# Mapping and evidence synthesis for assistive technologies to support adults living at home with long-term continence or toilet-use problems (CAT-MAP)

## Protocol

Version 1.1

19.01.24

This study/project is funded by the NIHR Health Technology Assessment (HTA) Programme (NIHR 152941). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care

**FULL/LONG TITLE OF THE STUDY**
Mapping and evidence synthesis for assistive technologies to support adults living at home with long-term continence or toilet-use problems

**SHORT STUDY TITLE / ACRONYM**

CAT-MAP

**PROTOCOL VERSION NUMBER AND DATE**

Version 1.1, 19 January 2024

**RESEARCH REFERENCE NUMBERS**

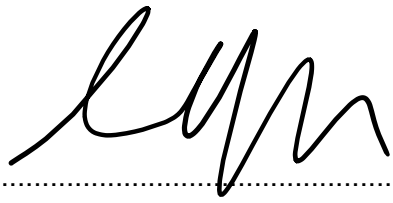
| | |
|---|---|
| **IRAS Number:** | Not applicable |
| **PROSPERO REG:** | TBC |
| **SPONSORS Number:** | Not applicable |
| **FUNDERS Number:** | NIHR152941 |

**SIGNATURE PAGE**

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, and other regulatory requirement.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

**Chief Investigator:**

Signature:  Date:

..... ....19../1../.24.....

Name: (please print):Dr Catherine Murphy

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## KEY STUDY CONTACTS

| | |
|---|---|
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| Sponsor | University of Southampton |
| Joint-sponsor(s)/co-sponsor(s) | Not applicable |
| Funder(s) | National Institute of Health Research (NIHR) Health Technology Assessment |
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| Committees | Project Management Group, led by Dr Catherine Murphy (contact details above) |

## STUDY SUMMARY

| | |
|---|---|
| Study Title | Evidence synthesis for assistive technologies to support adults living at home with long-term continence or toilet-use problems |
| Internal ref. no. (or short title) | CAT-MAP |
| Study Design | Mapping review and systematic review |
| Study Participants | Not applicable |
| Planned Size of Sample (if applicable) | Not applicable |
| Follow up duration (if applicable) | Not applicable |

| | |
|---|---|
| Planned Study Period | August 2023 - April 2025 |
| Research Questions | 1. What assistive technologies (ATs) are designed to help people living at home with containing urinary and faecal leakage or toilet-use problems and what specific problems are they designed to address?<br>2. What is the effectiveness and cost-effectiveness of ATs designed to help people living at home with long-term urinary and faecal leakage containment or toilet-use problems? |

## FUNDING AND SUPPORT IN KIND


| FUNDER(S) | FINANCIAL AND NON FINANCIAL SUPPORT GIVEN |
|---|---|
| National Institute of Health Research (NIHR) Health Technology Assessment | Awarded funding for the project (NIHR152941) |


## ROLE OF STUDY SPONSOR AND FUNDER

The project sponsor, the University of Southampton, will assume overall responsibility for the initiation and management of the study.

Funding for this project was awarded by the NIHR through their Health Technology Assessment programme. The study particulars described in this document were agreed with the funder. The funder does not have any input into the data analysis and interpretation, manuscript writing or dissemination of the project results.

## ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/ GROUPS & INDIVIDUALS

### Project Management Group

The project management group will meet every two months, with sub-meetings as required, to oversee the project's progress, provide expert advice on issues arising and plan the next actions.

### Stakeholder Group

The stakeholder group will be instrumental in shaping this project through Stakeholder Events (the focus of each event is described in Section 5- Study Design and Methods of Data Collection). The stakeholder group will include Assistive Technology users, their carers, and health and social care professionals with expertise in supporting individuals with continence needs (e.g. nurses, occupational therapists and adult social care practitioners).

