ISRCTN74109734 https://doi.org/10.1186/ISRCTN74109734

The better health in residents in care homes study: Pilot study

Submission date
06/11/2017

Recruitment status
No longer recruiting

Registration date
10/11/2017

Overall study status
Completed

Last Edited
05/03/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Early detection and intervention for ill health in residents in care homes with nursing is problematic. People living in care homes can be admitted to hospital for conditions which, if noticed and treated earlier, could be managed in the care home. The Better Health in Residents in Care Homes (BHiRCH) programme aims to reduce rates of avoidable hospital admissions from care homes (with nursing) for respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure by ensuring early detection and early intervention. This has the potential to prevent an emergency presentation to hospital. This project is focused on these four conditions which are responsible for a large proportion of unplanned hospitalisations. Our Programme Development Grant identified multi-component interventions which, when tested in other nursing homes, showed promise in reducing avoidable admissions. The aim of the research is to identify whether a further definitive study is warranted.

Who can participate?
Residents aged 65 and older of care homes.

What does the study involve?
The BHiRCH programme comprises the following components: Early Warning Tool (Stop and Watch Early Warning Tool), Care Pathway (clinical guidance and decision support system), Structured method for communicating with primary care, Knowledge and skills development for care home staff and family members, close friends or care partners, Family members, close friends or care partners' involvement, and implementation support. Nursing homes are randomly allocated one of two groups. Those in the first group receive the usual care. Those in the second group receive the BHiRCH programme. Two nurses within each home become Practice Development Champions who are trained to implement the intervention, and these nurses are supported by a Practice Development Support Group. Number of avoidable hospital admission are recorded along with other data collected from staff, residents and care partners through questionnaires.

What are the possible benefits and risks of participating?
Participants may value speaking to the research team about their experiences. There are no direct risks however participants may become tired when answering the questionnaires.

Participants are invited to let the researcher know and participants can take a break, re-schedule or stop taking part in the study.

Where is the study run from?
This study is being run by University College London (UK) and takes place in 14 care homes across Yorkshire and London.

When is the study starting and how long is it expected to run for?
April 2017 to April 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Murna Downs
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Study website
https://www.brad.ac.uk/health/dementia/research/bhirch

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35749

Study information

Scientific Title
BHiRCH: Pilot cluster randomised trial of an evidence based intervention to reduce avoidable hospital admissions in residents in care homes (the Better Health in Residents in Care Homes study)

Acronym
BHiRCH

Study objectives
The Better Health in Residents in Care Homes (BHiRCH) programme is developing an intervention that aims to reduce rates of avoidable hospital admissions from care homes (with nursing) for respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure by ensuring early detection and early intervention. The aim of this pilot trial is to test study procedures and outcome in order to assess whether a further definitive study is warranted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen Square Research Ethics Committee, 18/10/2017, ref: 17/LO/1542

Study design
Randomised; Interventional; Design type: Treatment, Screening, Diagnosis, Prevention, Complex Intervention, Management of Care, Active Monitoring

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Ageing, Primary sub-specialty: Ageing; UKCRC code/ Disease: Generic Health Relevance/ No specific disease

Interventions
The intervention is implemented at the level of the whole care home.
The BHiRCH programme is a complex intervention, with 4 key components. These are:
1. Early Warning Tool (Stop and Watch Early Warning Tool)
2. Care Pathway (clinical guidance and decision support system)

3. Structured method for communicating with primary care (SBAR)
4. Implementation support- practice development champions and support groups.

This is a cluster randomised trial conducted in 14 nursing homes. The 14 homes arerandomised 1: 1 between intervention and “usual care”, stratified by location. Randomisation is undertaken by an independent statistician from the CTU using a statistical programme called SAS. All homes are randomised at the same time, just prior to the intervention starting. The intervention takes place over 12 months, with a pre-intervention period of three months for recruitment and baseline data collection, and a post-intervention period of one month for completion of outstanding data collection.

This intervention acts upon a group of people (the nursing home staff who work with residents and their family carers) and thus the nursing home is the unit of intervention, allocation and analysis. Staff in nursing homes receiving the intervention receive training in the use of a new method of detecting, assessing and communicating changes in the health of residents. Staff, residents and family members may also opt in to individual level data collection, in which further information about their quality of life, perspectives on the care home, and usual care are collected.

The CONSORT guidelines for the reporting of randomised trials are followed however, given that this is a pilot study, the analysis will be mainly descriptive and will focus on the recruitment, participant characteristics, other baseline and outcome variables, loss to follow-up and any adverse events. Descriptive analysis of all the data (including the completeness of data collection) is done and the rates of hospital admission for ACS conditions and other important outcomes are compared between the control and intervention groups through the calculation of confidence intervals.

