A pilot cluster randomised trial of an evidence-based intervention to reduce avoidable hospital admissions in nursing home residents (Better Health in Residents of Care Homes with Nursing - BHiRCH-NH study)

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Abstract

Background: Nursing home residents are often frail and most have complex healthcare needs. Hospitalisation is distressing to the person, their family and nursing home staff and costly for health services. Early detection of changes in residents' health may reduce admissions. Our aim was to pilot a complex intervention with implementation support to improve early detection and treatment for four common Ambulatory Care Sensitive Conditions (ACSCs); urinary tract and respiratory infections, chronic heart failure and dehydration.

Methods: Pilot cluster randomised controlled trial in 14 nursing homes (7 intervention, 7 control). The intervention involved 1) "stop and watch (S&W)" early warning tool for changes in physical health, 2) condition- specific care pathways and 3) Situation, Background, Assessment and Recommendation (SBAR) to structure communication with primary care. of Intervention implementation was supported by Practice Development Champions (PDCs) in the care home, a Practice Development Support Group (PDSG) and regular telephone coaching with external facilitators. We collected data on nursing homes (quality ratings, size, ownership), residents, their family carers and staff demographics during the month prior to intervention and subsequently, numbers of admissions, accident and emergency visits and unscheduled GP visits monthly for 6 months during the intervention period. We collected data on how the intervention was used, healthcare resource use and quality of life data for economic evaluation. We assessed participant recruitment and retention and whether a full trial was warranted.

Results: We recruited 14 nursing homes, 148 staff, 95 family carers and 245 residents. One nursing home closed prior to the intervention starting and another withdrew during the data collection phase. We retained the majority of participants recruited (95%). 15% of residents had an unplanned hospital admission for one of the four study conditions during follow-up. We were able to collect sufficient data on study questionnaires (all were over 96% complete). No home implemented intervention tools as planned. Only 16 S&W forms and 8 Care Pathways were completed. There was no evidence that the intervention was harmful.

Conclusions: Study recruitment, retention, data collection and processes were effective but the intervention was not implemented in practice, therefore a full trial is not warranted.

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Background

Currently in the United Kingdom (UK) more than 420,000 people aged over 65 years live in residential care, of which approximately 220,000 reside in care home with nursing (referred to subsequently in this paper as "nursing homes") [1]. Older people living in nursing homes have complex healthcare needs with high levels of multi-morbidity, frailty and dementia. These conditions become more prevalent with age and demographic changes in the UK population have led to a 63% increase in all-cause hospital admissions from nursing homes between 2011-2015 [2].

As well as causing distress to residents, their families and staff, hospitalisation is expensive for health and social care systems, costing an estimated £1.2 billion per annum in the UK [3]. Hospital admission increases the risk of decline in functional ability, delirium, adverse events and prolonged stays [4, 5]. Areas with many nursing homes have higher rates of unplanned hospital admission in the over-75 age group [6]. The King's Fund [7] and British Geriatrics Society [8] have raised concerns about the quality of healthcare provision to nursing homes and the UK National Health Service (NHS) [9] has made reducing avoidable hospital admission from nursing homes a priority for the UK government.

Ambulatory Care Sensitive Conditions (ACSCs) are "conditions that can lead to unplanned hospital admissions that may have been avoidable or manageable by timely access to medical care in the community" [10]. The conditions include angina, asthma, cellulitis, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), dehydration, diabetes mellitus, gastroenteritis, epilepsy, hypertension, hypoglycaemia, urinary tract infections (UTI), pneumonia, severe ear, nose, and throat infections [11]. In the UK, ACSCs account for one sixth of hospital admissions from all age groups [7] [12]. Four ACSCs contribute to a 30% of hospitalisations from nursing homes [3]: respiratory infections [13] [14-16]; acute exacerbation of chronic heart failure [17, 18]; urinary tract infections [15, 19]; and dehydration [15] and may underlie other problems such as falls and delirium.

A number of interventions have been developed to reduce hospital admissions from nursing homes, falling broadly into two categories; multicomponent interventions (implementation of a range of tools) and single component interventions (predominantly advance care planning or single disease care pathways, e.g. for pneumonia). Multicomponent interventions show reductions in avoidable admissions [20-24]. Key characteristics include enhancing knowledge and skills of nursing home staff [25], clinical guidance and decision-support tools (care pathways), engaging with families [26], and specialist input from geriatricians or nurse practitioners [27]. In addition, research highlights the importance of collaborative development of interventions with nursing home staff [28], residents and families [26], underpinning implementation [18] and using local champions to support the implementation in practice.

Intervention development

The intervention with the strongest evidence base is "INTERACT" (Interventions to Reduce Acute Care Transfers). This complex intervention, based on principles of quality improvement, developed and implemented in the USA, aims to detect and diagnose a range of medical conditions in residents recently discharged from hospital to skilled nursing facilities in order to reduce readmissions. INTERACT focusses on managing acute changes in residents' condition using [18]:

- Communication tools, e.g. Stop and Watch early warning tool and SBAR (Situation Background Assessment Response) structured communication with primary care tool
- Care pathways or clinical tools addressing (for example) dehydration, UTI, fever and acute mental status change
- Advanced care planning (ACP), tracking and communication tools.

We worked with stakeholders including staff and our (family) Carer Reference Panel (CRP), to develop and adapt the INTERACT communication and care pathway tools for use in the UK [29] (paper in preparation). We did not include ACP tools in our version of INTERACT because this is already a separate area of focus in many UK nursing homes. The Promoting Action in Health Services (PARiHS) framework underpinned co-design of implementation support and guidance package for use in UK nursing homes [30].

Aim and objectives

The aim of this pilot trial was to indicate whether a definitive study is warranted.

Primary objective:

The primary objective was to indicate whether the intervention was acceptable and feasible.

Secondary objectives:

1. Establish whether consent procedures facilitate collection of sufficient individual-level data
2. Assess intervention fidelity
3. Assess the effectiveness of the implementation strategy and level of nursing home staff engagement with the intervention
4. Indicate whether the intervention would be sustainable outside the trial context
5. Assess potential primary and secondary outcome measures for a definitive trial
6. Measure completeness of data collection, documentation, return rate of questionnaires and assess potential primary and secondary outcomes for a definitive trial
7. Assess feasibility of collecting data for economic evaluation.

Methods

Trial design

A pilot cluster randomised trial in nursing homes with evaluation of the implementation strategy. In this paper we report the findings from the trial, findings from the implementation evaluation will be published separately. The nursing home was the unit of allocation with seven intervention and seven control sites. The trial was conducted and reported as per the CONSORT guidance [31].

