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The PATCH study: Posture and mobility in care homes

Submission date
20/03/2017

Recruitment status
No longer recruiting

Registration date
27/03/2017

Overall study status
Completed

Last Edited
16/05/2023

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Residents of care homes are amongst the frailest in our population. Many have a range of health conditions, which may lead to them becoming inactive and requiring the help of care home staff to move. Maintaining the best possible lying and sitting positions protects body shape and, along with keeping mobile, has important health benefits. A group of physiotherapists have developed a training programme called the Skilful Care Training Package (SCTP) which aims to teach care staff how to improve the posture of residents and support mobility. The aim of this study is to look at whether care homes, residents and staff are willing to be involved in the study, whether it is possible to collect information from residents and staff, and how staff find the training, in order to see if a large scale study looking at the effectiveness of the programme would be possible.

Who can participate?
Permanent residents of participating care homes aged 65 and over.

What does the study involve?
Participating care homes are randomly allocated to one of two groups. Those in the first group continue to provide usual care to residents. In the second group, staff are offered training in SCTP. The training aims to improve care assistant's manual handling skills (moving patients safely) to promote good positioning and posture. The training takes place in three 2.5 hour long sessions, after which, staff use the skills learnt when caring for residents. At the start of the study and then after three and six months, residents and staff complete a range of questionnaires and interviews in order to find out information about resident's well-being and staff skills and knowledge. In addition, information about residents' health and contact with health professionals is recorded from care records.

What are the possible benefits and risks of participating?
Residents may benefit from the skills learned by staff in training, but this is not guaranteed. There are no notable risks involved with participating.

Where is the study run from?
The study is being run from Bradford Institute for Health Research and takes place in 10 care homes from the West Yorkshire region (UK)

When is the study starting and how long is it expected to run for?
October 2016 to March 2019

Who is funding the study?
The Chartered Society of Physiotherapy Charitable Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33223

Study information

Scientific Title
Posture and Mobility (Skilful Care Training Package) for residents in Care Homes: Cluster Randomised Controlled Feasibility Trial

Acronym
PATCH

Study objectives
The aim of this study is to assess the feasibility of conducting a full-scale trial looking at the clinical and cost effectiveness of a tailored manualised competency based training programme for care and nursing staff, called the Skilful Care Training Package (SCTP), delivered in a care home setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & the Humber – Leeds East Research Ethics Committee, 17/05/2016, ref: 16/YH/0114

Study design
Randomised; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Physical, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Specialty: Ageing, Primary sub-specialty: Ageing; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
Participating care homes will be randomised (after consent and completion of all baseline assessments) on a 1:1 basis to receive either the Skilful Care Training Package (SCTP) or to continue with Usual Care (UC). Randomisation will be undertaken by the Clinical Trials Research Unit at the University of Leeds. Researchers will remain blind to allocation to ensure unbiased collection of outcome measures.

Treatment arm: Care Homes will be offered training sessions for all care and nursing staff. The training course aims to increase the skills of care assistants and qualified staff in handling

(techniques to facilitate movement) and to promote good positioning (to maintain functional posture) thus protecting body shape, avoiding choking, reducing pain and enabling residents to be as active and independent as they wish to be. The course is designed to be delivered to all care workers (assistants and nursing staff) rather than to be cascaded down to staff via the training of key workers. The course is practical in nature and emphasis is given to person centred care and the development of empathy towards residents. SCTP will be delivered by the trial physiotherapists to care workers who are involved in providing physical care to the residents in each of the care homes so randomised. Course content is manualised to ensure consistency, but the emphasis will be adapted according to the particular needs of that home and will ensure that content is in accordance with the policies and procedures of that organisation, for example, moving and handling methods used. This is done in consultation with the care home management team. The training is generally presented in three 2.5 hour sessions, with all staff receiving 7.5 hours training. Training will commence as soon as possible after randomisation and will be completed prior to the first follow-up assessment at 3 months post-randomisation.

Control arm: Care homes will continue to provide care as usual. Any new procedures or care processes adopted during their participation in the study will be recorded by a member of the research team.

All care homes will be followed up at 3 and 6 months post-randomisation.

Intervention Type
Other

Primary outcome measure
Residents:
1. Cognition is measured via researcher administration of the six-item cognitive impairment test (6-CIT) at baseline, 3 and 6 months
2. Pain is assessed using a researcher-administered visual analogue scale (VAS) at baseline, 3 and 6 months
3. Quality of life is measured via researcher administration of the EQ-5D-5L at baseline, 3 and 6 months (this is administered to both residents and care staff; the latter for proxy assessment)
4. Activity and mobility is assessed using the Physical Activity and Mobility in Residential Care (PAM-RC) at baseline, 3 and 6 months
5. Mobility is assessed using the Functional Ambulatory Classification (FAC) at baseline, 3 and 6 months
6. Activities of daily living are assessed using the Barthel Index (Activities of daily living) at baseline, 3 and 6 months
7. Movement ability is assessed using the Continuing Care Ability Measure (CCAM) at baseline, 3 and 6 months
8. Residents' posture is assessed via researcher observation and completion of a postural observation tool at baseline, 3 and 6 months
9. Health resource use data are collected from care notes at baseline, 3 and 6 months
10. Safety data (e.g. falls, pressure ulcers, hospital admissions) are collected for all participating residents on a monthly basis from randomisation until 6 months over the telephone, and also from care notes at baseline, 3 and 6 months

Staff members
11. Empathy will be assessed via staff completion of the Kiersma Chen Empathy Scale (KCES) at baseline, 3 and 6 months
12. Person-centred care approaches will be assessed via staff completion of the Person-Centred

Care Assessment Tool (P-CAT) at baseline, 3 and 6 months
13. Knowledge of posture and movement will be assessed via staff completion of a posture and movement questionnaire at baseline, 3 and 6 months

Whole-home data
14. Anonymised whole-home level data will be collected from the care home manager regarding care home demographics, health care resource use, resident safety and mobility levels, as well as usual care practices at baseline, 3 and 6 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria
Care Homes:
1. A residential or nursing home with residents aged 65+
2. Care Home manager in post for at least six months and likely to remain in post for the study period (indicates a stable care home environment)
3. Care Home manager willing to release staff to receive the intervention training and contribute to data collection
4. Training in Manual Handling is provided to all direct care staff
5. Anticipate 15 eligible residents could be recruited to take part in the trial (sufficient number of residents for outcome assessment)

Residents:
1. Aged 65 years and over (male and female)
2. Permanent resident within the care home – defined as a person residing in the care home and not present for receipt of respite, day-care or short-term rehabilitation
3. Appropriately consented (in accordance with the Mental Capacity Act and clinical trials guidance on informed consent)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Total final enrolment

Key exclusion criteria
Care homes:
1. In the view of the research team, is not suitable for inclusion due to being subject to CQC improvements in areas relevant to the trial, enforcement notices / inadequate ratings, admissions ban, or relevant moderate or major compliance breaches
2. Is receiving other special support for specific quality concerns, such as being currently subject to, or have pending, any serious safeguarding investigations, voluntary or compulsory admissions bans, or local commissioning special support
3. Homes that have had physiotherapy training delivered to staff which involved postural management and physical activity in the last 12 months
4. A home where the SCTP has already been delivered
5. Homes taking part in other trials or initiatives which would conflict with the SCTP and / or with data collection required for this trial

Residents:
1. Residents who are independently mobile (for previous week) measured by score 5 or 6 of the Functional Ambulation Classification will be excluded as they will gain little from the care staff's new skills and knowledge
2. Residents who are currently undergoing a course of NHS or private physiotherapy, occupational therapy or speech and language therapy
3. Expectation of less than three months' survival

Date of first enrolment
01/04/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Institute for Health Research
The Academic Unit of Elderly Care and Rehabilitation
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Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Charity

Funder Name
The Chartered Society of Physiotherapy Charitable Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/09/2018	01/04/2020	Yes	No
Results article	results	24/08/2020	05/05/2020	Yes	No
Participant information sheet	version 4.0	16/06/2017	16/05/2023	No	Yes
HRA research summary			28/06/2023	No	No