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Synopsis

Comparing the clinical and cost-effectiveness of various washout policies in preventing catheter associated complications in adults living with long-term catheters: synopsis of the CATHETER II RCT

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Abstract

Background: Approximately 90,000 people in the United Kingdom have a long-term catheter. Use of long-term catheters is associated with common adverse events including blockage of the catheter and symptomatic catheter-associated urinary tract infection. Washout solutions are often used prophylactically to prevent these adverse events, but evidence for the benefits and potential harms is insufficient.

Objectives: Does the addition of weekly prophylactic washouts of the catheter to standard long-term catheter care improve the outcomes of adults with long-term catheter.

Design and methods: A pragmatic three-arm multicentre open-label superiority randomised controlled trial with embedded qualitative study.

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Setting and participants: Adults with long-term catheter in situ (any route or type) with no plans to discontinue long-term catheter use were recruited in a community setting in the United Kingdom. Participants received training to self-administer the washouts, with/without the assistance of a carer.
Interventions: Participants were randomised 1 : 1 : 1 to standard long-term catheter care plus weekly prophylactic saline washouts; weekly prophylactic acidic washouts; or no prophylactic washouts.
Main outcome measures: The primary clinical and health economic outcomes were catheter blockage requiring intervention (/1000 catheter days) up to 24 months post randomisation and incremental cost per quality-adjusted life-year gained. Outcome data were patient reported.
Results: Eighty of the planned 600 participants were recruited (26 saline; 27 acidic; 27 control). There was a reduction in incidence of blockages requiring treatment (per 1000 catheter days) from 20.92 (control) to 9.96 (saline) and 10.53 (acidic). The incidence rate ratio favoured the washout groups [saline 0.65 (97.5% confidence interval 0.24 to 1.77); $p = 0.33$ and acidic 0.59 (97.5% confidence interval 0.22 to 1.63); $p = 0.25$] but was not statistically significant. There was a reduction in the secondary outcome of symptomatic catheter-associated urinary tract infection requiring antibiotic use (per 1000 catheter days) from 8.05 (control) to 3.71 (saline) and 6.72 (acidic). The incidence rate ratio favoured the washout groups [saline 0.40 (97.5% confidence interval 0.20 to 0.80); $p = 0.003$ and acidic 0.98 (97.5% confidence interval 0.54 to 1.78); $p = 0.93$]; however, the significance should be interpreted cautiously given the small sample size. There were few adverse events. Quality-of-life outcomes were similar between groups. Due to the low sample size, the health economic outcomes could not be analysed. The embedded qualitative work demonstrated that the study design was feasible and acceptable to healthcare professionals and participants involved with the trial. Healthcare professionals perceived the training of participants to have minimal impact on healthcare resources and participants were empowered to self-manage the washouts and integrate it into their routine care.
Limitations: COVID-19 led to recruitment difficulties and early termination of the study by the funder. Sample size was not met.
Conclusions: There is a suggestion that regular prophylactic washout use may result in the reduction of catheter blockage and symptomatic catheter-associated urinary tract infection. However, the results are inconclusive due to the small sample size. Participants found the washouts acceptable to use and could self-manage the washouts with training.
Future work: The study design was acceptable to involved participants and healthcare workers. We recommend a multinational randomised controlled trial to produce evidence on the clinical effectiveness of long-term catheter washout policies.
Funding: This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 17/30/02.
A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/GJMA0724.

Introduction

Rationale for research and background

Approximately 90,000 people in the UK have a long-term catheter (LTC) and there is a higher prevalence in those over the age of 75.[3,4] A catheter facilitates urine drainage in patients with incontinence or chronic retention due to conditions such as multiple sclerosis, spinal cord injury, underactive bladder and enlarged prostate.[5,6] LTC use is recommended when toileting is challenging and intermittent catheterisation is not possible.[7] A LTC is defined as a catheter in situ for more than 28 days.[7] A 6-year mean duration of use is reported.[8] Prevalence of LTC and catheter-related healthcare resource use is expected to rise with an ageing UK population.[9]

Long-term use of the catheter is commonly associated with adverse events which are traumatic to patients and a burden on NHS resources.[10] Gage *et al.* recently estimated that catheter management costs an average of £125M a year to the NHS.[11] Blockage is a common event in patients with LTC with incidence reported as 8.54–11.8 per 1000 days of catheter use.[5,12] The catheter may be blocked by debris or encrustation of the catheter lumen, the latter due to mineral deposit formation in an alkaline urine environment triggered by urease-producing bacteria colonisation.[13] Blockage requires emergency treatment and leads to distress for the patient and increased healthcare utilisation. Left untreated, blockage can lead to urosepsis or autonomic dysreflexia if there is a spinal cord injury at or above T6.[14] Symptomatic catheter-associated urinary tract infection (S-CAUTI) is another common event

with incidence reported as 4.49 per 1000 days of catheter use.[5] Other LTC-related adverse events include bladder spasm, urine retention, haematuria, pyuria and leakage.

The standard care of the LTC involves the weekly change of the valve or leg bag (by the patient or their carer) and of the catheter every 4–12 weeks (usually by the clinical team).[15] Some LTC users also practice washouts of the catheter in addition to standard care to prevent and/or treat blockage.[6] Washouts may act by flushing debris, dissolving mineral deposits and/or by reducing catheter biofilm formation and vary widely by type, volume, concentration and recommended frequency of use.[6,16] The 2017 Cochrane review systematically reviewed evidence to date and concluded there was insufficient evidence on the clinical effectiveness, benefits and potential risks, patient acceptability and impact on patients' quality of life (QoL) of various washout policies.[6] The introduction of infection during administration of the catheter washouts and damage of bladder mucosa were raised as potential safety concerns. In line with current (2017) evidence, National Institute for Health and Care Excellence (NICE) best practice guidelines do not recommend the use of catheter washouts to prevent LTC blockages and suggest the use of patient-specific regimens such as more frequent change of the catheter.[7] The authors of the Cochrane review recommend a high-quality randomised controlled trial (RCT) to assess the clinical effectiveness and cost-effectiveness of washout policies in adults with LTC.[6]

Objectives

The CATHETER II RCT aimed to evaluate clinical and cost-effectiveness, patient acceptability, safety and satisfaction of weekly prophylactic catheter washouts administered in addition to standard LTC care compared to standard LTC care alone.

The hypotheses tested were:

1. Does the addition of weekly saline prophylactic catheter washouts to standard LTC care compared to standard LTC care only, result in a ≥ 25% relative reduction in catheter blockage requiring intervention?
2. Does the addition of weekly citric acid prophylactic catheter washouts to standard LTC care compared to standard LTC care only, result in a ≥ 25% relative reduction in catheter blockage requiring intervention?

Methods for data collection and analysis

The RCT and embedded qualitative study protocols have been published.[1,17] The methods have been summarised below in accordance with Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.[18] *Figure 1* shows the research pathway.

Trial design

CATHETER II was a pragmatic three-arm, parallel-group, open-label multicentre superiority RCT.

Participants

Participants were recruited from general practitioner (GP) practices, secondary and tertiary care hospitals and community hospitals in Scotland, England and Wales. Participants were also identified by targeted advertisements on websites and social media platforms. All participants were provided with information about the study and provided fully informed written consent.

The inclusion criteria were:

- aged ≥ 18 years
- catheter has been in use for ≥ 28 days
- no plan for discontinuation of LTC at the time of recruitment
- able to undertake catheter washouts or has a designated person (relative, friend, other informal carer or paid/NHS healthcare worker) able to perform washouts
- able to complete the trial documentation or has a designated person able to assist with trial documentation
- any type and route of LTC can be included.

The exclusion criteria were:

- intermittent self-catheterisation
- pregnant or contemplating pregnancy
- spinal cord injury at or above the sixth thoracic vertebra (T6) (risk of autonomic dysreflexia)
- ongoing S-CAUTI (until treatment is complete)
- visible haematuria (unless investigated/treated)
- known allergies to either of the catheter washout solutions
- current bladder cancer (until treatment is complete and patient discharged from cancer surveillance programme)
- known bladder stones (until treatment is complete)
- unable to provide consent due to incapacity
- any other clinical and social reasons that would be deemed by the recruitment team to be unsuitable for the study.

Interventions

The interventions compared were:

- Intervention arm (A): Saline washouts. A policy of weekly prophylactic normal saline catheter washouts (Uro-Tainer® NaCl 0.9% 100 ml) plus standard LTC care.

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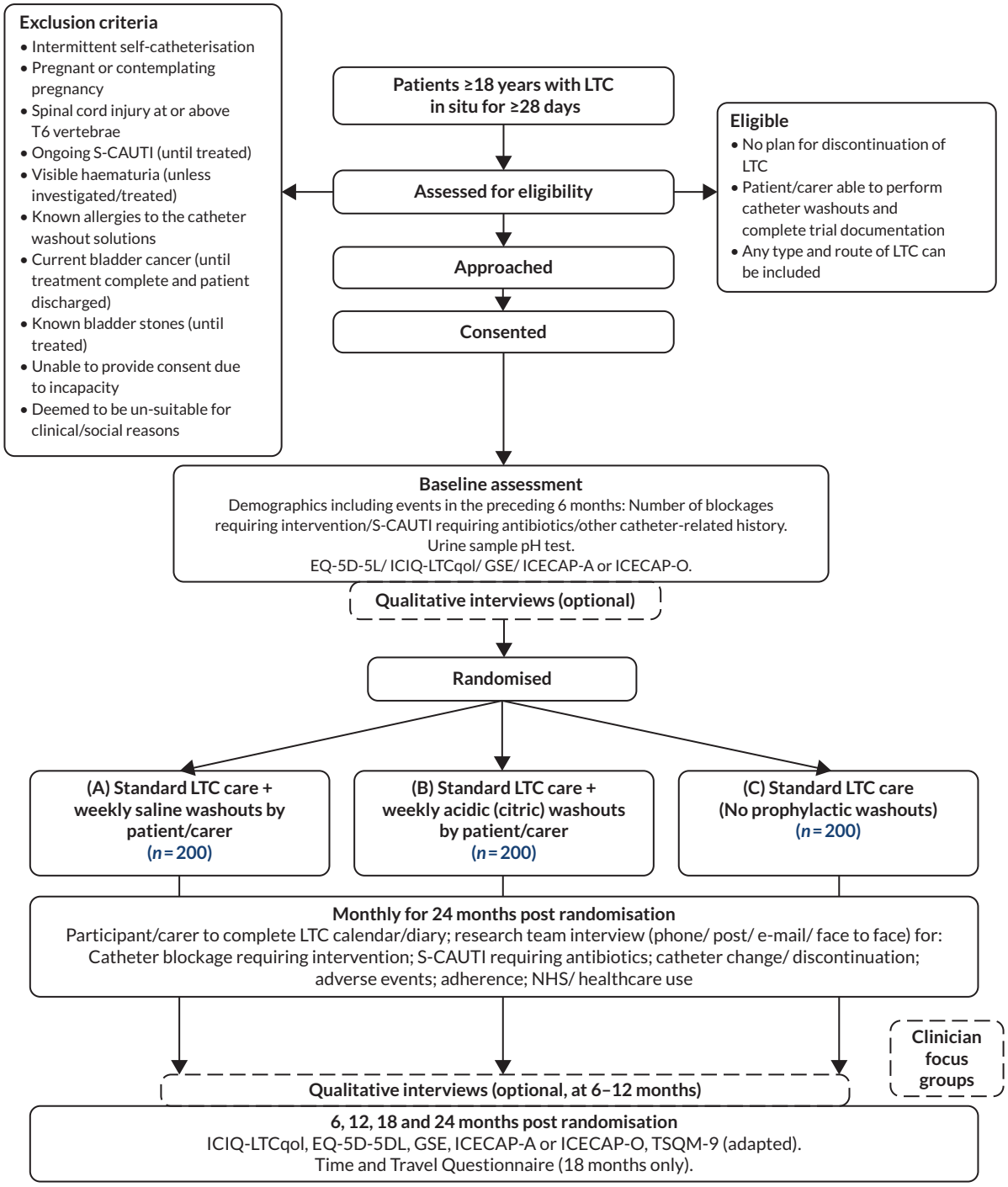

FIGURE 1 EQ-5D-5L, EuroQol-5 Dimensions, five-level version; GSE, General Self-Efficacy Scale; ICECAP-A or -O, ICEpop CAPability measure for Adults (A) or Older (O) people; ICIQ-LTCqol, International Consultation on Incontinence Modular Questionnaire – Long Term Catheter quality of life; TSQM-9, Treatment Satisfaction Questionnaire for Medication (adapted). This figure is reproduced with permission from Abdel-fattah *et al.*[1] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text. The figure contains formatting changes to the original figure.

- Intervention arm (B): Acidic washouts. A policy of weekly prophylactic acidic catheter washouts (two sequential applications of 30 ml 3.23% citric acid, Uro-Tainer® Twin Suby G) plus standard LTC care.
- Control arm (C): Standard LTC care only with no prophylactic catheter washout.

Washouts were administered in accordance with best practice technique at the time of the regular weekly catheter bag or valve change, to reduce the risk of introducing infection by minimising the breakage of the closed drainage system. Participants and/or their relative, friend or other informal carer received training

to administer catheter washouts from an appropriately trained member of the local study team to enable them to self-administer the washouts in accordance with best practice. Training was provided either face to face or by video/telephone consultation and was supported with an online training video and hardcopy instructions for use with troubleshooting advice (available on request to the corresponding author).[19,20] Washout solutions were couriered direct to the participant's homes approximately every 6 months.

Where deemed clinically necessary by the clinical team, the pragmatic design of the study permitted the following changes to washout policies:

- an increase in frequency of LTC washouts, at the onset of the study or following regular review during the course of the study
- a change in the type of washout, at the onset of the study or following regular review during the course of the study
- the use of prophylactic washouts in the control arm, following regular review during the course of the study (but not at the onset of the study).

Outcomes

The primary clinical outcome was catheter blockage requiring intervention up to 24 months post randomisation expressed as number per 1000 catheter days. Intervention was 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.

The primary economic outcome was the incremental cost per quality-adjusted life-year gained for each washout policy compared to standard LTC care only.

Secondary outcomes were:

- S-CAUTI requiring antibiotics use (as defined by Pickard *et al.*)[21]
- duration of LTC in use, catheter change due to other reasons than blockage
- adverse events
- hospital admissions, GP/nurse outpatient visits for catheter-related complications
- generic QoL as assessed by EuroQol-5 Dimensions, five-level version (EQ-5D-5L)[22]
- condition specific QoL assessed by International Consultation on Incontinence Modular Questionnaire – Long Term Catheter quality of life (ICIQ-LTCqol)[23]
- adherence to allocated interventions
- patients' convenience and satisfaction assessed by an adapted version of the abbreviated Treatment Satisfaction Questionnaire for medication[24]
- impact on day-to-day activities using the General Self-Efficacy Scale (GSE) and ICEpop CAPability measure for Adults (ICECAP-A) (≤ 65 years) or ICEpop CAPability measure for Older people (ICECAP-O) > 65 years[25–27]
- time and travel costs for patients and their relatives, friends or informal carers
- discontinuation of catheter use
- 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.