Study population and eligibility criteria

Nursing homes

We recruited 14 nursing homes with qualified nurses on site (8 in West Yorkshire and 6 in London) with adequate staffing to implement the intervention and support research activities. These were identified via

local Clinical Research Networks, and the ENRICH (Enabling Research in Care Homes) Network, purposively selected to include a range of providers (large and small chains, independent providers), urban, suburban and rural. Nursing homes rated “inadequate” by the Care Quality Commission (CQC) (UK body responsible for assuring care quality) were ineligible. Managers, regional managers, or owners gave written permission. We designed the Better Health in Residents of Care Homes with Nursing (BHiRCH-NH) intervention to deliver an enhanced version of “usual care” by existing staff, implemented at nursing home level. Therefore, individual consent was not required to receive the intervention.

Individual participants

We invited all English-speaking staff and residents over 65 years and their carers (family members or friends) to participate in individual-level data collection until we had recruited approximately 20 residents and 10 staff from each nursing home. We excluded residents receiving end-of-life care or those who did not wish to be involved in research. We did not collect further data from the carer if the resident died during follow-up.

Consent procedures

Ethical approval was given by the Queen Square London Research Ethics Committee (reference 17/LO/1542).

Residents

A Research Facilitator, employed by the nursing home assisted with study recruitment and provided pseudo-anonymised data at the nursing home level. The care home manager or deputy manager identified all potentially eligible residents. If necessary, the research team conducted a capacity assessment with respect to participation in this trial, adhering to the UK Mental Capacity Act (2005). If the resident lacked capacity to consent, we used a personal consultee (friend or family), or if not available, a professional consultee (member of health or social care staff with a professional relationship to the resident but no connection with the project). If a resident lost capacity during the study a consultee was found. During the study we considered ongoing (process) consent, checking willingness to participate with the resident or consultee.

Family carers and nursing home staff

We invited a family carer and nursing home staff associated with residents recruited to the study to answer questionnaires and they gave informed consent for this.

Intervention

For intervention details see Sampson et al. (2019) [29]. The pilot trial ran for 10 months between November 2017 and August 2018. Sites were set up in months one and two, in month three we collected pre-intervention (baseline) data over four weeks before the intervention was implemented. The intervention ran for 6 months with final follow up data collection and site closure occurring in month 10.

We originally planned for the trial to run for 16 months between November 2017 and March 2019 but had to reduce the follow up period due to delays in obtaining ethical approvals. Thus, the data collection plan differs from that published in our protocol paper [29]. The intervention was delivered by nursing home staff trained and supported by Practice Development Champions (PDCs) nominated from each intervention nursing home by its managers.

Implementation support

1)
Practice Development Champions' workshop

We delivered a one-day workshop to two PDCs from each nursing home by the research team comprising an introduction to the four key conditions (respiratory and urinary tract infections, dehydration and acute exacerbation of chronic heart failure) and elements of how to bring about organizational change. We gave an overview of intervention materials including the Stop and Watch, Care Pathways, and structured approach to effective communication with primary care staff (SBAR).

2)
Ongoing implementation support
1.
We supported PDCs with a project handbook and the Practice Development Workbook for Nursing, Health and Social Care Teams: Resources for Health and Social Care Teams [32].
2.
We expected PDCs to establish a Practice Development Support Group (PDSG) to support their work in the nursing home. This "quality collaborative" approach [33] involves diverse stakeholders working together to close the gap between actual and potential practice.
3.
We offered monthly telephone coaching to the PDCs by senior nurse researchers on our team (BMcC and KF).

The intervention (BHiRCH-NH)

This consisted of three key components, all paper-based as UK nursing homes have variable use of electronic records:

1.
Early Warning Tool (Stop and Watch Early Warning Tool) [34]
2.
Care Pathways (clinical guidance and decision support system)
3.
Structured method for communicating with primary care (SBAR)

Details of intervention components

1.
Stop and Watch Early Warning Tool: Care assistants or nurses were expected to use this when they noted a change in a resident's condition. They were to circle observed changes, notify the nurse and place the tool in the resident's nursing home records.
2.
Care Pathway: This was a two-step clinical guidance and decision support system. The initial "Primary" assessment comprised screening questions with the potential to trigger a more detailed "Secondary" assessment. If the Primary or Secondary Assessment result was ambiguous, the Care Pathway was to be administered at 6-hour intervals, until concerns had resolved and/or appropriate intervention was instigated. The nurse recorded the outcome of the Primary and Secondary Assessment and their care plan in the resident's records and decided on the next course of action. This may have included further monitoring using the Stop and Watch Early Warning Tool, treatment initiated in the nursing home, or communication with primary care using the SBAR. Copies of the completed Care Pathway were kept with the resident's record.
3.
The SBAR method: A structured method for communicating critical information to primary care used by nurses to seek primary care intervention for the resident after the Care Pathway indicated a risk of decline.

Treatment as usual (TAU) group

Residents in nursing homes randomised to control arms received usual care according to existing local policy and practice. We permitted all medications and treatments.

Data collection

Nursing homes

We collected data at the level of the whole nursing home for four weeks pre-intervention (baseline) including staff turnover and the number of beds available to new residents. For four weeks pre-intervention and then monthly for 6 months we documented the total number of contacts with GPs, ambulances, A&E attendances and hospital admissions.

Residents

We collected data pre-intervention on age, gender, ethnicity, marital status and highest level of education. Functional status was measured using the Barthel Index [35] pre-intervention, and at 6 months. For residents recruited into the cohort we collected data for the month pre-intervention and then for the following 6 months on healthcare use and QoL data for health economic analysis, hospital admission overall and admissions for the four ACSCs of interest, ambulances called, out of hours GP visits or telephone contacts, A&E attendances and deaths.

Family carers

Pre-intervention we collected data on socio-demographics including age, gender, ethnicity and marital status and preferred role, i.e. how involved they would like to be with the resident's medical care.

Staff

To gain contextual understanding we documented pre-intervention; staff age, gender, and education level and characteristics of their work (qualifications, role, length of employment, shift pattern and first language). Pre-intervention and at 6 months we measured the extent to which they perceived the organisation supported person centred care (Organisational Support for Person-centred Care [36] (P-CAT)) and nurses' confidence with communicating with primary care using the Nurse Ratings of Communication with Primary Care Questionnaire [37].

Outcomes

We collected data in three domains to assess whether we had met our objectives: 1) individual-level data on nursing home residents, their carers and staff where consent had been obtained, 2) system-level data collected by a Research Facilitator, employed by the nursing home to provide pseudo-anonymised data at the nursing home level, and 3) process data collected by the study team. For a summary, see Table 1.

