

# Randomised controlled trial comparing the clinical and cost-effectiveness of various washout policies versus no washout policy in preventing catheter-associated complications in adults living with long-term catheters

<b>Submission date</b> 04/11/2019	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/11/2019	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/04/2025	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Urinary catheters are soft tubes put into the bladder to drain and then collect urine. In the UK, an average of 1 in 1000 people use long-term indwelling catheters. People using these catheters can experience complications, like blockages (where the urine does not drain into the catheter bag properly), urinary infections, pain, and a type of incontinence called catheter bypass. These complications can affect a person's quality of life. They may also mean more emergency visits with nurses and GPs. Research shows that people consider blockage to be one of the most troubling aspects of using catheters over a long period. In current standard catheter care, catheter blockages are dealt with by either changing the catheter more often and/or using catheter washout liquids to washout the catheter. Some people are advised to do a catheter washout every week to try to reduce blockages. Others are not. The difference is because at present, there is no clear evidence to show whether doing regular washouts helps avoid blockages. People doing washouts also use different solutions. One is a weak salty (saline) solution, and the other is a citric mix, more like weak lemon juice. Both solutions are used in the NHS but it is not known which works best. The aim of this study is to find out the best way to reduce the number of blockages that can happen in people who have long-term indwelling catheters to find out if washing out the catheter every week using catheter washout liquids reduces catheter blockages and other problems like urinary incontinence or urinary tract infections.

### Who can participate?

Adult men and women who have been using a catheter for  $\geq 28$  days and for whom there is no plan for discontinuation of catheter use at the time of recruitment, who are able to or has someone who can do catheter washouts for them.

What does the study involve?

Participants are randomly allocated to one of three groups for 24 months:

1. Weekly normal saline catheter washouts plus standard care
2. Weekly acidic (citric) catheter washouts plus standard care
3. Standard care only (i.e. no catheter washouts)

Participants are given a special calendar to record any problems with their catheter. They are contacted each month by a member of the research team who asks about any catheter-related problems they may have had. Every six months, participants are asked to complete a questionnaire about their quality of life and satisfaction with treatment.

What are the possible benefits and risks of participating?

Participants will receive the same level of care from their healthcare team whether or not they take part in the study. Participants may not benefit personally from taking part, but will be directly helping us to improve the care of patients with a long-term catheter in the future. The washout solutions used in the study are already being used in the NHS. There may be a possible increase in the risk of urine infection when doing regular catheter washouts. The researchers will monitor this closely within the study and will ask participants about urine infections during every follow-up in the study. There are some side effects from the long-term use of catheters but the researchers do not think that the risk will be increased by introducing regular washouts.

Where is the study run from?

University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?

October 2019 to September 2023

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Dr Lynda Constable

[l.constable@abdn.ac.uk](mailto:l.constable@abdn.ac.uk)

### **Study website**

<https://w3.abdn.ac.uk/hsru/CatheterII>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Mohamed Abdel-Fattah

### **Contact details**

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AB25 2ZH  
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**Type(s)**  
Scientific

**Contact name**  
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3rd Floor  
Health Sciences Building  
University of Aberdeen  
Foresterhill  
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United Kingdom  
AB25 2ZD  
+44 (0)1224 438144/8174  
l.constable@abdn.ac.uk

**Type(s)**  
Scientific

**Contact name**  
Dr Diana Johnstone

**Contact details**  
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AB25 2ZD  
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diana.johnson@abdn.ac.uk

## **Additional identifiers**

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
259559

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 41284, IRAS 259559

## Study information

**Scientific Title**

Randomised controlled trial comparing the clinical and cost-effectiveness of various washout policies versus no washout policy in preventing catheter-associated complications in adults living with long-term catheters

**Acronym**

CATHETER II

**Study objectives**

In the UK, it is estimated that approximately 1 in 500 people live with a long term catheter. A urinary catheter is a thin, soft, flexible tube inserted into the bladder to drain urine to a collection bag. LTCs can be associated with complications including catheter blockage and urinary tract infections. Catheter blockages affect 50% of people with LTCs. Blockage and infection can impact upon quality of life and NHS resources.

There are two broad strategies for preventing and managing catheter blockage: more frequent change of catheter and/or the use of liquid solutions to washout or flush the catheters. We do not know enough about the benefits, harms or costs of regular prophylactic washouts, to recommend whether or not they should be standard care.