The source and timing of measures are summarised in *Table 1*. The baseline assessment was completed prior to randomisation. Urine sample for pH testing was completed by simple urine dipstick test. Participants (or their carer) recorded LTC-related events on an LTC calendar/diary. Outcomes were patient-reported and collected by the research team approximately monthly for up to 24 months by telephone call. Participants completed the baseline questionnaire prior to randomisation and follow-up questionnaires at 6, 12, 18 and 24 months after randomisation by post or web. An additional EQ-5D-5L questionnaire was collected where participant follow-up terminated early due to discontinuation of use of LTC or the early closure of the study.

Qualitative study outcomes were better understanding of:

- participants' experience of LTC-related adverse events such as blockage, S-CAUTI, urinary incontinence, bladder pain
- participants' attitudes/preferences to washout versus no washout policies and expected outcomes (prior to randomisation or knowing their allocated study group) (acceptability)
- participants' experience with washout/no washout policies and evaluation of outcomes (satisfaction)
- clinicians' attitudes towards influence of washout policies on outcomes
- participants' and clinicians' experience of training provided and enactment of the treatment skill.

Forty participants were interviewed pre-randomisation (T1) and at 6–12 months into the study (T2) for the embedded qualitative component. Ten participants from T1 were not available for interview at T2; therefore, 10 additional participants were recruited for T2 with similar characteristics. Participants were selected using maximum

TABLE 1 Source and timing of measures

Measure	Source	Randomisation				
		Pre[a]	Post			
Catheter blockage requiring intervention	D and CRF		Monthly completion for 24 months			
S-CAUTI requiring antibiotics Prophylactic antibiotic use						
Catheter change						
Adverse events						
NHS/healthcare use						
			Months			
			6	12	18	24
EQ-5D-5L	PQ	✓	✓	✓	✓	✓
ICIQ-LTCqol	PQ	✓	✓	✓	✓	✓
GSE Scale	PQ	✓	✓	✓	✓	✓
ICECAP-A or O	PQ	✓	✓	✓	✓	✓
Satisfaction with treatment	PQ	✓	✓	✓	✓	✓
Participant/relative, friend or informal carer's time and travel	PQ				✓	

CRF, case report form; D, LTC calendar/diary; PQ, participant/relative, friend or informal carer completed questionnaire.
a Pre randomisation is after informed consent has been given but prior to randomisation.

variation sampling (trial arm, gender, age) to ensure the diverse characteristics of the population. Healthcare workers were approached to take part in focus groups and/or interviews at least 6 months into the study.

Sample size

We used information from our survey of experts and patients and also from available literature[5,12] to decide that for washouts to be worthwhile there must be a reduction in LTC blockage of 25%. This was a reduction in the rate of blockage from 11.8 per 1000 days to 8.9 per 1000 days. The formula from Zhu and Lakkis was used to calculate the sample size for comparing two negative binomial rates.[28] Outcomes from 200 participants per arm were required for 90% power, a two-sided significance of 2.5% and 50 out of 730 days loss to follow-up. Participants would be followed for up to 2 years and all available days of follow-up were to be used.

Randomisation

Participants were allocated 1 : 1 : 1 to one of the three trial arms by a member of the local research team using a centralised computerised randomisation system [administered by the Centre for Healthcare Randomised Trials (CHaRT), University of Aberdeen]. Random allocation used the minimisation covariates: region; gender (male vs. female); age (< 45 years, 45–64 years and ≥ 65 years); residential status (care home vs. community); previous blockages requiring intervention in last 6 months (0 vs. ≥ 1); previous S-CAUTI requiring antibiotics in last 6 months (0 vs. ≥ 1); urine pH [acidic (< 5.1) vs. normal (5.1 to 6.7) vs. alkaline (> 6.7) vs. not available]. The allocation sequence was concealed by use of a centralised computerised randomisation system. Delegated site personnel enrolled participants on the study website in which the randomisation system was embedded. The centralised computerised randomisation system generated the allocation sequence and assigned the trial arm.

Blinding

It was not possible to blind the allocated study arm.

Statistical methods

All the main analyses were based on the intention-to-treat principle. Final analysis took place after recruitment and follow-up was complete. Baseline and outcome data were summarised as mean and standard deviation (continuous data) and count and percentage (categorical data). The number of blockages requiring intervention (the primary outcome) and instances of S-CAUTI were presented as a rate per 1000 days of catheter use. The number of blockages and instances of S-CAUTI were count data and it was likely that zero would be the most common count reported, but for those reporting events, a wide range of counts would be expected. Therefore, a mixed-effects negative binomial regression was used to analyse blockages and S-CAUTI with the log of catheter duration (in days) included as an offset. A random intercept was included for region. A post hoc analysis combined the washout groups. We reported effect sizes as incidence rate ratios (IRRs) with 97.5% confidence intervals (CIs) and QoL outcomes with repeated-measures mixed-effects linear regression. The fixed effects were the same as for the primary outcome. To account for repeated observations on the same participant, random intercepts were added for participant and region. A time point dummy variable was included. Adjusted mean differences with 97.5% CIs were used for effect sizes. To adjust for potential baseline imbalance, a sensitivity analysis was included adjusting for gender (male vs. female), age (< 45, 45–65, > 65), previous blockage (0, 1–3, 4 or more), previous infection (0, 1–3, 4 or more), catheter duration at baseline (< 1 year, 1–3 years, > 3 years), washout at baseline (yes vs. no), neuropathic bladder (yes vs. no) and change frequency of the catheter.

Due to low recruitment and small sample size, it was not possible to complete the planned subgroup analyses or to analyse and report the health economic outcomes. Healthcare resource use was presented descriptively.

Qualitative methods

Qualitative interview and focus group transcripts were analysed and coded both inductively and deductively using an explicit, structured qualitative method framework analysis approach. Analysis was guided by Theoretical Domains Framework (TDF) and Theoretical Framework of Acceptability (TFA).[29–32] Full qualitative methods are detailed in *Appendix 1*.

Clinical results summary

The clinical results were reported.[2] At baseline, there were slight differences between the groups in terms of catheter duration, frequency and washout. There were also more participants with neuropathic bladder in the control group. The mean age was 65 years (slightly older in the control group). The proportion of males and females were similar in all groups (*Table 2*). Outcome data are reported for 78 participants (of the 80 participants recruited). Due to the early closure of the study, participants were followed up for between 12 and 24 months. Follow-up is described in the CONSORT diagram (*Figure 2*).

TABLE 2 Baseline data

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Control (*n* = 27)
Age [mean (SD); count]	64.8 (17.9); (*N* = 26)	62.4 (16.7); (*N* = 27)	67.1 (15.3); (*N* = 27)
Female [count, (%)]	14/26 (54%)	12/27 (44%)	14/27 (52%)
Length of time catheterised [count, (%)]			
< 1 year	7/26 (27%)	5/27 (19%)	5/27 (19%)
1–3 years	9/26 (35%)	6/27 (22%)	9/27 (33%)
> 3 years	10/26 (38%)	16/27 (59%)	13/27 (48%)
Neuropathic bladder [count, (%)]	8/26 (31%)	9/27 (33%)	11/27 (41%)
Urine pH [mean (SD); count]	6.5 (0.8); (*N* = 24)	6.7 (1.0); (*N* = 25)	6.8 (0.8); (*N* = 25)
Current on washout [count, (%)]	3/26 (12%)	6/27 (22%)	6/27 (22%)
Catheter change frequency [count, (%)]			
Every week			1/27 (3.7%)
Every 2 weeks			2/27 (7.4%)

continued

TABLE 2 Baseline data (*continued*)

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Control (*n* = 27)
Every 3 weeks			1/27 (3.7%)
Every 4 weeks	4/26 (15%)	4/27 (15%)	5/27 (19%)
Every 5 weeks		1/27 (3.7%)	
Every 6 weeks	4/26 (15%)	3/27 (11%)	2/27 (7.4%)
Every 7 weeks		1/27 (3.7%)	1/27 (3.7%)
Every 8 weeks	3/26 (12%)	2/27 (7.4%)	2/27 (7.4%)
Every 10 weeks	2/26 (7.7%)	5/27 (19%)	3/27 (11%)
Every 12 weeks	13/26 (50%)	11/27 (41%)	10/27 (37%)
Blockages requiring treatment (prior 6 months) [count, (%)]			
0	13/26 (50%)	13/27 (48%)	12/27 (44%)
1–3	8/26 (31%)	9/27 (33%)	7/27 (26%)
4 or more	5/26 (19%)	5/27 (19%)	8/27 (30%)
Median (lower–upper quartile)	0.5 (0–3)	1 (0–3)	1 (0–5)
S-CAUTI requiring antibiotics (prior 6 months) [count, (%)]			
0	14/26 (54%)	13/27 (48%)	14/27 (52%)
1–3	9/26 (35%)	9/27 (33%)	10/27 (37%)
4 or more	3/26 (12%)	5/27 (19%)	3/27 (11%)
Median (lower–upper quartile)	0 (0–2)	1 (0–2)	0 (0–2)
GSE scale[a] [mean (SD); count]	29.1 (9.1); (*N* = 25)	29.4 (5.7); (*N* = 27)	27.8 (7.6); (*N* = 27)
ICIQ-LTCqol function and concern[b] [mean (SD); count]	18.3 (9.1); (*N* = 26)	17.3 (9.7); (*N* = 26)	19.1 (9.0); (*N* = 27)
ICIQ-LTCqol lifestyle[b] [mean (SD); count]	6.7 (3.4); (*N* = 24)	8.1 (3.3); (*N* = 27)	7.6 (2.9); (*N* = 27)
EQ-5D-5L[c] [mean (SD); count]	0.368 (0.405); (*N* = 25)	0.365 (0.359); (*N* = 26)	0.348 (0.373); (*N* = 27)
ICECAP-A[d] [mean (SD); count]	0.551 (0.216); (*N* = 10)	0.487 (0.223); (*N* = 11)	0.496 (0.218); (*N* = 9)
ICECAP-O[d] [mean (SD); count]	0.488 (0.320); (*N* = 15)	0.601 (0.206); (*N* = 14)	0.669 (0.204); (*N* = 15)

a The GSE scale assesses ability to cope with daily life. It has 10 questions and scores are between 10 and 40 with higher scores better.
b ICIQ-LTCqol questionnaire is a specific QoL measure. It produces the function and concern score and the lifestyle score. The function and concern score has 10 questions and is on the scale 0–42. The lifestyle score has three questions and is on the scale 3–15. For both higher scores are worse.
c The EQ-5D-5L is a generic QoL measure. It has five questions and is on the scale −0.594 to 1 where higher scores indicate better QoL.
d The ICECAP-A and ICEPOP-O measure capability in adults and older people respectively. Both have five questions and are on the scale 0–1 with higher scores better. The treatment satisfaction questionnaire assesses satisfaction with medication. It produces the effectiveness, convenience and overall satisfaction scores. Each score has three questions to give nine in total, with each score on the scale 0–100 with higher scores better.

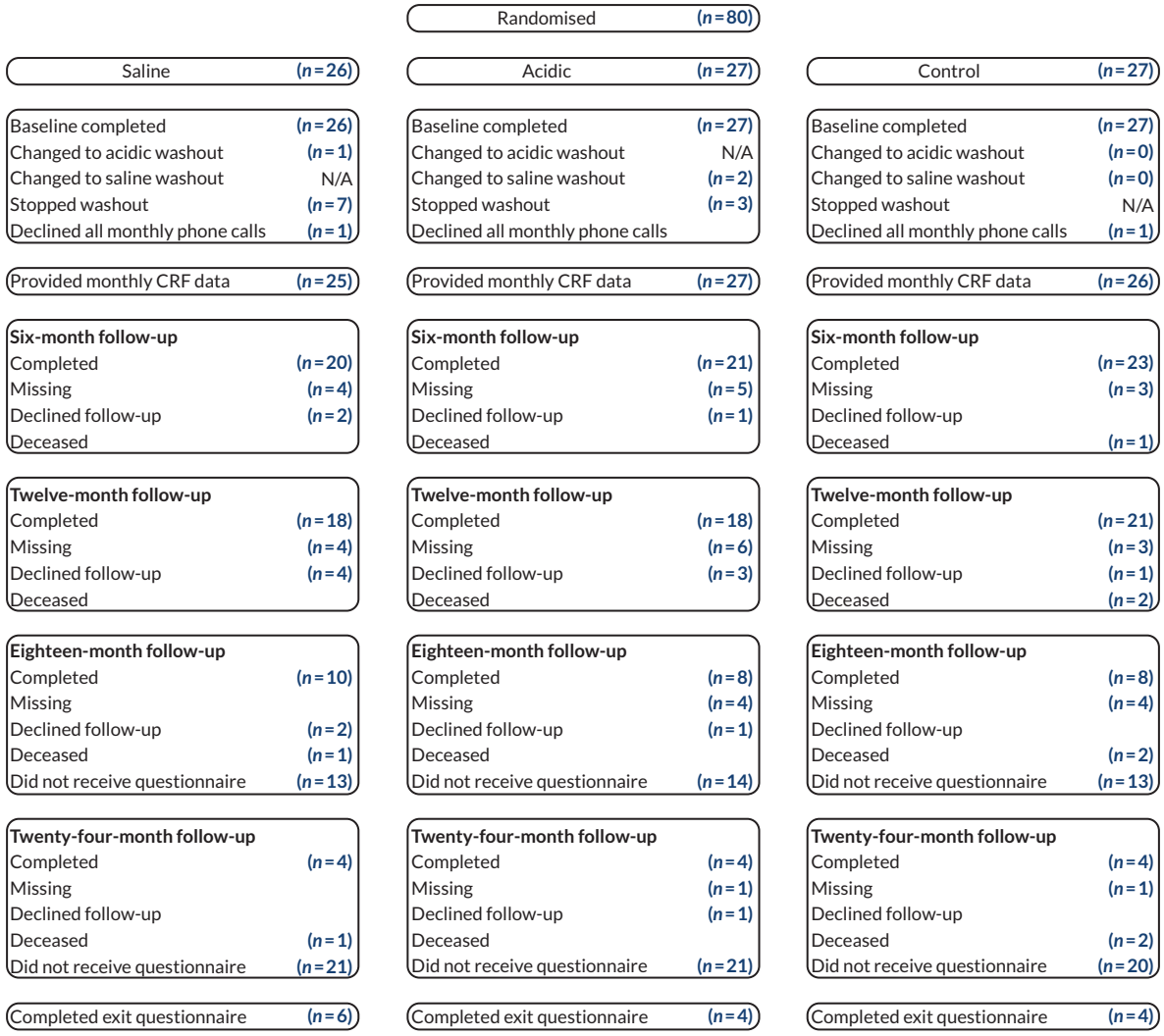

FIGURE 2 Consolidated Standards of Reporting Trials diagram. N/A, not applicable. This figure is reproduced with permission from Abdelfattah *et al.*[2] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

Primary outcome

Table 3 reports the primary outcome data. There was a reduction in rate of catheter blockage requiring treatment per 1000 catheter days from 20.92 (control group) to 9.96 (saline group) and 10.53 (acidic group). The IRR, while not statistically significant, favours the washout groups [saline 0.65 (97.5% CI 0.24 to 1.77); $p = 0.33$ and acidic 0.59 (97.5% CI 0.22 to 1.63); $p = 0.25$]. A post hoc analysis combining the washout groups also favours the washouts but is not statistically significant [IRR 0.62 (97.5% CI 0.26 to 1.49); $p = 0.22$]. Due to small sample size, a post hoc sensitivity analysis was completed to adjust for potential imbalance at baseline. The effects were not as strong as the trial analysis but do indicate in the combined washout group a reduction in the number of blockages requiring treatment [IRR 0.76 (97.5% CI 0.30 to 1.95); $p = 0.52$].

