Bathing adaptations in the homes of older adults

Submission date Recruitment status [X] Prospectively registered

10/07/2016 No longer recruiting [X] Protocol

Registration date Overall study status [] Statistical analysis plan

12/07/2016 Completed [X] Results

Last Edited Condition category [X] Individual participant data

30/08/2023 Other

Plain English summary of protocol

Background and study aims

People who have problems using the bath or the shower at home may contact the social care department of their local council for help. A care worker may then go into the person's home to assist with using the bath, shower or strip-washing. Alternatively, the council may help with making the bath or shower easier and safer to use. This might mean providing a shower with a level floor – a "wet room". This means that the person can often use the shower without needing help and may be less likely to have an accident. This may stop their health from getting worse. We also think that showers might make it easier for carers to manage. We want to find out whether showers affect the health and wellbeing of users and carers.

There are often long waiting times for showers to be installed. We think that people may lose some of their independence while they are waiting. This might mean that they end up using more services. Whilst providing a shower might seem expensive, it may cost less than having help from other services on a long-term basis. Although we believe this to be the case, there is no clear research that compares the costs of these showers in relation to the benefits for users and carers. We also want to find out whether waiting times have a negative effect on health and wellbeing and also lead to more costs. The aim is to show that it is possible to carry out a study using this method. If we do this, we will apply for funding to conduct a larger study so that we can carry out the necessary statistical tests. This information is needed to inform practice.

Who can participate?

People aged 65 or over who have been referred to the Adaptations and Renewals Agency for provision of an accessible shower

What does the study involve?

Participants are randomly allocated to either have their shower installed immediately, or to have a three-month wait. The two groups are compared at three months, when only one group has had the showers installed. They are also compared at six months when everyone has had their shower. Health (physical and mental), independence, and use of services are compared. Using this method is the best way to be sure that any differences are due to the shower installations rather than other factors. Users and carers are also interviewed about their situation and whether they think the shower has helped them.

The aim is to run this study with a council where the current waiting times for showers are

longer than three months. In many local authorities, the waiting times for housing adaptations are longer than three months. We think that a larger study would involve a longer waiting time in the control group. However, for this study a three month waiting list control period should allow us to collect the information we need to inform the main study.

Although people of any age may be provided with a shower we think that the benefits may be different for people at different ages. If we include all age groups this is likely to make it more difficult to see any benefits. We plan to include people aged 65 and over in this study. However, it is possible that this study could be applied to younger age groups in the future.

What are the possible benefits and risks of participating?

There may be no direct benefit to participants. The information we get from the study should help us to plan a bigger study. We do not anticipate that there are any risks involved in taking part.

Where is the study run from? Nottingham City Council - Adaptations and Renewals Agency (UK)

When is the study starting and how long is it expected to run for? March 2016 to October 2017

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

Who is the main contact?

- 1. Miriam Day (miriam.day@nottingham.ac.uk)
- 2. Dr Phillip Whitehead (phillip.j.whitehead@nottingham.ac.uk)

Study website

www.nottingham.ac.uk/go/bath-out

Contact information

Type(s)

Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Final1.0 10Mar16

Study information

Scientific Title

Bathing adaptations in the homes of older adults: a feasibility randomised controlled trial and nested qualitative interview study

Acronym

BATH-OUT

Study objectives

- 1. It is hypothesised that a randomised controlled trial of bathing adaptations using a waiting list control group will be feasible.
- 2. It is hypothesised that bathing adaptations will lead to improvements in health and social care related quality of life, functional ability and lead to reductions in the use of other health and social care services.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Social Care Research Ethics Committee, 21/04/2016, ref: 16/IEC08/0017

Study design

Single-centre feasibility randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Quality of life

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

Housing adaptations

Interventions

Randomisation to parallel groups in random varying block sizes via web-based randomisation. Randomisation will be stratified for privately and publicly owned properties. Outcome assessor will be masked to allocation.

The intervention is the provision of an accessible showering facility. This usually involves the removal of an existing bath and replacement with a flush floor anti-slip walk in 'level access' shower (which may also be termed a 'wet room'). Participants in both groups will receive this intervention; however they will be randomised to either:

Usual Adaptations Service (waiting-list control group)

Those randomised to the control group will receive the usual routine service provided by the Adaptations and Renewals Agency. This involves being allocated to a project officer to begin planning the accessible showering facility after a 3-month wait.

Intervention (no waiting list)

Those randomised to the intervention group will be allocated to a project officer begin planning the accessible showering facility immediately and will not go onto the routine waiting list.

Intervention Type

Other

Primary outcome measure

The main outcome for the study is to determine the feasibility of conducting a larger, powered study. This will be a composite of:

- 1. Whether the eligibility criteria are realistic
- 2. Whether users and carers are willing to be randomized
- 3. The study attrition rate
- 4. Whether the adaptations can be completed within 4 to 6 weeks of allocation to a project officer (in both groups)

- 5. The suitability and sensitivity of outcome measures
- 6. The most suitable outcome measure for use in the main study
- 7. The feasibility of collecting the data on costs and health and social care use

Secondary outcome measures

The service user outcomes to be assessed, at three and six months post-randomisation, will be:

- 1. Health-related quality of life EQ5D-5L
- 2. Social care related quality of life Adult Social Care Outcomes Toolkit (ASCOT)
- 3. Perceived physical and mental health/wellbeing Short Form 36 (physical and mental component summaries)
- 4. Personal activities of daily living Barthel Index
- 5. Fear of falling Falls Efficacy Scale
- 6. Falls
- 7. Number of care support hours
- 8. Health and social care service usage a purposely designed questionnaire will gather information on the use of other health and social care services, with particular emphasis on the use of homecare and residential care.

The carer outcomes to be assessed, at three and six months post-randomisation, will be:

- 1. Health related quality of life EQ5D-5L
- 2. Perceived physical and mental health/wellbeing Short Form 36 (physical and mental component summaries)
- 3. Carer Strain Caregiver Strain Index

We will also gather data on the carers' use of health and social care services.

Overall study start date

01/03/2016

Completion date

31/10/2017

Eligibility

Key inclusion criteria

Service users:

- 1. Aged 65 or over
- 2. Referred to the Adaptations and Renewals Agency, by a social care occupational therapy team member, for provision of an accessible showering facility.

Carers

1. Where a participant has a carer they will also be approached for informed consent to take part in the study. We will take a broad definition of 'carer' which will be led by the service user and carer's views of their role. This will encompass people who provide practical and/or emotional support, those who assist with personal care and those who do not.

NB where a service user consents to take part in the study but a carer declines then the service user will still be eligible to participate.

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

40 to 60

Key exclusion criteria

Service users:

- 1. Referred for an accessible showering facility plus one or more other adaptations (e.g. hoist, ramp, lift)
- 2. Priority 'A' referrals (those which are being 'fast-tracked' based on clinical assessment)

Carers:

1. Unable to provide informed consent

Date of first enrolment

01/09/2016

Date of final enrolment

30/04/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Nottingham City Council - Adaptations and Renewals Agency
United Kingdom
NG2 3NG

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Research & Graduate Services King's Meadow Campus Lenton Lane Nottingham England United Kingdom NG7 2NR

Sponsor type

University/education

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Research organisation

Funder Name

National Institute for Health Research School for Social Care Research (UK)

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

31/10/2018

Individual participant data (IPD) sharing plan

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	06/10 /2016		Yes	No
Results article	results	26/11 /2018		Yes	No
Results article	follow-up results	09/11 /2020	11/11 /2020	Yes	No
HRA research summary			28/06 /2023	No	No
<u>Dataset</u>	Participant's use of health and social care resources at baseline and 3 month follow-up	26/11 /2018	30/08 /2023	No	No