In this study the researchers will determine the clinical and cost-effectiveness, acceptability, satisfaction, and safety of weekly prophylactic catheter washout policies in addition to standard LTC care compared to standard LTC care only for adults living with LTC. The primary outcome is catheter blockage requiring intervention. The primary economic outcome is the incremental cost per quality adjusted life year (QALY) gained for each washout policy compared to standard LTC care only.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 22/03/2019, Wales REC6 (Health and Care Research Wales) (Wales National Pool, Sketty Lane, Swansea SA2 8QG; Tel: +44 (0)1267 611164, 01874 615949; Email: Wales.REC6@wales.nhs.uk), ref: 19/WA/0015

**Study design**

Randomized; Both; Design type: Prevention, Device, Qualitative

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Community

### **Study type(s)**

Prevention

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Catheter-associated complications

### **Interventions**

The researchers are recruiting 600 people who have a LTC from primary care, secondary care and care homes. They are randomising participants to one of three groups:

1. Saline washouts. A policy of weekly prophylactic normal saline catheter washouts plus standard LTC care
2. Acidic washouts. A policy of weekly prophylactic acidic (citric) catheter washouts plus standard LTC care
3. Standard LTC care only (i.e. no prophylactic catheter washouts)

The researchers are following participants for 24 months to assess catheter blockages, infections, and complications, plus their quality of life, satisfaction, costs to the participant and NHS. They are exploring the views, attitudes, experiences and expectations of washouts with participants, nurses, and doctors.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

Any catheter blockage requiring intervention up to 24 months post randomisation, from the question 'Have you had any catheter blockages since we last spoke to you?' from patient-reported monthly phone call CRF (monthly for 24 months) (Intervention is defined as any of the following: unplanned catheter removal or change or washout performed by the participant/designated person or required unplanned visits to/from any healthcare provider, or hospital admission)

### **Secondary outcome measures**

Current secondary outcome measures as of 22/04/2022:

1. S-CAUTI requiring antibiotics use from the questions 'Have you had a urine infection since we last spoke to you?' and 'How many infections required antibiotics?' from patient-reported monthly phone call CRF (monthly for 24 months)
2. Duration of LTC in situ, catheter change due to other reasons than blockage, discontinuation of LTC use; from the questions 'Has there been discontinuation of long-term catheter use?', 'For the (reported problem), what treatment did you have?' and Answers 'Catheter change' from patient-reported monthly phone call CRF (monthly for 24 months)
3. Adverse events; where participant has reported a treatment in the patient-reported monthly phone call CRF (monthly for 24 months) and the question of the clinical team is asked 'Is this a

SAE? Please tick'

4. Hospital admissions, GP/nurse outpatient visits for catheter-related complications from the questions 'Since we last spoke to you, have you had to stay in hospital overnight for any of the problems related to your catheter?', 'For the (reported problem), where did you have treatment or a consultation with a doctor or nurse?' and possible answers 'GP at home, Nurse at home, care home staff, GP at surgery, Nurse at practice, Self/informal carer, Staff at hospital' from patient-reported monthly phone call CRF (monthly for 24 months)

5. Generic quality of life assessed by EQ-5D-5L17 (EuroQol questionnaire – 5 dimensions – 5 levels) patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation

6. Condition-specific quality of life assessed by ICIQ-LTCqol18 (International Consultation on Incontinence Modular Questionnaire – Long Term Catheter quality of life) patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation

7. Adherence to allocated interventions, events changing type and/or frequency (or cessation) of catheter washouts in arms A and B and rates of commencing on prophylactic washouts in arm C; from the questions 'Have you done a weekly washout since we last called you?', 'Have you had any problems with the weekly washout?', 'Has your clinical care team recommended a change in washout frequency?', 'Has your clinical care team recommended a change in type of washout solution?' and 'Have you done any regular (preventative) washouts since we last called you?' from patient-reported monthly phone call CRF (monthly for 24 months)

8. Patients' convenience and satisfaction assessed by an adapted version of the abbreviated Treatment Satisfaction Questionnaire for medication; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation patient-reported questionnaire

9. Impact on day to day activities using the General Self-Efficacy Scale (GSE)<sup>20</sup> and ICECAP-A (ICEpop CAPability measure for Adults) ( $\leq 65$  years) or ICECAP-O21 (ICEpop CAPability measure for Older people)  $> 65$  years patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation

10. Time and travel costs for patients and their relatives, friends or informal carers, from patient-reported questionnaire questions 'We wish to know how much money and time were spent by you and any companion in attending health care appointments or being admitted to hospital', including travel costs, time and whether or not accompanied by another person.; Timepoint(s): 18 months post-randomisation