The health economic primary outcome was not analysed due to small sample size.

Secondary outcomes

There was a reduction in rate of S-CAUTI requiring antibiotics per 1000 catheter days from 8.05 (control group) to 3.71 (saline group) and 6.72 (acidic group). There was a significant reduction in S-CAUTI in the saline group [IRR 0.40 (97.5% CI 0.20 to 0.80); $p = 0.003$] and non-significant reduction in the acidic group [IRR 0.98 (97.5% CI 0.54 to 1.78); $p = 0.93$]. S-CAUTI outcome data are reported in *Table 3*. A post hoc analysis combining the washout groups (see *Table 3*) favours the washouts but is not statistically significant [IRR 0.69 (97.5% CI 0.39 to 1.23); $p = 0.14$]. A post hoc sensitivity analysis (*Table 4*) demonstrated a stronger effect than the trial analysis that both washouts reduce S-CAUTI [saline IRR 0.30 (97.5% CI

TABLE 3 Blockage requiring treatment (primary outcome) and S-CAUTI

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Either washout (*n* = 53)	Control (*n* = 27)
Participants providing follow-up data	25	27	52	26
Total months of follow-up	387	409	796	420
Catheterisation duration (days) [mean (SD)]	468 (182)	459 (191)	463 (185)	492 (167)
Total number of blockages requiring treatment	105	115	220	236
Blockages requiring treatment (rate per 1000 catheter days) [mean (SD)]	9.96 (14.48)	10.53 (15.77)	10.25 (15.02)	20.92 (27.77)
IRR (97.5% CI) compared to control	0.65 (0.24 to 1.77); 0.33	0.59 (0.22 to 1.63); 0.25	0.62 (0.26 to 1.49); 0.22	
Total instances of S-CAUTI	37	81	118	98
S-CAUTI (rate per 1000 catheter days) [mean (SD)]	3.71 (8.45)	6.72 (7.10)	5.27 (7.85)	8.05 (11.29)
IRR compared to control (97.5% CI)	0.40 (0.20 to 0.80); 0.003	0.98 (0.54 to 1.78); 0.93	0.69 (0.39 to 1.23); 0.14	

Note
The summary statistic in the IRR cells is 97.5% CI and *p*-value.

Source

0.16 to 0.56); $p \leq 0.001$; acidic IRR 0.66 (97.5% CI 0.38 to 1.15); $p = 0.09$]; combined washout group IRR [0.47 (97.5% CI 0.28 to 0.80); $p = 0.001$].

Mean duration of catheter use during follow-up was similar in the washout groups at 468 and 459 days and higher in the control group at 492 days (see *Table 3*). Routine catheter changes (mean number per month) were similar in all three groups (saline 0.34, acidic 0.33, control 0.36).

Table 5 reports adverse events of bladder spasm, urine retention, blood in urine, pus in urine, urine leakage and catheter kinks. Patient-reported bladder spasm and urine retention were similar in washout groups and slightly higher in the control group. Patient-reported urine leakage and pus in urine was higher in the washout groups than the control group. Patient-reported blood in urine was lowest in the saline group and highest in the acidic group. Catheter kinks were uncommon.

Few participants experienced other reported adverse events (*Table 6*) including bladder stones, epididymitis, urosepsis, pyelonephritis, pain at catheter site, skin irritation/penile trauma at catheter site, bleeding or discharge at catheter site, granulation problems, sepsis/pneumonia. Granulation and skin irritation were reported in patients with a suprapubic catheter. Penile trauma resulted in a change from a urethral catheter to a suprapubic catheter after which no further trauma or irritation was reported. Three deaths (any cause) were reported and were unrelated to the catheter or washouts.

Catheter-related complications were usually managed by the participant or their carer or by a home visit from a nurse (see *Table 5*).

Table 7 reports QoL outcomes. While not statistically significant, both washout groups reported better QoL (measured by EQ-5D-5L) and impact on day-to-day activity scores [measured by ICECAP-A (for adults)] than the control group. The acidic washout group reported better GSE scale, but this was not statistically significant. There was no evidence of difference between the groups in ICIQ-LTCqol scores. The splitting of the groups by receipt of either ICECAP-A (for adults) or ICECAP-O (for older population) increased the uncertainty of the effect sizes reported. The treatment satisfaction questionnaire suggested the saline group were more satisfied than the acidic group. Time and travel cost data are presented in *Table 8* but were not analysed due to small sample size.

TABLE 4 Sensitivity analysis

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Either washout (*n* = 53)	Control (*n* = 27)
Participants providing follow-up data	25	27	52	26
Total months of follow-up	387	409	796	420
Mean catheterisation duration (days) [mean (SD)]	468 (182)	459 (191)	463 (185)	492 (167)
Blockages requiring treatment (rate per 1000 catheter days) [mean (SD)]	9.96 (14.48)	10.53 (15.77)	10.25 (15.02)	20.92 (27.77)
IRR (97.5% CI) compared to control	0.65 (0.24 to 1.77); 0.33	0.59 (0.22 to 1.63); 0.25	0.62 (0.26 to 1.49); 0.22	
Sensitivity analysis	0.85 (0.29 to 2.49); 0.74	0.68 (0.24 to 1.94); 0.41	0.76 (0.30 to 1.95); 0.52	
S-CAUTI (rate per 1000 catheter days) [mean (SD)]	3.71 (8.45)	6.72 (7.10)	5.27 (7.85)	8.05 (11.29)
IRR (97.5% CI) compared to control	0.40 (0.20 to 0.80); 0.003	0.98 (0.54 to 1.78); 0.93	0.69 (0.39 to 1.23); 0.14	
Sensitivity analysis	0.30 (0.16 to 0.56); < 0.001	0.66 (0.38 to 1.15); 0.09	0.47 (0.28 to 0.80); 0.001	

Note
The summary statistic in the IRR cells is 97.5% CI and *p*-value.

Source

Six participants discontinued use of the LTC during the course of the study (three in saline group, two in acidic group, one in control group). Change of washout from the allocated intervention and discontinuation of washouts is described in the CONSORT diagram (see *Figure 2*). Changes of washout was recommended by the clinical team. Washouts were discontinued due to difficulties administering the washout (three participants) and for various medical reasons (six participants). The mean number (standard deviation) of preventative washouts per month was 3.1 (1.4), 3.9 (2.3) and 2.6 (6.5) in saline, acidic and control groups, respectively.

Qualitative results summary

The qualitative results were reported.[33]

A total of 50 (24 female and 26 male) trial participants from 16 CATHETER II recruitment sites across the UK were included (*Table 9*). Participants were aged between 23 and 100 years. Eleven participants had been living with LTC for less than a year, 16 for 1–3 years and 23 for more than 3 years. Seven healthcare professionals (HCPs) participated from six sites across the UK. Five HCPs were female and two were male. Six HCPs participated in a focus group and one HCP was interviewed. HCPs included one urogynaecologist and six research nurses with various nursing backgrounds (community, district, primary care, continence). Interviews were 22–58 minutes long and the focus group was 90 minutes long.

A thorough exploration and analysis of trial participants' and HCPs' perspectives provided insights around acceptability, feasibility and fidelity of the CATHETER II trial (e.g. weekly catheter washout behaviour) that were explained by participants' experience prior to the trial, their knowledge, attitude, intervention coherence, self-efficacy, optimism, environmental context and resources, and perception of skills, capability, burden, effectiveness and consequences. These prominent theoretical domains were summarised within three meta themes: 'I like the idea of washout' (acceptability of weekly washout behaviour and CATHETER II trial); 'it's quite straightforward once

TABLE 5 Secondary outcomes

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Control (*n* = 27)
Any catheter blockage (mean per month)	0.34 (0.45)	0.73 (1.84)	1.00 (1.97)
Bladder spasm (mean days per month)	3.5 (5.7)	3.2 (5.9)	4.4 (6.5)
Urine retention (mean days per month)	0.22 (0.45)	0.18 (0.38)	0.37 (0.57)
Blood in urine (mean days per month)	0.25 (0.51)	1.8 (3.8)	1.2 (1.8)
Pus in urine (mean days per month)	1.7 (5.6)	1.3 (4.0)	0.84 (3.3)
Urine leakage (mean days per month)	5.9 (8.7)	4.4 (7.7)	2.0 (6.0)
Catheter kinks (mean instances per month)	0.20 (0.50)	0.051 (0.11)	0.12 (0.31)
Routine catheter changes (mean number per month)	0.34 (0.22)	0.33 (0.23)	0.36 (0.23)
Regular/preventative washouts (mean number per month)	3.1 (1.4)	3.9 (2.3)	2.6 (6.5)
Treatment of LTC-related adverse events			
Hospital visits (mean number per month)	0.0067 (0.024)	0.034 (0.076)	0.051 (0.18)
Primary care visits[a] (mean number per month)	0.56 (0.41)	0.77 (0.47)	0.92 (0.67)
GP home visits (mean number per month)	0.014 (0.038)	0.031 (0.066)	0.0019 (0.0098)
GP surgery visits (mean number per month)	0.046 (0.12)	0.067 (0.11)	0.11 (0.17)
Nurse home visits (mean number per month)	0.49 (0.36)	0.58 (0.44)	0.72 (0.71)
Nurse practice visits (mean number per month)	0.0087 (0.026)	0.10 (0.24)	0.089 (0.13)
Complication managed by self or informal carer (mean number per month)	0.45 (0.78)	0.62 (1.74)	0.74 (1.59)

a Primary care visits are GP home or surgery visits or nurse home or practice visits.

Note
The summary statistic in the cells is the mean and standard deviation.

Source

it's sort of explained to you' (feasibility of weekly washout behaviour and CATHETER II trial) and 'I do it myself … each week' (fidelity of weekly washout behaviour and CATHETER II trial).

The study found that participants had positive attitudes towards weekly prophylactic (saline or acidic) catheter washouts and other elements of the trial, such as the washout training, catheter calendar/diary and monthly phone calls. They were motivated to take part in the trial due to their perceived effectiveness of, and optimism towards washouts, and their altruistic desire to contribute to research. HCPs highlighted that the current lack of robust evidence on best washout policies to guide clinical practice which makes the study crucial.

The 'ask' of the CATHETER II trial and the weekly self-administered prophylactic washout policies was found to be feasible by both participants and HCPs. The participants found the catheter washout training provided during the trial enhanced their self-efficacy, skills and self-reported capability to carry out the washout procedures. They were engaged in and adhered to all elements of the trial.

Healthcare professionals had a positive attitude regarding washouts and confirmed the participants' willingness and ability to self-manage their catheter washout after the

TABLE 6 Other adverse events

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Control (*n* = 27)
Any adverse event	9/26 (35%)	11/27 (41%)	12/27 (44%)
Bladder stones	0/25 (0%)	2/27 (7.4%)	4/26 (15%)
Long-term catheterisation discontinuation	3/25 (12%)	2/27 (7.4%)	1/26 (3.8%)
Epididymitis	0/26 (0%)	1/27 (3.7%)	0/27 (0%)
Urosepsis	0/26 (0%)	0/27 (0%)	1/27 (3.7%)
Pyelonephritis	0/26 (0%)	1/27 (3.7%)	0/27 (0%)
Pain at catheter site	1/25 (4.0%)	2/27 (7.4%)	2/26 (7.7%)
Skin irritation/penile trauma at catheter site	2/25 (8.0%)	1/27 (3.7%)	4/26 (15%)
Bleeding or discharge at catheter site	5/25 (20%)	4/27 (15%)	4/26 (15%)
Granulation problems	2/25 (8.0%)	4/27 (15%)	0/26 (0%)
Sepsis/pneumonia	0/26 (0%)	1/27 (3.7%)	0/27 (0%)
Cause of death certified as MI secondary to CCF and cardiomyopathy	0/26 (0%)	0/27 (0%)	1/27 (3.7%)
Death due to (1a) urosepsis, (1b) prostate cancer, (2) type 2 diabetes mellitus, ischaemic heart disease	1/26 (3.8%)	0/27 (0%)	0/27 (0%)
Death due to metastatic breast cancer	0/26 (0%)	0/27 (0%)	1/27 (3.7%)

CCF, congestive cardiac failure; MI, myocardial infarction.

Note
The summary in the cells is the count and percentage.
All instances of granulation are from participants using a suprapubic catheter at the time of the event. All patients reporting skin irritation had a suprapubic catheter at the time. One participant in the control group reported penile trauma and changed from a urethral catheter to a suprapubic catheter and did not report further trauma or irritation.

Source
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training provided. Participants and HCPs agreed that self-management for prophylactic catheter washouts is both feasible and, following either in-person or virtual training, achievable without any need for additional support for example, assistance from an HCP. The catheter washout training package within the trial was believed to be a key element in enabling participants to self-manage their LTC and washout. HCPs attested to the participants understanding of and adherence to the weekly washouts and other elements of the trial.

Participants in the washout groups reported having positive outcomes from the weekly washout. These included reduced blockage, pain or infection, reduced need for HCP support, and greater psychological reassurance because of their newfound ability to self-manage potential complications.

No notable differences in participants' descriptions of their experience of the training, self-management of washout, and outcomes between saline and citric acid washout groups were observed. Illustrative quotes are presented in a table of themed quotations below (*Table 10*).

