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Bathing adaptations in the homes of older adults 2

Submission date 09/04/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/04/2021	**Overall study status** Completed	
Last Edited 02/09/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Sometimes older people may become unable to use the bath or shower at home because it is difficult to get in and out of. An occupational therapist may recommend that they have a 'walk-in' shower put in. This may enable the person to continue to manage their personal care without help. It may also make it less likely that they have an accident or fall. However, there is limited research on how walk-in showers may help people to manage their personal care as they get older. We want to find out whether having a walk-in shower improves or maintains older people' s health, safety, quality of life, and ability to manage their personal care. We want to answer two important questions: is the provision of walk-in showers effective? If so, is quicker provision more effective?

Who can participate?
People aged 60 and over, who have been referred to the participating council's adaptations service for a walk-in shower, will be invited to join the study.

What does the study involve?
We will randomly allocate half to begin the process for walk-in shower installation straight away (intervention group). The other half will go on the usual waiting list (control group) which can be between 4 and 9 months before the shower is put in. We will compare the two groups 4 weeks after the intervention group has received their showers. We will also compare the groups again 4 and 12 weeks after the control group has received their showers. We want to see whether those who had to wait for their shower to be put in have more long-term difficulties with everyday activities, and whether they need more help from family, or health and social care services. As an additional part of the study, we will carry out interviews about the bathing adaptations process with people using the service and social care and housing professionals; and a survey of all local authorities with social care responsibilities.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants. The information we get from this study will help to determine how to organise adaptations services in the future. The study aims to help social care and housing staff best use the resources available to them when treating people in their own homes.

Where is the study run from?
The research is being organised by Newcastle University and York Trials Unit at the University of York (UK)

When is the study starting and how long is it expected to run for?
December 2020 to May 2024

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

Who is the main contact?
Dr Phillip Whitehead
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Contact information

Type(s)
Scientific

Contact name
Dr Phillip Whitehead

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
290805

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 48800, IRAS 290805, NIHR Grant Code 102645/T19-034/UN-P151

Study information

Scientific Title
Bathing adaptations in the homes of older adults: a randomized controlled trial, economic evaluation and process evaluation – the BATH-OUT 2 trial

Acronym
BATH-OUT 2

Study objectives
Earlier provision bathing adaptations will lead to improvements in their health and social care related quality of life. Our secondary hypothesis is that earlier and more rapid provision of bathing adaptations will lead to greater improvements in health and social care related quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2021, London - Camberwell St Giles Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8340; camberwellstgiles.rec@hra.nhs.uk), ref: 21/LO/0044

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Bathing adaptations in the homes of older adults

Interventions
Current interventions as of 13/07/2023:

Participants will be randomly allocated 1:1 to the usual care or intervention group. We will use “pairwise” randomisation. The randomisation will be stratified by ability to complete the SF-36; for those participants who can self-complete the SF-36, it will be further stratified by site and property tenure, and for those who can not, it will be stratified by site only. Additional flexibility of the strata will be considered in cases where finding a pair is problematic. The randomisation sequence will be generated by a statistician at York Trials Unit.

Study groups:
Control: Usual waiting list group. People in this group will remain on the usual waiting list and be allocated to a project officer surveyor to begin the adaptations process when they reach the top of the waiting list and/or by the usual processes and timescales within the local authority. The waiting list at our sites before the COVID-19 pandemic was between 4 and 9 months, but this can vary.

Intervention: Accelerated list group. People in this group will be allocated to a project officer /surveyor to begin the adaptations process and/or will have their adaptations process expedited by active management of the process and rapid or fast-tracked contracting.

Baseline consultation:
Local authority staff will contact people who have been referred for an accessible shower to let them know they have been added to a waiting list for this. If the person fulfils the eligibility criteria the administrator will also give a brief overview of the study and ask permission for a research assistant to make contact with them about the study and to send further information. If a participant requires consultee support either a personal or nominated consultee will attempt to be identified. Additionally, if the participant is unable to answer the questions, an "alternative participant" will be recruited. We will seek advice from the trial participant and the consultee about the most appropriate person to act as an "alternative participant". The research assistant will telephone the potential participant and/or a consultee and answer any questions they have about the study. The research assistant will also complete a screening form to confirm eligibility. If the potential participant/consultee wants to take part in the study at this initial contact they will undergo the consent process. If they are still undecided after the initial consultation the research assistant will arrange to contact them within a timescale agreed with the potential participant, leaving at least 24 hours since the previous consultation. After informed consent is gained the participant or "alternative participant" will complete a baseline questionnaire.

Follow-up:
The time points at which participants will be followed-up will be based on the completion of the walk-in shower installation. For each randomised pair, participant follow-up data will be collected at three time points:
(1) 4 weeks after the intervention participant receives their bathing adaptation,
(2) 4 weeks after the control participant receives their bathing adaptation, and
(3) 12 weeks after the control participant receives their bathing adaptation.
Participants will be sent a 'diary' sheet following the first follow-up visit and after each subsequent follow up visit to enable them to record contacts with health, social care and other services. This diary will be optional, for them to complete at home. The purpose is to aid their recall where there is a longer time period between each follow up. The diary will not be returned to the research team.