Previous secondary outcome measures:

1. S-CAUTI requiring antibiotics use from the questions 'Have you had a urine infection since we last spoke to you?' and 'How many infections required antibiotics?' from patient-reported monthly phone call CRF (monthly for 24 months)

2. Duration of LTC in situ, catheter change due to other reasons than blockage; from the questions 'Has there been discontinuation of long-term catheter use?', 'For the (reported problem), what treatment did you have?' and Answers 'Catheter change' from patient-reported monthly phone call CRF (monthly for 24 months)

3. Adverse events; where participant has reported a treatment in the patient-reported monthly phone call CRF (monthly for 24 months) and the question of the clinical team is asked 'Is this a SAE? Please tick'

4. Hospital admissions, GP/nurse outpatient visits for catheter-related complications from the questions 'Since we last spoke to you, have you had to stay in hospital overnight for any of the problems related to your catheter?', 'For the (reported problem), where did you have treatment or a consultation with a doctor or nurse?' and possible answers 'GP at home, Nurse at home, care home staff, GP at surgery, Nurse at practice, Self/informal carer, Staff at hospital' from patient-reported monthly phone call CRF (monthly for 24 months)

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6. Condition-specific quality of life assessed by ICIQ-LTCqol18 (International Consultation on

Incontinence Modular Questionnaire – Long Term Catheter quality of life) patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation

7. Adherence to allocated interventions; from the questions 'Have you done a weekly washout since we last called you?', 'Have you had any problems with the weekly washout?', 'Has your clinical care team recommended a change in washout frequency?', 'Has your clinical care team recommended a change in type of washout solution?' and 'Have you done any regular (preventative) washouts since we last called you?' from patient-reported monthly phone call CRF (monthly for 24 months)

8. Patients' convenience and satisfaction assessed by an adapted version of the abbreviated Treatment Satisfaction Questionnaire for medication; Timepoint(s): 0,6,12,18,24 months post-randomisation patient-reported questionnaire

9. Impact on day to day activities using the General Self-Efficacy Scale (GSE)<sup>20</sup> and ICECAP-A (ICEpop CAPability measure for Adults) ( $\leq 65$  years) or ICECAP-O21 (ICEpop CAPability measure for Older people)  $> 65$  years patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation

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### **Overall study start date**

01/10/2018

### **Completion date**

14/09/2023

### **Reason abandoned (if study stopped)**

Lack of funding/sponsorship

## **Eligibility**

### **Key inclusion criteria**

1. Aged  $\geq 18$  years
2. Catheter has been in-situ for  $\geq 28$  days
3. No plan for discontinuation of LTC at the time of recruitment
4. Able to undertake catheter washouts or has a designated person able to perform washouts
5. Able to complete the trial documentation or has a proxy able to complete the trial documentation
6. Any type and route of LTC can be included

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 600; UK Sample Size: 600

### **Total final enrolment**

80

### **Key exclusion criteria**

Current participant exclusion criteria as of 22/04/2022:

1. Intermittent self-catheterisation
2. Pregnant or contemplating pregnancy
3. Spinal cord injury at or above the sixth thoracic vertebra (T6) (risk of Autonomic Dysreflexia - AD)
4. Ongoing S-CAUTI (until treatment is complete)
5. Visible hematuria (unless investigated/ treated)
6. Known allergies to either of the catheter washout solutions
7. Current bladder cancer (until treatment is complete and patient discharged from cancer surveillance program)
8. Known bladder stones (until treatment is complete)
9. Unable to provide consent due to incapacity
10. Any other clinical and social reasons that would be deemed by the recruitment team to be unsuitable for the study

If a participant stops using a long-term catheter (no catheter in situ)  $\geq 28$  days. All data collected up to the point of stopping long term catheter use are retained and used in the analysis

Previous participant exclusion criteria:

1. Intermittent self-catheterisation
2. Pregnant or contemplating pregnancy
3. Spinal cord injury at or above the sixth thoracic vertebra (T6) (risk of Autonomic Dysreflexia - AD)
4. Ongoing S-CAUTI (until treatment is complete)
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7. Current bladder cancer (until treatment is complete and patient discharged from cancer surveillance program)
8. Known bladder stones (until treatment is complete)
9. Any other clinical and social reasons that would be deemed by the recruitment team to be unsuitable for the study

If a participant stops using a long-term catheter (no catheter in situ)  $\geq 28$  days. All data collected up to the point of stopping long term catheter use are retained and used in the analysis

### **Date of first enrolment**

01/12/2019

### **Date of final enrolment**

31/08/2022

## **Locations**



**Countries of recruitment**

England

Scotland

United Kingdom

Wales

**Study participating centre****NHS Grampian**

Summerfield House

2 Eday Road

Aberdeen

United Kingdom

AB15 6RE

**Study participating centre****Northumbria Healthcare NHS Foundation Trust**

Nursery Park

Nursery Road

Ashington

United Kingdom

NE63 0HP

**Study participating centre****West Rainton Surgery**

Woodland View

West Rainton

Houghton-le-Spring

United Kingdom

DH4 6RQ

**Study participating centre****Great Lumley Surgery**

Front Street

Great Lumley

Chester-le-Street

United Kingdom

DH3 4LE

**Study participating centre**

**The Haven Surgery**

The Haven  
Burnhope  
United Kingdom  
DH7 0BB

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust**

Addenbrookes Hospital  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**

**The Chalgrove & Watlington Surgeries**

Hill Road  
Watlington  
Oxford  
United Kingdom  
OX49 5AF

**Study participating centre**

**Aneurin Bevan University Health Board**

Royal Gwent Hospital  
Cardiff Road  
Newport  
United Kingdom  
NP20 2UB

**Study participating centre**

**St Bartholomew's Medical Centre**

Manzil Way  
Cowley Road  
Oxford  
United Kingdom  
OX4 1XB

**Study participating centre**

**Summertown Health Centre**

160 Banbury Road  
Oxford  
United Kingdom  
OX2 7BS

**Study participating centre****Priory Gardens Surgery**

The Health Centre  
Church St  
Dunstable  
United Kingdom  
LU6 3SU

**Study participating centre****Gosford Hill Medical Centre**

167 Oxford Road  
Kidlington  
Oxford  
United Kingdom  
OX5 2NS

**Study participating centre****Cwm Taf Morgannwg University Health Board**

Royal Glamorgan Hospital  
Ynysmaerdy  
Llantrisant  
United Kingdom  
CF72 8XR

**Study participating centre****Derbyshire Community Health Services NHS Foundation Trust**

Trust Hq, Ash Green Disability Ctr  
Ashgate Road  
Ashgate  
Chesterfield  
United Kingdom  
S42 7JE

**Study participating centre**

**Bicester Health Centre**

Coker Close  
Bicester  
United Kingdom  
OX6 7AT

**Study participating centre****Ashgate Medical Practice**

Ashgate Road  
Chesterfield  
United Kingdom  
S40 4AA

**Study participating centre****Royal Primary Care Chesterfield**

The Grange Family H/ctr  
Stubbing Road  
Grangewood  
Chesterfield  
United Kingdom  
S40 2HP

**Study participating centre****Royal Primary Care Clay Cross**

Eldon Street  
Clay Cross  
Chesterfield  
United Kingdom  
S45 9NR

**Study participating centre****Temple Sowerby Medical Practice**

Linden Park  
Temple Sowerby  
Penrith  
United Kingdom  
CA10 1RW

**Study participating centre****Humber Teaching NHS Foundation Trust**

Trust Hq, Willerby Hill

Beverley Road  
Willerby  
Hull  
United Kingdom  
HU10 6ED

**Study participating centre**  
**Aspatia Medical Group**  
West Street  
Aspatia  
Wigton  
United Kingdom  
CA7 3HH

**Study participating centre**  
**Leadgate Surgery**  
George Ewen House  
Watling Street  
Leadgate  
Consett  
United Kingdom  
DH8 6DP

**Study participating centre**  
**Vauxhall Health Centre**  
111-117 Limekiln Lane  
Vauxhall  
Liverpool  
United Kingdom  
L5 8XR

**Study participating centre**  
**Swanage Medical Practice**  
Railway Station Approach  
Swanage  
United Kingdom  
BH19 1HB

**Study participating centre**  
**Chilwell Valley and Meadows Practice**  
Chilwell Meadows Surgery

Ranson Road  
Chilwell  
Nottingham  
United Kingdom  
NG9 6DX

**Study participating centre**  
**Midlands Partnership NHS Foundation Trust**  
Trust Headquarters  
St Georges Hospital  
Corporation Street  
Stafford  
United Kingdom  
ST16 3SR