List of CATHETER II research papers synthesised in this synopsis

Protocol

DOI: 10.1186/s13063-022-06577-2

Abdel-fattah M, Johnson D, Constable L, Thomas R, Cotton S, Tripathee S, *et al.* 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

TABLE 7 Quality-of-life outcomes

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Control (*n* = 27)
EQ-5D-5L[a]			
Baseline	0.368 (0.405); (*N* = 25)	0.365 (0.359); (*N* = 26)	0.348 (0.373); (*N* = 27)
6 months	0.356 (0.513); (*N* = 18)	0.335 (0.313); (*N* = 20)	0.270 (0.348); (*N* = 22)
12 months	0.386 (0.430); (*N* = 18)	0.412 (0.321); (*N* = 17)	0.339 (0.414); (*N* = 21)
18 months	0.493 (0.403); (*N* = 10)	0.302 (0.453); (*N* = 7)	0.139 (0.264); (*N* = 8)
24 months	0.349 (0.414); (*N* = 4)	0.621 (0.339); (*N* = 3)	−0.077 (0.082); (*N* = 4)
Exit	0.445 (0.541); (*N* = 6)	0.327 (0.491); (*N* = 4)	0.229 (0.211); (*N* = 4)
Effect size compared to control	0.056 (−0.022 to 0.134); 0.11	0.053 (−0.024 to 0.131); 0.12	
GSE[b]			
Baseline	29.1 (9.1); (*N* = 25)	29.4 (5.7); (*N* = 27)	27.8 (7.6); (*N* = 27)
6 months	27.7 (9.3); (*N* = 19)	27.6 (6.0); (*N* = 20)	26.8 (8.5); (*N* = 23)
12 months	27.4 (9.7); (*N* = 18)	29.2 (5.5); (*N* = 18)	25.1 (7.5); (*N* = 21)
18 months	28.3 (7.7); (*N* = 9)	29.3 (6.0); (*N* = 8)	28.3 (3.6); (*N* = 9)
24 months	28.3 (3.3); (*N* = 4)	30.4 (4.9); (*N* = 4)	27.3 (7.4); (*N* = 4)
Effect size compared to control	0.9 (−1.5 to 3.2); 0.40	2.2 (−0.1 to 4.5); 0.030	
ICECAP-A[c]			
Baseline	0.551 (0.216); (*N* = 10)	0.487 (0.223); (*N* = 11)	0.496 (0.218); (*N* = 9)
6 months	0.671 (0.176); (*N* = 8)	0.592 (0.256); (*N* = 10)	0.620 (0.200); (*N* = 8)
12 months	0.606 (0.233); (*N* = 7)	0.450 (0.282); (*N* = 7)	0.611 (0.146); (*N* = 7)
18 months	0.849 (0.000); (*N* = 2)	0.246 (0.349); (*N* = 2)	0.669 (0.203); (*N* = 4)
24 months	0.766 (0.117); (*N* = 2)	0.304 (0.281); (*N* = 3)	0.486 (0.137); (*N* = 2)
Effect size compared to control	−0.076 (−0.221 to 0.068); 0.24	−0.086 (−0.214 to 0.042); 0.13	
ICECAP-O[c]			
Baseline	0.488 (0.320); (*N* = 15)	0.601 (0.206); (*N* = 14)	0.669 (0.204); (*N* = 15)
6 months	0.554 (0.268); (*N* = 12)	0.657 (0.227); (*N* = 11)	0.673 (0.241); (*N* = 15)
12 months	0.569 (0.329); (*N* = 11)	0.611 (0.239); (*N* = 9)	0.707 (0.161); (*N* = 13)
18 months	0.511 (0.239); (*N* = 7)	0.614 (0.331); (*N* = 6)	0.666 (0.230); (*N* = 5)
24 months	0.637 (0.078); (*N* = 2)	0.940 (N/A); (*N* = 1)	0.641 (0.219); (*N* = 2)
Effect size compared to control	0.036 (−0.069 to 0.142); 0.44	−0.038 (−0.145 to 0.070); 0.43	
ICIQ-LTC function and concern[d]			
Baseline	18.3 (9.1); (*N* = 26)	17.3 (9.7); (*N* = 26)	19.1 (9.0); (*N* = 27)
6 months	15.6 (10.1); (*N* = 19)	16.4 (10.2); (*N* = 19)	19.8 (9.6); (*N* = 23)
12 months	12.5 (6.9); (*N* = 15)	18.1 (11.6); (*N* = 15)	17.9 (10.7); (*N* = 20)
18 months	11.9 (5.5); (*N* = 7)	12.3 (7.5); (*N* = 7)	14.2 (12.5); (*N* = 6)
24 months	9.3 (3.3); (*N* = 4)	19.5 (4.4); (*N* = 4)	18.5 (10.0); (*N* = 4)
Effect size compared to control	−1.2 (−4.1 to 1.7); 0.34	0.7 (−2.2 to 3.5); 0.60	

TABLE 7 Quality of life outcomes (*continued*)

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Control (*n* = 27)
ICIQ-LTC lifestyle[d]			
Baseline	6.7 (3.4); (*N* = 24)	8.1 (3.3); (*N* = 27)	7.6 (2.9); (*N* = 27)
6 months	7.4 (3.8); (*N* = 19)	7.6 (4.0); (*N* = 17)	8.4 (3.2); (*N* = 21)
12 months	7.8 (4.3); (*N* = 16)	8.1 (3.7); (*N* = 14)	8.4 (3.6); (*N* = 20)
18 months	7.0 (2.6); (*N* = 8)	10.0 (3.5); (*N* = 7)	7.3 (3.4); (*N* = 6)
24 months	7.5 (2.1); (*N* = 2)	8.8 (4.2); (*N* = 4)	5.3 (2.9); (*N* = 4)
Effect size compared to control	−0.1 (−1.6 to 1.4); 0.90	−0.4 (−1.9 to 1.2); 0.60	
Treatment satisfaction questionnaire			
Effectiveness[e]			
6 months	67.0 (27.9); (*N* = 17)	67.6 (31.3); (*N* = 18)	
12 months	74.2 (30.5); (*N* = 14)	71.8 (18.9); (*N* = 14)	
18 months	83.3 (22.9); (*N* = 5)	77.8 (21.2); (*N* = 5)	
24 months	83.3 (23.6); (*N* = 2)	77.8 (25.5); (*N* = 3)	
Convenience[e]			
6 months	82.0 (15.3); (*N* = 17)	73.8 (23.3); (*N* = 18)	
12 months	89.7 (11.3); (*N* = 14)	77.0 (18.9); (*N* = 14)	
18 months	90.7 (13.5); (*N* = 6)	80.0(18.7); (*N* = 5)	
24 months	91.7 (3.9); (*N* = 2)	74.1(8.5); (*N* = 3)	
Overall satisfaction[e]			
6 months	76.1 (22.7); (*N* = 17)	78.2 (27.7); (*N* = 17)	
12 months	86.7 (20.2); (*N* = 14)	73.0 (29.5); (*N* = 14)	
18 months	88.1 (22.9); (*N* = 6)	84.3 (27.4); (*N* = 5)	
24 months	75.0 (15.2); (*N* = 2)	69.0 (28.9); (*N* = 3)	

a The EQ-5D-5L is a generic QoL measure. It has five questions and is on the scale −0.594 to 1 with higher scores indicating better QoL.
b The GSE scale assesses ability to cope with daily life. It has 10 questions and scores are between 10 and 40 with higher scores better.
c The ICECAP-A and ICEPOP-O measure capability in adults and older people, respectively. Both have five questions and are on the scale 0–1 with higher scores better.
d ICIQ-LTCqol questionnaire is a specific QoL measure. It produces the function and concern score and the lifestyle score. The function and concern score has 10 questions and is on the scale 0–42. The lifestyle score has three questions and is on the scale 3–15. For both higher scores are worse.
e The treatment satisfaction questionnaire assesses satisfaction with medication. It produces the effectiveness, convenience, and overall satisfaction scores. Each score has three questions to give nine in total, with each score on the scale 0–100 with higher scores better.

Note
The EQ-5D-5L exit questionnaire was for participants who exited the study early or were not at a notional follow-up point when the study ended.
All effect sizes come from a mixed-effects linear regression including fixed effects for the two treatment groups, gender, age band, previous blockage, previous S-CAUTI and baseline measure of the outcome. Dummy variables are also included for the time point when the follow-up is completed. Random effects (intercepts) are included for region and participant to allow for repeated measures across time. The summary statistics are the mean, standard deviation, and count and the effects sizes are the adjusted mean difference, 97.5% CI and *p*-value.

Source

TABLE 8 Time and travel data

	Saline washouts (*n* = 26)	Acidic washouts (*n* = 27)	Control (*n* = 27)
Participants completed questionnaire	8	7	9
Travel to outpatient consultation			
Distance (miles)	15.0 (N/A); (*N* = 1)	16.0 (12.5); (*N* = 3)	13.6 (6.5); (*N* = 7)
Cost (£)	0.00 (0.00); (*N* = 2)	0.00 (0.00); (*N* = 3)	1.11 (1.97); (*N* = 7)
Total outpatient time (hours)	5.33 (N/A); (*N* = 1)	3.33 (1.53); (*N* = 3)	3.09 (1.80); (*N* = 7)
Travel to GP appointment			
Distance (miles)		1.0 (N/A); (*N* = 1)	3.3 (1.9); (*N* = 6)
Cost (£)		0.00 (N/A); (*N* = 1)	0.00 (0.00); (*N* = 6)
Total time for GP appointment (hours)		1.00 (N/A); (*N* = 1)	1.56 (1.12); (*N* = 6)
Travel to hospital admission			
Distance (miles)		8.0 (0.0); (*N* = 2)	13.8 (1.5); (*N* = 4)
Cost (£)		0.00 (N/A); (*N* = 1)	1.00 (1.73); (*N* = 3)
Total time for hospital admission (days)		6.00 (N/A); (*N* = 1)	6.76 (2.06); (*N* = 4)

N/A, not applicable

Note

The summary statistic in the cells is the mean, standard deviation and count.

Source

TABLE 9 Summary of qualitative interview participants' characteristics

Arm 1 (sa): Allocated standard LTC care + saline washout	Arm 2 (ca): Allocated standard LTC care + citric acid washout	Arm 3 (uc): Allocated standard LTC care (no washout)
n = 14	*n* = 19	*n* = 17
Female = 9 Male = 5 T1 interviews = 11 T2 Interviews = 13 Interviewed only at T1 = 1 Interviewed only at T2 = 3 Moved from citric acid to saline washout = 1	Female = 7 Male = 12 T1 interviews = 14 T2 Interviews = 12 Interviewed only at T1 = 7 Interviewed only at T2 = 5	Female = 8 Male = 9 T1 interviews = 15 T2 Interviews = 15 Interviewed only at T1 = 2 Interviewed only at T2 = 2 Moved from saline washout to standard LTC care = 1
Duration of LTC < 1 year = 3 1–3 years = 8 > 3 years = 3	Duration of LTC < 1 year = 4 1–3 years = 4 > 3 years = 11	Duration of LTC < 1 year = 4 1–3 years = 4 > 3 years = 9

ca, allocated standard LTC care + citric acid washout the CATHETER II trial; sa, allocated standard LTC care + saline washout the CATHETER II trial; uc, allocated standard LTC care (no washout) the CATHETER II trial.

Source

TABLE 10 Representative quotations within meta themes

Themes	Quotes
1. I like the idea of washout' (acceptability of weekly washout behaviour and CATHETER II trial)	
Positive affective attitude and perceived effectiveness	*'I didn't know much about the catheters and what the difference is with each one (washout), … I mean I've never spoken to anybody that has one so … I just want to learn as much as I can about it'. Pauline 63, uc.* *'I prefer the washout because hopefully that would prevent me getting any blockages'. Mark 69, ca*
Perceived lack of negative consequences, opportunity cost or burden	*'Well, it's choosing something you've never experienced. I like the idea of the washout. It seems to me that to wash the thing out on a weekly basis would well-prevent the thing from blocking'. Gorden 80, ca* *'I mean it can't do any harm, and if it does any good then I'm on a winner'. Kenny 75, uc*
Contribution to knowledge	*'Yes, it could help people in the future and of course it might help myself as well'. Stephen 53, uc*
HCPs: evidence need for policy and practice	*'We don't know whether what we're doing is good or bad or whether it's useful at all beyond the anecdote'. Keith, HCP2* *'Everything that we are doing is based on anecdotal evidence … you cannot really base a decision on the current available evidence […] At the moment, there is no recommendation that there should be any prophylactic washouts using any solutions and that's not a reflection on evidence but it is a reflection on the fact of the lack of evidence'. Lawrence, HCP7*
2. 'It's quite straightforward once it's sort of explained to you' (feasibility of weekly washout behaviour and CATHETER II trial)	
Perceived ability	*'Once I've been shown how to do I think I can do it. I mean I was shown how to do insulin injections, now I do it myself. I think if somebody shows me I can do it myself'. Bruce 86, ca* *'If I do get one of the washouts training I can carry it on'. Anderson 73, uc*
Intervention coherence, self efficacy and resources needed	*'Nurse showed us how to do it … It was very helpful … it was fine just at once'. Caroline 65, sa* *'There was a video online […] All looked very straightforward, and I followed the instructions and had no problems'. Kevin 72, sa* *'It was easy, the patients followed the instructions. They were able to look at it before we actually come online to them as well to go through it, so they'd gone through the video prior to us coming on and watching them do the procedure themselves, so yeah, it was good'. Jill, HCP6*
3. I do it myself … each week' (fidelity of weekly washout behaviour and CATHETER II trial)	
Participants' adherence and commitment	*'Every Thursday I do my washout'. Elizabeth 24, sa* *'It's [weekly washout] very much just part of a routine'. Paul 72, ca* *'… it is six months since I started it and it's not an issue … if things really open [after the COVID-19 lockdown] and I go away for a week … I just take it with me'. Rachel 70, sa* *'It's been amazing … my bladder spasms stopped … I used to bypass quite a bit and I've not bypassed, and I have not had any infections since we started doing the washouts at all'. Kirsty 58, sa* *'It was quite interesting as well from a research point of view, the number of patients that are joining the study and everyone has done what they've been randomised'. Jill, HCP6*
HCP engagement	*'I love doing these studies because actually you see a difference in what's going on with the patients quite quickly'. Jill, HCP6* *'… it was my passion that pushed it to our research department, and I'm so glad we did … I'm so glad we did because … patients really look forward to those monthly phone calls … and I have to say it's a testament to the actual CATHETER II trial that it's so well set up that I can leave as a research nurse and my colleagues can take over running the study with absolutely no hitch whatsoever to the patients and to the running of the trial'. Keith, HCP2* *'It's a shame that we didn't recruit as many as we should have because from our point of view COVID affected that greatly'. Wendy, HCP4* *'As soon as we got that list, we recruited the number of patients we could recruit because we sent a letter out to every single person on that list who was still alive or not in a nursing home, and basically the recruitment figure we got was everybody who said yes after sending everybody a letter'. Keith, HCP2*

ca, allocated standard LTC care + citric acid washout the CATHETER II trial; sa, allocated standard LTC care + saline washout the CATHETER II trial; uc, allocated standard LTC care (no washout) the CATHETER II trial.

Source

Themes and some quotes from this table are reproduced with permission from Tripathee *et al.*[33] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The table includes minor additions and formatting changes to the original text.

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Discussion/interpretation

Clinical aspects of CATHETER II

The CATHETER II RCT ended early mainly because of the impact of the COVID-19 pandemic. Most of the NHS UK research capacity, especially in primary care, was directed to COVID-19 research with QoL research, including CATHETER II, categorised as lower priority. Four months after starting CATHETER II, recruitment was temporarily stopped and could not be resumed satisfactorily due to limited research capacity in primary and secondary care. The funder opted for early termination of the trial. As a result, our findings are limited by the significantly smaller sample size (n = 80) than originally planned (n = 600).

