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Synopsis

Challenges to overcome in a randomised trial for Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in women: the PURSUIT RCT

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Abstract

Background: Recurrence or persistence of symptoms after interventions to treat stress urinary incontinence in women is common, but without robust evidence to base treatment recommendations.
Objectives: To investigate whether endoscopic or surgical treatments for stress urinary incontinence in women are effective and cost-effective.
Design: A multicentre, unblinded, parallel-group randomised controlled trial.
Setting: Fifteen centres across the United Kingdom.
Participants: Adult women with recurrent or persistent stress urinary incontinence.
Intervention: Individual randomisation to endoscopic (urethral bulking) or surgical (autologous sling, colposuspension, artificial urinary sphincter) interventions. Women randomised to surgery chose their operative intervention.
Main outcomes: Primary outcome self-reported International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form at 1 year post randomisation. Secondary outcomes included International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form, Patient Global Impression of Improvement and Pelvic Organ Prolapse/Urinary Incontinence Sexual questionnaires up to 3 years post randomisation, operative assessment measures and adverse events, cost-effectiveness from National Health Service and societal perspectives (quality-adjusted life-years and International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form) at 1 year, and a secondary care perspective (quality-adjusted life-years) at 3 years. Semistructured qualitative interviews at baseline (post randomisation), follow-up (3–6 months) and longer-term (12 and 36 months), to explore stress urinary incontinence generally, the acceptability and attitudes to treatments and to improve understanding of

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outcomes. Qualitative interviews with clinicians at baseline were focused on potential difficulties of recruitment and optimising patient-facing information and training materials for clinicians.

Results: Fifty-five women were deemed eligible after screening (*n* = 328 screened) from October 2019 to June 2022. Twenty-four eligible women consented, and 23 were randomised (between January 2020 and July 2022) from 8 sites with the average age of 57 years (standard deviation: 10.7) and all self-reported 'white' ethnicity. Participants reported a median International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form score at baseline of 16 (interquartile range: 13–19) and mean post-void residual volume of 4.64 ml (standard deviation: 8.45). Eleven participants received their allocated intervention, 2 participants withdrew prior to receiving their intervention and 10 were waiting for their intervention when the study closed. The most common reason for declining participation was a treatment preference (*n* = 14). Recruitment training sessions and recruitment tips documents were developed and implemented to address challenges centred around patient treatment preferences and clinicians' equipoise. However, the most important recruitment challenge was the low number of eligible patients, driven primarily by the COVID-19 pandemic preventing referrals and surgery, and related wider issues in the National Health Service which led to study closure in January 2023.

Conclusion: In its early stages, the initial recruitment rate was on target (four participants randomised in the first 3 months of recruitment), but once the pandemic started, the study was unable to recruit and so closed early. The main limitation was the occurrence of the global pandemic soon after the commencement of recruitment, profoundly affecting service delivery and patient presentations. Under normal healthcare service conditions, the study may be deliverable.

Limitations: Failure to recruit under pandemic conditions rendered the study unfeasible.

Future research: Practical experience with the study and development of patient-facing and staff training materials will help delivery of the study once patient referrals and healthcare services fully return to normal.

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Synopsis

Urinary leakage with physical activity is known as stress urinary incontinence (SUI), and primary SUI affects a quarter (16–35%) of women after pregnancy. Surgical options include colposuspension, fascial sling, artificial urinary sphincter (AUS) or endoscopic bladder neck injections. In many cases, symptoms may come back, or persist, after surgical treatment. This situation is called recurrent, or persistent, SUI. Little is known about the chance of cure or potential treatment-related problems for women. There is also no consensus on how to treat women with failed primary continence surgery.

The Proper Understanding of Recurrent Stress Urinary Incontinence Treatment (PURSUIT) study opened in April 2019. It planned to recruit and follow up women for 3 years but closed early in January 2023 due to failure of recruitment. This synopsis describes the original intention of the study and reports the limited findings related to the number of women recruited and the circumstances that led to study closure.

Protocol

PURSUIT was a two-arm (1 : 1), parallel-group randomised controlled trial (RCT) comparing endoscopic urethral bulking injections with a surgical intervention (based on currently available NHS options).[1] The primary objective was to identify whether surgical treatment achieves a superior symptomatic outcome compared to endoscopic bulking injection(s) at 1 year post randomisation in women with recurrent or persistent SUI. The secondary objectives were to assess: the longer-term (up to 3 years) clinical impact of the interventions on continence; the improvement of symptoms; procedure/operative measures; sexual function; safety of intervention and likelihood of retreatment; the cost-effectiveness from both NHS and societal perspectives at 1 year post randomisation and from a secondary care NHS perspective at 3 years; women's experiences of interventions and associated quality of life (QoL) and clinicians' views of interventions. A 6-month internal pilot (started in January 2020) tested recruitment and delivery of the interventions, with a target to recruit 24 women by the end of the pilot phase. The full study planned to recruit 250 women, in 20 hospital urology or urogynaecology units. The sample size calculation is discussed in *Statistical analysis*.[1] The design of PURSUIT was determined with feedback from the Patient Advisory Group (PAG) and women affected by recurrent SUI. The full study protocol is available online via the NIHR funding award records,[2] the International Standard Randomised Controlled Trial Number (ISRCTN) registry[3] (both publicly accessible), and in the published protocol.[1] A summary of key elements of the protocol are provided in *Appendix 1*.

Statistical analysis

Statistical power

As outlined elsewhere,[1] the sample size calculation for PURSUIT was informed by the literature on the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) of women with SUI. One study suggested that the minimum clinically important difference in scores could range between −5 and −2 depending on the methods used.[4] The more conservative estimate of treatment to detect a difference of −2 was adopted for this study, and to allow for contamination (up to 5% of women randomised to surgery receiving endoscopic treatment before 1-year follow-up), that difference was reduced to −1.9. Based on this, we estimated that 250 women would need to be recruited to detect such a difference with 90% power assuming a standard deviation (SD) of 4.1 (in line with the assumptions made by Sirls *et al.*)[4] and allowing for 20% lost to follow-up.

Statistical methods

Analyses and reporting of the trial data are in line with Consolidated Standards of Reporting Trials (CONSORT) guidelines.[5] The overall baseline sociodemographic and clinical characteristics were described using means and SDs, medians and interquartile ranges (IQRs) or frequencies and proportions as appropriate. The summary statistic will not be presented by arm, given the limited number of data available resulting from the study closing.

The completeness of follow-up data and measures of clinical effectiveness were summarised using means and SD, medians and IQRs or frequencies and proportions as appropriate.

Site and participant recruitment

Recruitment of sites and the impact of the COVID-19 pandemic

The target was to open 4 sites to recruitment for the 6-month internal pilot phase and open a further 16 sites for the main recruitment phase (*Figure 1*). Between January 2020 and March 2022, 15 secondary care sites in England and Scotland were opened to recruit women to participate in PURSUIT (see *Figure 1*, *Table 11*, *Appendix 2*). Three sites were opened in 2020 prior to the COVID-19 pandemic being declared, and it was not until November that year when other sites were opened to recruitment.

At the start of the pandemic, recruitment was formally halted (by the sponsor) for 6 months from 1 April 2020 to 22 September 2020. Although recruitment (and therefore screening for potentially eligible patients) was then restarted at different points across sites (three sites restarted from 22 September 2020), surgery for patients eligible for PURSUIT was on hold across sites at various time periods (due to wider pauses for elective procedures in the NHS), and the availability of diagnostic testing (e.g. urodynamics) was variable over this period (see *QuinteT Recruitment Intervention implementation and results*, COVID-19 pandemic-related issues for further details).

Recruitment and randomisation of participants

Across the 15 sites, 328 women were screened for eligibility and 247 (75.3%) were identified as having recurrent or persistent SUI by the site team (*Figure 2*). These women were invited to go through further screening (assessed against the full study inclusion/exclusion criteria), where 192 were excluded (*Table 12*, *Appendix 2*); the most common reasons for exclusion were having predominant urgency incontinence (n = 48), having pelvic organ prolapse (POP) more than or equal to stage II (n = 37) or being unwilling to be randomised (n = 22).

Fifty-five women were deemed eligible after this screening process. Twenty-four eligible women consented to take part in PURSUIT, and 23 were randomised (1 woman changed their mind prior to randomisation) from 8 of the 15 open sites (*Table 11*, *Appendix 2*). By the time study recruitment was closed, recruitment was pending for 9 additional women, and 22 of the eligible patients declined to participate. The most common reason for declining participation was preference for a particular treatment and not wanting to be randomised (n = 14; *Table 13*, *Appendix 2*).

It is noteworthy that there was great variability between women in terms of time to consent and time to randomisation. Of the 23 women randomised, the number of days between urodynamics to confirm recurrent or persistent SUI and consent ranged from 9 to 791 days [median = 98 (IQR: 40–512)]. The effect of the COVID pandemic on healthcare delivery was an explanation for this wide range. Once consent was obtained, randomisation was generally performed swiftly, but there were cases of extended delays [minimum = 0 days, maximum = 455 days; median = 0 days (IQR: 0–5)]. This was mostly related to the COVID-19 pandemic and the cessation of elective surgical procedures. A protocol amendment was implemented at the start of the pandemic to enable women to give informed consent to take part even when procedures were paused at participating sites. In these cases, once treatment interventions could proceed, recruiting staff ensured with the participant that consent and eligibility remained valid before proceeding with data collection and randomisation.

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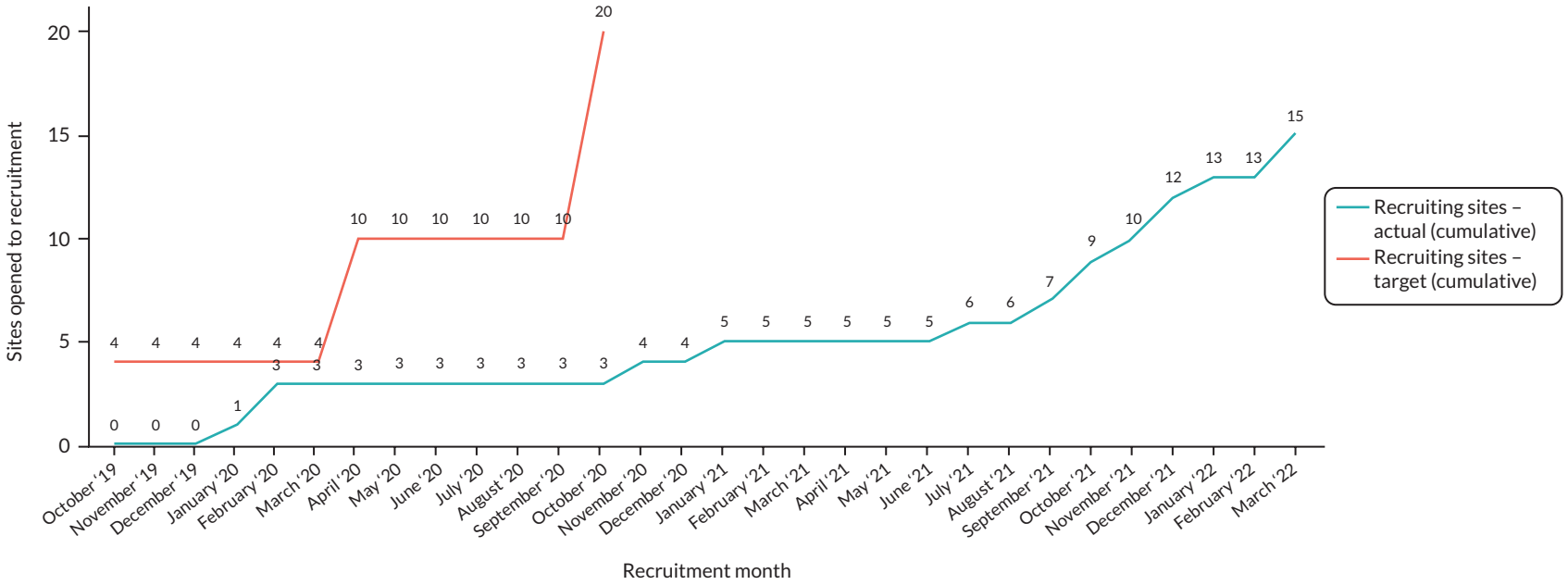

FIGURE 1 Cumulative site opening (to recruitment) over time.

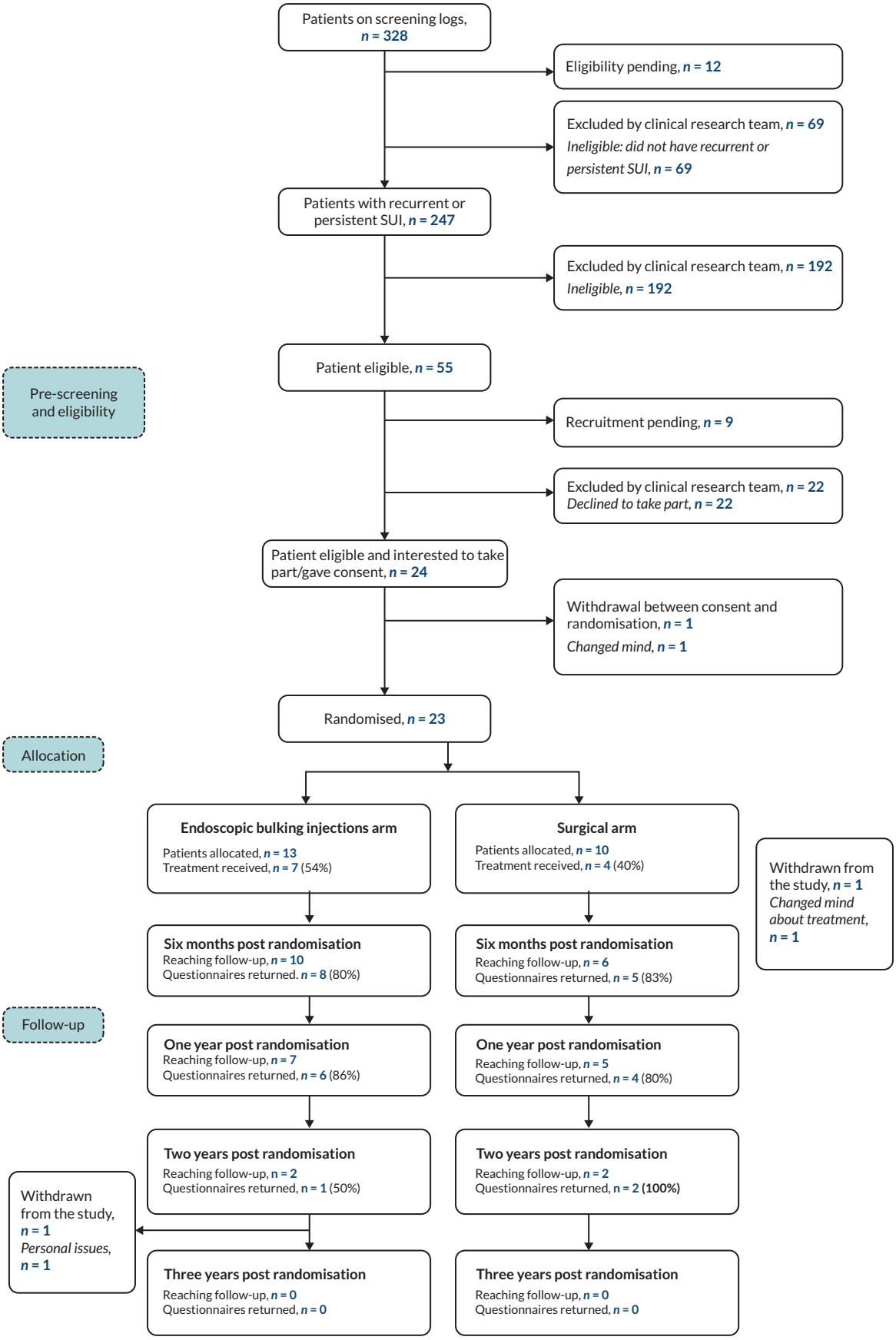

FIGURE 2 Consolidated Standards of Reporting Trials flow diagram.

Randomisation to treatment groups was performed between January 2020 and July 2022 (*Figure 3*). As part of the internal pilot, our target was to recruit 24 women by March 2020, and, in agreement with NIHR Health Technology Assessment, that target remained unchanged while the trial was open. Despite a delay in starting recruitment, by the time recruitment was halted due to the COVID-19 pandemic in March 2020, we had met our pilot recruitment target rate (see *Figure 3*), with four women randomised by the end of the third month of recruitment. Recruitment began again in November 2020 and was slow until March 2022 when randomisations picked up markedly. By the time the study was closed, recruitment was 23, just 1 woman below the internal pilot target of 24.

Two participants withdrew from PURSUIT post randomisation. One due to personal issues 2 years post randomisation, and the other at 20 days post randomisation, was due to concerns about the risks of surgery as the woman believed her urological problems were increased frequency, urgency and nocturia.

Baseline characteristics of randomised participants

For the 23 recruited patients, the average age at baseline was 57 years (SD: 10.7), and all described themselves as of 'white' ethnicity (see *Table 1*). The median comorbidity index was 0 (IQR: 0–1) – a reflection of the age of the patient group, given the three grades for the severity of comorbidity: mild, moderate and severe with Charlson Comorbidity Index scores, respectively, of 1–2, 3–4 and ≥ 5.

Participants reported a median ICIQ-UI-SF score at baseline of 16 (IQR: 13–19) and mean post-void residual volume of 4.64 ml (SD: 8.45). The median number of any prior deliveries (childbirth) was 2, where most were spontaneous vaginal deliveries (median= 0, IQR: 0–2). The most reported prior pelvic procedures for incontinence were bulking injections, mid-urethral tape (MUT) (39.1% had had both procedures previously) and hysterectomy (26%). Prior colposuspension and anterior repair occurred less frequently in this study (4.4% for both). The most common anticipated cause of SUI was intrinsic sphincter deficiency (83.3%). Most participants had a prior urinary flow rate test (87.0%) and/or cystoscopy (56.5%).

Data completeness

The completeness of the data collected from participants is described in *Table 14* (*Appendix 2*). All randomised participants completed their baseline questionnaires and provided sufficient data to derive ICIQ-UI-SF scores and EuroQol-5 Dimensions, five-level version (EQ-5D-5L) utility scores, that is, the primary outcome and health economic analyses. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-IUGA Revised (PISQ-IR) was less well completed at 82.6% and remained poorly completed at 1 year (in 50% of women reaching follow-up). Of the 16 participants reaching 6-month follow-up, 81.3% returned their questionnaire, and all provided complete ICIQ-UI-SF and EQ-5D-5L data. Twelve participants reached the 1-year end point, where the primary outcome data are collected, and 10 returned their questionnaire (83.3%). Primary outcome data on the ICIQ-UI-SF were available for 75% of participants reaching this time point. Only four participants reached 2-year follow-up, and none reached the 3-year follow-up point.

Outcomes at follow-up

Outcome data for those returning follow-up questionnaires at 6 and 12 months are presented in *Table 2* (data at 24 months are not presented due to the extremely limited number of data returned). ICIQ-UI-SF scores in both arms changed very little between 6 and 12 months' follow-up and generally appeared higher in the endoscopic bulking arm. At 6 months, the median score among the 8 patients allocated to endoscopic bulking was 16 compared to 11 in the 5 patients allocated to the surgical arm. At 12 months, the medians were 16 (n = 6) and 11 (n = 3) in the endoscopic bulking and surgical arms, respectively. These results must be interpreted with due caution, however, given the small sample size.

When women described when they leaked at 6 months, those in the endoscopic bulking arm frequently reported leaking when they sneezed (75.0%), before they got to the toilet (87.5%), when physically active (75.0%), after urinating (50.0%) and at unexpected times (87.5%). In the surgical arm, most reported leaking when exercising (60.0%) or before getting to the toilet (60.0%).

At 12 months, patients were asked how they felt post treatment. Only four women in each arm responded to this question; three in the endoscopic bulking group reported no change, whereas three in the surgical arm reported feeling either very much better or a little better. The PISQ-IR tool was used at 12 months to assess women's sexual function, and subscale scores could be derived on three or fewer women in each group. As such, mean scores cannot be reliably interpreted.

Delivery of study intervention

When the study closed early in January 2023, 23 participants had been randomised (see *Figure 2*). Of these, 11 had received their allocated intervention, with no crossover between study arms (n = 7 endoscopic bulking

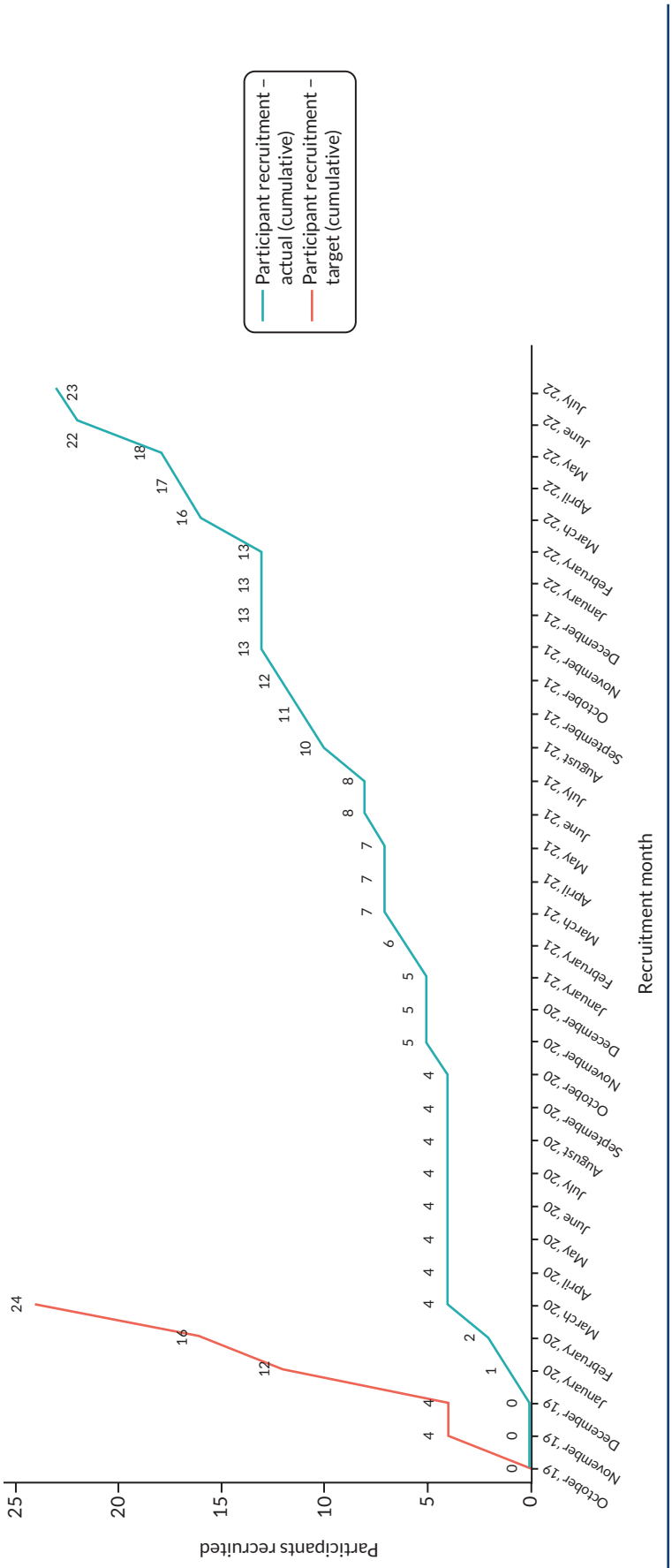

FIGURE 3 Cumulative participant recruitment over time.

TABLE 1 Baseline characteristics of randomised participants

	N[a]	
Age; years, mean (SD)	23	56.5 (10.7)
Ethnic origin; *n* (%)	23	
White		23 (100%)
Disclosure declined		0 (0%)
Black/African/Caribbean/Black British/black other		0 (0%)
Mixed/multiple ethnic groups		0 (0%)
Asian/Asian British/Asian other		0 (0%)
Other ethnic group		0 (0%)
Charlson Comorbidity Index; median (IQR)	23	0 (0–1; 0–2)
EQ-5D-5L (VAS score); median (IQR)	22	75 (60–90; 30–100)
ICIQ-UI-SF; median (IQR)	23	16 (13–19; 9–21)
Post-void residual volume (ml); mean (SD)	22	4.64 (8.45)
Number of previous deliveries by mode; median (IQR)	23	
Vaginal – spontaneous		2 (0–2; 0–5)
Vaginal – forceps		0 (0–1; 0–1)
Vaginal – vacuum		0 (0–0; 0–1)
Caesarean section		0 (0–0; 0–2)
Total number of previous deliveries; median (IQR)		2 (2–3; 0–5)
Diagnostic assessment: did the participant have. . .?; *n* (%)	23	
Detrusor overactivity		5 (21.7%)
Detrusor overactivity incontinence		4 (17.4%)
Bladder outlet obstruction		0
Reduced detrusor contractility		4 (17.4%)
Urinary flow rate test		20 (87.0%)
Cystoscopy		13 (56.5%)
Anticipated cause of SUI; *n* (%)[b]		
Urethral hypermobility only	18	9 (50.0%)
Intrinsic sphincter deficiency only	18	15 (83.3%)
Both above	16	5 (31.3%)
Previous pelvic surgery/procedures; *n* (%)		
Anterior repair	23	1 (4.4%)
Posterior repair	23	3 (13.0%)
Bulking injection	23	9 (39.1%)
MUT	23	9 (39.1%)
Autologous sling	23	3 (4.4%)
Colposuspension	23	4 (4.4%)
Hysterectomy	23	6 (26.1%)

VAS, visual analogue score.
a Number with data.
b SUI could have multiple causes.

TABLE 2 Clinical effectiveness outcomes at follow-up by treatment arm

Outcomes	Allocated to endoscopic bulking arm (*N* = 13)			Allocated to surgical arm (*N* = 10)		
	n	Mean (SD)	Median (IQR) (minimum–maximum)	*n*	Mean (SD)	Median (IQR) (minimum–maximum)
6-month follow-up: 13 questionnaires returned						
ICIQ-UI-SF score	8	15.1 (5.06)	16 (12–20) (7–21)	5	8.8 (3.96)	11 (5–12) (4–12)
When does urine leak?	***N***	***n***	**%**	***N***	***N***	**%**
Never – urine doesn't leak	8	0	0.0%	5	0	0.0%
Leaks before you can get to the toilet		6	75.0%		3	60.0%
Leaks when you cough or sneeze		7	87.5%		2	40.0%
Leaks when you are asleep		3	37.5%		1	20.0%
Leaks when you are physically active/exercising		6	75.0%		3	60.0%
Leaks when you have finished urinating and are dressed		4	50.0%		1	20.0%
Leaks for no obvious reason		7	87.5%		0	0.0%
Leaks all the time		1	12.5%		0	0.0%
12-month follow-up: 10 questionnaires returned						
ICIQ-UI-SF score	6	15.8 (4.71)	16 (16–18) (7–21)	3	8.7 (4.04)	11 (4–11) (4–11)
When does urine leak?	***N***	***n***	**%**	***N***	***N***	**%**
Never – urine doesn't leak	6	0	0.0%	4	0	0.0%
Leaks before you can get to the toilet		1	16.7%		2	50.0%
Leaks when you cough or sneeze		4	66.7%		2	50.0%
Leaks when you are asleep		3	50.0%		0	0.0%
Leaks when you are physically active/exercising		3	50.0%		3	75.0%
Leaks when you have finished urinating and are dressed		2	33.3%		2	50.0%
Leaks for no obvious reason		3	50.0%		1	25.0%
Leaks all the time		1	16.7%		0	0.0%
Patient Global Impression of Improvement (PGI-I) – post-operative condition	***N***	***n***	**%**	***N***	***N***	**%**

continued

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TABLE 3 Clinical effectiveness outcomes at follow-up by treatment arm (*continued*)

Outcomes	Allocated to endoscopic bulking arm (*N* = 13)			Allocated to surgical arm (*N* = 10)		
	n	Mean (SD)	Median (IQR) (minimum–maximum)	*n*	Mean (SD)	Median (IQR) (minimum–maximum)
1 – very much better	4	0	0%	4	2	50%
3 – a little better		1	25%		1	25%
4 – no change		3	75%		1	25%
PISQ-IR subscales (mean summary score)						
NSA-PR	2	2.5 (2.12)	2 (1–4) (1–4)	0		
NSA-CS	1	2.0 (.)	2 (2–2) (2–2)	0		
NSA-GQ	2	3.2 (0.35)	3 (3–4) (3–4)	0		
NSA-CI	2	3.0 (1.41)	3 (2–4) (2–4)	0		
SA-AO	3	2.9 (0.12)	3 (3–3) (3–3)	3	3.4 (0.60)	3 (3–4) (3–4)
SA-CS	3	2.9 (1.56)	2 (2–5) (2–5)	3	4.3 (0.58)	4 (4–5) (4–5)
SA-PR	3	3.3 (0.00)	3 (3–3) (3–3)	3	3.7 (0.58)	4 (3–4) (3–4)
SA-D	3	3.0 (0.89)	3 (2–4) (2–4)	3	3.3 (0.91)	4 (2–4) (2–4)
SA-CI	3	1.8 (1.08)	1 (1–3) (1–3)	3	2.8 (1.08)	2 (2–4) (2–4)
SA-GQ	3	1.9 (1.01)	2 (1–3) (1–3)	3	3.0 (1.57)	2 (2–5) (2–5)

NSA-CI, not sexually active condition impact, NSA-CS, not sexually active condition-specific; NSA-GQ, not sexually active global quality; NSA-PR, not sexually active partner-related; SA-AO, sexually active arousal/orgasm; SA-CS, sexually active condition-specific; SA-CI, sexually active condition impact, SA-D, sexually active desire; SA-GQ, sexually active global quality; SA-PR, sexually active partner-related.

injection arm, *n* = 4 surgical arm); 2 had withdrawn prior to receiving their allocated intervention (*n* = 1 endoscopic bulking injection arm, *n* = 1 surgical arm); and 10 participants were on waiting lists for their allocated treatment (*n* = 5 endoscopic bulking injection arm, *n* = 5 surgical arm). Waiting times for treatments varied across study sites.

Health economics

Introduction

The primary objective of the economic evaluation was to estimate the 1-year cost-effectiveness, from an NHS perspective, of endoscopic intervention compared to surgical intervention, for the treatment of women with recurrent SUI after failed primary surgery. The secondary objectives were to estimate cost-effectiveness: (1) at 1 year from a societal perspective; and (2) at 3 years from an NHS secondary care perspective. As the study stopped before the 3-year follow-up date, a 3-year cost-effectiveness analysis (CEA) from the NHS secondary care perspective was not conducted.

Methods

Measurement and valuation of resource use and costs

Community-based NHS resource use, patient out-of-pocket expenses and productivity losses were captured via patient self-report questionnaires at 6 months and 1 year post randomisation. It was intended that patient-level NHS secondary care data would be extracted from the participating hospital's informatics systems once all the participants had reached the 1-year and 3-year follow-up time points. However, the early closure of this study meant these data were not collected.

For NHS community care, patients were asked to report: (1) the number and type of contacts they had with various NHS community care healthcare professionals (HCPs); (2) the number of packs of incontinence pads/pants provided by the NHS; (3) if they had used an indwelling or intermittent catheter; and (4) if they had been prescribed medication by their general practitioner (GP).

For out-of-pocket expenses and productivity losses incurred by the patient because of their urinary problems, relevant costs included: (1) hours lost spent doing non-work activities due to urinary symptoms (e.g. leisure activities); (2) days off from paid and unpaid work because of urinary problems; (3) mode of travel to the GP surgery and hospital; (4) use of private healthcare services; and (5) out-of-pocket expenses for incontinence pads/pants/mattress covers, over-the-counter medications and health products, and any major (£50 or more) one-off expenses.

If a resource use question was incomplete but other resource use questions in the same section of the questionnaire had been completed, then it was assumed that no resources were consumed. In addition, the free-text comments box was reviewed for additional information relating to the patient's resource use.

Contacts with NHS HCPs were valued using published national unit costs for health and social care (*Table 15*, *Appendix 3*).

Measurement and valuation of outcomes

The EQ-5D-5L questionnaire was administered at baseline, 6 months, 1 year and 2 years. It was intended that the questionnaire would also be administered at the 3-year time point. However, early closure of the trial resulted in no patients reaching their 3-year follow-up period. Using the approach currently recommended by National Institute for Health and Care Excellence (NICE), patients' descriptive system responses for the EQ-5D-5L questionnaire were mapped and transformed into individual EQ-5D-3L utility scores.[6]

Analysis

It was intended that mean resource use, total costs, EQ-5D-5L utility scores and quality-adjusted life-years (QALYs) would be presented by trial arm. However, the limited number of data meant it was more appropriate to report summary statistics at each time point for resource use and EQ-5D-5L utility scores for the entire sample, rather than calculating between arm differences in mean costs and mean QALYs.

We calculated mean costs for each NHS community care category and each patient out-of-pocket cost category at both 6 months and 1 year. In order to support interpretation of the small number of data collected on productivity losses, these data were presented in the units they were measured in. The study closure meant we were unable to review NHS secondary care records and therefore we were not able to estimate women's NHS secondary care use, including our intervention costs (endoscopic intervention compared to surgical intervention).

As a result of the study closing, the planned intention-to-treat CEAs were not conducted. Planned CEAs had included: (1) a base-case cost–utility analysis (CUA) at 1 year from an NHS perspective, where incremental

between group differences in costs were to be compared to incremental between group differences in QALYs; (2) a CUA at 1 year conducted from a societal perspective; and (3) a CUA at 3 years from an NHS secondary care perspective. Additionally, a cost–consequences analysis was planned, where incremental differences in costs were to be compared with incremental differences in ICIQ-UI-SF score.

Results

Of the 23 participants recruited and randomised, 12 patients at 6 months and 10 patients at 1 year provided self-report resource use data. *Table 3* shows how online/telephone consultations with a primary care staff member (e.g. GP, nurse or other HCP) as well as face-to-face contact with a continence nurse were the most common type of community care contact at both 6 months and 1 year. At 6 months, the two categories with urogynaecology contacts had the highest mean costs, a reflection of their high unit costs rather than frequency of contact. For other types of NHS resource use, a quarter (n = 3/12) and almost half (n = 4/10) used a catheter at 6 months and 1 year, respectively, and around a third were prescribed medication for their urinary problems at both time points (*Table 16*, *Appendix 3*).

Household tasks, sport/outdoor activities, socialising, shopping and being intimate were the activities that were impacted most by the patients' urinary problems (*Table 4*). Some patients felt reporting the number of hours impacted would not capture the extent to which their urinary problems were impacting on their activities and reported additional comments on their questionnaires. A quarter of patients (n = 3/12) at 6 months reported that they were no longer intimate due to their urinary problems (see *Table 4*). Paid and unpaid work were not impacted by patients' urinary problems (*Table 17*, *Appendix 3*). At both 6 months and 1 year, patients incurred high costs due to purchasing incontinence pads/pants/mattress covers (*Table 5*).

For the EQ-5D-5L questionnaire, data were provided by all 23 patients at baseline, 13 patients at 6 months, 10 patients at 1 year and 3 patients at 2 years (*Table 6*). Considering the first three time points for which there were data, patients' mean utility score varied between 0.71 and 0.74. In terms of the five health-related quality-of-life (HRQoL) domain scores, patients had slightly worse scores for anxiety/depression compared to the other domains.

Discussion

Our findings highlight the importance of capturing patient costs, particularly women's out-of-pocket expenses and the impact of their urinary problems on their ability to participate in numerous activities, including socialising, being intimate, household tasks and sport/outdoor activities. As the prevalence of urinary incontinence is twice as high in women than in men,[7] the out-of-pocket cost and productivity loss burden on women could be an equity concern of interest to decision-makers.

Due to the lack of NHS secondary care data, it was not possible to estimate women's NHS secondary care use, including our intervention costs (endoscopic intervention compared to surgical intervention). Nevertheless, our self-report NHS community care data suggest women are accessing a range of NHS community services for their urinary problems, including consultations with HCPs, and prescribed medications. Additionally, it is possible our findings have underestimated the impact that urinary problems have on women's use of NHS services as well as social activities, since our study took place during the COVID-19 pandemic when national restrictions were in place. Furthermore, it is possible that the higher mean number of online/telephone consultations we observed compared to in-person consultations could also be related to the changes in primary care practice due to the COVID-19 pandemic. If the trial were rerun, we may therefore observe more in-person consultations.

A key limitation of our methods relates to one of the questions in our self-report resource use questionnaires. We asked participants to quantify how many hours they lost per week spent doing non-work/leisure activities due to their urinary problems. A small number of participants were unable to quantify their experience in hours and, instead, reported free-text comments explaining how they were no longer able to do the specified activity at all due to their urinary problems. Future studies should consider including a response option that captures this scenario.

At baseline, women's mean HRQoL score was 0.71. This score is considerably worse than the mean QoL score of 0.90, reported for the female general population.[8] Overall, given recurrent SUI is a common urinary problem for women, further research is needed to understand which interventions can improve women's QoL, as well as reduce the financial impact on both the NHS and women.

QuinteT Recruitment Intervention

Introduction and aim

The QuinteT Recruitment Intervention (QRI),[9] developed by the QuinteT (Qualitative research integrated within Trials) team, was integrated within PURSUIT to optimise recruitment and informed consent. The QRI was pioneered in a urology trial – the Prostate testing for

TABLE 3 NHS healthcare services resource use and costs in the last 6 months because of urinary problems

Resource	6 months (*n* = 12)		1 year (*n* = 10)	
	Resource use, mean (SD)	Costs (£/GBP), mean (SD)	Resource use, mean (SD)	Costs (£/GBP), mean (SD)
Number of visits to see GP at GP surgery or health centre	0.42 (0.90)	15.83 (34.21)	0.10 (0.32)	3.80 (12.02)
Number of visits to see continence nurse at GP surgery or health centre	0.75 (1.14)	10.07 (15.29)	0.20 (0.42)	2.67 (5.66)
Number of visits to see another HCP (e.g. a nurse or physiotherapist) at GP surgery or health centre	0.50 (1.17)	6.72 (15.68)	0.10 (0.31)	1.34 (4.25)
Home visit by GP	0.17 (0.58)	15.87 (54.99)	0	0
Home visit by another NHS HCP (e.g. a district nurse)	0	0	0	0
Online or telephone appointment in primary care (e.g. GP, nurse, other HCP)	0.58 (0.79)	23.99 (32.61)	0.60 (0.84)	24.68 (34.68)
Number of visits to see urologist at a community urology service (i.e. outside of a hospital)	0.17 (0.39)	28.94 (67.60)	0	0
Online or telephone appointment with hospital consultant	0.25 (0.62)	32.92 (81.86)	0.10 (0.32)	13.17 (41.64)

TABLE 4 Patients' resource use and costs in the last 6 months because of urinary problems

Question: In the past week, how many hours would you have liked to have spent on the following activities, but you were unable to do so because of your urinary problem?	Data type	6 months		1 year	
		n	Mean (SD)	*n*	Mean (SD)
Shopping	Hours	10	1.00 (3.16)	10	0.20 (0.63)
	Free-text comment[a]	1	Shopping quickly due to leakage	0	*n*/a
Household tasks	Hours	11	2.72 (9.04)	10	0
	Free-text comment[a]	0	N/A	0	N/A
Being intimate	Hours	8	0.25 (0.71)	9	0.56 (1.13)
	Free-text comment[a]	3	No longer intimate due to urinary problems	1	No longer intimate due to urinary problems
Socialising	Hours	8	0.25 (0.71)	10	1.20 (1.98)
	Free-text comment[a]	2	Don't go socialising anymore	0	N/A
		1	Would like to do more socialising	0	N/A

continued

This synopsis should be referenced as follows: Pope C, Cochrane M, Clement C, Liu Y, Paramasivan S, Noble S, *et al.* Challenges to overcome in a randomised trial for Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in women: the PURSUIT RCT [published online ahead of print July 2 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/AKAK8992

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TABLE 4 Patients' resource use and costs in the last 6 months because of urinary problems (*continued*)

Question: In the past week, how many hours would you have liked to have spent on the following activities, but you were unable to do so because of your urinary problem?	Data type	6 months		1 year	
		n	Mean (SD)	*n*	Mean (SD)
Sports/outdoor activities, for example, walking the dog	Hours	9	1.67 (3.24)	10	0.70 (1.34)
	Free-text comment[a]	1	All hours	1	Still some leakage and need to use continence pads
		1	Not enjoyable due to leakage	0	N/A
Attending events, for example, concerts, school play	Hours	10	0	10	0.40 (0.84)
	Free-text comment[a]	1	Short events only	0	N/A
Caring duties, for example, school run	Hours	10	0	10	0.10 (0.31)
	Free-text comment[a]	1	Short time	0	N/A
Other leisure activities	Hours	9	0	10	0.70 (2.21)
	Free-text comment[a]	1	All hours	0	N/A
Voluntary work	Hours	9	0	10	0
	Free-text comment[a]	0	N/A	0	N/A

N/A, not applicable.

a There were numerous participant comments with these questions; we have, therefore, included comments related to urinary problems in the table. In addition, there were five comments in relation to how the COVID-19 pandemic impacted their activities.

TABLE 5 Patients' travel and other out-of-pocket expenses

Resource use	6 months		1 year	
	n	% or mean (SD)	*n*	% or mean (SD)
Typically travel by car to hospital	7	58.3%	7	70.0%
Typically travel by taxi to hospital	2	16.7%	1	10.0%
Typically travel by bus/tram to hospital	1	8.3%	1	10.0%
Typically travel by train to hospital	1	8.3%	1	10.0%
Typically travel by bicycle/walk to hospital	0	0.0%	0	0.0%
Did not report how they typically travel to hospital	1	8.3%	0	0.0%
Typically travel by car to GP surgery	8	66.7%	8	80.0%
Typically travel by taxi to GP surgery	0	0.0%	0	0.0%
Typically travel by bus/tram to GP surgery	1	8.3%	0	0.0%
Typically travel by bicycle/walk to GP surgery	2	16.7%	1	10.0%
Typically travel by other mode to GP surgery	0	0.0%	1	10.0%
Did not report how they typically travel to GP surgery	1	8.3%	0	0.0%
Number of private health services used and paid for by the patient	11	0.64 (1.80)	10	0
In the last 6 months because of urinary problems, the approximate amount spent on incontinence pads/pants/mattress covers[a]	11	£69.90 (£138.65)	10	£96.00 (£154.50)
In the last 6 months because of urinary problems, the approximate amount spent on over-the-counter medications or health products, such as paracetamol, cranberry supplements, herbal remedies	11	£9.09 (£14.29)	10	£11.00 (£20.79)
In the last 6 months because of urinary problems, the approximate amount spent on other major (£50 or more) one-off expenses (e.g. new mattress, duvet)	11	£14.09 (£27.64)	10	£6 (£18.97)

a Participant reported 'a few hundred', £300, was assumed in the base-case analysis. If we assumed £200, the mean would be £86.00 (£142.61).

This synopsis should be referenced as follows: Pope C, Cochrane M, Clement C, Liu Y, Paramasivan S, Noble S, *et al.* Challenges to overcome in a randomised trial for Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in women: the PURSUIT RCT [published online ahead of print July 2 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/AKAK8992

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TABLE 6 Mean EQ-5D-5L domain and utility scores

	Baseline (*n* = 23)	6 months (*n* = 13)	1 year (*n* = 10)	2 years (*n* = 3)
Domain	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Mobility[a]	1.61 (0.94)	1.54 (0.78)	1.70 (1.06)	2.00 (1.00)
Self-care[a]	1.26 (0.62)	1.15 (0.55)	1.00 (0.00)	1.00 (0.00)
Usual activity[a]	1.87 (1.14)	1.77 (0.83)	1.60 (0.70)	1.67 (1.15)
Pain/discomfort[a]	1.87 (1.17)	1.84 (0.80)	1.80 (0.92)	2.33 (1.15)
Anxiety/depression[a]	1.96 (1.11)	1.92 (1.19)	1.90 (1.20)	2.00 (1.73)
Utility score[b]	0.71 (0.29)	0.74 (0.17)	0.74 (0.27)	0.68 (0.33)

a Scores 1–5; higher scores represent worse QoL.
b Higher scores represent better utility.

cancer and Treatment[10,11] study – and was further refined and applied in nearly 70 RCTs (including surgical),[12–15] with support from the Medical Research Council ConDuCT-I/II Hub.[16] The PURSUIT RCT team anticipated recruitment challenges in relation to identifying potentially eligible women, differences in equipoise levels among clinicians, women's treatment preferences for endoscopy or surgery, and organisational issues. The QRI was aimed at identifying and understanding recruitment issues in PURSUIT and developing and implementing solutions to address them. The QRI methods employed in PURSUIT and the results are detailed below.

QuinteT Recruitment Intervention research and implementation methods

Overview

The QRI team's recruitment-related insights were used to ensure that the trial treatments were described in a balanced manner from the funding application, through to the patient-facing documentation. The PURSUIT QRI began with an upfront QRI-informed recruitment training session for recruiters from the internal pilot sites during the trial launch event (December 2019). The aim was to provide recruitment tips and strategies drawing from published evidence[17–21] generated from previous QRIs to help prepare recruiters for impending recruitment activities and to prevent the development of recruitment challenges. Recruitment strategies discussed at this first training workshop included issues that are often raised by trial teams (clear obstacles,[16] such as logistical issues) and those that are seldom discussed by recruiters (hidden challenges around addressing patient preferences[18,19] and conveying equipoise).[21]

The training workshop was followed by the application of the standard QRI for the first year of the 2-year recruitment period. QRI methods were adapted to the emerging COVID pandemic when the PURSUIT RCT commenced. Phase I (data collection/analysis) of the QRI[9] was intended to be integrated within the 6-month internal pilot phase, in the initial four sites, to understand recruitment problems in PURSUIT. Phase II (implementing the lessons learnt and solutions developed to improve and sustain recruitment) was to be conducted over the subsequent 6 months, across all open sites, as the trial moved into the main trial phase.