### PPI Group

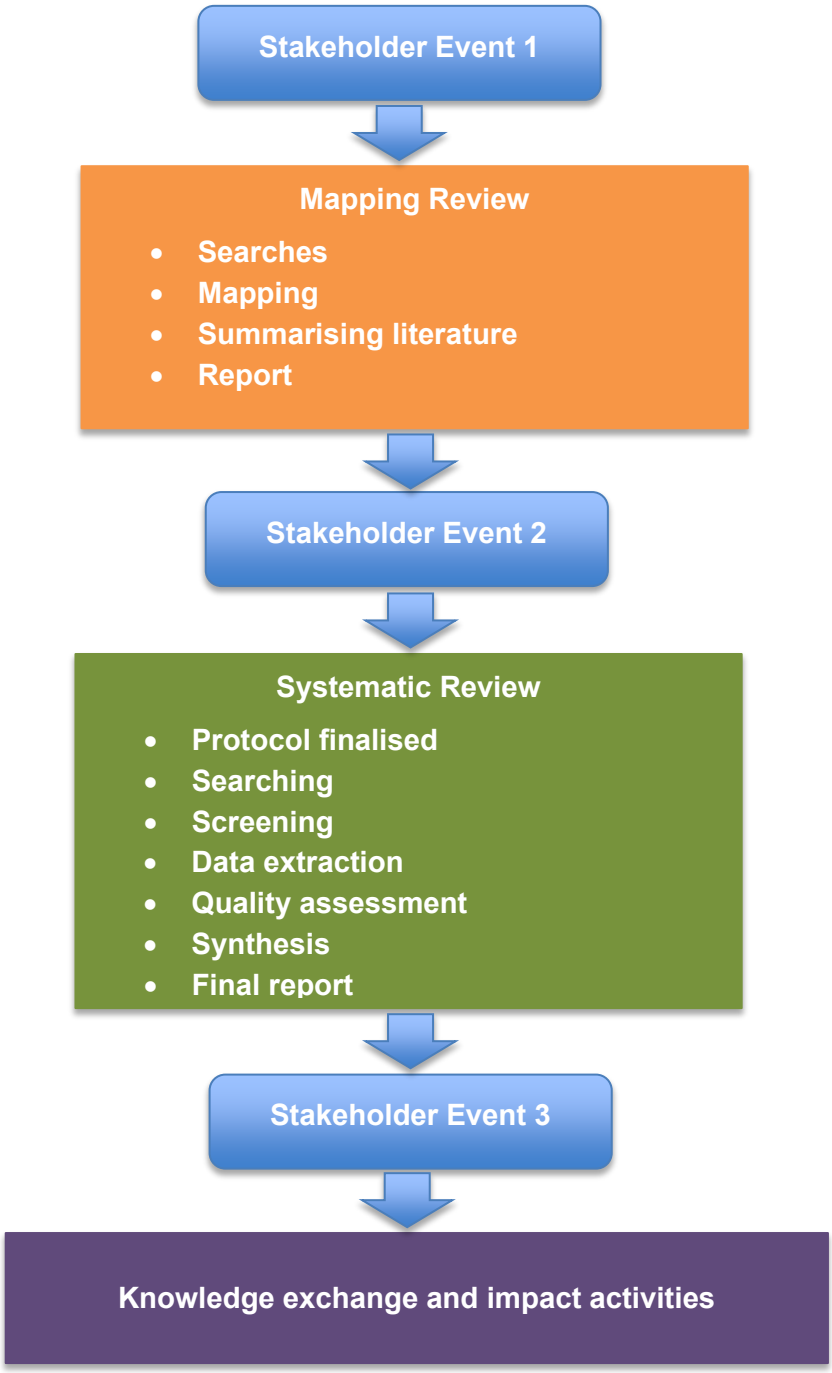
The PPI group will include individuals with continence problems and lay carers with experience of caring for individuals with continence needs. PPI meetings will be held 3-4 monthly, or at times to fit with key project milestones. In addition to scheduled meetings, we will work closely with the PPI group throughout the project, e.g. to discuss matters arising, provide feedback on documents etc. PPI group members will be invited to participate in all Stakeholder Events.

## PROTOCOL CONTRIBUTORS

Patient and public involvement (PPI) has been integral to the design of this project. Patients have told us the importance of getting the right continence products, the limitations of current product designs, and the challenges in finding out what ATs are available to meet their needs. Feedback on the project was sought from the Wessex Public Involvement Network. Many members had personal experience of the topic area and were supportive of the need to advance the evidence base. They highlighted the considerable amount of money (whether local authority or personal) spent on assistive technologies to tackle long-term incontinence but without any guidance on what works for who or whether value for money is achieved. They emphasised the need for a broad approach to dissemination of findings and as a result we have added dissemination as a topic for discussion in one of the planned Stakeholder Events. This protocol was developed in partnership with a PPI co-applicant with direct experience of caring for family members with incontinence.

**KEY WORDS:** Continence, incontinence, toilet, assistive technology, device, product

## STUDY FLOW CHART



**STUDY PROTOCOL**

Evidence synthesis for assistive technologies to support adults living at home with long-term continence or toilet-use problems

## 1 BACKGROUND

Approximately 23% (urinary) and 6% (faecal) of adults in the UK suffer from or have suffered from some form of incontinence (Buckley et al. 2009). Incontinence can be both a consequence of disability (e.g. decreased mobility leading to incontinence) and a cause of disability (e.g. inability to manage bladder or bowel leakage leading to loss of independence). Causes of incontinence are wide-ranging, but both older age and dementia are strongly associated with increased risk (Grant et al. 2013, Sørbye et al. 2009). Healthcare professionals should always seek to reverse the cause of incontinence, but this is often not possible or can take time and as a result, many people live with long-term or permanent incontinence (Riemsma et al. 2017).