Principal findings

The results of the CATHETER II trial indicated a favourable trend for lower rates of LTC blockages in both the prophylactic washouts groups, although the results were not statistically significant. The rate of LTC blockages per 1000 catheter days requiring treatment were 9.96, 10.53 and 20.92 in the saline, acidic and control groups, respectively. The IRR favoured the washout groups [0.65 (97.5% CI 0.24 to 1.77); p = 0.334 and 0.59 (97.5% CI 0.22 to 1.63); p = 0.25 for saline and acidic respectively], but neither reach statistical significance which could be due to the small sample size. Gage *et al.* reported that hospital resource utilisation accounted for almost half of the healthcare costs in the management of patients who were long-term catheterised, mainly due to unplanned hospital admission for LTC blockage or CAUTI.[11] Reduction in LTC blockage and/or S-CAUTI is likely to reduce the healthcare costs by reduction in emergency treatment. In CATHETER II, there were fewer visits in the washout groups to and by HCPs. However, a full health economic analysis was not feasible due to the early termination and consequently small sample size.

Contribution to existing knowledge

Catheter blockage

Catheter blockages impact up to 50% of people living with LTC leading to discomfort and emotional distress.[34] A Cochrane systematic review conducted by Shepherd *et al*. compared washout policies in patients with LTC.[6] They summarised results of 7 RCTs and included 349 participants, out of which 217 participants continued to use washouts for the duration of the trial follow-up. The authors concluded that the evidence on the benefits and harms of various washout policies were limited and generally low quality. Moore *et al*. conducted a three-arm RCT using saline or acidic solutions and compared it with standard care with no washout.[35] They reported results from 53 participants and found insufficient evidence to determine whether prophylactic LTC washout with saline or acidic solution was more effective than standard care without washout in preventing blockages. Muncie (n = 32) provided data on the mean catheter replacement rate per 100 days of catheterisation.[36] They found that the mean was 5.5 catheters replaced for the saline washout period and 4.7 catheters replaced for no washout periods, indicating no significant impact on the incidence of the total number of catheter replacements. The consensus document by British Association of Urological Surgeons (BAUS) and British Association of Urological Nurses (BAUN) indicates that prophylactic bladder washouts or catheter maintenance solutions can be employed to minimise the risk of catheter blockages in patients with LTC.[37] In the CATHETER II trial, the observed trends in reduced LTC blockage rates in the washout groups, despite the lack of statistical significance, suggest a potential benefit of prophylactic washouts in preventing LTC blockages. Therefore, we propose conducting further

research with larger sample sizes to validate these findings. This can be best achieved by a larger RCT in countries with similar healthcare systems. If regular prophylactic washouts are proven effective in preventing LTC blockage, this has potential to reduce the use of unplanned healthcare resources.

Symptomatic catheter-associated urinary tract infection

National Institute for Health and Care Excellence (NICE) and Royal College of Nursing (RCN) guidelines suggest that S-CAUTI is a potential harm and one of the main reasons for not recommending prophylactic LTC washouts.[7,38] The Cochrane review included four trials that compared saline or acidic washouts with no washout.[6] However, there was insufficient evidence from these trials and the Cochrane review could not come to a robust conclusion if there was an effect on S-CAUTI incidence or catheterisation duration. It is therefore reassuring to see in CATHETER II, despite the small sample size, that the S-CAUTI rate is significantly lower at 3.71 per 1000 catheter days in the saline washout group compared to 8 per 1000 catheter days in the standard LTC care only group [IRR is 0.40 (97.5% CI 0.20 to 0.80); $p = 0.003$]. There are also lower rates of S-CAUTI in the acidic washout group at 6.72 per 1000 catheter days [IRR of 0.98 (97.5% CI 0.54 to 1.78): $p = 0.926$], albeit this is not statistically significant. Moore *et al*. ($n = 32$) reported no incidence of S-CAUTI in their trial participants.[35] If regular prophylactic washouts are proven effective in preventing S-CAUTI, this has potential to reduce use of unplanned healthcare resources and antibiotics.

Other adverse events

In the CATHETER II trial, the mean monthly occurrence of bladder spasms was comparable between the washout groups and slightly higher in the control group. All three groups experienced < 1 day of urine retention per month. In the Cochrane review, only one trial reported results of bladder spasm; saline 0/29 participants, acetic acid 1/30 participants, neomycin–polymyxin washout 2/30 participants.[6,39]

Participants receiving a saline washout experienced fewer episodes of blood in urine compared to the control group, while those on an acidic washout had higher occurrences. Moore *et al*. presented findings from urine dipstick testing, indicating a consistent presence of blood in the urine for all participants, regardless of their assigned groups.[35]

Washout groups had more days of leakage (catheter bypass) on average than the control. The crossover trial by Muncie *et al*., reported 32 events of urine leakage, 11/32 in the saline washout period and 21/32 in the no washout period.[36]

The incidence of adverse events among participants in all groups was low. Most complications were primarily managed by either the individual themselves, their carer, or through a nurse's home visit in CATHETER II.

Patient acceptability and quality of life

In the CATHETER II trial, participants performed prophylactic washouts with self-care and minimal dependence on healthcare resources. The participants were provided with video training which appears to have been effective as only three participants stopped the regular washouts during trial follow-up due to difficulties with administration. Results of the Treatment Satisfaction Questionnaire for Medication (adapted) indicated relatively high scores for convenience, effectiveness and overall satisfaction in both the LTC washout groups. There are no other studies in the literature that made similar comparisons.

The Cochrane review noted that none of the RCTs assessed patients' acceptability and/or impact on QoL and recommended these outcomes should be assessed in future RCTs.[6] In CATHETER II, participants in both washout groups showed higher EQ-5D-5L scores than the control group, indicating the potential for greater improvement in QoL, although not statistically significant. There was little evidence of differences between groups in terms of ICIQ-LTC scores. We also confirmed acceptability of prophylactic LTC washouts and the self-care programme in the embedded qualitative study.

Strengths and weakness of the trial

CATHETER II is a robustly designed and well-conducted pragmatic RCT that followed the principles and recommendations of the CONSORT statement.[18] The RCT included an embedded qualitative study highlighting the views and experiences of patients and HCPs. The trial evaluated a comprehensive list of outcomes which are relevant for patients, HCPs, guideline developers and other stakeholders' decision-making. However, the outcomes were patient reported. To facilitate recall, participants were provided with a catheter calendar to record catheter-related events. To aid collection and interpretation of the data, the calendar was reviewed monthly, over the telephone, with the research nurse. Additionally, a S-CAUTI event required antibiotic use, which would require a prescription from the participants' healthcare provider, reducing potential for self-reporting bias for this event. The study included a control arm with

no prophylactic washouts; therefore, it was not possible to blind participants to their allocated treatment. The prophylactic washouts were administered weekly, for up to 2 years, by the participant or their carer in the community. While it was not possible to monitor variation in administration technique of the washouts, participants (and/or their carer) were trained and deemed competent to manage the washout in accordance with best practice by a trained research nurse. Participants were further supported with a training video, written instructions, and contact details for the research nurse in the event of any queries. In this pragmatic trial, the delivery of the intervention and the support provided are generalisable to how the intervention could be managed as standard of care. Despite being the largest reported RCT on this topic, a significant limitation is the small sample size. Hence, the study was underpowered to detect the 25% reduction in catheter blockage it aimed to demonstrate.

Challenges faced and limitations

COVID-19 contributed to recruitment difficulties as described earlier and early termination of the study by the funder. The target sample size was not met. Due to the small sample size, it was not possible to complete the subgroup or health economic analyses. The generalisability of the study findings may be limited by challenges faced during the set-up and delivery of the trial to increase inclusivity of patients – particularly patients who were unable to self-manage the prophylactic washouts. The ethics application to include adults who lacked capacity to consent was not successful; the study was closed prior to opening of care homes as recruitment sites; and complex pathways and COVID-19 effectively excluded patients who would rely on healthcare workers to manage the prophylactic washouts. However, recruitment was not limited to patients who were able to self-manage the washout. Approximately half of the trial's participants relied on a carer, such as a friend or family member, to manage the washouts. These recruitment challenges are further explored in the *Impact and learning* section.

Qualitative aspects of CATHETER II

Principal findings

The participants' and HCPs' views on and experience of the CATHETER II trial provide a thorough understanding of the enablers and barriers to enactment of behaviour, acceptability and satisfaction, and the potential implications for future policy and practice of LTC care. Trial participants and HCPs both highlighted the importance of the trial, suggesting that the trial was necessary and its design and management was suitable, acceptable and feasible for both providers and recipients.

LTC-related complications

In line with previous reported findings, the qualitative study found that LTC-related complications are common, and these complications impact patients' experience of LTC and their QoL.[5,8] LTC-related issues cause a significant burden on NHS resources, as incidences of blockage and related complications require treatment by HCPs either at patients' residences or at the hospital.

A lack of current guidance for prophylactic washout policies was highlighted by HCPs. This was not completely surprising, given the limited evidence in the literature on the effectiveness or benefits of prophylactic catheter washout or any type of washout solution over the other.[6,35,36] Therefore, robust evidence is needed to inform understanding of the most effective practice to reduce LTC blockage and complications.

Acceptability, feasibility and self-reported fidelity

Our findings, from both trial participants and HCPs, demonstrate acceptability and feasibility of the CATHETER II trial design, and self-reported fidelity (conducting the washout behaviour as per protocol). Those in the washout group reported positive outcomes from the trial, such as reduced blockage, pain or infection, reduced need of HCP support and greater psychological reassurance due to their ability to self-manage potential complications. Similar results were reported with clinical analysis of CATHETER II trial, which found favourable trends for lower rates of LTC blockages without a rise in S-CAUTI when employing prophylactic LTC washouts. Previous studies have reported that enabling patients to effectively self-manage their illness could lead to reduced symptom severity, improved QoL, as well as lower healthcare costs.[40–42] Provision of support is crucial when devolving routine care in patient self-management, so that individuals are confident and capable in managing their care appropriately. Our study found that self-administered catheter washout is an acceptable behaviour that could be enacted with fidelity given appropriate training. The training provided in the trial was an essential element for the washout behaviour and was reported to be feasible and effective for participants receiving this and HCPs providing the training.

Self-management and resources

It was evident from the qualitative study that most participants were unaware of washout policies and lacked LTC skills prior to the trial, which highlights a significant clinical gap in existing patient care. Nonetheless, participants were willing and keen to self-manage their catheter, and, following provision of training, were able to conduct the washout behaviour without any additional support beyond their usual LTC care. The findings clearly

suggest that the washout training provision was effective in promoting patient self-management of LTC washout confidently. Such training and education could empower patients in their self-management capabilities and confidence and help reduce the burden of LTC care on the NHS.[43]

Both participants and HCPs demonstrated a thorough awareness of the HCPs' role in the delivery of the trial and provision of the washout training. Additionally, participants' understanding and receipt of the training, and their ability to carry out the washout behaviour and complete the catheter calendar/diary and research telephone calls was evident from both interviews and focus group. Participants reported that the training as part of the trial was a key component for enacting the washout behaviour. This observation is in line with existing literature that suggests that participants' engagement with the intervention and use of intervention skills in daily life relates to treatment adherence and intervention effectiveness and that enactment of skills taught in the intervention relates to intervention effectiveness on behavioural outcomes.[44–46]

Adherence

Despite a few reports of reluctance among patients without complications to undertake prophylactic washout beyond the trial context highlighted by HCPs, most participants in this study appeared engaged regardless of their LTC experience. Unlike previous studies which have shown a lack of evidence on effective strategies on participant retention and found diaries not to be helpful, our study found that the catheter calendar/diary and monthly phone calls, which were a key component of the CATHETER II trial, might have contributed to participant retention and may also have important clinical translational considerations for optimising patient care and support.[47] Although retention strategies were not directly assessed, participant retention was found to be high between interview time points T1 (pre-randomisation) and T2 (6–8 months into the trial) within the qualitative study and the majority of participants completed interview at both time points.

Strengths and limitations of the qualitative study

Although the COVID-19 pandemic posed a challenge in recruiting trial participants, the qualitative study participants represent a diverse sample of 62% of the total CATHETER II trial participants from 76% of the recruiting sites. The use of virtual interviews supported successful patient recruitment and data collection. Longitudinal data from patients prior to and after taking part in the trial and theory-based analysis provide rigour to the interpretation of the findings.

The use of theory within the embedded qualitative study allows us to state with some degree of confidence that the CATHETER II trial is acceptable, feasible and can be delivered with fidelity. A combination of an inductive and deductive approach for the analysis, and use of the theoretical frameworks ensured that contextual nuances were carefully considered in reporting the findings and meta themes in this study.

The number of HCP participants within the embedded qualitative study was lower than we initially anticipated. However, these views are representative of 6 out of the 21 recruiting sites, and the similarity in views provides confidence in the findings.

It is however important to note that all participants recruited to the qualitative study were already engaged with the CATHETER II trial. The findings from the qualitative study need to be interpreted with this in mind as those who had already selected themselves out of the study are excluded in this sample. Therefore, this report may lack the views of those patients who may not be interested or hold negative views towards LTC washouts, and who might have different attitude or abilities regarding self-management of catheter washouts. Further research in patients with LTC who are not taking part in the CATHETER II trial would be useful to explore their thoughts about weekly prophylactic washouts.

Patient and public involvement

The aim of patient and public involvement (PPI) within CATHETER II was to contribute to the development of the research plan and to provide advice and guidance throughout the study.

Patients and carers, Bladder Health UK and nurses were included in a survey of opinion and practice that informed the design of the study, with a preference for a three-arm design that included the two main types and most commonly used LTC washouts (acidic and saline).

The research team included PPI partners from Bladder Health UK, RCN and Queens Nursing Institute. The RCN were unable to support CATHETER II throughout the trial, due to capacity constraints during the pandemic. The Trial Steering Committee included a PPI member who was actively involved in discussions at meetings, reviewing and commenting on patient facing materials and contributing to the review of the Plain language summary.

Patient and public involvement partners provided valuable feedback that supported the resumption of recruitment to

the trial following a pause during the COVID-19 pandemic. The trial required a face-to-face visit to ensure participant (and/or carer) competence with washout technique. To permit resumption of recruitment activities during the pandemic, while minimising face-to-face contact, training for washout technique required to be delivered remotely. Advice from PPI partners Bladder Health UK and the RCN indicated that participants were more likely to be comfortable with videocall technology than in the past, due to the pandemic. Additionally, where patients had used videocall for clinical appointments, patients had given good feedback on the format. With support from PPI partners, we were able to recommence recruitment with washout training delivered by video or telephone consultation, supplemented with an online video detailing technique and hardcopy instructions containing advice and troubleshooting.

The study results have been disseminated to PPI partners, participants and their GPs. This summary/infographic was developed with feedback and contributions from our PPI partners.

In summary, PPI contributed positively to study development, delivery and dissemination. There are no negative outcomes from PPI contribution to report.

Equality, diversity and inclusion

Age and gender were reasonably representative of the general population. A recent study in the UK indicates 59.6% of LTC users are men, 71.2% of LTC users are over the age of 70 and neuropathic bladder represents 57% of LTC users.[11] We did not collect participant ethnicity.

Manual dexterity is necessary for the management of the washouts and some LTC users are known to have comorbidities which could impact on manual dexterity such as spinal injury and multiple sclerosis. Manual dexterity could also prove challenging in an older population. To facilitate inclusion of these populations a participant's carer, such as a family member, could be consented into the study to support the participant with study documentation and/or the administration of the washouts. Half of the CATHETER II participants required the help of a carer.

We worked with the ENRICH network to establish the study in care homes, but we were not able to open the first care home prior to early closure of the study. According to the Alzheimer's Society, a relatively high proportion of care home residents have a degree of dementia or memory problems.[48] The initial ethics application for the study included provision to recruit patients with incapacity (Scotland) and patients who lack capacity (England and Wales). The ethics application to include this population was not successful because it would be possible to do this research without including this group. Additional barriers to inclusion of participants from this sector are detailed in the *Impact and learning* section of this synopsis.

Nurses (e.g. district and community nurses; continence clinics; GP practices) play a key role for LTC users with the regular change of catheter and for catheter-related events. Accordingly, nurses were permitted to take on the role and responsibility of principal investigator (PI), sometimes for the first time – this will help build research capacity for the future.

Participants were provided with a calendar/diary to record catheter-related events and these data were collected monthly by phone call, minimising study-related visits to site. To further minimise travel to site (and additional burden on participants and their carers), alternative formats of training to administer the washouts were utilised including remote video/telephone consultation and supported with YouTube (YouTube, LLC, San Bruno, CA, USA) training videos, written instruction and pictorial instruction.

A pictorial information leaflet about the study was available to potential participants to aid understanding.

We considered the use of local NHS translation services for non-English speakers but would not be able to use this service to obtain patient-reported follow-up data. There were insufficient resources to enable translation of the key study materials and data collection tools.

Impact and learning

There were several setbacks to delivery of CATHETER II. This included delays in contracting and securing the washout solutions for the study from the manufacturer and then the COVID-19 pandemic with resulting pause/restart of recruitment and ongoing NHS capacity issues impacting on site set-up and participant recruitment.

Adaptations to the study (detailed below) were implemented to improve recruitment, retention and to enable restart of recruitment during the pandemic. Despite these interventions, recruitment difficulties led to the funder terminating the study early. Recruitment

ended August 2022. Follow-up of participants recruited to the study continued until August 2023, or until the 24 months time point, whichever was first. This allowed for a minimum of 12-month follow-up for participants on study, maximising data collection to support analysis and the completion of the qualitative component of the study.

The small sample size limits the impact of CATHETER II results. However, lessons have been learnt that can support future research within LTC populations in the UK.

Reasons for declining participation

We regularly engaged with sites to obtain feedback from LTC users that declined to participate in CATHETER II:

- some were satisfied with their current catheter management and were unwilling to change (this included those who already used washouts declining to join the trial in case they would be randomised to the standard care only arm and those who did not use washouts declining to join the trial in case they would be randomised to washouts)
- potential participants with complex health issues/ comorbidities had limited time to commit to research
- some potential participants preferred face-to-face training and this was not available from September 2020 to January 2021 due to COVID-19 restrictions
- some potential participants had research fatigue during the COVID-19 pandemic (due to the number of urgent public health studies with a strong drive for recruitment)
- some potential participants felt they could not administer the washouts without the help of a healthcare worker.

Shepherd *et al*. cited the first two as potential recruitment barriers in a hypothetical clinical trial comparing regular catheter washouts against standard care (no regular washouts).[49] The CATHETER II protocol permitted changes to prophylactic washout type, frequency, and the commencement of prophylactic washouts in the standard care arm if clinically necessary. Emergency clinically indicated washouts were also permitted. There was a clear preference (among participants recruited to CATHETER II) to be randomised to a washout arm.[33] With CATHETER II providing evidence favouring the use of prophylactic washouts to prevent blockage and S-CAUTI, a case could be made to exclude a standard care only arm in a subsequent trial. Tripathee *et al*. also report participants gained confidence and skill to self-manage their catheter care throughout CATHETER II, evidence which could highlight the benefits of trial participation to potential participants in similar studies in the future.[33]

Adaptations to permit resumption of recruitment during the COVID-19 pandemic

The first site for CATHETER II opened December 2019 with the first participants recruited in February 2020. Recruitment was paused in March 2020 due to the pandemic and resumed in September 2020 with the following adaptations to minimise face-to-face contact:

- Prior to the pandemic, participants provided written consent at a face-to-face recruitment visit. To enable resumption of recruitment activities, potential participants were provided with a recruitment pack in the post to support consent and baseline activities. The participant provided written consent and returned this by post. The site countersigned the consent form following a consent discussion by telephone.
- Prior to the pandemic, a urine pH value was required at baseline for the randomisation algorithm. The recruiting team would collect a urine sample and complete a simple urine pH dipstick test at a face-to-face recruitment visit. This was replaced with a simple urine pH dipstick test kit with instructions, provided to participants in the post with their recruitment pack. The urine pH value would be collected over the telephone by the recruiting team. If a participant or their carer was not able to complete the test (which was only 7.5% of participants, see *Table 2*), randomisation parameters were updated to permit a 'not available' option.
- Prior to the pandemic, participants (and their carer if applicable) were trained face to face by the recruiting team to administer washouts in accordance with best practice. This was supplemented with an instruction leaflet including troubleshooting advice. Participants would be able to obtain advice over the telephone and repeat their training as needed. When the study re-opened to recruitment in September 2020, face-to-face training was replaced with remote video and/or teleconsultations with the recruiting site, supplemented with the instruction leaflet, a short URL link to access training videos on YouTube, and site contact details to obtain further advice. From January 2021, participants and sites were offered the option to complete the training face to face or remotely. Participants and HCPs reported in qualitative interviews that the remote study training was easy to follow and effective.[33] The feasibility and acceptability of remote delivery of washout training to participants

and HCPs could impact service delivery, with the potential to reduce staff support time and associated costs, should regular washouts be implemented in routine practice. This learning would also be important for future research studies in this area.
- Prior to the pandemic, sites received face-to-face site initiation training with the trial manager with significant time resource for the trial manager and costs associated with travel and subsistence. This was replaced with remote delivery of pre-recorded online webinars to complete site initiation and training and the support of the trial manager to answer any queries. Individuals within the site teams would self-certify completion of the training. This was time effective, enabling rapid phased set up of sites and eliminated travel and subsistence costs for study training, and is likely to have considerably reduced the carbon footprint of the study.

Adaptations to improve recruitment

Difficulties identifying LTC users

Long-term catheter users are a heterogeneous patient group with catheter care managed in various settings (community, secondary, emergency care, local authority, privately, care home). The challenges of accessing best quality continence care are well reported and identifying LTC users and continence care services with capacity to support research proved challenging.[50,51] Deterioration in continence services was highlighted in the 2013 Continence Care Services Survey Report with noted staffing reductions, increase in patient numbers, limited funding and increasing waiting times for clinical assessment.[50] Poor integration of continence care across services and variable adherence to NICE guidelines for urinary and faecal incontinence were reported in a 2010 National Audit of Continence Care.[51]

Poor coding of continence issues in clinical record systems has been previously reported in 2010, impacting on patient identification.[51] In our experience, coding continued to be poor in 2020–2. LTC users were not reliably coded on GP databases. Searches therefore identified LTC users by recent prescription of a catheter with mixed success. There were reports from some sites that patients without LTC were being identified in the searches. In some localities, the prescribing of catheters was moved from GP practices to local continence services further limiting the success of the searches undertaken by GP practices. Adding to the difficulties, district/community/continence teams that were approached did not reliably keep current lists of LTC users on their caseload. Appropriate coding of LTC users in clinical record systems would assist with future research involving LTC users.

Centralised recruitment model

To expand the potential participant pool for CATHETER II, we developed (with assistance from our PPI members) a centralised recruitment model inspired by the ASCEND and TIME trials.[52,53] Targeted advertising was utilised, with the assistance of a digital advertising agency, on Google (Google Inc., Mountain View, CA, USA) and via social media for a period of 3 months (March–June 2022). Our PPI partners Bladder Health UK also advertised the study across their active message boards. Interested patients would express interest via a webpage and then be followed up by the Trial Office to confirm suitability. In addition, GP practices without capacity to open as a site were recruited as participant identification centres with any interested patients returning an expression of interest form to the Trial Office. The site team at the Sponsor site took responsibility for confirming eligibility, recruitment, training and follow-up for potential participants identified via these routes. All training would require to be completed remotely. Recruitment via these methods was ultimately disappointing, with only eight participants (six from targeted advertising; two from participant identification centres) recruited from March to August 2022.

Face-to-face washout training

Sites reported feedback that approximately 25% of potential participants who had returned an expression of interest were reluctant to be involved in the study due to the remote delivery of washout training. Reasons cited were technological barriers and preference for face-to-face training. There was also a reluctance by a few sites to participate in the study until face-to-face training was available again, with concerns that they would not be able to effectively train participants. In response, we applied to Sponsor to resume face-to-face training with risk mitigation measures in place (detailed in Appendix II of the Protocol available at https://fundingawards.nihr.ac.uk/award/17/30/02). Sites were able to offer remote or face-to-face training from January 2021.

Prioritisation of sites

Stronger recruitment performance was identified in community healthcare and secondary care sites that had capacity to support research, particularly where it was possible to engage with local continence/bladder and bowel services at the research site. A recent point prevalence survey in the UK identified 10.8% of patients on district nursing caseloads have a LTC.[54] We recommend further similar trials based in the UK engage with continence/bladder and bowel services at trusts to identify if LTC patient lists are readily available and prioritise the opening of these trusts if research support is also available. The Community Healthcare Alliance of Research Trusts were particularly supportive and promoted the study to their

network of R&D leaders and research staff in community healthcare settings.

Recruitment from care homes

Prevalence of LTC users in care homes is considerably higher than estimated in the community. Point prevalence of catheterisation in care homes in the UK is estimated at 8% (and as high as 43.8% in some care homes) compared to an estimated prevalence in the community of 0.14%.[3,55] We worked with our lead clinical research network and the ENRICH network to attempt set up of CATHETER II for delivery in the care home setting but were not able to open any care homes prior to closure of the study.[56] In addition to being unsuccessful in obtaining ethical permission to consent patients into CATHETER II who lack capacity (detailed in the *Equality, diversion and inclusion* section of this synopsis), we encountered a number of other challenges:

- Care homes are complex to set up as sites and study pathways in this setting are not as well defined as recruitment in the NHS.
- Care homes are non-NHS (local authority, private, charity) and accessing funding for excess treatment costs can be challenging with different processes in England, Wales, and Scotland.
- Additional research funding may be required to deliver research in care home settings, as research costings may be higher. Fortunately, CATHETER II had secured additional funds at the outset for study delivery in care homes.
- Care home capacity was stretched with other research work including major COVID-19 trials.
- High turnover of care home managers and staff and lack of essential research training by care home staff can impact on successfully delivering research with medium to long-term follow-up of participants.
- Care requires to be taken to simplify and streamline study delivery processes into routine care pathways to minimise burden on very busy staff.
- Median life expectancy for people living in care homes is 15 months (admission to death) and there is a need to consider impact of this on trial outcomes if there is a longer follow-up period.[48] A reduced life expectancy was not expected to impact on the CATHETER II primary clinical outcome but considerable missing data at later time points could impact on reporting of economic and secondary outcomes.
- Additional feasibility work completed by ENRICH identified lower than expected potentially eligible residents per care home due to regional policies encouraging removal of LTCs when possible. The relatively small size of a care home (10–100 residents) in comparison to other settings also limits the number of potential participants per care home site.

Adaptations to improve participant retention

Some participants reported to the trial office the following difficulties administering the washout solutions:

- airlocks
- the washout solution not entering the catheter at all
- the full volume of the washout solution not entering the catheter
- the connector nozzle slipping out of the catheter during the washout procedure, and
- retention of some of the washout solution.

Further training and troubleshooting between participants and site staff helped to resolve most of these issues. Three participants (out of 80) withdrew from the washouts due to participant (or carer) difficulties with administering the washouts which could not be overcome with further training or support.

To improve retention of participants, and to better support sites to support participants, we provided sites with a detailed troubleshooting guide. This was developed with the support and feedback from the nursing community and the manufacturer of the washouts. It included hints and tips such as:

- Checking for kinks/twists of the catheter.
- Checking if the catheter or washout tubing was trapped on the underside of the thigh/leg.
- Confirming if the catheter was running freely before/after the washout. If the catheter was not running freely, this could indicate a blockage.
- Confirming that the washout was held above the level of the bladder when flowing the solution into the catheter.
- Confirming that the washout was held below the level of the bladder when flowing the solution out of the catheter.
- Confirming that the washout solution had been warmed up to body temperature.
- Confirming that the clamps on the washout tubing were open when flowing the solution in or out of the catheter.
- Suggesting that the participant tried changing their position, such as laying down or sitting, as this may help the solution flow into/out of the catheter.
- Suggesting very gentle manipulation of the catheter using aseptic technique to release possible suction of the bladder wall into the eyelets of the catheter, which would prevent flow of the washout solution.

- Checking for debris in the catheter blocking the solution from flowing. A very gentle squeeze of the washout chamber with thumb and forefinger could help clear debris and start the flow of the washout solution.
- Confirming if the participant was constipated.

Healthcare workers administering washouts for participants

CATHETER II intended to recruit participants who could self-manage the washouts or who would require the help of a carer (such as a relative or friend) or a healthcare worker. Recent evidence suggests 47.1% of LTC users self-manage their catheter care and 53.8% of LTC users have a visiting carer.[11] It was anticipated that if a participant could manage their weekly catheter bag or valve change (with or without the help of a carer) they would be able to administer the washouts when provided with training.

Healthcare workers can be continence teams employed by NHS third-party providers or carers employed by non-NHS third-party providers (e.g. councils, private agency). Given the variable catheter care pathways, a single recruiting site may have potential participants with healthcare workers employed by multiple third parties. Adding to the complexity, site feedback indicated a high changeover of healthcare workers with the same person being unlikely to deliver this activity week to week for a potential participant. Thomas surveyed community nursing staff at two localities in a health board in Wales and noted insufficient training on the use and indications of catheter washout solutions.[57] This further raised concerns for ensuring administration of the washouts in accordance with best practice during the study. The implications for oversight, healthcare worker training, contracting and costings was a logistical challenge out with the capacity of the trial management team. Additionally, healthcare workers may not have the capacity to take on the catheter washout task regularly, or at all, which would impact adherence to the intervention.