PURSUIT QuinteT Recruitment Intervention Phase I: understanding recruitment challenges

During the ethics approval application, the QRI team co-designed patient-facing trial documentation with the Bristol Trials Centre (BTC). The QRI team ensured that the information was comprehensive and that the treatments described were presented in a balanced manner and demonstrated equipoise.[21]

The pandemic necessitated the adaptation of the QRI methods to an uncertain environment. Given the recruitment pauses over the initial months of the pandemic and the lack of opportunities to generate QRI data to understand potential recruitment problems, the QRI team devised newer ways of identifying future recruitment issues, primarily around equipoise. Trial recruiters in the four internal pilot sites were requested to complete a 'balance' document to help them consider how they would present the trial treatments to potential participants [$n = 8$ recruiters from four sites; three principal investigators (PIs), five research nurses (RNs)]. The document required recruiters to provide written descriptions of how they would explain the two trial treatments in relation to: (1) name of the treatments, (2) what they each involve/entail, (3) possible advantages (clinical, practical, psychological) and (4) possible disadvantages (clinical, practical, psychological). A simple content analysis (i.e. coding and counting/listing) was carried out to provide an initial insight into recruiters' equipoise.

In-depth interviews ($n = 12$) were conducted with a purposive sample of staff involved in trial design/management and/or recruitment and informed consent in the internal pilot sites. Interviewees were asked about their views on the (anticipated) clear obstacles and hidden recruitment challenges to recruitment[16] and intended plans for recruitment at their site. Interviews were transcribed verbatim and in full and analysed thematically using constant comparison techniques[20,21] with the aim of identifying similarities and discordance in views within and between participants and sites. Identified themes were then explored in subsequent interviews. The findings were written up descriptively to inform future recruitment training sessions.

Sites were requested to audio-record trial discussions with patients ($n = 7$ audio-recordings from $n = 4$ sites involving $n = 5$ recruiters and $n = 6$ patients). Key sections of the recordings were transcribed verbatim (e.g. discussions about the trial and surgical options). Targeted content and conversation analysis focused on identifying 'hidden challenges' around how the trial and concepts, such as randomisation were explained, how uncertainty was conveyed and how imbalances in the presentation of the two treatments potentially influenced patients' decision-making processes.

Sites were requested to routinely capture detailed information on eligibility and recruitment logs for all patients who were screened, eligible, approached and randomised (Screened, Eligible, Approached, Randomised framework).[22] The intended patient pathway for each site was also mapped out to explore areas of complexity in practice and potential bottlenecks to recruitment.

PURSUIT QuinteT Recruitment Intervention Phase II: actions to optimise recruitment

The analysed data were used to summarise the recruitment challenges and inform a plan of action that was collaboratively developed with key stakeholders, with the aim of overcoming the identified recruitment issues. Actions included conducting confidential feedback sessions with recruiters and other HCPs involved in the patient pathway. A total of 9 group training sessions were conducted from July 2021 to March 2022, attended by 32 HCPs from 13 sites [chief investigator (CI), 9 PIs, 1 associate PI, 17 RNs, 4 others (i.e. research team leader, support officer/practitioner, data manager)]. An A4-sided recruitment tips document was also developed and circulated to all open sites (*Figure 4*, *Appendix 4*).

QuinteT Recruitment Intervention implementation and results

Pre-recruitment: potential recruitment challenges and actions

At the funding application and trial designing stages, the QRI team helped with the redrafting of the study flowchart such that it demonstrated equipoise. Also, early discussions on the recruitment pathway indicated that patients could opt out of the trial very early on in the pathway through a reply slip that they were to send back to the trial team to indicate their interest in hearing about the trial. If they did not send back the reply slip or sent it to indicate they were not interested in the trial, their recruitment pathway ended there. This would have meant patients could opt out of considering study participation before being given detailed information about the study. Based on the QRI team's advice, this was amended so that patients' interest in the study was only elicited after full study information was provided.

During recruitment: recruitment challenges and actions

The most important recruitment challenge in the PURSUIT RCT was the low number of eligible patients to approach for the study (17%; 55/328 screened patients were eligible). This was driven primarily by the COVID pandemic-related wider issues within the NHS, given that the first site opened for recruitment in January 2020 (2 months prior to the start of pandemic-related restrictions in the UK), with two further sites opening soon after (February 2020). Two other recruitment issues were centred around patient preferences and clinicians' equipoise. Each of these is explained in detail below, alongside suggestions provided during recruitment training sessions to overcome these barriers.

COVID-19 pandemic-related issues

Interviews with members of the Trial Management Group (TMG), PIs (consultants) and RNs indicated that they perceived site staff as being engaged with the trial, seeing the trial as answering an important question and believing that they were in a good position to recruit to and deliver the trial on time.

> *I think the sites certainly seem very engaged which is fantastic and that's absolutely one key element of it being a success, is that the site teams are engaged with it and see the need for it and want to talk to their participants about it.*
>
> *P4, TMG, interview*

> *Especially in the light of all the mesh complications and, sort of, everything that's happened with that, I think it is really important that we have strong evidence to guide what we do.*
>
> *P5, consultant, interview*

> *They [PIs] were very, very keen and very, very proactive and I think that's going to go very, very well.*
>
> *P2, RN, interview*

However, the pandemic created larger operational, staffing and resource-related issues that were insurmountable from a trial recruitment perspective. Interviewees mentioned the challenges around many RNs being redeployed to clinical duties or having to prioritise COVID studies. They reported that they were still in the process of recovering from the impact of the pandemic and dealing with the backlog of delayed treatments and diagnostic tests. Interviewees contextualised the recruitment issues in PURSUIT in relation to the recruitment halts in the early part of the pandemic, the subsequent pauses in elective procedures, including surgery for patients eligible for PURSUIT, and the variations in the availability of diagnostic testing (see *Recruitment of sites and the impact of the COVID-19 pandemic* in *Statistical analysis* for information on recruitment pause timelines).

> *Now you have to remember COVID has not helped PURSUIT in the slightest because we, all our elective operating was put on hold for the first four months. Then we were up and running again for three months*

> *and we're now back on hold again. So, I am seeing virtually no patients with incontinence wanting to go ahead with surgery at this point in time, because it's considered a category four and the lowest possible priority unfortunately.*
>
> *P5, consultant, interview*

> *It has all been a bit strange because of COVID. So, seeing patients has been unusual. Last year we did little activity, this year in fact because we didn't get redeployed in the same status as last year we are operating. We did a lot more clinics, so we have been seeing a lot more clinic patients a lot quicker but then they haven't had their usual investigations, which was video urodynamics, so we've got a big backlog of video urodynamics so the whole thing is made difficult by COVID.*
>
> *P7, consultant, interview*

> *We are having some face-to-face consultations. So they've started, they've been, you know, set-up again. We're just not doing any operating.*
>
> *P1, consultant, interview*

Interviewees also felt that women, particularly those with recurrent SUI who were aware of the potential outcomes, were possibly unlikely to come forward to have treatment, knowing they will have to wait due to the pandemic.

> *They know that elective operating has been put on hold so they're not possibly going to their GPs as well. So it's a step-wise process isn't it? They're less likely to go to their GP if they've already had a continence procedure previously because they know what the outcomes are. They're obviously wet again. That maybe five years or ten years or fifteen years later but they know what the outcome of the, you know, how continence can be and therefore they are less likely to be in a rush than a woman who is incontinent for the first time who has the rest of her life in front of her and wants to get this sorted ASAP, as soon as COVID is sorted or resolved. So I think the mindset of the primary incontinent woman and the secondary incontinent woman is always going to be different in COVID times.*
>
> *P1, consultant, interview*

E-consent for PURSUIT was introduced as a mitigating measure to overcome the lack of in-person consultations during the pandemic. This was generally well-received across sites, with some indicating that remote consultations could make communication and therefore, potentially, recruitment to the study difficult.

> *We're not really doing face-to-face appointments for routine stuff at the minute. So we're really only seeing our cancers or urgent things coming through the clinic. If things settle down then, hopefully, we'll be able to just go back to our, sort of, normal hospital clinics. But socially distant consultations . . . I guess the only thing is, it's that lack of the, sort of, personal, not touch, because you're not meant to touch people, contact . . . like I think you do have a sort of, a better communication style, a better way of communicating with people when you're physically in a room with them. You can, sort of, see if they really understand what you're saying or, like, the sort of non-verbal cues that you just don't pick up on.*
>
> *P5, consultant, interview*

Obtaining regular screening logs from sites was delayed throughout the time period that the trial was open to recruitment, including when NHS research and routine services resumed after the initial pandemic-related pauses, meaning that a real-time investigation of the recruitment numbers was challenging. At recruitment training sessions and TMG meetings, surgeons expressed disappointment at the lack of eligible patients coming through as well as being unable to perform surgery for extended periods of time due to the pandemic. This led to concerns among some recruiters (expressed primarily during recruitment training sessions) as it created huge variability in waiting lists across the two treatments (endoscopy at 6–8 weeks and surgery as unknown duration).

Pandemic-related concerns were frequently raised and discussed during recruitment training sessions and TMG meetings, with collaborative potential solutions discussed for some issues. For instance, the delays with urodynamic testing due to staffing issues was identified during a recruitment training session and escalated to the TMG. Discussions were then initiated with another site to offer staff support to overcome these delays. Although there were other recruitment issues in PURSUIT (as discussed below), the pandemic-related issues contributed primarily to the PURSUIT study being unable to achieve recruitment success.

Clinicians' equipoise

In interviews, clinicians appeared to be in equipoise, clearly expressed uncertainty over which treatment was best for women with recurrent SUI and seemed comfortable with not disclosing their personal opinions to patients. However, clinicians perceived their peers as not being in equipoise and as gatekeepers of potentially eligible patients (i.e. in order to prevent patients from being randomised to a treatment the clinicians do not

prefer). Some interviewees perceived surgeons as having a preference towards surgery. Others felt that junior and inexperienced members of staff may particularly have fixed views about the best treatment and therefore not believe in the PURSUIT study, but that this challenge can be overcome through training (*Table 7*).

When recruitment was halted soon after trial launch due to the pandemic, the 'balance' documents that recruiters filled out to describe the two trial treatments acted as a proxy indicator of what recruiters may say to patients when recruitment restarted. They revealed that the language used by recruiters for endoscopic treatment was more tentative and uncertain compared to surgical treatment, which was described with more positive terminology and certainty. Endoscopic treatment was described as easy to do with fewer complications and quicker recovery, but as a short-term strategy with lesser chances of success and needing reintervention soon. Surgical treatment was described as having more complications and a longer recovery period but was viewed as a permanent and long-term treatment option with a higher success rate (*Table 8*).

These views regarding endoscopic and surgical treatments were reflected in subsequent interviews with recruiters.

> *Well, if you're asking about success, I know that bulking agents isn't as successful without a shadow of a doubt. Because we see patients with one or the other. And we see lower success rates. But I also know that with the bulking agents there are virtually no risks, it's such a safe, I mean, I do mine in an out-patients setting. They just walk in, pop on the couch, have the bulking, walk out, within minutes. And you cannot do that with any of the other continence procedures. They're all bigger operations, with significant risks. Success is definitely much better with them, though, than it is with the bulking agent one.*
>
> *P1, consultant, interview*

> *I think they (patients) will know that it's (bulking agents) less effective and that it's very minimally invasive.*
>
> *P7, consultant, interview*

In the same vein, audio-recordings of consultations also showed that recruiters led the discussion with or placed more emphasis on surgery (*best operation*, *best surgical option*, *gold standard*). Bulking injections, on the other hand, were sometimes presented in a negative manner (*bottom of the rung*).