Table 1

Summary of data collected, outcome measures and time schedule

Data collected and tool used		Pre-intervention	Monthly	6 months
Resident				
Socio-demographics	Age, gender, ethnicity, marital status, highest level of education	S	-	-
Service use in the prior month	Client Service Receipt Inventory (CSRI). Calculates service and total care costs	S	S	-
Functional status	The Barthel Index	S	-	S
Resident quality of life-self rated	EQ-5D-5L self-rated health index and visual analogue scale of current health state	P	-	P
Resident quality of life-proxy rated	EQ-5d-Proxy family carer or staff member view of the resident's QoL	FC/S	-	FC/S
Family carer				
Socio-demographics	Age, gender, ethnicity, marital status, years of schooling, highest level of education	FC	-	-
Quality of life	EQ-5D-5L	FC	-	FC
Preferred role	How much and how they like to be involved in the residents' care	FC	-	-
Staff				
Staff socio-demographics	Age, gender, ethnicity, number of years of education,	R	-	-
Staff work characteristics	Highest qualification, role in nursing home, length of service, shift pattern, first language	R	-	-
Organisational support for person-centered care	The Person-Centred Care Assessment Tool (P-CAT)	S	-	S
Communication with primary care	Nurse-GP Communication Needs Assessment Questionnaire	S	-	S
Perceived knowledge and skills for early detection in changes in health	Developed from feasibility study. Assesses key knowledge and skills needed to implement the intervention. Rated on 5-point Likert scale.	S	-	S
System-level data				

Data collected and tool used		Pre-intervention	Monthly	6 months
Number of hospital admissions	Respiratory infection, exacerbation of CHF, UTI and dehydration	S	S	-
“Avoidability” of admissions	Structured Implicit Record Review (SIRR; Saliba et al., 2000)	S	S	-
Use of Primary assessment tool	Respiratory infection, exacerbation of CHF, UTI and dehydration?	S	S	-
Use of Secondary assessment	Respiratory infection, exacerbation of CHF, UTI and dehydration	S	S	-
Out of hours GP contacts	GP visits or telephone contact	S	S	-
Ambulances and hospital use	Number of hospital admissions, A&E attendances and readmissions	S	S	-
Deaths in the last calendar month		S	S	-
Staff turnover		S	-	-
Nursing home occupancy level	Number of available beds to new residents	S	-	-

Measure assessed by: P, participant; FC family carer; R researcher; S, nursing home staff

Primary objective

To ascertain whether the intervention was acceptable and feasible we collected data monthly from the nursing home on how the intervention was used in practice; the number of “Stop and Watch” Early Warning Tools and primary (initial screening) and secondary (more detailed) assessment tools that were completed. As part of our acceptability and feasibility study, where we had permission to collect individual level data, we monitored participants monthly for serious adverse events (SAEs). These were defined as “any untoward occurrence that resulted in death, was considered life-threatening at the time of the event, required hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability or incapacity or was any other important medical condition”.

Secondary objectives

1. Establish whether consent procedures facilitate collection of sufficient individual-level data

We collected data on consent and recruitment rates of residents, carers and staff.

2. Assess intervention fidelity

To explore fidelity to the intervention two nurse researchers reviewed a convenience sample of five records for residents who had been admitted to hospital, or received treatment in the nursing home, for ACSCs. They used a free-text review sheet to record references to any aspect of the trial intervention tools (Stop & Watch, the Care Pathway and SBAR) and assessed compliance with the care pathway principles. We noted where nursing homes made amendments to the structure or content of the care pathway.

3.
Assess the effectiveness of the implementation strategy and level of nursing home staff engagement with the intervention

PDCs were offered a monthly support phone call with the research team to reflect on their activities and achievements. They kept an activity log of work with Practice Development Support Groups to document the level of facilitation required to support the implementation process. Qualitative interviews were conducted to better understand the barriers and facilitators to implementation. Data and learning from the implementation analysis will be presented in a separate paper.

4. Indicate whether the intervention would be sustainable outside the trial context

Data from objectives 2–3 were considered by the independent study steering group at the end of the study.

5. Assess potential primary and secondary outcomes for a definitive trial

We assessed numbers of admissions to hospital for the four ACSCs as a potential primary outcome. The number (%) of residents requiring one or more ambulance calls, one or more unscheduled out of hours GP visits or phone calls and having one or more accident and emergency department visits were documented as potential secondary outcomes. We tested the assumption that a hospitalisation for an ACSC was a proxy for an avoidable hospital admission using the Structured Implicit Record Review (SIRR) tool [38]. Two independent clinical experts (geriatrician and community nurse) used this tool to assess whether the admission was “avoidable”. This takes account of the resident’s pre-existing health, any advance directives and the care options available at the time. We aimed to select 30 admissions (where we have individual consent from a resident to access their health records), to represent a range of underlying ACSC diagnoses.

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

We assessed completeness of outcome measures, data collection and return rate of questionnaires.

7. Assess feasibility of collecting data for economic evaluation

We collected data on resident service use with the Client Service Receipt Inventory [39] (CSRI), completed pre-intervention and then monthly for 6 months. Data on quality of life (QoL) was collected using the self-completed EQ-5D-5L [40] questionnaire where participants had the capacity to do this. Where a resident could not complete the EQ-5D-5L questionnaire, the proxy version was completed by the carer or a member of staff. We also collected data on carer QoL using the EQ-5D-5L questionnaire. All QoL data were collected pre-intervention and at 6 months.

Sample size

This was a pilot study to inform the sample size calculation for a definitive trial, so no sample size calculation was conducted. The number of care homes was chosen on pragmatic grounds to allow testing of study procedures and variability in settings and practice.

Randomisation

Nursing homes were randomised prior to intervention; 4 in West Yorkshire and 3 in Greater London (7 total) to the intervention and 4 in Yorkshire and 3 in Greater London (7 total) to “usual care”, stratified by location. We used the SAS statistical programme to generate a randomisation list drawn up by a clinical trials unit statistician not otherwise involved in the study.

Blinding

This was not feasible for research staff collecting data, but the statistician and health economists were blinded to allocation. The randomisation variable was supplied to them unlabelled, and the main analysis was completed using this.

Data management

All data was entered onto paper case report forms (CRFs) and then into an encrypted password protected database in accordance with the UK Data Protection Act and General Data Protection Regulation (GDPR). We followed a standardised process for database lock.

Statistical methods

Given this was a pilot study, analyses are mainly descriptive (counts, means, standard deviation (SD), medians with interquartile range (IQR)) focussing on recruitment, participant characteristics, other baseline and outcome variables, loss to follow-up and tabulation of serious adverse events. We summarised completeness of data on outcome measures and questionnaire response rates.