There is now a moderate body of literature on understanding the problems, experiences and impact of living with long-term incontinence, including social isolation (Yip et al. 2013), skin damage (Beeckman et al. 2016), increased carer workload (Tamanini et al. 2011), depression and anxiety (Felde et al. 2017), damage to home environment and increased likelihood of admission to residential care (Schluter et al. 2016). Many reports have highlighted the importance of well-managed incontinence in social care in the UK but that it is often not achieved. These include “A Road Less Rocky: Supporting Carers of People with Dementia” (Newbronner et al. 2013) reporting that the onset of incontinence is a key stage where support is needed and “My bladder and bowel own my life” (2018) a paper from a collaboration of UK charities highlighting the harm caused by poorly managed incontinence and the need for improved technological solutions. In this second report, one carer is quoted,

> “The indignity of incontinence is often worse than the illness that has caused it, the devices are not practical or well designed, and care for people with incontinence can become a burden. We hope for a better solution for the care and management of incontinence.” (p10).

Assistive products, often referred to under the umbrella term of assistive technologies (ATs), are products that enable an individual to improve or maintain their functioning and independence (WHO 2023). The importance of ATs in supporting continence management was recognised by the World Health Organisation which listed incontinence products as one of its top 50 Priority Assistive Technologies (WHO 2016) and have since published detailed specifications for absorbent washable and reusable incontinence products (WHO 2019). Despite the fact that AT play a crucial role in supporting people with long-term incontinence and/or toilet-use problems, we do not have a thorough understanding of which ATs might help which people with which problems. We do not know which ATs should be recommended to different people and we do not know whether money spent on these ATs would provide good value for money.

This study will map assistive technologies that are designed to help people living with different long-term incontinence problems and evaluate their effectiveness and cost-effectiveness.

## 2 RATIONALE

There is no comprehensive publication describing the full range of ATs available to support people living with incontinence, let alone evaluating their effectiveness. The chapter "Management using continence products" in the 7th edition of Incontinence, a global review published by the International Consultation on Incontinence (Cardozo et al. 2023), provides a review of a range of continence technologies. However, it is not intended to cover the full range of ATs (for example sensors) and focuses on specific health outcomes (e.g. urinary tract infection) and does not include social care or broader well-being outcomes. Without this knowledge, decisions on purchasing and using incontinence-related ATs are not evidence (or even expert knowledge) based. This situation is further exacerbated by the distributed nature of AT decision-making; for example, in one locality absorbent pads might be provided by community NHS trusts (need assessed by a nurse), commodes by the local authority (need assessed by an occupational therapist) and a handheld urinal might be self-purchased by the AT user (need assessed by self or carer). This means that almost no one stakeholder (or provider organization) has a full understanding of the range of ATs that are available to help.

A further considerable challenge for people living with incontinence is the lack of continence AT innovation with many designs remaining unchanged for decades despite considerable advances in comparable medical devices. Examples of such devices are shown below.

Figure 1 Female urinal

Figure 2 Penile compression device

Figure 3 Commode

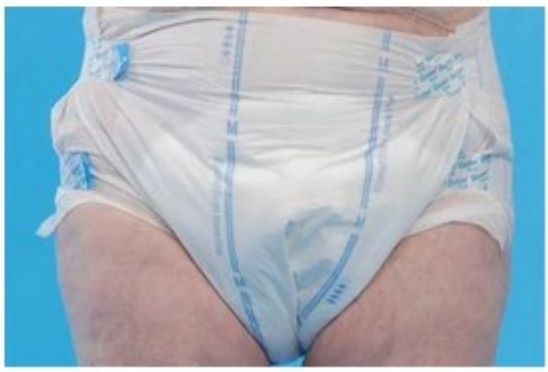


Figure 4 Unisex absorbent product

This project will benefit product users in two ways:

1. Firstly, immediately at the end of this study, we will support clinicians, service commissioners, social care practitioners and AT users and their carers to choose the most appropriate AT for individual circumstances by providing them with accessible information on which ATs are available to address specific urinary and/ or faecal containment or toilet-use problems, and how effective and cost-effective these ATs are.
2. Secondly, we anticipate that this study will highlight important opportunities for research and innovation in continence product design. We will use these results to highlight to industry and research colleagues that there is significant potential for progress in this area both in terms of developing an evidence base and AT innovation.