> *The problem we have is that we don't know what is the best operation to give ladies that have had something initially. So the idea behind this PURSUIT study, that hopefully you are going to potentially agree to take part in, is to work out, should we repeat the injections, or*

TABLE 7 Recruiters' perceptions on conveying equipoise

For self: comfortable with uncertainty and with not disclosing personal opinions	*I think because we know that actually both arms are suitable for women who have got stress incontinence. So, I don't think, you know, well actually surgery is better than the other because there's pros and cons with both. So, I do think it's a good thing that it's an* RCT. *(P6,* RN, *interview)*
	The majority accept it, not everyone accepts it some people are surprised at, you know, we don't know for certain and they prefer something a bit more black and white and I have to actually say it isn't black and white. Frequently patients do say, 'well, what would you have done? You know, if it's your mother or your sister, what would you have done?' I say, 'it's a good question, I know it's very difficult, but really I can't make the suggestion or comment or guide you because I really don't know which is the best option and then only you know how tolerable the symptoms are to you and you have to weigh up the pros and cons of each, my job is to tell you all the pros and cons of each and then you have to weigh up'. (P7, consultant, interview)
For peers/colleagues: views that equipoise may be compromised	*They (other consultants) are technically part of* PURSUIT *as they can refer patients . . . if it's (bulking agents) not something they like to recommend to their patients then they are understandably wary about recommending that they are potentially randomised to that. (P8,* RN, *interview)*
	Whatever you've been told is actually based purely on very limited data extrapolated from the different situations of primary stress incontinence with a lot of bias imposed from people . . . . Basically, many surgeons like to do operating and so they will encourage people to have an operation in the belief that it'll be a good outcome. (P6, RN, *interview)*
	A slight bias towards doing surgery because of the perceived better efficacy and long-term response, which is an implicit tendency for a surgeon to follow. There might be an assumption that if a woman comes in to have some treatment, then the best treatment is the one with the greater success and longer-term response. (P12, consultant, interview)
	They're [clinicians] very fixed in their ideas. They don't engage, they think, 'oh yes, I think this is the best treatment, I don't really see the purpose of this study and . . . you know. I think we might come across that particularly with some of the junior staff that come through. So they might have only experienced one or two things and then, you know, it would be just changing their mind-set and, you know, helping them to understand equipoise. (P2, RN, *interview)*

TABLE 8 Views expressed by recruiters in relation to the two treatment arms in PURSUIT ('balance' documents)

	Endoscopic treatment	Surgical treatment
Effectiveness	Reduced SUI	Resolution of SUI
	May not cure, may not work, lower success rate, lower efficacy outcome, not as effective in terms of curing SUI	High success rate, greater chance of success
	Lower dry rate; good dry rate	High dry rate
Recovery	Quick recovery, lesser time off work	Longer recovery, including time off work
Complications, risks	Low complications/side effects	Higher ratio of side effects/risks
Hospital stay	Day case, done in OP	Overnight stay
Time effective for/need for reintervention	May need repeat/top-up; can last a few years Can be repeated	Longer-lasting results; can be permanent Less need for repeat/reintervention
Invasiveness	Minimally invasive	Major surgery
Ease of operation	Quick/easy/simple to do	-
Cuts	No cuts	Involves cuts to abdomen and vagina

OP, outpatients.

should we actually move on to offering the larger, more invasive surgery for you.

Consultation, recruiter 1, consultant

Okay, so the point of this study, which we've talked about previously just very briefly, is to work out what is the best surgical option for people, for ladies that have already had surgery for stress urinary incontinence.

Consultation, recruiter 1, consultant

(discussing the surgical options) It [colposuspension] is considered to be the gold-standard operation, so what lots of studies are based against that is the sort of marker.

Consultation, recruiter 1, consultant

At the bottom of the rung are the injections, so that is the less invasive, the less risk of complications but the balance is it might not be as effective because it is not a major, major operation.

Consultation, recruiter 1, consultant

It is likely that this influenced patients' views and preferences for surgical treatment as indicated below in staff interviews.

I get the sense from a lot of patients that they feel there is something more permanent about surgery, women come in feeling it's a better solution, it's a more permanent, long lasting solution and I think the fact that there's one of the consultants who's not convinced by bulking can put them off as well.

P10, RN, interview

Recruiters sometimes presented bulking agents in a positive light; although, given that only a few of the consultations were audio-recorded, it is unclear if this was an exception rather than the norm.

Women like it [bulking agents] because it is not invasive. It is just a day case. You don't need a long time off work or time off whatever you are doing. Risks, less than 1% risk of getting an infection, but you get some antibiotics when you are asleep, and less than a 1% risk of not being able to pee afterwards which again, lots of women find more attractive than the major surgery which can be slightly higher, and we'll talk about that in a minute.

Consultation, recruiter 1, consultant

Some recruiters clearly demonstrated equipoise in their consultations with patients.

At the moment, there's no real evidence for whether surgery or bulking agents are more effective in treating women with recurrent stress incontinence.

Consultation, recruiter 2, RN

Recruitment suggestions to convey equipoise

During recruitment training sessions, a tabulated representation of recruiters' views from the 'balance'

documents (see *Table 8*) was used to initiate the discussions around clinicians' equipoise. It helped raise awareness of 'loaded terminology' and its potential influence on patients. For instance, the QRI team highlighted that while 'reduced' SUI in relation to endoscopic treatment sounds like a good outcome on its own, it may not feel the same to patients when juxtaposed against 'resolution' of SUI in relation to surgical treatment. This was followed up with examples of imbalanced descriptions of the treatment arms from interviews and consultations, with suggestions on how to convey and demonstrate equipoise in consultations through balanced explanations of the treatment arms (also in the tips document, *Figure 4*, *Appendix 4*).

Patient preferences

Recruiters perceived patient preferences as an important recruitment barrier, especially among patients who had had previous treatments that did not work for them and therefore did not want to risk being randomised to the same treatment. These preferences were viewed as firm opinions, with recruiters making assumptions on what treatments women may want. Recruiters also varied in whether or not they felt comfortable exploring patient preferences (*Table 9*).

Recruitment suggestions to address patient preferences

During feedback sessions, the above data were presented alongside interview data that questioned recruiters' previously held beliefs that patient preferences were set in stone. This was aimed at helping them understand the benefits of exploring patients' treatment preferences, such as correcting any misconceptions patients may have of the treatments or the study and ensuring the patient was fully informed. These suggestions were also reinforced through the tips document (see *Appendix 4*). Similarly, consultation data were presented to demonstrate that patients' previous treatments were not a barrier to recruitment and that patients may be in equipoise despite their past experiences (*Table 10*).

Interviewees mentioned a few helpful aspects in relation to recruitment. These were the RNs' presence at multidisciplinary meetings, having the RN as a key contact point for patients and the CIs' recruitment video. These aspects were then included during the recruitment training sessions as strategies that could aid recruitment.

> *When we fit-in at patient's visit and we're included as part of the care team, we get a higher uptake for the trial than if we just do it by screening alone . . . I've had somebody identify a potential patient next week so I'm going to sit in that clinic, you know, so that when that, when the – if the patient is then suitable, and the conversation goes round, they think oh actually we've got a research nurse here would you like to have a quick chat.*
>
> *P8, RN, interview*

TABLE 9 Interviewees' views on patient preferences (what treatment they perceived women would want and on engaging with patient preferences)

1. Patient preferences perceived as firm opinions	*She just knows she wants an operation. (P1, consultant interview)* *So we had one who categorically said no, did not want to be randomised. She wanted surgery and wasn't going to be swayed on that one. (P4,* TMG, *interview)* *One of the particular patients that I approached for the study she really had her heart set on the autologous sling. She liked it. She liked the whole concept of it rather than having something artificial in her body. (P2,* RN, *interview)* *She was saying, well I've already had bulking and it didn't work. (P6,* RN, *interview)*		
2. Interviewees' views on what treatment women would want	Would not want surgery	May want either treatment but have already made their decisions	Would not want bulking injections
	If I'd already been through a complicated surgical procedure, ended up with pain, or something, and it's been affecting my quality of life, would I then want to go through all of that again and be randomised? Probably not, and I think that's – but I would want the condition resolved. (P4, TMG, *interview)*	*So women will often come in already having made up their mind that they either want nothing invasive, i.e., a urethral bulking agent and that's it. Or they will have come in having made up their mind that they want something that they know is going to work because actually they were quite well following their first continence surgery and would like another ten years of dryness. And that I see as the main deterrent to recruitment to* PURSUIT. *Because if a woman has already decided she wants something minimally invasive or an invasive operation she won't agree to be randomised. (P1, consultant, interview)*	*So patients who've had previously bulking agents who have recurrent incontinence, they are a tricky one. Because if you've already had bulking, again, you are less likely to want another bulking. You may have had two the first time around, for example. And I think that is the criteria for inclusion, they have to have had two urethral bulking. But there's no way they are going to agree to a third bulking versus – well, I shouldn't say no way, they are less likely to agree to be randomised if they're still wet. (P1, consultant, interview)*

TABLE 9 Interviewees' views on patient preferences (what treatment they perceived women would want and on engaging with patient preferences) (*continued*)

3. Engaging with preferences	Reluctant/less likely to engage	Varies – sometimes engage, sometimes do not	More likely to engage
	One lady said she's fed up, she's got all these problems. She can't live like this anymore. But then she did say, I don't want to have surgery. So I said this study, one of the arms is surgery. So if it's something that you don't want, then I wouldn't be encouraging you to go into the study. (P6, RN, *interview)*	*If I feel like they are quite open to it I might say you're not obliged to answer this question, but do you mind if I asked what put you off, why you decided that today. Sometimes I just don't feel like that's an appropriate question so I don't. (P8,* RN, *interview)*	*They (patients) may have been misinformed, and it's worth re-exploring the information using a patient information leaflet. (P12, consultant, interview)*

TABLE 10 Patient preferences are fluid (not fixed opinions)

Patient preferences may not be firm opinions	*We did have one lady who wasn't keen on the surgical procedure that their urogynecologist could offer but she was still happy to be randomised to the injections or the procedure that could be carried out by the urologist, so I think women are quite well-informed. (P10,* RN, *interview)*
	Anecdotally, our experience would be when women come in, they tend to have quite clear ideas of whether or not they want surgery or bulking, so we thought that the randomisation may not appeal to a lot of our women … since opening we've had a couple of patients who were maybe more willing to consider the randomisation than we expected which was good. (P8, RN, *interview)*
	It isn't just success of an operation that makes a woman decide or choose one procedure or operation over another. And that's where the uncertainty lies. Not just with the science that already exists, but with the patients and what their choices would be. Because that is a decision that a clinician, no clinician can make on behalf of a patient. (P4, TMG, *interview)*
Previous treatments may not be a barrier to recruitment or to patient equipoise	*I guess for me having had a mesh sling before and having no problems with it before and being quite successful, but now it's just had its day and it's worn out and getting old … and I understand it might not be successful the second time around or maybe I would be looking at one of the other options anyway, so I really do feel very indecisive. (patient, consultation)*
	I mean with the surgical options, I probably have a preference but I don't really know, it would be quite interesting to know if bulking agents work because it's a much more minor procedure, so I would go with either. (patient, consultation)

Having another, sort of, contact for their journey does seem to reassure them. And I've found that over the years on several studies. So, yes, I think we take the place of the specialist nurses sometimes because they're so busy and they're very difficult – so they see us as, you know, an easier person to contact and they'll probably get a quicker response just because of the way our workloads are.

P2, RN, interview

I've watched (CI name) a couple of times just to hear his – how he talks about the study and the types of operation which I think is really good as well. And I'm more than happy to signpost to the website. I think it's very self-explan – yeah and I think it's very clear and how he's describing things and actually it helped me to watch it. It gives me an idea of how to explain things to patients as well.