Economic evaluation

The aim of the economic evaluation was to provide a preliminary estimate of the costs, effects and relative cost-effectiveness of the intervention compared to TAU. Analyses conformed to accepted economic evaluation methods. We calculated costs associated with the intervention, including the cost of enhancing staff's knowledge and skills and resources associated with implementation. Resource use associated with hospital admissions, primary care and other NHS and social care services were collected using the CSRI and costed using published sources [41–43]. Costs were reported from the NHS/ personal social services (PSS) perspective. All costs are reported in 2016/2017 British Pounds (£). Quality-adjusted life years (QALYs) for residents were calculated using the EQ-5D-5L questionnaire and associated algorithms [44, 45] mapping the 5L descriptive system data onto the 3L valuation set as recommended by the National Institute for Health and Care Excellence (NICE) [46, 47]. We report only results based on QALYs calculated using the resident self-completed EQ-5D-5L questionnaire as these had higher return. There was no discounting of costs or QALYs given that they were reported over 6 months only. Multivariate imputation by chained equation for missing data, generating 20 imputed data sets were used. For each of these, we ran 1,000 bootstrap replications using non-parametric bootstrapping. The bootstrap results were combined to calculate the mean values for costs and utilities and the standard errors around the imputed values, used to calculate 95% CI around point estimates. To report the probability that the intervention is cost-effective compared to TAU for a range of values of willingness-to-pay (WTP) for a QALY gained, the bootstrap results have been used to generate a cost-effectiveness acceptability curve (CEAC) [48] and the probability that the intervention is cost-effective compared to TAU at a £20,000 for a QALY gained reported.

Results

Recruitment

Nursing homes

Nursing homes were recruited to the target number of 14 and randomised as planned; seven to intervention (3 London, 4 Yorkshire) and seven to control (3 London and 4 Yorkshire). One Yorkshire intervention nursing home dropped out during pre-intervention as it was closed by its owners. A further intervention group nursing home in London dropped out following PDC training as they were unable to implement any aspects of the intervention. Most nursing homes were privately managed with a median 50 residents (IQR 34, 68) (appendix 1). The majority (73%) were "Dementia Registered". In terms of their CQC ratings, one home (7%) was "outstanding", eleven (79%) were "good" and two (14%) were "requires improvement".

Residents

We recruited 237 residents (Fig. 1), two thirds were female, predominantly white (90%) with a median age of 86 years (IQR 80, 91).

Figure 1 here

The median Barthel Index score was low at 27 (IQR 9, 64) indicating a high level of dependency in activities of daily living. Only six residents (3%) had an admission for an ACSC in the pre-intervention period, 11 (5%) residents had at least one ambulance called and 12 (5%) had an unscheduled GP visit or telephone contact (Table 2).

Family carers

We recruited 91 family carers (Fig. 2), two thirds were female (Table 2). Median age was 63 years (IQR 57, 71). Most (91%) wished to be involved in noticing early changes in the resident's health.

Figure 2 here

Table 2
Characteristics of residents and family carers

Characteristic	Cohort	TAU	BHiRCH-NH
	n or median (% or IQR)		
RESIDENTS			
Demographics	N = 234	N = 137	N = 97
Male	73 (31)	46 (34)	27 (28)
Age	86 (80,91)	86 (80, 91)	84(78, 91)
Ethnicity	N = 225	N = 131	N = 94
White	203 (90)	117 (89)	86 (91)
Black	14 (6)	9 (7)	5 (5)
Asian	5 (2)	4 (3)	1/(1)
Other	3 (1)	1 (1)	2(2)
Marital status	N = 223	N = 127	N = 96
Married or cohabiting	49 (22)	28 (22)	21 (22)
Single	59 (26)	40 (32)	19 (20)
Divorced or widowed	115 (52)	59 (46)	56 (58)
Education	N = 184	N = 133	N = 71
Completed years of education	11 (9,12)	11(10, 12)	11(9, 11)
No qualifications or GCSE or equivalent	107 (58)	63 (56)	44 (62)
A Level/NVQ/ HNC/ HND or equivalent	18 (10)	11 (10)	7 (10)
Degree or higher degree	23 (13)	14 (12)	9 (13)
Other qualification	36 (20)	25 (22)	11 (15)
Function			
Barthel Index score	27 (9, 64)	27(9, 66)	30(8, 63)
CARERS			
Demographics	N = 91	N = 56	N = 35

Characteristic	Cohort	TAU	BHiRCH-NH
Male	31 (34)	17 (30)	14 (40)
Age	63 (57, 71)	62(57, 71)	64(58, 74)
Ethnicity	N = 87	N = 52	N = 35
White	72 (83)	43 (83)	29 (83)
Black	12 (14)	7 (13)	5 (14)
Asian	3 (3)	2 (4)	1(3)
Marital status	N = 87	N = 53	N = 34
Married or cohabiting	65 (75)	36 (68)	29 (85)
Single	10 (11)	8 (15)	2 (6)
Divorced or widowed	12 (14)	9 (17)	3 (9)
Education	N = 86	N = 53	N = 33
Completed years of education	11 (11,12)	12(11, 13)	11(11, 12)
No qualifications or GCSE or equivalent	35 (41)	21 (40)	14 (42)
A Level/NVQ/ HNC/ HND or equivalent	13 (15)	9 (17)	4 (12)
Degree or higher degree	26 (30)	14 (26)	12 (36)
Other qualification	12 (14)	9 (17)	3 (9)
Preferred role	N = 87	N = 52	N = 35
Noticing early signs of changes in health	79 (91)	49 (94)	30 (86)
Informing staff about early signs of changes in health	77 (89)	48 (92)	29 (83)
Educating staff about how early signs of changes in health present	51 (59)	28 (54)	23 (66)
Educating care staff about health history of their family member	57 (66)	33 (63)	24 (69)
Prefer not to be involved	5 (6)	2 (4)	3 (9)
Other	18 (21)	9 (17)	9 (26)

Staff

We recruited 132 staff (Fig. 3), with a median age of 42 years (IQR 30, 53), 12% were male, 50% of nurses spoke English as a first language and 59% of staff described themselves as white. Most staff had worked at the care home for a year or more (71%) and 30% were qualified nurses. Scores on the P-CAT scale (possible range 13–65) were generally positive with a median score of 49 (IQR 46, 53) (for staff characteristics see appendix 2). Most nurses were positive about the quality of communications they had with the residents' GP (appendix 3) and positive about their self-rated knowledge and skills (appendix 4).

Figure 3 here

Primary objective-feasibility and acceptability

Use of the intervention

Across the five intervention homes, only sixteen stop and watch forms were completed of which eleven came from a single nursing home. Eight Care Pathways were reported as completed but only three were located by the study team. This included both residents who had given consent to participate and anonymised S&W forms and Care Pathways collected from residents who had not given consent. There was a median of one Stop and Watch form (IQR 0,3) and a median of zero Care Pathways (IQR 0,2) completed per month. In a few cases, routine clinical observations (e.g. temperature, blood pressure etc.) were carried out, but were not reported systematically or presented as part of a coherent assessment plan. One home had a policy of recording routine observations once per month.

Serious adverse events

There were no differences in SAEs between TAU and intervention groups. There were 104 SAEs in 74 residents during the study and 33 residents died (19 in TAU group and 14 in the intervention group). Of the 104 SAEs, hospitalisation (any cause) was the most common (N = 50, 48% of SAEs) (appendix 5).

Secondary objectives

1. Resident consent procedures and collection of sufficient individual level data

We screened 680 residents of whom 557 met eligibility criteria and 245 were recruited into the study (35% recruitment rate). Our recruitment target was 20 residents per nursing home. Taking into account that two homes dropped out, leaving 12 in the study, our target of 240 residents (20 residents per care home) was reached. Most eligible residents (364, 65%) did not have capacity to give consent to participate in the study. During the six-month study period in the TAU group, 19 residents died, four moved to different nursing homes and four withdrew. In the intervention group 13 residents were lost when two nursing homes withdrew, 14 residents died, two residents moved to a different home and two did not wish to continue in the study. Thus, a total of 73% of recruited residents completed the study with 10% lost to follow up due to mortality (Fig. 4).

Figure 4 here

2. Assess intervention fidelity

It was not possible to assess fidelity to the intervention as the intervention was not implemented as intended and the documentation required to assess fidelity was not available.

3. Assess the effectiveness of the implementation strategy and level of nursing home staff engagement with the intervention

The implementation strategy was not effective and nursing home staff did not engage with or use the intervention tools. Data and learning from the implementation analysis will be presented in a separate paper.

4. Investigate whether the intervention would be sustainable outside the context of a trial

Despite the implementation support given, the intervention was not widely used in the nursing homes; 16 Stop and Watch forms were completed and we found eight completed Care Pathway documents. The research team and steering group concluded the intervention in its current form would not be sustainable outside of the context of a research project.

5. Assess potential primary and secondary outcome measures for a definitive trial

Rates of hospitalisation for ACSCs

At baseline the rates of hospitalisation for ACSCs (respiratory infection, exacerbation of CHF, UTI and dehydration), our potential primary outcome, were low and 0.4% of the cohort had an admission for respiratory infections, 1% for UTI, none for dehydration and 0.4% had an admission for chronic heart failure in the month before the trial started. There were six admissions in total from the 235 residents in the study. Considering the whole six-month study period, 25 study participants (15%) had an unplanned hospital admission for one of the ACSCs. The low rates of unplanned hospital admission (per 100 person months) suggested this might not be the best primary outcome measure in a future study (Table 3).

Considering secondary outcome measures for a definitive trial, we found a slightly higher proportion of participants (n = 38, 16%) had an accident or emergency attendance during the follow up period, 42 (18%) had at least one ambulance called, 29 (12%) had an unscheduled (out-of-hours) GP visit and 21 (11%) died. The incidence of these events was still relatively low and not sufficiently frequent for an outcome in a definitive study. Comparing TAU and intervention nursing homes the difference in percentages for those who had an admission who were in the study at baseline (BHIRCH-NH versus TAU group) was 3.0 (95% CI -6.4, 12.4). This comparison is limited as the nursing homes that withdrew were in the intervention arm and their residents were lost to follow up, resulting in fewer admissions from that arm.

Table 3

System-level outcome data

	Pre-intervention			Over 6 month follow up period	
	Whole cohort	TAU	BHiRCH-NH	TAU	BHiRCH-NH
	n or median (% or (IQR)				
Study cohort	N = 235	N = 139	N = 96	N = 139	N = 96
At least one admission in the last month	6 (3)	2 (1)	4 (4)	19 (14)	16/96
Respiratory infection admission	1 (0.4)	0	1 (1)	8 (6)	5/96
Urinary tract infections admission	2 (1)	1 (1)	1 (1)	5 (4)	2/96
Dehydration admission	0	0	0	0	1/96
Congestive heart failure admission	1 (0.4)	0	1 (1)	0	1/96
At least one ambulance called	11(5)	4 (3)	7 (7)	20 (14)	22/96
At least one out of hours GP visit or telephone contact	12 (5)	11 (8)	1 (1)	14 (10)	15/96
At least one Accident and Emergency attendance	10 (4)	6 (4)	4 (4)	17 (12)	21/96
Died	1 (0.4)	1 (1)	0		
Care home data					
Number hospital admissions	3 (2, 5)	4 (2, 7)	3 (2, 4)	12 (12, 16)	12 (7, 18)
Number of ambulances called	3 (2,6)	4 (2,9)	3 (2, 6)	12 (11,17)	19 (7, 22)
Unscheduled (out of hours) GP visits or telephone contacts	1 (1,3)	2 (1,3)	1 (1, 3)	8 (7,13)	9 (4, 25)
Accident and Emergency attendances	3 (2,5)	3 (1,4)	3 (2, 6)	12 (11,13)	8 (7, 13)
Rate of hospital admissions per 100 person months		-	-	5.3 (2.3, 8.3)	5.9 (1.7, 7.1)

	Pre-intervention		Over 6 month follow up period	
Rate of ambulances called per 100 person months	-	-	5.7 (2.3, 8.0)	6.0 (2.0, 9.3)
Rate of unscheduled (out of hours) GP visit or contacts per 100 person months	-	-	2.5 (1.8, 4.0)	5.1 (1.1, 6.0)
Rate of Accident and Emergency attendances per 100 person months	-	-	4.3 (2.5, 8.3)	3.9 (2.0, 5.6)

Hospitalisation for an ACSC as a proxy for avoidable hospital admission

We intended to use the Structured Implicit Record Review (SIRR) tool to assess the appropriateness of 30 resident admissions for ACSCs, but it was not always possible to identify if an admission was for an ACSC and numbers of admissions were low overall. We therefore expanded our sample to include any hospital admission. One nursing home had no eligible residents, because those admitted to hospital had died and/or their care records were no longer available. For the same reason, we also included residents who died in hospital, as long as their records were still available. We were able to assess 10 admissions from a total of 24 which occurred during the study period. Using the SIRR tool, three of the ten admissions assessed were deemed to be potentially avoidable. None of the care records provided a complete picture of residents' health in the period leading up to admission. Only one was classified as 'unable to decide' due to lack of information. From this review of care records an ACSC admission was not a reliable proxy measure for an "avoidable admission".

6. Completeness of data collection and documentation, return rate of questionnaires

Care staff-related data

We collected data on most recruited care staff at baseline (N = 132). For example, 129 care staff gave demographic detail (98%) and 127 (96%) completed the P-CAT scale. Attrition in response to these scales was secondary to nursing homes dropping out of the study, rather than staff being unwilling or unable to complete the forms.

Resident-related data

Demographic and functional ability data were available on most residents at baseline (N = 235) including gender (99%), ethnicity (95%), marital status (98%) and functional ability (Barthel Index) (98%). We cannot be sure that no admissions or visits to acute hospital were missed as nursing homes did not have centralised systems for collecting these data.