To do this, we must embed people's needs at the heart of this study by focusing on the problems people face and identifying the ATs designed to address these problems. People might have varying underlying causes of incontinence (e.g. dementia, diabetes, arthritis, cancer, frailty), but share the same problems. For example, men with poor dexterity might

struggle to direct urine flow. The poor dexterity could be caused, for example, by frailty, a stroke or arthritis, but the shared problem is needing a device to help direct urine flow. Therefore, in Phase 1 we will take a problem-based approach to the containment (of urinary and faecal leakage) and toilet-use problems people might experience and subsequently identify and map the full range of ATs that are designed to help with these problems. Following this, in Phase 2 of this study, we will undertake systematic reviews of the evidence available to support the use of the ATs identified in Phase 1.

## 3 THEORETICAL FRAMEWORK

In this two-phase project, we will undertake a mapping review (Phase 1) followed by a systematic review (Phase 2) with narrative synthesis and, where possible, meta-analysis of the data. We carried out a scoping search in MEDLINE database on the incontinence aspect of the population using generic terms for assistive technologies as well as terms for specific ATs. The results of this have guided the search strategy and synthesis methods described in this document.

Phase 1: Mapping review

The purpose of the mapping review is to '"map out" and thematically understand the pre-existing research' (Grant & Booth 2009). This will allow us to map ATs to the problem that they are designed to address which will in turn facilitate the full systematic evidence synthesis in Phase 2. We considered using realist methodologies for this work but concluded that the nature of the interventions and limited foundation knowledge (i.e., which ATs are designed for which problems) meant that the dual approach of undertaking a mapping review and subsequent systematic review and evidence synthesis better addressed the research question. However, we will consider realist principles (including "what works for who and in what circumstances") in our mapping review. Where appropriate, we will collate data on the World Health Organisation's Global Collaboration on Assistive Technology (GATE) strategic "P"s (People, Products, Provision, Policy and Personnel), for example by, where available, capturing data on who provided the ATs and practitioner involvement in delivering the AT. This comprehensive approach will support the full description of not just the assistive technology, but also any service delivery processes described.

The scoping search revealed that certain free-text terms had few or no results (e.g. bottom wipers and faecal pads) demonstrating that certain assistive technologies are not found in published academic literature. This emphasises the importance of grey literature and commercial directories as evidence sources for the mapping phase, where the focus is on identifying the full range of ATs that might support specific containment and toilet-use issues.

Phase 2: Systematic review

The scoping search identified no recent (in the 6 years prior to our search) systematic reviews of all continence assistive technologies. 124 results were found when the Scottish Intercollegiate Guidelines Network (SIGN) economics search filter was applied to find cost-effectiveness studies supporting our anticipation of limited cost-effectiveness

evidence thus our intention to provide a narrative commentary for this aspect of the review. Initial assessment of study designs suggests variability between product groups. Some groups (e.g. absorbent continence products) include multiple randomized controlled trials plus multiple quasi-experimental or non-experimental trials. However, these trials are heterogenous in terms of sample population, products included, settings and outcomes and meta-analysis of results is unlikely. Other groups (e.g. toilet grab bars) have predominantly preliminary feasibility trials or small-scale acceptability/usability studies, again with varied settings and outcomes. Therefore, we will invite health and social care professionals with the appropriate expertise (e.g. occupational therapists, nurses and adult social care practitioners) to form a Stakeholder Group to advise regarding heterogeneity between groups of end-users and ATs appropriate for their needs. This will inform decision-making for the non-quantitative analysis.

## 4 RESEARCH QUESTION/AIM(S)

1. What assistive technologies (ATs) are designed to help people living at home with containing urinary and faecal leakage or toilet-use problems and what specific problems are they designed to address?
2. What is the effectiveness and cost-effectiveness of ATs designed to help people living at home with long-term urinary and faecal leakage containment or toilet-use problems?

### 4.1 Objectives

1. To identify ATs aimed at supporting people (or carers) living at home with long-term containment of urinary and faecal leakage, or toilet-use problems.
2. To categorise ATs and map them to the specific containment or toilet-use problems they are designed to address (e.g. unable to reach the toilet promptly or lack of recognition of bladder sensations).
3. To search for, assess and synthesise evidence on the effectiveness and cost-effectiveness of the ATs.
4. To report findings in order to provide guidance for:
    a. users, carers and practitioners seeking solutions.
    b. industry seeking to innovate in the area and researchers seeking to develop or evaluate interventions.

### 4.2 Outcome

A comprehensive directory of the ATs available to help people living at home with urinary or faecal containment or toilet-use problems and a review of the evidence regarding the effectiveness and cost-effectiveness of these ATs.

