

FOR INFORMATION: BHiRCH-NH Pilot study set-up plan

9th October 2017

Visit 1: with care home manager and research facilitator

1. Obtain care home-level consent from the care home manager
2. Obtain consent from research facilitator
3. Clarify key points that have emerged from the feasibility study:
 - a. Emphasise the importance of management support for the intervention
 - b. Clarify the allocation and purpose of control/intervention conditions
 - c. Emphasise the benefits of participation
 - d. Provide detail of post-study offer and benefits to the care home
4. Assist in identification of Practice Development Champions:
 - a. Remind manager of role of Practice Development Champions – go over Job description and person specification, remind that they are released for training on work time
 - b. Remind manager of dates in January for PDC training (London 24th Jan, Yorkshire 26th Jan)
5. Agree date that would suit to come back to meet with Research Facilitator
6. Agree launch event dates
7. Agree that certificates of participation will be awarded
8. Distribute posters and flyers in the care home
9. Discuss financial incentive and key expectations from both sides (see Appendix for a list of things you might cover, page 4).
 - a. Request a contact to arrange payment.

Documents to bring:

- b. Launch event poster; BHiRCH-NH project posters (Staff and family); BHiRCH-NH flyers; public sign-up sheet,
- c. Job description and person specifications: Research facilitator & PDCs
- d. Information sheet/consent form: Care home manager, GP, resident, care partner, personal consultee, professional consultee
- e. Cover letter and reply slips: Care Partner, Personal consultee
- f. Electronic copies of letters, etc that will need to be tailored to individual residents (e.g. resident/GP letters)

After the meeting:

Send an email recapitulating what you have covered and agreed, in particular:

- g. Expectations on both sides (Appendix A – briefly)
 - h. Key actions to take in the short-term
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Visit 2: with research facilitator (in same month ethics has been granted)

Planning recruitment of residents, staff and families:

- Describe our intended approach to recruitment
- Identify suitable meetings to attend for recruitment (staff, resident, family meetings)
- Obtain list of all **residents**
 - Determine eligibility and potential mental capacity assessment needs
 - Identify who can introduce researchers to residents
- Obtain list of all **staff** (plus staff rota)
 - Identify how to contact staff to gain consent
- Discuss procedures around mailing out study information (information sheets, consent forms, etc) to family members of care home residents
- Discuss need for professional consultees
 - Identify existing professional consultees
 - Explore options for providing light training to new professional consultees from the care home staff

Planning data collection:

- Identify staff rotas to facilitate collection of data from staff
- Ask the research facilitator to identify a quiet space to carry out data collection (e.g. questionnaires)
- Ask the research facilitator to identify a secure location for storage of study materials
- Identify how to access residents' care and medication records
- Identify times of day that are most acceptable to residents for data collection

Documents to bring:

- participant log;
- pre-intervention CRFs.

After the meeting

Send an email recapitulating what you have covered and agreed, in particular:

- i. Key actions to take in the short-term

Visit 3: with research facilitator (within one month of ethical approval)

- Review how recruitment and data collection are proceeding
- Documents to bring: Additional publicity materials and CRFs as necessary

Visit 4: with research facilitator (within two months of ethical approval)

- Review how recruitment and data collection are proceeding
- Documents to bring: Additional publicity materials and CRFs as necessary

Visit 5: with research facilitator and care home manager (Following randomisation)

- Discuss the outcome of randomisation and address any concerns
- Discuss plans for ongoing data collection

Appendix A – Expectations and Payments

This document outlines key expectations of the Research Team and Care Home staff during the BHiRCH-NH Pilot Trial.

What you can expect from the Research team

Set-up

- We will hold set-up meetings with the manager and subsequently a member of administrative staff (a Research Facilitator) who will be able to assist in setting up the research.
- With this Research Facilitator, we will identify members of staff, residents and family members who are eligible to participate in the research.
- We will work with the Research Facilitator to hold a Launch Event for the study in the care home on a suitable date.

Recruitment and data collection (all nursing homes)

- Members of the research team will be in the care home several days each week until the end of 2018, recruiting and collecting data.
- Researchers will be in the care home for 2-3 days per month for ongoing data collection throughout 2018.

Allocation to groups

- At the end of December, nursing homes will be randomised to a Control group (do not receive the intervention) and an Intervention group (receive the intervention). We will notify you of the outcome for your care home at this time.
- Care homes which are randomised to the intervention will receive a total payment of £1500, and care homes which are randomised to the control group will receive £1000. These payments are provided to reimburse the time care home staff have

spent being involved in research activities. Payments are distributed across the course of the study as shown in table 1.

Training

- (Intervention Group) We will provide a training course to two nurses in January 2018, which will help them implement the intervention.

What we expect from the Nursing Home

Set-up

10. The care home manager and a member of administrative staff (the Research Facilitator) will meet with a researcher at the start of the project to help set up research activities.
11. The care home manager will work with researchers to identify two nurses to be trained as Practice Development Champions on one-day training course in January.
12. The Research Facilitator will continue working with researchers to identify participants and contact family members, etc.
13. The Research Facilitator will help to introduce researchers to care home residents.
14. The care home will collaborate in organising a Launch Event for the study on a suitable date.

Changes to usual care

15. Practice Development Champions will be authorised to make changes in how the care home monitors changes in health, and to set up a working group (Practice Development Support Group) to facilitate adoption of these changes.

Data collection

16. Care home staff will be authorised to give up some time to participate in filling in questionnaires or attending focus groups if they choose to do so.
17. The research facilitator will assist researchers in collecting data on hospitalisations, resident contact with primary care, etc.