7. Cost and outcome data for use in an economic evaluation, key cost components and probability of cost effectiveness

The cost of intervention included the cost of training the nursing home staff and the cost of delivering the intervention. It did not include the costs of monthly telephone coaching. One nursing home withdrew after randomisation and therefore, we considered the cost of intervention to be £0 (as “per randomised” approach). Assuming the intervention is offered to all 89 residents randomised to the intervention group, the mean cost per resident would be £74 (95%CI £64 to £84).

During follow-up, there were no significant differences in the majority of the components of healthcare resource use between the intervention and TAU groups (appendix 6). Mean differences in costs, utility values and QALYs (complete cases and with imputation) are presented in appendix 6 and appendix 7. Differences in mean utility values and QALYs were not statistically significant when carers assessed their QoL and therefore, no further analysis has been performed. The mean total cost of healthcare resource use per resident over 6 months was £1,458 (95%CI £1,351 to £1,566) in the intervention group and £1,233 (95%CI £1,171 to £1,295) in the TAU group (appendix 8). Non-parametric bootstrapping after multiple imputation produced a mean total cost per resident in the intervention group of £1,479 (95%CI £757 to £2,200), compared with £1,271 (95%CI £975 to £1,566) in the TAU group. The mean difference in cost between the BHiRCH-NH and TAU group was £208 (95%CI -£561 to £977) (Table 4). Non-parametric bootstrapping after multiple imputation produced 0.315 (95%CI 0.304 to 0.326) QALYs in the intervention group and 0.298 (95%CI 0.290 to 0.307) QALYs in the TAU group, generating a mean difference in QALYs of 0.016 (95%CI 0.003 to 0.300) which was statistically significant (Table 4).

Table 4
Cost-effectiveness of BHiRCH-NH intervention versus TAU: complete case and imputed data analyses

	Incremental cost		**QALY gained**	
	Mean	(95% CI)	Mean	(95% CI)
Base case*	£208	-£561 to £977	0.016	0.003 to 0.300
Complete case^	£352	-£745 to £1,448	0.018	-0.012 to 0.048

*Data include values imputed using multiple imputation with standard errors corrected to account for uncertainty in the imputed values. QALYs gained are adjusted for baseline utility values and care home clustering. The incremental costs are adjusted for costs in the 1 month period prior to baseline and care home clustering. ^As for the base case analysis except there is no multiple imputation for missing data

The incremental cost per QALY gained of BHiRCH-NH versus TAU was £12,633. Residents receiving the intervention accrued a non-significantly higher cost, and a very small statistically significant increase in QALYs; the intervention has a 65% probability of being cost-effective at a WTP of £20,000 (Fig. 5).

Figure 5 here

Discussion

Our cluster randomised pilot trial of the BHiRCH-NH intervention in 12 homes found our study processes were effective. We successfully recruited, retained and obtained individual-level data from nursing homes, residents, staff and family carers. Data on adverse events and qualitative interviews did not suggest the intervention caused harm. Our carer reference panel worked with us throughout, advising on study set-up, engaging with homes and potential participants, data collection and contributing to data analysis and interpretation. However, despite excellent recruitment and retention, there was limited engagement with the intervention tools and the support offered for their implementation. Our economic analysis showed the intervention is cost-effective as the mean incremental cost per QALY gained of £12,633 is below the NICE threshold, but with a relatively low probability (65%) at a WTP of £20,000 per QALY gained. The lack of use of the intervention coupled with the economic analysis means that we would not recommend a definitive randomised controlled trial of the BHiRCH-NH intervention.

We focussed on four key ACSCs (pneumonia, dehydration, urinary tract infection and exacerbation of chronic heart failure) because they are common causes of potentially avoidable hospital admissions and a significant area of health policy focus. There is lack of national comparative data, but we found lower hospitalisation rates for these conditions than we expected. Categorising admissions to hospital is complex and people may present with broader symptoms i.e. delirium or falls. ACSCs may be more of an administrative label to be used in large data analyses rather than a sensitive tool for assessing the “avoidability” or otherwise of acute hospital admissions.

We found little evidence of staff engagement with the intervention tools. It is possible that the nursing homes in our sample already had working practices that ensured early detection and assessment. There is some support for this as evidenced by the low rates of hospitalisation and health service use in the homes in our sample. Furthermore, our intervention tools may duplicate existing records already used to note observations of changes in residents’ health.

Implementing changes in practice in nursing homes can be challenging. Whilst the INTERACT programme, from which our BHiRCH-NH intervention was adapted, demonstrated reductions in all-cause hospitalisations among actively participating nursing homes, a subsequent larger randomised controlled implementation trial in 85 USA nursing homes had no effect on emergency department visits or hospital admissions [18]. Resources, competing demands and instability of nursing home leadership were all barriers to successful implementation [49] and it is possible that these factors were also present in our study.

Strengths and limitations

We were able to recruit nursing homes, residents, staff and family carers to target, although two nursing homes dropped out from the intervention arm. Our nursing homes may be atypical as 79% were rated as “good” by the CQC, compared to the UK national average of 73%. Residents in our sample may have been atypical, less frail and likely to develop the four index conditions. Certainly, we had more residents who

were able to consent for themselves than might be expected in this population [50]. This has implications for the generalisability of our findings. Monthly visits from research fieldworkers and the appointment of Research Facilitators who were existing nursing home staff fostered positive relationships between nursing homes and the research team and facilitated access to data, including nursing home records.

We cannot verify that data on hospital attendances, staffing and support from external health care services is complete, as most homes did not routinely record hospital admissions or ambulance and GP call-outs. Nursing staff self-rated their knowledge and skills regarding health conditions and their communication with primary care and research assistants collecting outcome data were not blind to nursing home allocation. We assumed we could use admission for ACSCs as a proxy for avoidable admissions, but even using the SIRR tool [51] it was difficult to identify whether an admission was for an ACSC or not. Future studies should include consent to access hospital records so this can be more thoroughly assessed.

An alternative research design to the cluster RCT may be more appropriate. Current UK policy focus on reducing hospitalisations and enhanced health care in nursing homes has led to significant levels of activity in local health and social care services. Research in such a fast-moving landscape is challenging. NHS England's demonstration projects "Vanguards" and other quality improvement initiatives means usual care will be improving, making trials challenging to conduct. It is possible that the cluster RCT design was too constraining for practice development of this nature [52]. Had we taken a quality improvement approach we could have worked in closer partnership with each home to understand the problem better and co-design tailored solutions. Participating homes may have seen themselves as 'involved in research' rather than 'involved in practice development'. Although our intervention was co-designed with staff, this involved an extra burden of observation and documentation, which was difficult for staff who were already pressed for time. However, it was important that this pilot trail was conducted as this has avoided the risk of embarking on a full trial and subsequent waste of resources and time [53].