## 5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

The project will be undertaken in two phases: a mapping review to identify the range of ATs that are available to address containment or toilet-use problems, and a systematic review of the ATs identified. Three stakeholder events will be held with health and social care professionals, AT product users, and their carers to inform each review phase and upon review completion to discuss the next steps.

### Stakeholder Event 1

The first stakeholder event will help to define the boundaries of the review by informing the development of a comprehensive range of containment and toilet-use problems which could be addressed by the ATs that are to be included in the mapping review. We will further finalise the eligibility criteria for the ATs that will be included in the mapping review and elicit perceptions on outcomes that are important to end users.

## Phase 1: Mapping Review

Applying the eligibility criteria from the first Stakeholder Event, we will undertake a literature review of the eligible ATs, including research of any design and grey literature. The purpose of this review is to identify the full range of ATs aimed at supporting people (or carers) living at home with long-term containment or toilet-use problems (as defined in Stakeholder Event 1).

Searches

Based on our scoping search findings we intend to search the following sources with an emphasis on using the grey literature to help identify the full range and terminology of ATs in use:

1. Grey literature: commercial directories and online product catalogues; community nursing/occupational therapy websites; theses databases; and other grey literature.
2. References from 'Management using continence products', chapter 19 of the 7th International Consultation on Continence (Cardozo et al. 2023), and any key references identified during the search.
3. Electronic bibliographic databases: MEDLINE, MEDLINE In-Process, and CINAHL.
4. Consultation with experts, product users and their carers and care practitioners.

The search strategy will involve hand searching the grey literature and key references followed by searching the electronic databases in order to apply as full a list of relevant search terms for the range of ATs as possible to the databases. An English language limit will be applied.

Population and Eligible Assistive Technologies

The population will be any adult (≥18) living at home with long-term continence or toilet-use problems or caring for a person with long-term continence or toilet-use problems.

The list of eligible ATs will be refined during the first Stakeholder Event but will include any AT, suitable for the population specified above, that is designed to contain urinary or faecal leakage or enable safe and/or independent toilet-use, including but not limited to:

- Disposable absorbent body-worn products
- Disposable absorbent products for beds/furniture
- Washable absorbent body-worn products
- Washable absorbent products for beds/furniture
- Male devices, e.g. penile compression devices
- Toilet adaptations (e.g. raised seats, intelligent toilets)
- Clothing adaptation
- Sensors
- Hand-held urinals/bedpans
- Commodes
- Virtual assistants and other digital technologies
- NB. Urinary catheters will be excluded as they are the device of last resort for managing incontinence and, unlike many of the other included products, should only be provided by healthcare professionals.

At this stage we will include ATs used in residential care settings in addition to community settings as it is possible that some ATs only have literature from a residential care setting. If this is the case, the setting will be noted in the interim report.

We will group the ATs identified into categories based on the containment/toilet-use problem that they are designed to address. We will map individual AT designs to more than one problem area if relevant, for example different types of sensors could be used either to prompt someone to use the toilet by letting them know the volume of urine in their bladder or to reduce the need for pad changes by indicating pad fullness. Using the WHO GATE 5Ps as a framework, we will additionally note where literature includes findings on provision/access to ATs and environmental impact. Based on the findings of Phase 1, we will finalise the methods for Phase 2, including AT definitions, search terms and search strategy.

**Stakeholder Event 2**

During the second Stakeholder Event we will review the results of the mapping review and elicit stakeholders' perceptions of the key points raised, and how best to disseminate the findings of the mapping review to a broad audience in a useable format. This event will also serve to finalise the boundaries of the systematic review, including the range of ATs to be evaluated.

**Phase 2: Systematic Review**

The review protocol will be registered with the International Prospective Register of Systematic Reviews (PROSPERO) database. We will use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA) (Page et al. 2021) statement to guide reporting of the review.

Searches

Database searches will include but not be limited to the following: MEDLINE and MEDLINE In-Process, CINAHL, PsycINFO, AMED, REHABDATA, SSCI, and SCIE Online. Either Web of Science or the Scopus database will be used to assist any reference or citation searching as key papers are identified. Grey literature searching in this phase is to identify evaluative research, as opposed to the discovery search in Phase 1. Therefore, it will be more focused consisting of a title-only search to be undertaken on Google Scholar using guidance from Haddaway et al (2015) with the first 1000 results screened for eligibility and a search of ProQuest Dissertations & Theses Global. Reference lists of included articles will be hand-searched for potentially eligible studies.

