRI from records

Resident number of acute hospital admissions from respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure

Resident number of hospital admissions

Resident number of ambulances called

Resident number of unscheduled (out of hours) GP visits or telephone contacts

Resident number of Accident and Emergency attendances

Resident length of hospital admissions

Resident death

Month 6

Resident

EQ-5D-5L

Care partner

EQ-5D-5L

Staff

P-Cat

Nurse ratings of communication with primary care

Core competencies for early detection in changes in health

Staff on behalf of residents

Barthel Index

EQ-5D-5L proxy for resident

**Data entry**

Data will be entered using a web based system set up by Sealed Envelope11 by the researchers. 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 the 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/ researchers for checking and changing as necessary.

**Statistical analyses**

The CONSORT flow diagram will be constructed by/ in collaboration with the Study Manager/ researchers/ Study Administrator who will have logs of care homes, paid carers, residents and care partners who do and do not agree to take part in the study. It will include number of care homes randomised to each arm of the trial, and the number of residents it encompassed at baseline (pre-intervention) and follow up and those who explicitly refused. The process outcomes related to recruitment and retention will be calculated from the data required to construct the CONSORT diagram.

All analyses will be on an intention to treat basis.

Analyses will be conducted using Stata version 1412.

*Descriptive statistics*

Individual level data (paid carers, residents and care partners)

The distribution of continuous variables will be explored, both overall and by randomised group, with measures of central tendency, and variability. For categorical variables examination of the data will calculate frequencies and percentages with given characteristics, both overall and by randomised group. Large differences between randomised groups will be noted.

Rates of admission for respiratory infections, urinary tract infections, dehydration and exacerbation of chronic heart failure will be presented as the difference between rates of admissions and 95% CI.

The intraclass correlation coefficient will be calculated for the outcome that is likely to be the primary outcome in a full trial. Other parameters needed to calculate the sample size for a full trial will be presented.

Aggregate level data (care home)

Descriptive statistics will be calculated for these data. However, they should be interpreted with caution as there will only be seven care homes in each randomised group.

*Missing data*

Missing data will be explored to determine its patterns and extent. This will be in terms of data from individual participants over time and whether there are given questions/ items within scales that have large percentages of missing data.

**Health economic analyses**

The health economic analyses will provide estimates of the costs, effects and relative cost-effectiveness of the BHiRCH intervention compared to treatment as usual. Analyses will conform to accepted economic evaluation methods13.

We will calculate mean cost per resident of the BHiRCH intervention. The cost of intervention will include staff training, learning materials and time spent by staff with residents when the intervention is implemented.

Resource use associated with hospital admissions, primary care and other NHS and social care costs will be collected using the CSRI at baseline and months 1 to 6 post-randomisation. These will be costed for each resident using unit costs from the most recent Unit Costs of Health and Social Care published by the Personal Social Services Research Unit (PSSRU)14 and NHS reference costs15. The cost of prescriptions will be taken from the British National Formulary16.

Mean cost per resident for the BHiRCH intervention and treatment as usual will be reported by type of service use. Costs will be reported from an NHS/PSS, government and societal perspective.

We will calculate the mean cost per quality-adjusted life years (QALYs), using the EQ-5D-5L and the associated algorithms17, 18 mapping19 the 5L descriptive system data onto the 3L valuation set as recommended by NICE20. The mean QALY per resident will be calculated as area under the curve for the duration of the trial, adjusting for baseline values.

In the societal level analysis, a calculation of carers’ QALYs will be included.

Confidence intervals for mean costs and QALYs will be calculated using non-parametric bootstrap with replacement.

We will calculate the incremental mean cost per QALY gained in BHiRCH intervention compared to treatment as usual for the duration of the trial. The results of the non-parametric bootstrap will be presented on a cost-effectiveness plane (CEP). Cost-effectiveness acceptability curves (CEACs), showing the percentage of cases that the BHiRCH intervention is cost-effective, over a range of values of willingness to pay for a QALY gained, will be constructed using the bootstrap data from a range of values of willingness to pay for a QALY gained for each different costing perspective and for the different methods of calculating QALYs. The probability that the BHiRCH intervention is cost-effective compared to treatment as usual at a willingness to pay for a QALY gained of £20,000 and £30,000 will be reported.

We will model the lifetime costs and outcomes of the BHiRCH intervention compared to treatment as usual. This will involve assessing the quality of the published information available, the development of an initial model and identification of which cost and outcome components would benefit most from further research, i.e. extra value of perfect information (EVPI) and extra value of partial perfect information (EVPPI) analysis21, 22 for a single and groups of parameters using the Sheffield Accelerated Value of Information (SAVI) model23.

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