Follow-up data collection is likely to be conducted using remote methods to ensure the safety of participants and research assistants. However, if possible, we will offer face-to-face visits to participants' homes if circumstances change during the study.

Internal Pilot Phase:
During the first six months of the study we will assess the progress of the study in terms of recruitment and questionnaire completion to identify any whether any modifications need to be made to the study.

Process evaluation:
We will undertake a mixed methods process evaluation comprised of interviews with stakeholders and a survey of local authorities with social care responsibilities in England.

National survey of local authorities:
The survey will focus on understanding providers' experiences of implementing bathing adaptations in order to understand the determinants of provision of adaptations.

Previous interventions as of 27/07/2021:

Participants will be randomly allocated 1:1 to the usual care or intervention group. We will use "pairwise" randomisation. The randomisation will be stratified by ability to complete the SF-36; for those participants who can self-complete the SF-36, it will be further stratified by site and property tenure, and for those who can not, it will be stratified by site only. Additional flexibility of the strata will be considered in cases where finding a pair is problematic. The randomisation sequence will be generated by a statistician at York Trials Unit.

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Control: Usual waiting list group. People in this group will remain on the usual waiting list and be allocated to a project officer surveyor to begin the adaptations process when they reach the top of the waiting list and/or by the usual processes and timescales within the local authority. The waiting list at our sites before the COVID-19 pandemic was between 4 and 9 months, but this can vary.
Intervention: Accelerated list group. People in this group will be allocated to a project officer /surveyor to begin the adaptations process and/or will have their adaptations process expedited by active management of the process and rapid or fast-tracked contracting.

Baseline consultation:
Local authority staff will contact people who have been referred for an accessible shower to let them know they have been added to a waiting list for this. If the person fulfils the eligibility criteria the administrator will also give a brief overview of the study and ask permission for a research assistant to make contact with them about the study and to send further information. If a participant requires consultee support either a personal or nominated consultee will attempt to be identified. Additionally, if the participant is unable to answer the questions, an "alternative participant" will be recruited. We will seek advice from the trial participant and the consultee about the most appropriate person to act as an "alternative participant". The research assistant will telephone the potential participant and/or a consultee and answer any questions they have about the study. The research assistant will also complete a screening form to confirm eligibility. If the potential participant/consultee wants to take part in the study at this initial contact they will undergo the consent process. If they are still undecided after the initial consultation the research assistant will arrange to contact them within a timescale agreed with the potential participant, leaving at least 24 hours since the previous consultation. After informed consent is gained the participant or "alternative participant" will complete a baseline questionnaire.

Follow-up:
The time points at which participants will be followed-up will be based on the completion of the walk-in shower installation. For each randomised pair, participant follow-up data will be collected at four time points:
(1) 4 weeks after the intervention participant receives their bathing adaptation,
(2) 2 weeks before the control participant receives their bathing adaptation,
(3) 4 weeks after the control participant receives their bathing adaptation, and
(4) 12 weeks after the control participant receives their bathing adaptation.
Participants will be sent a 'diary' sheet following the first follow-up visit and after each subsequent follow up visit to enable them to record contacts with health, social care and other services. This diary will be optional, for them to complete at home. The purpose is to aid their recall where there is a longer time period between each follow up. The diary will not be returned to the research team.

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Study groups:
Control: Usual waiting list group. People in this group will remain on the usual waiting list and will be allocated to a project officer to plan their walk-in shower when they come to the top of the list. The waiting list at our sites before the COVID-19 pandemic was between 4 and 9 months, but this can vary.
Intervention: Accelerated list group. People in this group will be allocated to a project officer to plan their walk-in shower as soon as possible.

Baseline consultation:
Local authority staff will contact people who have been referred for an accessible shower to let them know they have been added to a waiting list for this. If the person fulfils the eligibility criteria the administrator will also give a brief overview of the study and ask permission for a research assistant to make contact with them about the study and to send further information. If a participant requires consultee support either a personal or nominated consultee will attempt to be identified. Additionally, if the participant is unable to answer the questions, an "alternative participant" will be recruited. We will seek advice from the trial participant and the consultee about the most appropriate person to act as an "alternative participant".
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After informed consent is gained the participant or “alternative participant” will complete a baseline questionnaire.

Follow-up:
The time points at which participants will be followed-up will be based on the completion of the walk-in shower installation. For each randomised pair, participant follow-up data will be collected at four time points:
(1) 4 weeks after the intervention participant receives their bathing adaptation,
(2) 2 weeks before the control participant receives their bathing adaptation,
(3) 4 weeks after the control participant receives their bathing adaptation, and
(4) 12 weeks after the control participant receives their bathing adaptation.