**Study participating centre**  
**St Francis Surgery**  
Pilgrims Close  
Valley Park  
Chandlers Ford  
Southampton  
United Kingdom  
SO53 4ST

**Study participating centre**  
**Hockley Farm Medical Practice**  
39 Hockley Farm Road  
Braunstone  
Leicester  
United Kingdom  
LE3 1HN

**Study participating centre**  
**Wellbrook Medical Centre**  
Welland Road  
Hilton  
Derby  
United Kingdom  
DE65 5GZ

**Study participating centre**

**Banbury Cross Health Centre**

South Bar House  
6 Oxford Road  
Banbury  
United Kingdom  
OX16 9AD

**Study participating centre****Pelton & Fellrose Medical Group**

Unit 1, the Lavender Centre  
Pelton Lane  
Pelton  
Chester Le Street  
United Kingdom  
DH2 1HS

**Study participating centre****The Shirley Health Partnership**

Shirley Health Centre  
Grove Road  
Shirley  
Southampton  
United Kingdom  
SO15 3UA

**Study participating centre****Highcliffe Medical Centre**

Heila House  
Lymington Road  
Highcliffe  
Christchurch  
United Kingdom  
BH23 5ET

**Study participating centre****East Lancashire Hospitals NHS Trust**

Royal Blackburn Hospital  
Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**Study participating centre**  
**Church Street Practice**  
The Health Centre  
Mably Way  
Grove  
Wantage  
United Kingdom  
OX12 9BN

**Study participating centre**  
**Derby Road Health**  
336 Derby Road  
Nottingham  
United Kingdom  
NG7 2DW

**Study participating centre**  
**King's College Hospital NHS Foundation Trust**  
Denmark Hill  
London  
United Kingdom  
SE5 9RS

**Study participating centre**  
**Manchester University Hospital NHS Ft (hq)**  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Solent NHS Trust**  
Solent NHS Trust Headquarters  
Highpoint Venue  
Bursledon Road  
Southampton  
United Kingdom  
SO19 8BR

**Study participating centre**



**The White Horse Medical Practice**

The Faringdon Medical Centre  
Volunteer Way  
Faringdon  
United Kingdom  
SN7 7YU

**Study participating centre****Mendip Vale Medical Practice (yatton)**

155 Mendip Road  
Yatton  
Bristol  
United Kingdom  
BS49 4ER

**Study participating centre****Brierley Park Medical Centre**

127 Sutton Road  
Huthwaite  
Sutton-in-ashfield  
United Kingdom  
NG17 2NF

## Sponsor information

**Organisation**

NHS Grampian

**Sponsor details**

-  
-

Scotland  
United Kingdom  
AB15 6RE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/00ma0mg56>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes:

# Results and Publications

## Publication and dissemination plan

The protocol will be publicly available on the study website and the NIHR HTA website. The researchers intend to publish the study protocol as soon as practicable.

Updated 08/08/2022:

The protocol has been published on 4th August 2022 and is available at <https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-022-06577-2>

## Intention to publish date

31/03/2025

## Individual participant data (IPD) sharing plan

A request to access the datasets generated during the trial should be directed in the first instance to the corresponding author (Professor Mohamed Abdel-fattah, [m.abdelfattah@abdn.ac.uk](mailto:m.abdelfattah@abdn.ac.uk)). The datasets collected in questionnaires at all timepoints and the baseline, monthly and serious adverse event case report forms for all 80 participants recruited to the trial are available. The dataset is available in fully anonymised electronic form, at an individual level, and in accordance with participant consent. The data dictionaries, study protocol, statistical analysis plan, patient information leaflets and template case report forms are also available on request to facilitate interpretation of data. Questionnaire templates, or parts thereof, may be available pending review of the relevant licensing agreements. Data for the study is currently available within a local repository at the University of Aberdeen and will be retained for a period of at least 10 years after close of trial in accordance with funder, Sponsor and local archiving procedures. Applicants will require to complete a data request form, which will be reviewed by a Data Sharing Committee which includes the Chief Investigator. Applications will be considered on a case-by-case basis from bonafide researchers. We are obligated to ensure that optimal use is made of the data that is collected for research and we recognise the value of sharing individual level data. The interests of research participants, researchers and other stakeholders will be considered when considering each application. A fully authorised data sharing agreement will be required prior to the release of data.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Protocol article</a>		04/08/2022	05/08/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		02/12/2024	03/12/2024	Yes	No
<a href="#">Other publications</a>	Embedded longitudinal qualitative study	07/04/2025	08/04/2025	Yes	No