P7, consultant, interview

Discussion

Key findings from the QuinteT Recruitment Intervention

The QRI was integrated in the PURSUIT RCT to overcome anticipated recruitment barriers. Some recruitment barriers were addressed prior to recruitment start (e.g. removing the early opt-out reply slip option for patients to ensure they were given full study information prior to deciding about study participation). Two of the three main recruitment barriers identified in PURSUIT, namely clinicians' equipoise[21] issues and patient preferences,[18,19] have been well-documented in previous QRIs. These challenges can be overcome through feedback and training workshops for recruiters, as has been previously demonstrated.[10,11,23] A similar approach was adopted in the PURSUIT RCT, with tips documents and recruitment workshops that covered a substantial number of recruiters and sites. The recommended recruitment strategies included avoiding loaded terminology, presenting the

treatment arms in the trial in a balanced manner, exploring patient preferences, addressing any misconceptions or concerns patients may have and ensuring patients are well-informed to make a decision regarding trial participation (see *Figure 4*, *Appendix 4*). However, given that the trial opened for recruitment immediately prior to the onset of pandemic-related restrictions in the UK in March 2020, there were insurmountable challenges due to the wider operational and staffing issues faced within the NHS during that period. The main pandemic-related issues were the lack of eligible patients being seen in clinics, the de-prioritisation and pause of elective procedures overall in the NHS which meant the surgical options in PURSUIT could not be carried out for extended periods of time, delays with diagnostic testing (urodynamics), the imbalances in waiting times (quicker endoscopy vs. uncertain waiting period for surgery), staff redeployments to cater to the pandemic, prioritisation of COVID studies and women's likely reluctance to come forward during the pandemic. The nuances around these challenges were well identified through the QRI, with some barriers addressed (e.g. exploring support from other sites when there were staffing concerns with urodynamic testing in one site; introduction of e-consent). However, such challenges need solutions that change the systemic issues around resourcing and staffing, as well as clear guidance for non-prioritised studies in crises situations.

In the UK and internationally, research activities, primarily those that were not related to COVID-19, had to be paused or stopped, trial activations reduced and patient recruitment declined.[24–27] The pandemic-related recruitment issues identified in PURSUIT above have been documented in an article that summarised the impact of the pandemic on non-COVID studies in the UK.[28] The article reviewed 13 RCTs that had an integrated QRI and found that, in most trials, recruitment was lower than even the lowest anticipated rates due to similar reasons as in PURSUIT.

Strengths and limitations

The flexible nature of the QRI is its primary strength because this facilitated the introduction of methods that were suited to the no-contact pandemic situation. While waiting for research and services to resume, the QRI team utilised the time to understand recruiters' equipoise through the 'balance' documents that acted as a proxy indicator of how the treatments may be described to patients when recruitment recommenced. It helped identify recruiters' biases (often in favour of surgery) and set the scene for future recruitment training sessions. The QRI also helped provide a nuanced understanding of the pandemic-related recruitment issues, with a focus on issues that can be addressed and those that could not be addressed at a site or trial level.[28] The support of the CI, TMG, BTC and the recruiters attending the recruitment workshops ensured that the QRI team were able to achieve wide dissemination of key findings and potential solutions.

The QRI in PURSUIT has not been formally evaluated, due to the upfront training provided prior to trial-specific data collection, its flexibility and the overall context of the pandemic. These may be considered its limitations. The feedback from recruiters who attended the recruitment training sessions was positive and included:

> *I found the part of the session that I was able to attend so incredibly informative, not just in relation to PURSUIT but also when thinking about our research practice in general.*
> *The session was very good; thank you for arranging it.*

> *I have just re-watched the Pursuit study training slides and found them to be a great help on what to say and what not to say. I will definitely use the slides to refresh myself before talking to a potential participant.*

Conclusion

The QRI was successful in identifying recruitment issues in detail and addressing the communication and organisational issues that were unrelated to the pandemic. The PURSUIT RCT could not meet its recruitment target primarily due to insurmountable organisational issues that stemmed from a health crisis, the pandemic, that affected all countries.

Qualitative interviews

Aims

The interview study aimed to explore patient attitudes to, and experiences of, endoscopic and surgical interventions. Also, to explore clinician views on the interventions along with facets of trial participation.

Through interviews with study participants at different time points [baseline (following randomisation), follow-up (3–6 months) and long-term follow-up (12 and 36 months)], we intended to explore SUI generally, the acceptability and attitudes to the proposed treatments and to improve understanding of the shorter- and longer-term outcomes.

Due to the challenging circumstances within PURSUIT (described elsewhere) and a limited number of women

recruited for the study, we were unable to fully address this aim.

Recruitment and sampling

Women taking part in the study were invited to take part in semistructured interviews. We planned to use a theoretical purposive (non-probability) sampling strategy to ensure the diverse characteristics of the population were sampled [e.g. participants varying in age, intervention arm and severity of symptoms (ICIQ-UI-SF scores at baseline)]. Potential participants who agreed to be contacted about an interview were contacted by the qualitative researcher (Clement C) via e-mail and telephone and invited to take part after randomisation and before baseline measures. The number of women approached was limited by delays in obtaining letters of access at the sites for the qualitative researcher and by limited number of data availability within the contact time window. Participants were asked to provide their audio-recorded verbal consent to take part immediately before the interview.

Interviews

The interviews were conducted by telephone by the qualitative researcher, who is an experienced social scientist. A flexible topic guide was used to assist questioning during interviews but allow participants to introduce and discuss topics not anticipated by the researchers (*Figure 5*, *Appendix 5*). With informed consent from participants, interviews were audio-recorded using a digital voice recorder, transcribed using a professional transcription service and anonymised to protect confidentiality. Interviews lasted 19–35 minutes.

Analysis

Due to the limited number of data, we were unable to undertake any formal analysis. However, conveying the women's narrative accounts may still be useful. Therefore, we provide descriptive accounts of the two interviews.

Results

Seven women were invited to take part. One declined, four did not respond and two were interviewed. The interviewees were from two sites and both study arms. Participant names have been replaced with pseudonyms.

Interviewee 1 (endoscopic arm, baseline) descriptive account

Sally is in her 60s with two sons, one living separately and the other living with her. She used to work but stopped after being diagnosed with cancer, and her incontinence makes it difficult to work.

Sally has been dealing with recurrent incontinence for years. She feels damp all the time and leaks urine when walking or coughing. The symptoms have worsened over the years, impacting her daily life and confidence. The incontinence affects Sally's ability to go out for extended periods, interact with family and perform daily activities. She needs to wear pull-up pants and pads all the time, which are expensive and need changes frequently. Sally admits her confidence is low, and she feels self-conscious about her condition. She considers it the worst thing that could happen to someone while they are well. Sally expresses a desire to be 'normal' again and hopes for further treatment to address her incontinence.

Sally believes her incontinence might be related to two previous operations for prolapses, which may have weakened her muscles. She was referred for a consultation in secondary care and treatment following a discussion with her GP. She indicates that she has received sufficient information about her condition and available treatments.

Sally explained that she had bulking agents injected previously, which provided 6 months of relief before the symptoms returned. Sally felt discouraged upon learning that she wouldn't have the surgery (in the trial) as she believed the bulking agent procedure was temporary. However, she agreed to undergo the bulking agent procedure to gain some relief and she could have surgery at a later point. She also hoped having the bulking agents would not delay her position on the surgery list.

Sally has experienced delays with her treatment (within the trial) and is uncertain about the reason for the delay. She speculates whether her participation in the study has affected her position on the waiting list but hasn't received clarification.

Interviewee 2 (surgical arm, 3–6 months after treatment) descriptive account

Jane is in her 50s and is married with two sons – one adult and one teenager – whom she lives with. She retired a few years ago and now does voluntary work. While she is generally in good health, she developed hypertension after a recent operation.

Her recovery from the surgery for incontinence was smooth, and she did not require painkillers afterward. She experienced only mild discomfort like menstrual cramps. Jane noticed improvements soon after the treatment, including a quicker recovery compared to a previous operation. Positive differences, such as a dry bed after catheter removal, increased her confidence in the success of the procedure. She emphasises the importance of

following recovery guidelines and gradually returning to her daily routine, including walking her dog and increasing her activity level over time.

Jane returned to work within 6 weeks, but not at full capacity to allow for proper recovery. She avoids heavy lifting and certain tasks to ensure a full recovery without setbacks. Being able to return to work and walk her dog were important milestones for her.

Regarding SUI, Jane notes improvement since joining the study. Before the operation, she experienced leakage when coughing, sneezing or near a toilet. While she acknowledges that previous surgeries may have affected the success rate, she is content with the perceived 65–70% improvement. Jane still uses underwear liners but notices a significant difference when coughing and sneezing. She is cautious after urination to avoid accidents and expresses a desire to engage in activities like swimming and aerobics to further test the procedure's effectiveness.

Before the operation, Jane felt down, and her confidence was affected by her symptoms. She shares experiences of urinary leakage during public activities like swimming and aqua aerobics, which further diminished her confidence. However, she is hopeful that the operation will provide a permanent solution and boost her confidence to engage in these activities again.

Jane has concerns about a previous mesh procedure for SUI and the male consultant who performed it. She felt that her symptoms were not properly addressed, and her concerns were not taken seriously. It took a year and seeing a female physiotherapist and urology specialist before she felt understood and received appropriate treatment. Jane feels more comfortable and understood by female HCPs, suggesting a potential preference for their approach and communication style. She clarifies that this preference is not a bias but a personal observation.

Overall, Jane is satisfied with the results of the operation, even though she did not expect a complete resolution of her symptoms. She appreciates the more permanent nature of the operation compared to temporary solutions like bulking agents. Given her long-term symptoms and previous treatment failures, Jane expresses satisfaction with the surgery as part of the PURSUIT study and praises the medical team for their understanding, attentiveness and positive impact on her confidence.

Discussion/interpretation

Stress urinary incontinence is a common problem, and large numbers of women receive treatment for this in the NHS. Symptoms can persist despite treatment (unsuccessful intervention), while recurrence of symptoms can occur as a result of the effects of ageing on pelvic floor function, or a decline in the effectiveness of treatment. Consequently, symptoms may return over a wide time frame. Coming on top of a protracted treatment pathway, the ongoing experience of such symptoms can make them increasingly intrusive for important aspects of life.

A clear and effective approach to dealing with recurrent symptoms is highly desirable. The PURSUIT study aimed to close this important gap in knowledge by providing information about the available options to help patients and clinicians decide on the most suitable intervention to consider. The options fall into two basic categories, which are minimally invasive or full surgical. Endoscopic bulking injections to enhance urethral closure are minimally invasive, relying on visual guidance with a cystoscope for accurate placement of a needle to inject the substance intended to enhance urethral closure. The procedures can be done as a day-case option, sometimes under local anaesthetic. This type of intervention often may not have long-lasting benefit, but the ability to repeat it means it is a therapeutic strategy which some women opt for. The surgical interventions require detailed counselling, as each has significant implications. For example, autologous fascial sling may necessitate the use of intermittent self-catheterisation (ISC) if voiding dysfunction were to arise. Colposuspension has a risk of inducing POP in another vaginal compartment, and if the prolapse is severe, another operation might be needed. AUS is an implant and requires activation of a pump component at the time the woman wishes to pass urine, so she has to manipulate that component placed within one of her labia majora at the time of the operation. Women discussing these options are likely to place different emphasis on the potential advantages and disadvantages of each. Hence, the structure of the study was to randomise between minimally invasive and surgical arms; if randomised to the surgical arm, the woman would be able to choose which specific operation she underwent.