Participants will be sent a ‘diary’ sheet following the first follow-up visit and after each subsequent follow up visit to enable them to record contacts with health, social care and other services. This diary will be optional, for them to complete at home. The purpose is to aid their recall where there is a longer time period between each follow up. The diary will not be returned to the research team.
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During the first six months of the study we will assess the progress of the study in terms of recruitment and questionnaire completion to identify any whether any modifications need to be made to the study.

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National survey of local authorities:
The survey will focus on understanding providers’ experiences of implementing bathing adaptations in order to understand the determinants of provision of adaptations.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 13/07/2023:

Physical Component Summary score (PCS) of the SF-36 measured in:
1. Both groups at baseline
2. Four weeks post-adaptation in the intervention group
3. Four weeks post-adaptation in control group
4. 12 weeks post-adaptation in control group

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Previous primary outcome measure:

Physical Component Summary score (PCS) of the SF-36 measured in:
1. Both groups at baseline

2. Four weeks post-adaptation in the intervention group
3. Two weeks pre-adaptation in control group
4. Four weeks post-adaptation in control group
5. 12 weeks post-adaptation in control group

Key secondary outcome(s))

Current secondary outcome measures as of 13/07/2023:

1. Perceived mental health status measured via the Mental Component Summary score (MCS) of the SF-36 measured at the above timepoints.
2. Number of falls (self reported) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
3. Health and social care service use and associated costs measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
4. Health related quality of life using the EuroQol EQ-5D-5L measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
5. Social care related quality of life using the Adult Social Care Outcomes Toolkit (ASCOT) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
6. Perceived risk of falling (Short falls efficacy scale) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
7. Independence in bathing (bathing question of the Barthel Index) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
8. Ability to manage personal activities of daily living (Barthel Index) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
9. Perceived difficulty in bathing (0-100 scale) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.

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1. Perceived mental health status measured via the Mental Component Summary score (MCS) of the SF-36 measured at the above timepoints.
2. Number of falls (self reported) measured at baseline, four weeks post-adaptation in the intervention group, 2 weeks pre-adaptation in control group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
3. Health and social care service use and associated costs measured at baseline, four weeks post-adaptation in the intervention group, 2 weeks pre-adaptation in control group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
4. Health related quality of life using the EuroQol EQ-5D-5L measured at baseline, four weeks post-adaptation in the intervention group, 2 weeks pre-adaptation in control group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
5. Social care related quality of life using the Adult Social Care Outcomes Toolkit (ASCOT) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-

adaptation in control group and 12 weeks post-adaptation in control group.
6. Perceived risk of falling (Short falls efficacy scale) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
7. Independence in bathing (bathing question of the Barthel Index) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
8. Ability to manage personal activities of daily living (Barthel Index) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.
9. Perceived difficulty in bathing (0-100 scale) measured at baseline, four weeks post-adaptation in the intervention group, 4 weeks post-adaptation in control group and 12 weeks post-adaptation in control group.

Completion date
31/05/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/07/2023:

1. People aged 60 years or over
2. People referred for a major adaptation for provision of an accessible (level or easy access) showering facility. This may be by removal of an existing bath or shower cubicle.
3. People living in housing owned by the local authority or living in privately-owned housing (owner-occupied, privately rented, housing association owned) and appear to be eligible for a Disabled Facilities Grant (DFG) and/or assistance from the local authority.

The study will include people who do not speak English and will provide interpreters. The researchers will use the interpreting agency at the site.

Previous inclusion criteria as of 27/07/2021:

1. People aged 65 years or over
2. People referred for a major adaptation for provision of an accessible (level or easy access) showering facility. This may be by removal of an existing bath or shower cubicle.
3. People living in housing owned by the local authority or living in privately-owned housing (owner-occupied, privately rented, housing association owned) and appear to be eligible for a Disabled Facilities Grant (DFG) and/or assistance from the local authority.

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3. People living in housing owned by the local authority or living in privately-owned housing (owner-occupied, privately rented, housing association owned) and appear to be eligible for a Disabled Facilities Grant (DFG)

The study will include people who do not speak English and will provide interpreters. The researchers will use the interpreting agency at the site.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 years

Sex
All

Total final enrolment
299

Key exclusion criteria
1. People referred for an accessible showering facility plus one or more other adaptations (e.g. ramps, hoists, lifts) as these adaptations are more complex and will involve extended timescales
2. People referred for a rapid, fast-tracked or urgent priority bathing adaptation
3. People who lack the mental capacity to provide informed consent and we are unable to identify a personal or nominated consultee
4. People who lack the mental capacity to provide informed consent and who are unable to provide any study outcomes with support or where we are unable to identify an “alternative participant” to provide data

Date of first enrolment
14/09/2021

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Not provided at time of registration (no centres confirmed yet)
-
-
United Kingdom
-

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
The datasets generated and/or analysed during the current study will be available upon reasonable request from the Chief Investigator (phillip.whitehead@northumbria.ac.uk) following completion of the trial and publication of trial results. Requests will be considered by

the Trial Management Group on a case-by-case basis. Data will be made available for secondary analyses, and only anonymised data will be provided.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/01/2024	23/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes