

REACH: research exploring physical activity in care homes

Submission date 24/06/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2023	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A large proportion of people living in a care home spend most of their time inactive and this is one of the leading preventable causes of death. Encouraging residents to be more active could deliver benefits in terms of physical and psychological health, and quality of life. The REACH intervention aims to encourage care home residents to move more with the aim of improving their physical, psychological and social well-being. In the present project we will be finding out only whether it is feasible to run a large trial i.e. finding out how many care homes and residents we can recruit, recording how well the REACH intervention is used within each care home and how this impacts on care home staff and residents, and whether we can collect information regarding residents health and well-being via the use of questionnaires.

Who can participate?

Any permanent resident of a residential Care Home, over the age of 65yrs can participate in the REACH study given that they are not terminally ill, permanently bed bound or already taking part in another conflicting research study.

What does the study involve?

Half the care homes participating in the study are randomly allocated to receive the REACH intervention alongside the usual care provided in the home, the other half are allocated to continue providing usual care to residents. The REACH intervention is a package of information, suggestions and practical ideas which can be used to help care homes to introduce more movement into residents' every day care home life.

What are the possible benefits and risks of participating?

The level of movement among care home residents may be improved with the use of the REACH intervention, increasing their well-being. No risks are expected.

Where is the study run from?

The trial will be administered from the Clinical Trials Unit at the University of Leeds, in conjunction with Bradford Teaching Hospitals NHS Foundation Trust. The sites for the trial will be care homes in the Yorkshire region (and possibly wider in the UK)

When is the study starting and how long is it expected to run for?
October 2015 to January 2017

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

Who is the main contact?
Mr John Green
John.Green@bthft.nhs.uk

Contact information

Type(s)
Public

Contact name
Mr John Green

Contact details
Bradford Institute for Health Research
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
+44 (0)1274 383402
John.Green@bthft.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19087

Study information

Scientific Title
Research Exploring physical Activity in Care Homes: an interventional and observational study

Acronym
REACH

Study objectives
The aim of the REACH study is to determine the feasibility of conducting a large-scale cluster-randomised controlled trial comparing the REACH intervention plus usual care (UC) vs. UC only, for permanent residents living in residential care homes in the UK. We also aim to evaluate the

acceptability of the REACH intervention. The main research questions which will be addressed in this study are:

1. What is the optimum strategy to facilitate recruitment at both the care home and resident level?
2. Is the uptake and compliance with the REACH intervention by care home staff at an acceptable level to be evaluated in a full-scale RCT? If not, why not?
3. What are the characteristics of Usual Care within residential care homes?
4. Is the uptake and compliance with the measurement tool to assess the proposed primary trial outcome (level of physical activity) by the residents at an acceptable level to be evaluated in a full-scale RCT? What are the reasons for non-participation?
5. Are the most appropriate outcome measures being considered for the trial?
6. What are the optimum strategies for data collection?
7. To calculate reliable estimates to feed into sample size calculations for a full-scale RCT.
8. Do the implementation resources required impact on the feasibility of conducting a full-scale RCT?

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS HRA NRES Committee East of England – Norfolk, 27/03/2015, ref: 15/EE/0125

Study design

Randomized; Interventional and Observational; Design type: Process of Care, Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Topic: Ageing; Subtopic: Ageing; Disease: All Ageing

Interventions

1. The REACH intervention is a package of information, suggestions and practical ideas which can be used to help care homes to introduce more movement into residents' every day care home life. The intervention is currently being developed as part of workstream 4 of the NIHR programme grant which aims to develop, enhance and refine the intervention via feedback and input from care home staff, residents and their relatives/friends. The finalised intervention will be implemented by care home staff.

2. Usual Care (UC), defined as normal care delivered within the setting, will continue in both arms. No restrictions will be imposed on current practices or on homes undertaking additional development or training as part of usual care. Details of usual care will be recorded to inform the context in which the study is being conducted.

Intervention Type

Other

Primary outcome measure

Recruitment methods, uptake and follow-up; Timepoint(s): Number of care homes screened for eligibility and interest and reasons for non-selection.

Secondary outcome measures

N/A

Overall study start date

01/10/2015

Completion date

31/01/2017

Eligibility

Key inclusion criteria

We have inclusion and exclusion criteria for care homes and residents.

Care homes meeting all of the following criteria at screening will be eligible for this trial:

1. Has a sufficient number of permanent eligible residents
2. Has a manager or nominated person agreeing to sign up to the trial protocol as research lead for the duration of the project, based on appropriate discussions and permissions
3. Agrees to release of staff time for intervention meetings, intervention implementation and provision of data for the trial

Residents meeting all of the following criteria at screening will be eligible for the trial:

1. Aged 65 years or over
2. Is a 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. Is appropriately consented (in accordance with Mental Capacity Act and clinical trials guidance on informed consent

Note that residents will NOT be excluded if they lack capacity to consent. Guidance on consent where persons lack capacity will be followed for residents assessed to lack capacity.

Target Gender: Male & Female

Lower Age Limit 65 years

Participant type(s)

Patient

Age group

Senior

Lower age limit

65 Years

Sex

Both

Target number of participants

Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment

153

Key exclusion criteria

Care homes meeting any of the following criteria will not be eligible for this trial:

1. In the view of the research team, is not suitable for inclusion due to being subject to CQC enforcement notices, admission bans or relevant moderate or major CQC 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, or receiving voluntary or compulsory admissions bans, is in receipt of local commissioning special support due to quality concerns
3. Has taken part in any of the earlier work streams of the REACH program
4. Is taking part, has recently taken part in, or is planning to take part, in another trial or initiative that conflicts with the REACH intervention or with the data collection during the course of trial involvement

Residents meeting any of the following criteria will not be eligible for this trial:

1. Is known by the care home manager and/or relevant senior staff member to be terminally ill, e.g. formally admitted to an end of life care pathway
2. Is permanently bedbound/ cared for in bed
3. Is taking part in, has recently taken part in, or is planning to take part in another trial that conflicts with the REACH intervention or with the data collection during the course of their involvement in the REACH study

Staff meeting any of the following criteria will not be eligible to provide data on staff or resident measures for this trial:

1. Be acting as a personal nominee for any residents participating in the trial

Date of first enrolment

01/10/2015

Date of final enrolment

31/01/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Bradford Institute for Health Research
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details
Duckworth Lane
Bradford
England
United Kingdom
BD9 6RJ

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/05gekvn04>

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

The plan is to formerly disseminate findings from the trial between August 2017 and February 2018. Findings will be tailored to the needs of different stakeholders and disseminated through a series of workshops, lay summaries, presentations at conferences and academic peer reviewed papers. Care home staff and residents will be involved in the production of dissemination materials to ensure they are presented in a format accessible and meaningful to care home residents.

This trial will make a significant contribution to the evidence base relating to physical activity and sedentary behaviour in care home residents. The trial will report on the applicability of methods to objectively assess physical activity in the oldest old residing in care homes and assess the quality and quantity of physical activity and sedentary behaviour typical of care home residents.

The trial will report on the feasibility of the developed intervention. This will include an economic evaluation and estimation of cost effectiveness. The trial will also report on the feasibility of a large trial (e.g. recruitment rates (care homes and residents), compliance, follow-up rates, adverse events, variability of outcomes and estimation of intra-cluster correlation coefficient and sample size to design a large trial).

The trialists believe the methods will also be transferable to other behaviour change initiatives in care homes.

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/04/2017		Yes	No
Results article	results	03/10/2018		Yes	No
Results article		01/11/2021	17/11/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/08/2021	10/07/2023	Yes	No