Database search strings and search terms will be similar to those used in the scoping search but refined as a result of the Stakeholder Event 1 and the search strings from Phase 1 and limited to the range of ATs to be evaluated as finalised during the second Stakeholder Event. A limit will be applied for English language as per the inclusion/exclusion criteria below. A published search filter for economics studies will be used to identify cost-effectiveness and cost data studies, e.g. the Scottish Intercollegiate Guidelines Network (SIGN) economics filter or the Canadian Agency for Drugs and Technologies in Health (CADTH) economic evaluations & models filter. No further limits will be applied.

References will be managed and deduplicated in the EndNote™ reference management software. PRISMA-S, the searching extension of PRISMA 2020, will be used to guide reporting the searches.

Inclusion criteria and PICOS framework

**Inclusion criteria:** English language, no date restriction, experimental, quasi-experimental and non-experimental designs.

**Population:** Any adult (≥18) living at home with long-term incontinence or caring for a person with long-term incontinence.

**Interventions/phenomenon:** The list of included ATs will be refined during Phase 1 but within these boundaries we will include any AT with the primary aim of containing urinary or faecal leakage or enabling safe and/ or independent toilet-use, including but not limited to the list of ATs provided in Phase 1.

**Comparator:** We will include studies with a range of designs, not all of which will have a comparator. The comparator will include usual care when we incorporate RCTs.

**Outcomes:** We will finalise the list of outcomes during Phase 1, but an indicative list is as follows:

- Effectiveness, including but not limited to:
  - Use of domiciliary care
  - Social isolation/loneliness
  - Health-related quality of life measures
  - Ability to perform Activities of Daily Living
  - Carer workload/burden/stress
  - Carer QoL
  - Incontinence associated harms, including but not limited to skin damage, anxiety, depression, falls and urinary tract infection
  - Admission to hospital
  - Admission to residential care
  - Toilet-use related mobility
  - User experience including acceptability and continuation of use
  - Cost effectiveness
  - Any cost data

**Setting/Context:** We are interested in interventions that might work in the UK for people living at home. We will not limit country. In Phase 1 we will assess the merit of including studies reporting on the use of ATs within residential care and the method of assessing and synthesising this data if it is included (e.g. where there is no data for community settings, then residential care setting data could be used, but clearly flagged as such).

Review strategy

*Screening*

Two reviewers will independently screen all titles and available abstracts identified in the searches to determine whether the study meets the eligibility criteria, before retrieving the full text for review by the research team.

*Data extraction*

Data from included studies will be extracted using a standard form tested by the research team which will include country, setting, study design, problem(s) being addressed (using terms from Phase 1), context, description of intervention (using the TIDieR Framework, Hoffman et al. 2014), outcome data and methods of measurement. A single reviewer will complete this process and accuracy will be verified by a second reviewer on 20% of sources, which will be selected at random.

*Quality assessment*

As a range of study designs will be included, the Joanna Briggs Institute (JBI) suite of Critical Appraisal Tools (https://jbi.global/critical-appraisal-tools) will be used to assess quality/bias (potentially with additional questions to ensure full coverage of relevant study characteristics). The JBI tools were designed for use in systematic reviews of effectiveness research, and they include tools that are designed to assess the range of study designs that we expect to identify, lending consistency to our assessments. These assessments will be used to evaluate the overall evidence base rather than to include/exclude studies, therefore we will customize the overall appraisal decision options within the tools.

Data synthesis

*Quantitative evidence synthesis*

Prior to any quantitative analysis, a qualitative assessment of heterogeneity will be undertaken. There is likely to be considerable heterogeneity between studies (in terms of inter alia study design, patient groups [e.g. gender, frail elderly, dementia/neurological conditions, learning disabilities], participant baseline characteristics, outcomes reported, and outcome definition). Particular attention will also be paid to prognostic factors to determine the extent of between-study heterogeneity.

Depending upon the findings of our heterogeneity assessment, and data permitting, the following statistical analyses will be conducted:

i: Conventional pairwise analyses (Egger 2001) will be used to directly compare ATs where we have multiple randomised or controlled comparisons. Fixed and random effects models will be conducted with heterogeneity measured using the I^2 statistic (Higgins 2002). If I^2 is low, fixed effects will be favoured. Meta-regression or subgroup analysis may also be used to adjust for heterogeneity.

ii. Network meta-analysis (Dias 2011; Hawkins 2016), an extension to pairwise meta-analysis, which builds a network of evidence around common comparators, could potentially be used to compare ATs used to tackle the same underlying problem. If a network of controlled trials exists, fixed and random effects will be conducted with best model fit determined by the deviance information criterion (DIC), a relative measure of model fit. Such models are usually conducted in a Bayesian framework; where there may be insufficient data to estimate between-study heterogeneity, the use of informative prior distributions will be considered. Again, meta-regression or subgroup analysis could be used to adjust for heterogeneity.

iii. A weighted average of single arms across studies reporting the same AT will be considered where there are few RCTs or controlled studies. Outcomes will be weighted by the square root of the study sample size, and regression analysis considered to adjust for heterogeneity.

