

REACH: research exploring physical activity in care homes

Submission date 24/06/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 25/06/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/07/2023	Condition category Signs and Symptoms	☐ 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
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

N/A

Completion date

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

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 Years

Sex

All

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

United Kingdom

England

Study participating centre

Bradford Institute for Health Research

Duckworth Lane

Bradford

United Kingdom

BD9 6RJ

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust

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

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?
Results article	results protocol	03/10/2018		Yes	No
Results article		01/11/2021	17/11/2021	Yes	No
Results article		01/08/2021	10/07/2023	Yes	No
Protocol article		19/04/2017		Yes	No
HRA research summary			28/06/2023	No	No