Intervention Type
Other

Primary outcome measure
Reduction in avoidable acute hospital admissions for respiratory infections, urinary tract infections, dehydration and exacerbation of chronic heart failure. The number of hospital admissions will be recorded from care home records. Residents who have been hospitalised and have consented to individual level data collection will be eligible for analysis for this outcome. Their care records will be analysed using the SIRR tool, and this data will be further assessed by an expert panel of geriatricians to identify whether the hospitalisation was avoidable. This assessment will be carried out shortly after the hospitalisation of any resident.

Secondary outcome measures
1. Establish whether resident consent procedures allow the collection of sufficient individual level data using the number of residents who have consented at the end of the Pilot Trial
2. Effectiveness of the implementation strategy is assessed using qualitative data on barriers and facilitators to implementation. This will be recorded from telephone calls with Practice Development Champions on a monthly basis, and from qualitative interviews with care home staff at the end of the Pilot Trial
3. fidelity to the intervention is assessed using research field notes from telephone calls with Practice Development Champions on a monthly basis, and from qualitative interviews with care home staff at the end of the Pilot Trial
4. The level of nursing home staff engagement with the intervention is assessed using qualitative interviews with care home staff at the end of the Pilot Trial, and the number of

recorded usage of the intervention tools (on a monthly basis)
5. Sustainability of the intervention outside the context of a trial is assessed using qualitative interviews with nursing home staff (at the end of the Trial) and researcher field notes on support provided, from monthly telephone calls with Practice Development Champions
6. Potential primary and secondary outcomes for a definitive trial are assessed using an analysis of the completeness of data at the end of the pilot trial
7. Cost and outcome data is measured using an economic evaluation based on prescription medication usage and the CSRI tool, collected monthly from residents who have consented
8. Probability of the intervention being cost-effectiveness is assessed using an analysis of prescription medication usage, CSRI data and staff time spent on the intervention, collected monthly from resident care home data and telephone calls with staff
9. Key cost components through economic analysis and the expected value of perfect information (EVPI) is assessed using an analysis of prescription medication usage, CSRI data and staff time spent on the intervention, collected monthly from resident care home data and telephone calls with staff
10. Completeness of data collection is assessed using the completion of documentation and return rate of questionnaires on a monthly basis throughout the trial

Overall study start date
03/04/2017

Completion date
30/05/2019

Eligibility

Key inclusion criteria
1. The study implements an enhanced version of usual care and because of the clustered nature of the setting this will be implemented across the care home. All residents will be invited to be involved in the collection of individual level outcome data.
2. Aged 65 and older

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 700; UK Sample Size: 700

Key exclusion criteria
1. Residents receiving end of life treatment or palliative care, under the age of 65, those who are not english speaking or those who have stated they do not wish to be involved in research
2. Care partners will be excluded from the project, and no more data will be collected if their relative/friend passes away during the project

Date of first enrolment
31/10/2017

Date of final enrolment
26/01/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Albany Nursing Home
London
United Kingdom
E10 7EL

Study participating centre
Albany Park,
43 St Stephens Road
Enfield
United Kingdom
EN3 5UJ

Study participating centre
Azalea Court
58 Abbey Road
Enfield
United Kingdom
EN1 2QN

Study participating centre
Stamford Nursing Home
21 Watermill Lane
London
United Kingdom
N18 1SH

Study participating centre

Aspray House
481 Lea Bridge Road
London
United Kingdom
E10 7EB

Study participating centre
Manor Farm
211/219 High Street South
London
United Kingdom
E6 3PD

Study participating centre
Apley Grange Care Home
35 Oatlands Drive
Harrogate
United Kingdom
HG2 8JT

Study participating centre
Bilton Hall Nursing Home
Bilton Hall Drive
Knaresborough
United Kingdom
HG1 4DW

Study participating centre
Fulford Nursing Home
43 Heslington Lane
Fulford
United Kingdom
YO10 4HN

Study participating centre
Kingston Nursing Home
7 Park Crescent
Leeds
United Kingdom
LS8 1DH

Sponsor information

Organisation
University College London

Sponsor details
1st Floor Maple House
149 Tottenham Court Road
London
England
United Kingdom
W1T 7DN

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will publish a protocol paper in 2018, and a paper on the effectiveness and cost-effectiveness of the intervention in late 2019.

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V3	11/10/2017	14/09/2018	No	No
Participant information sheet	version V3	11/10/2017	01/04/2019	No	Yes
Protocol article	protocol	27/05/2019	19/02/2020	Yes	No
Results article	results	01/02/2021	05/03/2021	Yes	No
Results article	results	13/12/2020	05/03/2021	Yes	No
HRA research summary			28/06/2023	No	No