Recent studies conducted in care homes suggest that a higher level of support and facilitation may be required for successful implementation. The Palliative Care for Older People Steps to Success Programme (PACES), conducted in 78 nursing homes across seven countries, which involved a complex intervention to improve end of life care, did not improve resident comfort or staff knowledge despite using a train-the-trainer approach [54]. However, the Well-Being and Health for People with Dementia (WHELD) programme was successfully implemented in 69 UK care homes and showed a significant effect on reducing agitation possibly through a much higher intensity of external facilitation that may not be sustainable or cost effective [55].

Since we designed our intervention and conducted our pilot trial, our knowledge on improving healthcare for care home residents has developed. Key components for resident health care, identified in the 2017 "Optimal" study were GP involvement supported by integrated external services [56]. These findings are reflected by emerging evidence that change to the wider health and social care system may be more effective in reducing the number of care home residents admitted to hospital. For example a programme

implemented between 2013 and 2017, in east London, which provided residents of nursing homes with increased GP access and continuity of primary care with increased support to nursing home staff reduced emergency hospital admission and A&E attendances [57].

Conclusions

We were unable to demonstrate that our co-designed complex intervention of tools for early detection, monitoring and communication of change in residents' health, warranted a future definitive trial because it was not implemented in practice. Our study contributes to learning in the under-researched but vital field of nursing home research. Nursing homes engaged well with the research process itself but not so well with intervention processes intended to improve care.

Abbreviations

A&E	Accident and Emergency
ACP	Advance Care Planning
ACSC	Ambulatory Care Sensitive Condition
BHiRCH-NH	Better Health in Residents of Care Homes with Nursing study
CCG	Clinical Commissioning Group
CHF	Congestive Heart Failure
CONSORT	CONsolidated Standards of Reporting Trials
CQC	Care Quality Commission
COPD	Chronic Obstructive Pulmonary Disease
CRF	case Report Form
CRN	Clinical Research Network
CRP	Carer Reference Panel
CSRI	Client Services Receipt Inventory
CTU	Clinical Trials Unit

CQC	Care Quality Commission
ENRICH	ENabling Research in Care Homes
EQ-5D-5L	EuroQol-5D-5 level
GDPR	General Data Protection Regulations
GPs	General Practitioners
INTERACT	Interventions to Reduce Acute care Transfers
IQR	Inter-quartile Range
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PACES	Palliative Care for Older People Steps to Success Programme
PARiHS	Promoting Action on Research Implementation in Health
P-CAT	Person-centred assessment tool
PDC	Practice Development Champion
PDG	Programme Development Grant
PDSG	Practice Development Support Group
PPI	Public Patient Involvement
PSS	Personal Social Services
QALYs	Quality Adjusted Life Years
QoL	Quality of Life
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SAS	Statistical Analysis Software
SBAR	Situation, Background, Assessment, Recommendations
SD	Standard Deviation

S&W	Stop and Watch Early Warning Tool
SIRR	Structured Implicit Record Review
TAU	Treatment as usual
UK	United Kingdom
USA	United States of America
UTI	Urinary Tract Infection
WHELD	Wellbeing and Health for People with Dementia Study
WTP	Willingness to pay

Declarations

Ethics approval and consent to participate: Ethical approval was obtained from the Queen Square London Research Ethics Committee (reference 17/LO/1542). Participants gave written informed consent to participate. Where nursing home residents lacked mental capacity to do this, we gained the written agreement of a personal or professional consultee for the resident to participate.

Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available, the small number of nursing homes means that data may be identifiable. Data are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Figures