Outcomes are expected to include inter alia quality of life, use of domiciliary care, hospital admission, activities of daily living, and residential care admission. Where heterogeneity precludes meta-analysis, we will discuss this with the funder.

*Cost-effectiveness analysis*

There is a scarcity of economic evaluations of ATs for incontinence. Those that there are, including our own (Clark 2016), are generally focused in the area of catheterisation (Xi 2021) where data are more prevalent. Those evaluating the cost-effectiveness of non-catheter products tend to be more simplistic evaluations not fully exploring the costs and benefits nor utilising cost-utility analysis (e.g. Yamasato 2014). Presently, reimbursement, funding, or individual spending decisions on ATs for incontinence are being made with incomplete data thus good quality economic evaluations are urgently needed to evaluate the cost-effectiveness of ATs. Our economic analysis will compare the health-related costs and benefits of alternative ATs with efficacy and resource usage informed by the systematic review. The research team will collect system-level data relevant to NHS costs. We will construct a decision-tree model to compare the costs and outcomes of each AT pathway, assumed to be effective or ineffective management, and subdividing by heterogeneous patient populations such as those with underlying conditions.

Costs will be calculated from an NHS and societal perspective, using observed resource use (costs of the AT, use of health care resources, carer costs, and lost productivity costs), multiplied by NHS unit costs (National Schedule of NHS Costs, 2020, Curtis 2021). Ideally, results will be reported as the additional cost per quality-adjusted life year (QALY) gained, the favoured generic measure of cost-effectiveness, although additional outcomes such as cost per hospitalisation or long-term care admission, and cost per infection averted will also be reported to provide a clear picture of the value of the intervention. Comprehensive sensitivity analysis will be conducted to explore uncertainty over the results. Where heterogeneity precludes economic evaluation, we will discuss this with the funder.

*Narrative analysis*

Where quantitative synthesis is not feasible, we will undertake narrative analysis using Synthesis Without Meta-analysis (SWiM) (Campbell et al 2020) guidance to report our results. We will investigate similarities and differences between studies, explore relationships within the data and assess the strength of any conclusions by intervention type. Numerical and statistical data will be presented in tables and figures/graphs as appropriate including sample size, common measures of effect, such as odds ratios, mean differences, direction of effect, strength of effect, p-values/confidence intervals.

*Grading of Recommendations, Assessment, Development and Evaluations (GRADE)*

Where feasible and prioritizing key outcomes as identified in Stakeholder Event 1, we will use GRADE (Guyatt et al 2011) as a framework to assess certainty of evidence and present our conclusions. Where certainty is low or very low, based on their extensive experience in the areas the research team will assess the theoretical mechanism of action and where possible provide an opinion on whether they offer a promising mechanism of action.

**Stakeholder Event 3**

At the final Stakeholder Event, we will present the findings of the systematic review and elicit stakeholder perspectives on the implications of the findings for adult social care in the UK. We will discuss gaps in evidence and/or areas where AT innovation is needed, plus discuss the research team's opinions of ATs that are not supported by evidence but have a theoretically sound mechanism of action. We will discuss next steps including developing recommendations for incontinence associated AT use within adult social care, gather views on innovation and research priorities and finalise dissemination plans.

## 6 STUDY SETTING

We are interested in interventions that might work in the UK for people living at home. We will not limit country. In Phase 1 we will assess the merit of including studies reporting on the use of ATs within residential care and the method of assessing and synthesising this data if it is included (e.g. where there is no data for community settings, then residential care setting data could be used, but clearly flagged as such).

## 7 SAMPLE AND RECRUITMENT

### 7.1 Eligibility Criteria

The eligibility criteria are described in Section 5- Study Design and Methods of Data Collection.

#### 7.1.1 Inclusion criteria

The inclusion criteria can be found in Section 5- Study Design and Methods of Data Collection.

#### 7.1.2 Exclusion criteria

Not applicable.

### 7.2 Sampling

Not applicable.

#### 7.2.1 Size of sample

Not applicable.

#### 7.2.2 Sampling technique

Not applicable.

### 7.3 Recruitment

Not applicable.

#### 7.3.1 Sample identification

Not applicable.

#### 7.3.2 Consent

Not applicable.