It is our opinion that only a community trust, set up as a recruiting site, with significant capacity to support research and an embedded continence team dedicated to administering the washout for participants would feasibly be able to recruit participants requiring healthcare worker support. We had identified one such trust prior to the COVID-19 pandemic. However, weekly visits to a participant's home to administer the washout for research purposes was not an appropriate risk to take during the COVID-19 pandemic. Recruitment was therefore limited to potential participants who could manage the washout themselves (with or without a carer). In CATHETER II, approximately half of the participants recruited to the study had a carer to support them.

Daily fluid intake and urine output

Increasing fluid intake is a recommended management strategy to prevent urinary tract infection and blockage.[7,37,58] There is limited evidence that decreased urinary output (which may be related to blockage) may be associated with urinary tract infection.[13,59,60] Daily fluid intake and urine output were not collected for CATHETER II and could potentially be a confounding variable. However, this would be difficult to collect reliably and consistently for participants in the community over a 24-month follow-up period. We anticipate in CATHETER II that this confounder was factored out by the inclusion of a minimisation variable for previous incidence of S-CAUTI.

Implications for decision-makers

CATHETER II was underpowered, limiting any implications for decision-makers.

Current guidelines do not recommend the use of prophylactic catheter washouts for the prevention of catheter blockage or S-CAUTI.[7,38,58] The RCN guidelines in particular note a high risk of urinary tract infection if the closed catheter drainage system is repeatedly broken to administer a catheter washout.[38] As evidenced in CATHETER II, it is possible to integrate a weekly catheter washout into standard care by administration at the time of the routine weekly catheter bag/valve change, minimising the breakage of the catheter system, and with no evidence for increased incidence of S-CAUTI.

We have recommended an updated systematic review is completed, with meta-analysis, with the inclusion of the results of CATHETER II. If a clear benefit is seen for prophylactic washouts in meta-analysis, this might guide future policy, notably catheter management guidelines from NICE, RCN, European Association of Urology Nurses (EAUN), and BAUS and BAUN.

Research recommendations

In order of priority:

1. Systematic review and meta-analysis.

A systematic review of available evidence of washout policies in LTC was reported by Shepherd *et al.*[6] Seven trials reported to 23 May 2016 met the inclusion criteria

for review. Shepherd reported the trials to be poor quality methodologically and the evidence on the benefit or harms of catheter washouts was inconclusive, and they could not complete a meta-analysis due to insufficient data. CATHETER II was a robust RCT reporting outcomes from 78 participants, the largest data set available to date. We recommend the results of the CATHETER II study are included in an updated systematic review with a meta-analysis to determine clinical effectiveness of regular catheter washouts in preventing catheter blockage and S-CAUTI. If a clear benefit is seen for prophylactic washouts in meta-analysis, these findings could guide future policy in catheter management guidelines from NICE, RCN, EAUN, BAUS and BAUN.

2. Completion of a RCT.

CATHETER II set out to provide high-quality evidence regarding the clinical and cost-effectiveness of regular prophylactic LTC washouts. Based on the limited and inconclusive evidence at the time, a sample size of 600 participants with a 24-month follow-up period and a standard care control arm was required to detect a 25% relative reduction in catheter blockage requiring intervention against standard LTC care alone. However, with the early termination of the study by the funder, only 80 participants were recruited, and the study was underpowered. It was not possible to complete the embedded health economics analysis due to the small sample size. We recommend an appropriately powered RCT to investigate the clinical and cost-effectiveness of regular prophylactic LTC washouts to prevent catheter blockage and S-CAUTI, potentially in a larger multinational setting to increase the LTC population pool.

CATHETER II reported results favouring a reduction of catheter blockage and S-CAUTI across a mean 15.6-month follow-up in 78 participants with the regular use of prophylactic washouts. Given these results, a reduction in total sample size (from 600 participants) and length of follow-up (from 24 months) may be feasible in a subsequent RCT to demonstrate a significant relative reduction in catheter blockage and S-CAUTI. Additionally, the inclusion of a standard LTC care control arm may not be ethically justifiable in a subsequent RCT. CATHETER II's results are inconclusive but do favour the use of prophylactic washouts against standard LTC care alone. The reduction of sample size and length of follow-up will improve the likelihood of recruiting to target and reduce the cost of delivering a subsequent RCT investigating this important question.

3. Further research empowering self-management of catheter care.

This qualitative study suggests washout training could be crucial in enhancing patients' self-efficacy and skills. Self-management for prophylactic catheter washouts could be both feasible and achievable, when appropriate training is provided, without any additional support. Further research to empower patients to self-manage their catheter and catheter-related adverse events could inform catheter washout policies and help ease burdens on healthcare providers, including those supporting LTC patients outside of the CATHETER II trial population.

4. Other mechanisms to reduce blockage and S-CAUTI.

Research into prophylactic catheter washouts is one tool of many in current research to reduce urinary tract infection and catheter blockage. The current scope of research includes catheter material (including antiseptic or antimicrobial coatings and impregnations),[61–63] catheter design,[64,65] monitoring devices (e.g. early warning sensors for blockage),[66,67] meatal care[68] and other types of washout solutions.[69,70] Where interventions are found to be safe and effective, clinical trials utilising multimodal approaches should be considered.

Conclusions

The delivery of the CATHETER II study was heavily impacted by the COVID-19 pandemic. Even without a pandemic, it proved difficult to identify potentially eligible patients. Several strategies were implemented to improve recruitment in a healthcare system with strained research capacity – but recruitment did not recover, and the study was closed early. The resulting small sample size of the study limits the ability to answer the question of the clinical and cost-effectiveness of regular prophylactic saline or acidic catheter washouts in preventing catheter blockage when administered in addition to standard LTC care.

Although not statistically significant, the results favour lower rates of catheter blockage when catheter washouts are administered prophylactically in addition to standard LTC care. Concerns of prophylactic washouts leading to an increase in the incidence of S-CAUTI are not supported by the results of CATHETER II. Indeed, we report a significant reduction in S-CAUTI requiring antibiotics with the regular prophylactic use of saline washouts. These results must be interpreted cautiously given the small sample size and

This synopsis should be referenced as follows:
Johnson D, Tripathee S, Cooper D, Constable L, Omar MI, MacLennan S, *et al.* Comparing the clinical and cost-effectiveness of various washout policies in preventing catheter associated complications in adults living with long-term catheters: synopsis of the CATHETER II RCT. *Health Technol Assess* 2026;**30**(26). https://doi.org/10.3310/GJMA0724

warrant a larger RCT to investigate the clinical and cost-effectiveness of prophylactic washouts of LTC.

The qualitative aspects of CATHETER II were successfully completed. The qualitative study shows acceptability, feasibility and self-reported fidelity of the CATHETER II trial (e.g. demonstration of conducting the washout behaviour as per protocol) on a behavioural level for both patients and HCPs. When appropriate training is provided self-management for prophylactic catheter washouts could be both feasible and achievable without any need for additional support. Washout training could be crucial in enhancing patients' self-efficacy and skills and empowering them in self-management of their catheter care.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

CATHETER II was reviewed by Wales Research Ethics Committee 6 and received ethical approval on 22 March 2019 (reference 19/WA/0015).

Information governance statement

The University of Aberdeen and NHS Grampian is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Aberdeen and NHS Grampian is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.abdn.ac.uk/staffnet/governance/data-protection-6958.php.

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Award publications

This synopsis provided an overview of the research award *The CATHETER II study: 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*.

Other articles published as part of this thread are:

Abdel-fattah M, Imran Omar M, Johnson D, Cooper D, Constable L, Tripathee S, *et al*. CATHETER II: a randomised controlled trial comparing the clinical effectiveness of various washout policies versus no washout policy in preventing catheter associated complications in adults living with long term catheters. *BMJ Open* 2024;**14**:e087203. https://doi.org/10.1136/bmjopen-2024-087203

Tripathee S, Abdel-fattah M, Johnson D, Constable L, Cotton S, Cooper D, *et al*. Patient and healthcare professionals' perception of weekly prophylactic catheter washout in adults living with long-term catheters: qualitative study of the CATHETER II trial. *BMJ Open* 2025;**15**:e087206. https://doi.org/10.1136/bmjopen-2024-087206

For more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/17/30/02).

Additional outputs

Abdel-fattah M, Johnson D, Constable L, Thomas R, Cotton S, Tripathee S, *et al*. 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: study protocol for the CATHETER II study. *Trials* 2022;**23**:630.

Tripathee S, Omar MI, Abdel-fattah M, MacLennan SJ. Patients' and healthcare professionals' expectations, experience, and perception of the outcomes of various washout policies in preventing catheter-associated complications: qualitative study of the CATHETER II trial. *Eur Urol Focus* 2022;**8**:235–8.

Conference papers/seminars

Abdel-fattah M, Omar M, Johnson D, Cooper D, Constable L, Tripathee S, *et al*. *CATHETER II, a 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*. Abstract

submitted to: International Continence Society; 23–25 October 2024; Madrid, Spain.

Tripathee S, Abdel-fattah M, Johnson D, Constable L, Cotton S, MacLennan G, *et al*. *Patient and Healthcare Professionals' Perception of Weekly Prophylactic Catheter Washout in Adults Living with Long-term Catheters: Qualitative Study of the CATHETER II Trial*. Abstract submitted to: International Continence Society; 23–25 October 2024; Madrid, Spain.

Abdel-fattah M, Omar MI, Johnson D, Cooper D, Constable L, Tripathee S, *et al*. *RCT Comparing the Clinical and Cost Effectiveness of Various Catheter Washout Policies*. Abstract submitted to: Royal College of Obstetricians and Gynaecologists World Congress; 15–17 October 2024; Muscat, Oman.

Tripathee S, Abdel-fattah M, Johnson D, Constable L, Cotton S, MacLennan G, *et al*. *Patient/Healthcare Professionals' Perception of Weekly Prophylactic Catheter Washout: CATHETER II Qualitative Study*. Abstract submitted to: Royal College of Obstetricians and Gynaecologists World Congress; 15–17 October 2024; Muscat, Oman.

Johnson D, Constable L, Cotton S, Tripathee S, Abdel-fattah M. *Challenges Delivering CATHETER II: A UK Community-based Trial in a Long-term Catheter Population*. Abstract submitted to: International Clinical Trials Methodology Conference; 30 September–3 October 2024; Edinburgh, UK.

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List of abbreviations

BAUN	British Association of Urological Nurses
BAUS	British Association of Urological Surgeons
CHaRT	Centre for Healthcare Randomised Trials
CONSORT	Consolidated Standards of Reporting Trials
COVID-19	coronavirus disease 2019
EAUN	European Association of Urology Nurses
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
GSE	the General Self-Efficacy Scale
HCP	healthcare professional
ICECAP-A	ICEpop CAPability measure for Adults
ICECAP-O	ICEpop CAPability measure for Older people
ICIQ-LTCqol	International Consultation on Incontinence Modular Questionnaire – Long Term Catheter quality of life
LTC	long-term catheter
NICE	National Institute for Health and Care Excellence
PI	principal investigator
PPI	patient and public involvement
QoL	quality of life

RCN	Royal College of Nursing
RCT	randomised controlled trial
S-CAUTI	symptomatic catheter-associated urinary tract infection
TDF	Theoretical Domains Framework
TFA	Theoretical Framework of Acceptability

References

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Appendix 1 Qualitative study methods

Methods

This was a qualitative study component of the CATHETER II trial.[71] The participants who consented to be contacted for the qualitative study were sent a participant information sheet and consent form. Consenting participants were then contacted by the qualitative research team to respond to any queries, confirm participation and schedule the interview. The consent form included consent to record the interviews; transcription by an external provider to the University of Aberdeen; and use of anonymised quotations for publication. Maximum variation sampling was used to include participants from all trial arms, genders and ages to maximise the potential for diverse perspectives.

Healthcare professionals involved in the trial were given information about the qualitative component and invited to take part in focus groups or for interview. During and after the COVID-19 pandemic, both interview and focus group participants were contacted and interviewed virtually using telephone or Microsoft TEAMS.

The study has been reported according to Consolidated Criteria for Reporting Qualitative research.[72]

Data generation and management

Data were collected between February 2020 and August 2023. Semistructured interviews were conducted with 40 participants at 2 time points: the first interview (T1) was conducted prior to the participants' knowledge of which study arm they were randomised to, and the follow-up interview (T2) was conducted 6–12 months later. Ten participants from the T1 cohort were unavailable for follow-up interview at T2. Four reported being unwell or unable to attend the T2 interview, two withdrew from the trial, one withdrew from Qualitative study, one was deceased, one had LCT removed/discontinuation, and one was not interested. Therefore, an additional 10 participants with similar characteristics were recruited and interviewed for T2 data collection.

Focus group and interviews were conducted with seven HCPs at least 6 months after the study commenced. Topic guides for the interviews and focus group were developed following discussions with the study team, review of the scientific literature (ref) and existing patient interviews on www.healthtalk.org.[17,73] The topic guide for the T1 interviews (*Figure 3*) included questions on participants' LTC-related complications, such as blockage, urinary incontinence and bladder pain, their attitudes and catheter washout preference and expected outcomes. The topic

guides were piloted with public and patient representatives and refined. The topic guide for the follow-up (T2) interviews (*Figure 4*) included questions on experience of, and satisfaction with the trial process, washout training and self-management skills, and outcomes-related LTC management and complications. The HCP focus group and semistructured interviews focused on exploring attitudes towards washout policies, perception and experience of the CATHETER II trial (*Figure 5*). HCPs' views on likely outcomes and their significance were also explored.

All the interviews and focus group were conducted by a female researcher (ST) with PhD in Health Sciences and expertise in qualitative research methods. Majority of the interviews were conducted with participants alone, however some participants preferred and consented for their carer to answer the interview question on their behalf in their presence. During the interviews and focus group, participants were encouraged to discuss any relevant issues important to them beyond the topic guide. Reflective notes taken during the interviews/focus group were used to help support decision-making in the analysis. This facilitated transparency and trustworthiness of the data. The interviews and focus group were recorded using a digital recorder and professionally transcribed verbatim. All transcripts were checked for accuracy and anonymised by removing all identifiable information and replacing the names with pseudonyms. An NVivo (QSR International, Warrington, UK) file (version 12 for Windows, QSR International, www.qsrinternational.com/nvivo-qualitative-data-analysis-software/support-services) was used to organise the data and support analysis.

Topic guides

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Data analysis

All interviews and focus group transcripts were analysed using a structured qualitative method, Framework analysis approach, guided by the TDF and the TFA (*Table 11*). The TDF is an integrated theoretical framework that guides content analysis of qualitative data within defined domains of behaviour change. It helps to rigorously identify the behavioural processes or barriers and facilitators involved in behaviour change and assess implementation processes.[29–32] TFA provides a comprehensive guide for the assessment of acceptability of healthcare interventions and is used to inform a robust understanding of acceptability across core constructs.[74,75]

The interview and focus group data were coded both inductively, and deductively within TDF and TFA domains. After the first reading of the transcripts, initial themes were identified relating to each TFA and/or TDF domains. Deductive coding within TDF and TFA included patients' and HCPs' knowledge, skills, self-confidence, optimism, intentions, goals, memory and attention, behavioural regulations, environmental and social context, intervention coherence, perceived effectiveness, self-efficacy, burden, affective attitude, opportunity cost and ethicality. Any other statements relevant to the study but not within the scope of the TFA or TDF domains were coded inductively including participants' experience of LTC-related complications prior to the trial. Statements relevant to multiple TDF and TFA codes were coded within all the relevant codes.