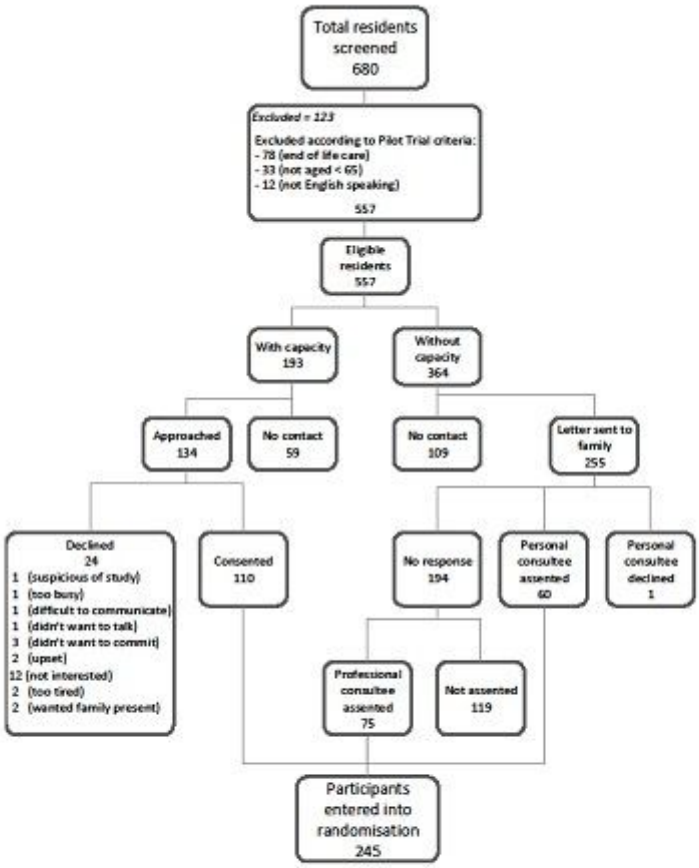

Figure 1

Resident recruitment flowchart

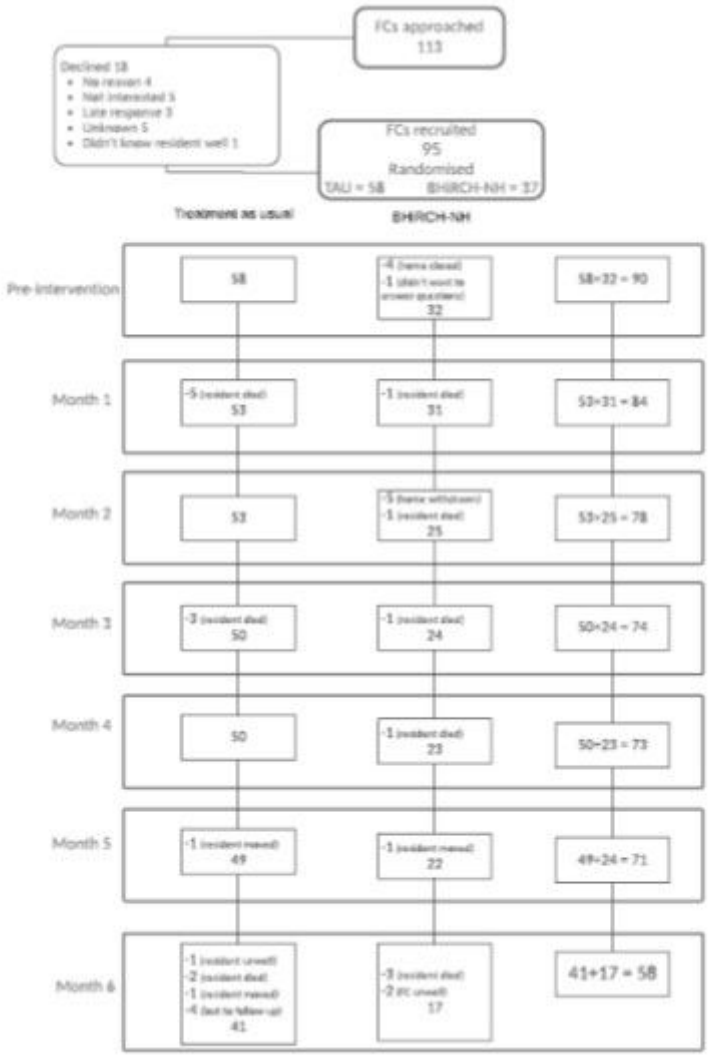

Figure 2

Family carer recruitment and retention

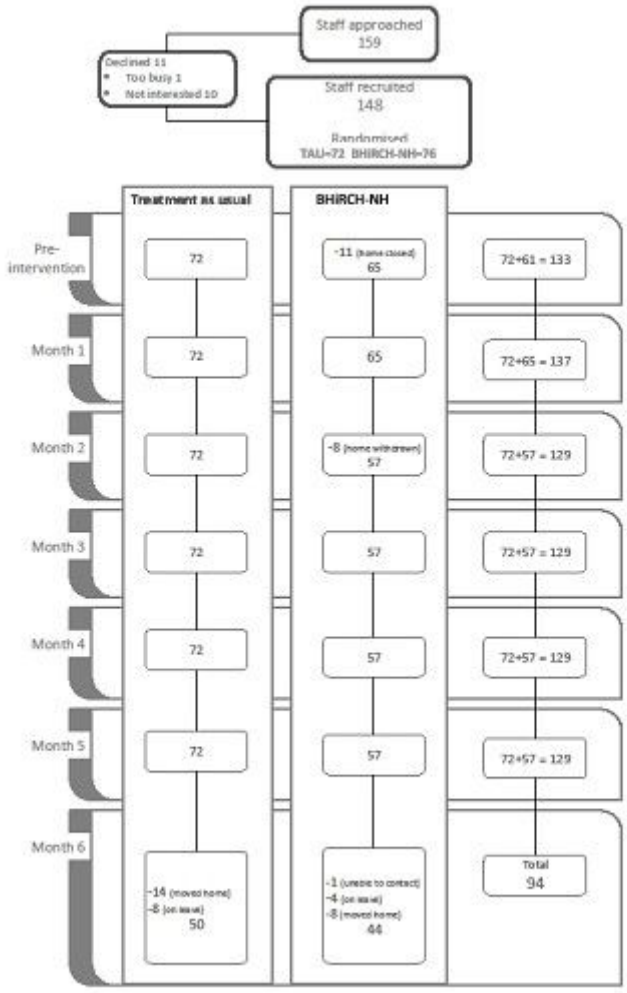

Figure 3

Staff recruitment and retention flowchart

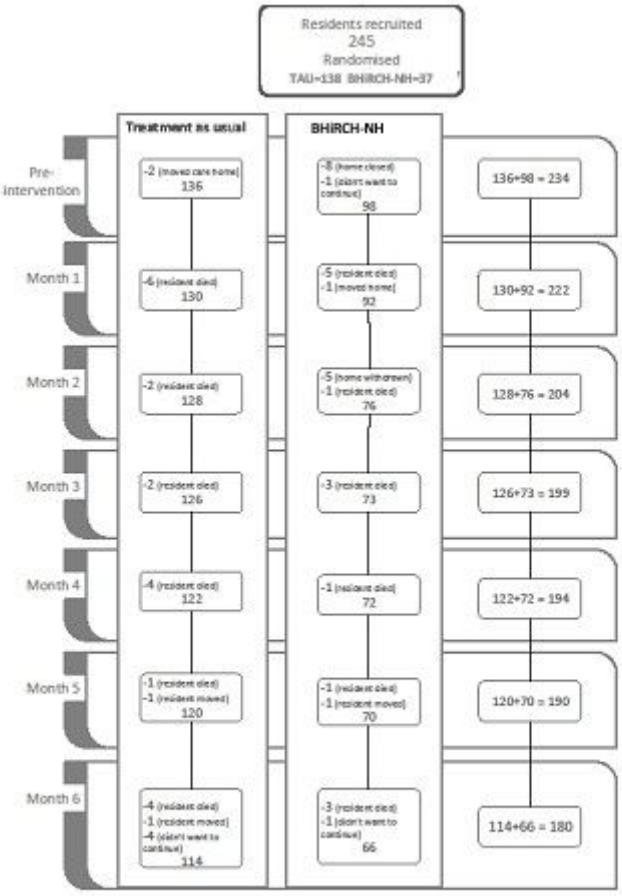

Figure 4

Resident retention flowchart

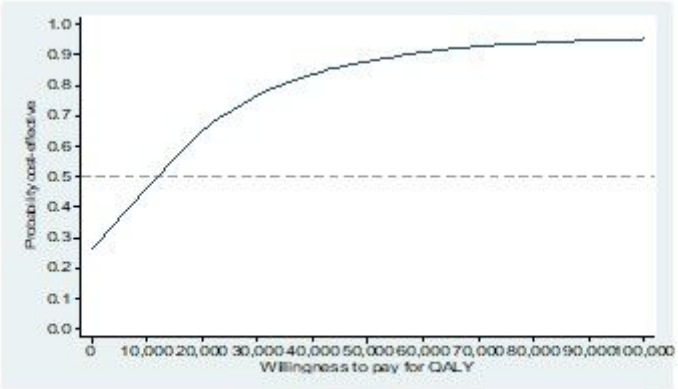

Figure 5

Cost-effectiveness acceptability curve showing the probability that BHiRCH-NH intervention is cost-effective versus TAU at different values of the WTP for a QALY, N=237 Figure 5 legend: Abbreviations: BHiRCH-NH-Better Health in Residents of Care Homes with Nursing study, QALY- Quality Adjusted Life year, TAU-Treatment as usual, WTP-Willingness to Pay,

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SampsonBetterHealthinResidentsofNursingHomesConsort.docx
- Appendix.docx