# 8 ETHICAL AND REGULATORY CONSIDERATIONS

Not applicable, no primary or other sensitive data will be generated as a result of this project.

## 8.1 Assessment and management of risk

Not applicable.

## 8.2 Research Ethics Committee (REC) and other Regulatory review & reports

No primary data will be collected for this project and therefore ethical review and other regulatory reviews are not required.

## 8.3 Peer review

This project been independently peer reviewed by the NIHR Health Technology Assessment funding committee.

## 8.4 Patient & Public Involvement

We will continue to collaborate with our PPI group throughout this project and they will contribute to all aspects of this project. In particular, the PPI group will ensure appropriate representation on the stakeholder group, define the boundaries of the included ATs, advise on the presentation of the product map and finalise the knowledge exchange and impact strategy.

## 8.5 Protocol compliance

If it becomes apparent that substantial changes to the protocol are required, as agreed by the project management group, permission for the proposed changes will be sought from the project funder.

### 8.6 Data protection and patient confidentiality

Not applicable, no primary or other sensitive data will be generated as a result of this project.

### 8.7 Indemnity

Not applicable.

### 8.8 Access to the final study dataset

The results of the mapping review will be shared with AT end users and other stakeholders. The route and format of this will be refined at planned stakeholder events and is described in further detail in section 9- Dissemination Policy. Papers included in the systematic review will be referenced in the final report and planned publications.

## 9 DISSEMINATION POLICY

### 9.1 Dissemination policy

A final study report will be submitted to the NIHR Health Technology Assessment upon project completion. We will acknowledge the financial support provided by the NIHR in any publications arising from this project with the notice provided by the funder.

In order to achieve maximum benefit from this work, we have devised the Knowledge Exchange and Impact Strategy described below. However, our planned outputs and routes to our key audiences will be further refined during discussions with the PPI group and stakeholders.

At the end of the project we will have:

1. Mapped ATs with the problems that they are designed to address
2. Identified any ATs where there is sufficient evidence to have a moderate to high level of certainty regarding effectiveness for key outcomes
3. Identified ATs with good empirical indications for effectiveness, but where definitive evidence is required
4. Identified ATs that do not have an evidence base, but appear to offer a sound theoretical mechanism of action
5. Identified gaps where innovation is required to address common incontinence or toilet-use problems

We will design our outputs to benefit two key audience groups:

A. People and organisations who need to make decisions about ATs at an individual or population level; AT users (end-users and carers) and health and social care practitioners, service providers or commissioners or those providing information/training on ATs
B. Researchers (who want to undertake research involving continence ATs) and innovators (industry or academics who wish to develop innovative continence AT designs)

Outputs to disseminate these results in useable formats to the key groups will include:

- A map (likely in tabular form with illustrations) of continence and toilet-use problems faced by people living at home and the AT groups designed to help will be made freely available via the www.continenceproductadvisor.org website (the only independent, evidence-based website for continence products endorsed by the NHS) in addition to routes recommended by the stakeholder group. This map will provide information on the range of ATs available, even when the provision is distributed across multiple providers.
- A publication for a peer-reviewed academic journal presenting the evidence to support those ATs, including where there is currently certainty regarding the evidence on outcomes, where there is sufficient evidence to warrant full scale evaluations and where further AT innovation is required.
- Professional journal articles and guest blog posts (e.g. with Alzheimer's Society, Carer organisations, Homecare Association, Nursing Times, Proceedings of the Institution of Mechanical Engineers, Journal of Dementia Care etc) geared towards providing guidance and sign-posting to the map for users, practitioners seeking solutions and industry seeking to innovate in the area.

We will collaborate with the Wessex AHSN to plan dissemination that will encourage innovation in this area with industry and other stakeholders, including Integrated Care Services. We will raise awareness with relevant industry and third sector stakeholders via routes including our stakeholders and research group collaborators, NIHR Evidence Briefs and the biennial IMECHE Incontinence: the Engineering Challenge– the only global conference focusing on innovation of incontinence technology, bringing together industry, academics, practitioners, charities and individuals. We will publish our results in peer reviewed academic journals and present at conferences, such as the 2025 International Continence Society conference and 2025 Association of Continence Advice UK conference.

### 9.2 Authorship eligibility guidelines and any intended use of professional writers

All project management group members will author the final report and papers resulting from this project.

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# 11. APPENDICES

## 11.1 Appendix 1- Required documentation

Not applicable.

## 11.2 Appendix 2 – Schedule of Procedures (Example)

Not applicable.

## 13.3 Appendix 3 – Amendment History

| Amendment No. | Protocol version no. | Date issued | Author(s) of changes | Details of changes made |
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