To enrich rigour, selected transcripts and thematic outputs emerging from the interviews were read by multiple researchers, and any inconsistencies were discussed among the research team. Multiple coding by ST and SJM tested the reliability of the designated codes (see *Table 11*).

Acceptability of an intervention by the providers and recipients is an important factor in successful implementation and effectiveness, including adherence and outcome. The TFA provides a comprehensive guide for investigation and assessment of acceptability and can inform necessary adjustments to an intervention and its implementation. In this study, six of the seven TFA domains appeared to cover the acceptability of the weekly catheter washout and the catheter II trial by the participants and HCPs. These six TFA domains were: affective attitude (participants' feeling about catheter washout and taking part in the trial), self-efficacy (how confident participants were/believed to be to carry out the weekly washout out and other elements of the trial), intervention coherence (whether participants understood the trial process and catheter washout), burden (effort required to carrying the weekly washout and other aspects of the CATHETER II trial), perceived effectiveness (their perception of whether weekly catheter washout or their taking part in the trial

CATHETER II participant pre-randomisation interview schedule

You have been invited to take part in these interviews because you will be taking part in the CATHETER II study.
Our topic today is your thoughts on the treatments that you may be offered and the training that may receive about this.

The results will be used to understand your opinions on the washout provided and the training available for people living with a long-term catheter like you.
Guidelines … No right or wrong answers and please feel you can be as open as you like…
We are tape recording…

- Please tell me about your experiences of living with a catheter and what has brought you to consider washout treatment.
    - Prompts to consider if necessary: experiences of health-related problems e.g. experience of catheter blockage, S-CAUTI, urinary incontinence, bladder pain? physical activity/sedentary behaviour
- Please tell me about how you deal with any problems that you experience because of your catheter?
- Do you have any experience of washing your catheter out with anything?
    - Prompts to consider if necessary: what was this, why was this needed, who conducted the washout, how easy / hard was this?
- What do you know about the possible types of catheter washout that may be offered to you?
    - What do they understand about the differences between arms of the study?
    - What is their understanding of the catheter washout process?
    - What do they think might be the benefits of washout and the benefits of no washout?
    - What do they think about the training that will be provided
- What are you hoping for as a result of taking part in the CATHETER II study?
    - What would be a satisfactory outcome?
        - Prompts to consider if necessary: numbers of catheter blockage, S-CAUTI, urinary incontinence, bladder pain?
- Do you have any preference between doing and not doing a weekly catheter washout as part of the CATHETER II study?
    - Why is this your preference (if applicable)?
    - As clinicians are unsure of the usefulness of catheter washout in this situation what are their thoughts on the randomisation process (i.e. are they happy to have the decision made for them)?
- Do you have any preferred type of catheter washout that you are hoping for?
- Why is this your preferred type of catheter washout (if applicable)?
- How have your previous experiences with your symptoms affected your expectations for the outcomes of carrying out a weekly catheter washout?
- Would anything influence your decision to accept the type of catheter washout offered?
    - Probes
        - perceived difference in outcomes
        - likely side effects
        - availability
        - ability to carry out the weekly washout–skills, training
        - waiting time
- Reflection on discussion. Is there anything else you would like to add?

Thank you for taking part.

FIGURE 3 T1 interview topic guide. S-CAUTI, Symptomatic Catheter Associated Urinary Tract Infection.

CATHETER II participant post-randomisation interview schedule

You have been invited to take part in these interviews because you are taking part in the CATHETER II study.

Our topic today is your thoughts on the treatments that you have been offered and the training that you may have received about this. The results will be used to understand your opinions on the washout provided (or not) and the training available for people living with a long-term catheter like you.

Guidelines … No right or wrong answers and please feel you can be as open as you like…

We are tape recording…

- Please tell me about your experiences of living with a catheter.
  - Prompts to consider if necessary: experiences of health-related problems e.g. experience of catheter blockage, S-CAUTI, urinary incontinence, bladder pain, mobility?
- Please tell me about how you deal with any problems that you experience because of your catheter?
- Has the way that you deal with these problems changed since being part of the CATHETER II study?
  - Please tell me how: e.g. role of individual, role of healthcare team, role of family / carer?
- If you are carrying out weekly washouts as part of the CATHETER II study, please talk me through how you manage this?
  - Prompts to consider include asking them to describe the steps they go through in carrying out a washout; are there any difficulties / issues with this?
- If you are carrying out weekly washouts, can you tell me about the training that you received to carry out your washout?
  - Prompts include how easy it was to understand this, how easy is it to carry this out, any questions about this, need for further information or training? Is there anything that could be improved in this training?
- Has the treatment you receive as a part of the trial changed? (i.e Increase in frequencies, changes in types of washout, no washout)
- What are you hoping for as a result of taking part in the CATHETER II study?
  - What would be a satisfactory outcome?
    - Prompts to consider if necessary: numbers of catheter blockage, S-CAUTI, urinary incontinence, bladder pain?
    - Would you recommend this option to a friend?
- Would you offer any further advice to a friend with a long-term catheter (about carrying out washouts)?

- Reflection on discussion. Is there anything else you would like to add?

Possible further topics include reflection on choices made and their decision-making process:
Influence of clinical teams or others on decision-making
Reasons for choosing/declining to take part
Reasons for changing in mind (who consented and then go on to cross over to another treatment)

Thank you for taking part.

FIGURE 4 T2 interview topic guide. S-CAUTI, Symptomatic Catheter Associated Urinary Tract Infection.

CATHETER II Qualitative study: Healthcare workers Focus Groups

Focus Group/interview topics for healthcare professionals

Background

Could you please share your experience and/or understanding of long-term catheter management and catheter washouts? *(Knowledge, self efficacy)*

Catheter II trial

Study rationale and design

Could you tell us a bit more about catheter washout, different washout solutions and catheter washout policies? *(knowledge, receptivity)*

What do you think is the purpose and principles Catheter II trial? *(knowledge and belief, individual Readiness change, compatibility, complexity)*

Prompts: views about the suitability and importance

What are your views on training individuals to carry out weekly catheter washouts in situ?

What could be the potential Barriers and facilitators to effectively carrying out the washout behaviour **for patients?**

- Individual-level e.g. skills, ability (physical and cognitive)
- Context e.g. help needed, support of others, attitudes of HCPs
- Others e.g. economic

Implementation

Could you tell us about the current practices (in your site) and your experiences of the two different catheter washout solutions?

How do you feel about the suitability and effectiveness of the current practice?

(what are the gaps and challenges?)

How could the outcome of catheter II study help in **your** current role and **others in your practice**?

- Adoption
- Implementation
- Sustainment

What could be the barriers and facilitators to incorporating **weekly catheter washout** protocols into current practice? (prophylactic aspect, weekly aspect, for either washout types if any difference)

- Acceptability
- Feasibility

General reflection on the Catheter II trial process/management

what do you think are the barriers towards recruitment of this study?

Prompts view on recruitment, randomisation and consent

FIGURE 5 Healthcare professional focus group and interview topic guide.

TABLE 11 Theoretical coding framework

Theoretical Domains Framework	Theoretical Framework of Acceptability
Knowledge of LTC/blockage/washout/scientific rationale Related to the use of Catheter or washing it out (or lack thereof), Awareness of guidelines, or lack of awareness (available washout products, technique, times, frequencies) Descriptions of research/evidence that would convince them to use a certain washout policy	**Intervention coherence** The extent to which the participants understood the trial process and catheter washout, burden (effort required to carrying the weekly washout and other aspects of the CATHETER II trial)
Skills (needed for washout/catheter management/training) Skills development/Competence/Ability Interpersonal skills/Practice Skill assessment, the training and relationship between HCP and patient may facilitate weekly catheter washout	**Self-efficacy (including that of the carer if applicable)** The participant's confidence that they can perform the behaviour(s) required to participate in the intervention. How confident participants were/believed to be to carry out the weekly washout out and other elements of the trial
Beliefs about consequences (self, carer or for research) Outcome expectancies/Characteristics of outcome Expectancies/Anticipated regret/Consequents Positive and negative outcomes from taking part in the study. Beliefs about treatment outcomes – both theoretical and based on experience due to using weekly washout. Descriptions/explanations of if a particular washout is effective. Potential long-term outcomes of using weekly washout (anticipated regret or negative consequence also coded under opportunity cost)	**Perceived effectiveness** (could be optimism) The extent to which the weekly catheter washout or their taking part in the trial will be/was beneficial and is perceived to (or have) achieve its purpose
Optimism Optimism/Pessimism/Unrealistic optimism about the outcome from the weekly catheter washout or the trial, belief about whether washout will or will not give them a positive outcome, hypothetical – optimistic about the outcome of the study (Pessimism also coded under burden)	**Affective attitude** Participants' feeling about catheter washout and taking part in the trial prior to/After taking part (Code understanding of the intervention component under intervention coherence) (Code feelings about effectiveness under perceived effectiveness)
Beliefs about capabilities (washout/trial-related commitment. Including capabilities to receive support or capabilities of the carer) Self-confidence/Perceived competence/Self-efficacy Perceived behavioural control/Beliefs/Self-esteem for catheter washout and/or trial-related commitment, how easy or difficult it will/would be to do the weekly washout or catheter care-related tasks, how confident a participant feels that they would be able to follow the washout training	**Burden** The perceived (and actual) amount of effort required to carrying the weekly washout and other aspects of the CATHETER II trial (to be combined with opportunity cost for T1 interviews)
Professional/social role and identity (self/HCPs) Professional identity/Professional role Social identity/Professional boundaries/Professional confidence/Group identity/Leadership/Organisational commitment in carrying out weekly washout and other trial tasks in certain way because of their personality, or personal commitment or identity	**Opportunity cost** The extent to which benefits, profits, or values must be given up to engage in the CATHETER II trial. (to be combined with burden for T1 interviews)
Environmental context and resources (Physical resources) Environmental stressors/Resources/material resources/Organisational culture/climate Salient events/critical incidents/Person/environment interaction/Barriers and facilitators related to allocated washout, catheter management or other trial commitments, training prior catheter treatment and resources, advice and services received, HCPs support, whether or not a certain catheter care pathways were prescribed	**Ethicality** The extent to which CATHETER II trial had good fit with an with the participants' personal values
Memory attention and decision process (T1 prospective) Memory/Attention/Attention control Decision-making/Cognitive overload/tiredness for managing catheter washout, monthly phone call and catheter calendar. At T1 code participant's descriptions of when they think they would forget as well as reasons why they don't think they would forget at this domain and description of any strategies	
Intentions Stability of intentions/A conscious decision to perform a behaviour (related to allocated washout, catheter management or other trial commitment) in a certain way, how inclined they are carryout weekly washout, inclinations to be complete the study, when they are and are not inclined to not do the weekly washout. (i.e. 'Beliefs about Consequences') Note: Indicator of intention must be explicit and not inferred	

continued

TABLE 11 Theoretical coding framework (*continued*)

Theoretical Domains Framework	Theoretical Framework of Acceptability
Motivation and goals Goals (distal/proximal)/Goal priority/Goal/target setting/Goals (autonomous/controlled)/Action planning Implementation intention of any plan or target behaviour or outcome. Whether weekly wash out is a priority. How carrying out weekly washout is (or is not) in conflict with other daily life routines or responsibility (goal conflict) (including desire to contribute to research)	
Behavioural regulation (T1 prospective) Aimed at managing or changing objectively observed or measured actions managing catheter washout and catheter calendar. Self-regulatory strategies already in place that would influence the weekly washout. Coping plans, problem solving. Strategies used in response to any potential hurdles form HCPs or resources. (Strategies to remember to do the weekly washout code at 'Memory')	
Social influences (including but not limited to that of carer) Social pressure/Social norms/Group conformity/Social comparisons/Group norms/Social support/Power, Intergroup conflict/Alienation, Group identity Modelling about how others influence whether or not a particular washout policy is adopted including influence of other HCPs, family members/friends support or lack thereof, others attitude and any need of their support (instrumental or emotional)	
Emotion (around catheter management/washout) Fear/Anxiety/Stress/Depression Positive/negative affect/Burn-out experienced by participants while carrying out weekly washout, about doing the specific washout. Include 'no' answers (Descriptions of HCPs' emotions regarding the participants washout code at Environmental resources, friends or families' emotions code at 'Social influence')	
Reinforcement (Reinforcement/reward of catheter washout based on past experiences that is not knowledge) Incentives/Punishment/Consequents/Reinforcement Contingencies/Sanctions Also code 'no' answers	
Nature of behaviour: Catheter Blockage or any LTC experience relevant to washout (coded here in addition to LTC experience)	
Inductive codes:	
LTC **Experience** (emotion/past experiences that is not knowledge) Catheter related AE/Catheter Non AE	
Awareness (or experience) of washout prior to trial	

AE, adverse event.

Source

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will be/was beneficial) and opportunity costs (what they needed to give up in order to take part in the CATHETER II trial). The remaining TFA domain, ethicality (the extent to which the CATHETER II trial fits with the participants' personal values), was not prominently discussed by the participants.

Theoretical Domains Framework is a theoretical framework that helps identify influence on behaviour and help understand the behavioural process or facilitators/barriers involved in the behaviour change and determine the implementation of interventions. TDF provides a high-level explanation for constructs related to change, both at individual and organisation levels. The prominent TDF domains related to participants' reports in this study that were: knowledge (of LTC/blockage/washout/scientific rationale), beliefs about capabilities (for catheter washout and/or trial-related commitment, including capabilities to receive support or capabilities of the carer), beliefs about consequences (outcome expectancies/characteristics of outcomes, expectancies/anticipated regret/consequences for self, carer or for research), optimism (about the outcome from the weekly catheter washout), skills (already possessed or needed for washout/catheter management/training), memory attention and decision process, behavioural regulation (aimed at managing catheter washout and catheter calendar/diary), motivation and goals (including desire to contribute to research), intention, environmental context, and resources (related to allocated washout, catheter management or other trial commitments). Some TDF domains, such as professional/social role and identity (self/HCPs), reinforcement, emotion, and ethicality, were less prominent in participants' reports in both T1 and T2 interviews.

After the initial coding, domains addressing common related research objectives were grouped into themes and frameworks were generated. The research team discussed these frameworks and themes, and generated belief statements (representative description of the statements within the domains). Any conflict in interpretations were discussed between the researchers, and themes were redefined accordingly. Frameworks were created to map the complete data set to identify patterns within and across arms of the trial, and participant profiles according to the study aims. This process helped identify themes and sub-themes across all interviews and domains and examined any potential inter-connected relationships. HCP focus group and interview data were initially coded separately and analysed and triangulated with the participants' interview data of key common themes for final analysis.