Until recently, the most widely used surgical intervention was MUT. Complications resulting from this type of surgery led to their discontinuation from use in the NHS. Hence these were not included as an option in PURSUIT. However, if they had been reintroduced into practice during the recruitment time frame, the study was set up to enable their incorporation into the surgical arm, provided it was in line with regulated guidance.

The design followed extensive public and patient consultation. In practice, just under half of eligible women

were willing to take part, specifically 23 women were randomised of the 55 deemed eligible after screening. Achieving this comparatively high proportion necessitated careful approaches to supporting potential participants with carefully prepared information and documentation. There was also care to ensure the HCPs had equipoise, and that when they approached patients, they did not risk appearing to favour either arm of the study. Emphasising the importance of these crucial aspects in what was potentially a 'difficult to recruit to study', the trial included the QuinteT approach. The background experience of the QuinteT team led to the introduction of several adjustments, given that seemingly small factors can have considerable influence on a potential participant's view. Hence, the targets set for the feasibility phase appeared within reach.

The pandemic had a profound effect on all aspects of health care, and at its full height, the health crisis rendered the study undeliverable. The PURSUIT study researched a condition that rapidly declined in priority in light of the global healthcare challenges. Health services focused on emergency and cancer care, and people generally did not attend to seek treatment for conditions like stress incontinence. As the situation eased, services were slow to return to caring for benign conditions, and it became apparent that redeployment of staff to respond to the health crisis had depleted expertise in many areas of health care, including management of stress incontinence. When the study closed, 10/23 randomised participants were still on waiting lists to receive their allocated intervention, as waiting lists were negatively impacted by de-prioritisation of these procedures during the pandemic. The reduction in potential participants presenting, and the refocusing of health services, meant that the study could not be delivered and had to be concluded prematurely.

The challenge of recurrent stress incontinence remains; the best approach to managing this has not been identified, due to early closure of the PURSUIT study. There is nothing to suggest that the experience of women having stress incontinence surgery is any different now than it was before the pandemic, so this clinical question continues to be a high priority. Women experiencing this problem are still suffering consequences for their QoL, relationships and occupation. The limited amount of health economic information that was gathered highlighted patients' costs, including out-of-pocket expenses and ability to participate in numerous activities. Consequently, revisiting this protocol with a view to setting up the study again in the future may be appropriate.

No major modifications to the protocol emerged as desirable during the experience of running the PURSUIT study. The recruitment process would benefit from the experience gained, and access to patient-facing materials and training resources already developed. The QuinteT methods would be applied to encourage equipoise among clinicians. Co-operation between the urogynaecology and functional urology services would again be needed, but this was straightforward during the PURSUIT study. Up-to-date review of research on the topic, contemporaneous information on the number of women presenting and being treated for this problem, evaluation for any change in interventional technique possibilities, and scrutiny of any new information in collaboration with patient and public involvement (PPI) would be appropriate. While a challenging study to deliver, the circumstances may arise in the future, in which it could possibly be delivered.

Patient and public involvement

Due to the nature of the study population, the sensitivity of the problem being addressed and the need to ensure due consideration of the implications of the study, PPI in PURSUIT was crucial for its successful delivery.

The TMG had an experienced PPI member (and co-applicant) who is familiar with the care pathways of this patient group, and the Trial Steering Committee (TSC) had an independently nominated PPI representative. These oversight committee members were present at meetings throughout the duration of the study.

During the design phase, the study PAG was set up, including five members from both primary and secondary care. The PAG was chaired by the PPI co-applicant/TMG member. Discussions with the PAG, and additional discussions between co-applicant clinicians and individual women affected by recurrent SUI, were held.

Key messages from these discussions were:

- The PAG emphasised the overall importance of this topic due to the huge impact on women, families and healthcare services. This patient group has already experienced a protracted clinical course.
- Considering the prior history of long-standing symptoms and the distress associated with failed surgery, the group felt that this will be a difficult group of patients for research.
- The type of operation should be appropriate for the mechanism of the individual patient's recurrent SUI (some treatments are appropriate for one mechanism but not both).

- The lack of real evidence to inform therapy choice is a great concern, and each potential intervention carries significant aspects which would be very influential on the women's attitudes.
- All contributors had serious concerns about the widely known controversy of vaginal surgery using MUT and a randomisation structure, including MUT as one of the arms would not be acceptable; in an exercise of acceptability in which the PAG imagined themselves in the scenario of seeking recurrent SUI therapy, none of the contributors was willing to countenance a tape procedure.
- Colposuspension may have a prolonged recovery and risk of POP, leading to yet another operation; in the exercise of acceptability, the majority of PAG contributors would accept colposuspension, despite these concerns.
- Autologous sling may require the patient to use ISC, which potentially could be lifelong; in the exercise of acceptability, the majority of the PAG contributors would consider trialling ISC to consider how its potential impact could influence willingness for surgery.
- AUS uses an implant, has a risk of erosion, and when the woman wishes to pass urine, an AUS requires her to press a device component which is located in one of the labia; in the exercise of acceptability, the majority of the PAG contributors had concerns about the use of an AUS following a previous MUT (the likely main cohort to participate in the study).
- Randomising between surgical interventions is not acceptable due to the highly personal nature of the options and the potentially lifelong implications.
- Endoscopic intervention (urethral bulking injections) was considered safe, but the duration of effectiveness needs to be studied properly.
- The endoscopic intervention (urethral bulking) could appropriately be compared against the other interventions (surgical operations).

Thus, PPI input led to the fundamental approach of the entire study in randomising between endoscopic and surgical arms, and the ability for women to have some influence on the type of surgery they receive.

In the first 2 years of the study, during the set-up and recruitment phases, a further four meetings took place with the PAG to discuss the development of patient-facing materials, including the design of the study logo and the content of the participant information leaflet (PIL) and some of the study questionnaires. Input on the content of the PIL was critical to ensure clarity and avoidance of any potential ambiguity in the descriptions of consent, randomisation and the interventions. Feedback was also given on optimal ways to communicate information to the public and potential participants via a study website, X [X Corp. (formerly Twitter), San Francisco, CA, USA] account, video and newsletters. PAG meetings were organised and facilitated by an experienced PPI manager at North Bristol NHS Trust.

During the pandemic, newsletters and video conferencing were used to update the PAG on study progress. Changes were made to enable the study to continue, such as the introduction of electronic e-consent and remote study appointments. Feedback from the PAG enabled the changes to factor in key influences regarding their acceptability.

Overall, PURSUIT was strongly led by PPI input, which was informative and valuable, and influenced both the design and conduct of the study.

Equality, diversity and inclusion

We opened (and aimed to open further) recruiting sites across the UK to ensure that the participants taking part in the study were representative of the population affected by recurrent SUI. The PURSUIT PAG reviewed and supported the development of the PIL, study questionnaires and other patient- and public-facing materials to ensure that the language and terminology used was as clear and inclusive as possible. Consent to take part in the study could be provided by patients during a face-to-face clinic appointment or remotely during a telephone or video-call consultation to ensure as many eligible people as possible had the opportunity to take part. Participant questionnaires were designed so that they could be completed on paper (and returned by pre-paid post) or electronically, and participants were offered the option to complete questionnaires verbally with a researcher via telephone or video call if additional support was needed.

Of the 23 participants randomised, all described themselves as of 'white' ethnicity (*Table 1*). Ethnicity data were only collected from randomised participants, so it is not possible (with the current data set) to assess the lack of ethnic diversity in the recruited population or know whether the screened cohort (or those patients who were eligible and approached but declined participation) represented a more diverse population. Inclusive recruitment strategies that enable the participation of women from ethnic minority backgrounds as well as measures to document and monitor ethnicity data of women who are screened, eligible, approached and randomised would need careful consideration in any future trial of this population.

Impact and learning

The underlying design of the study appeared suitable for answering the research question, and no major concerns were expressed by PPI prior to or following commencement of the study, nor by participants who experienced the assessments and outcome measures. This suggests that this type of research is potentially possible for the clinical area.

Use of the QuinteT team to support women in their decision-making related to participation identified a clear need to reduce risk of clinician bias affecting potential participant recruitment.

Our qualitative interviews found that some women would not countenance receiving the same intervention if they were randomised into the relevant arm. If that was the case, they were not deemed eligible (did not meet the study inclusion criteria '*Patient willing to be randomised and willing to give consent*') for the study and so were not invited to participate. For other women, they could countenance it, and considered subsequent receipt of further treatment to be acceptable. This reflects that there were wide-ranging views expressed by potential participants, and that the decision is personal and individual, even more so than in many other surgical studies.

The health economic analysis successfully captured data for the modest number of patients recruited. It found a wide range of costs experienced by patients, and impact on social or occupational activities. Consequently, it is clear that there is potentially a high cost associated with the condition. However, the full elaboration of the cost, and benefit or otherwise of treatment, was not possible from the amount of information gathered.

The study was designed before the COVID pandemic, using data on the numbers of women presenting with recurrent or persisting SUI prevalent at the time. The major shifts in presentations and referrals associated with the pandemic mean that the assumptions used may no longer be valid.

Implications for decision-makers

Failure to move to the main study and therefore answer the primary research question means that no clinical recommendations can be made from the PURSUIT study. The need for an evidence base to inform practice in this problematic area remains, such that future research will need to be undertaken. Guideline panels need to emphasise the lack of an evidence basis, and it should be policy that any woman considering intervention for recurrent or persistent SUI receives effective counselling about potential outcomes.

Currently, it is not clear how many women are presenting with recurrent SUI and how many choose to avoid further healthcare contact for whatever reason. It is likely that patient numbers are down compared with pre pandemic, so that attempts to fund this type of research in future may require determined efforts to maximise identification of patients, increase the number of contributing centres and improve the way they invite people to participate. Both urology and urogynaecology need to work together at an organisational level to have a realistic chance of succeeding, and they need to engage the individual surgeons in order to achieve a united effort.

Research recommendations

The fundamental need for the information the PURSUIT study aimed to deliver remains. Accordingly, the following research recommendations are made:

- To assess the number of women being referred to secondary care with SUI as this may now be lower than pre pandemic. This is necessary before attempting to answer the following research recommendations.
- To identify whether surgical treatment achieves a superior symptomatic outcome compared to endoscopic bulking injection(s) treatment at 1 year or another key time point.
- To assess the longer-term clinical impact of the interventions on continence and lower urinary tract symptoms, procedure/operative measures, sexual function, the safety of each intervention, the likelihood of retreatment, women's experiences of interventions and associated QoL and clinician's views of interventions.
- To evaluate cost-effectiveness from both NHS and societal perspectives in the longer term.
- To understand influences on the likelihood and timing of presentation seeking HCPs' support for recurrent or persistent SUI.

Conclusions

Experience establishing the PURSUIT study indicated the protocol in which women were randomised to surgery or a minimally invasive treatment is potentially deliverable. In the circumstances in which the study took place, it was unable to recruit, and so closed early. A protocol involving randomisation between surgical interventions was not considered acceptable by our PAG. Various potential influences were identified, consideration of which could potentially facilitate delivery of an equivalent study in the future.

This synopsis should be referenced as follows:
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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

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

Ethical approval was obtained from the South West – Frenchay Research Ethics Committee (REC) on 24 October 2019 (reference number: 19/SW/0209) and applies to all NHS sites which took part in the study. Health Research Authority (HRA) and Heath and Care Research Wales (HCRW) approval was obtained on 19 December 2019.

Written informed consent (including electronic e-consent) was obtained, according to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice guidelines, from all patients who were eligible and agreed to take part before they entered the study.

Information governance statement

The Bristol Trials Centre (University of Bristol) and North Bristol NHS Trust are 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 Bristol Trials Centre (University of Bristol) and North Bristol NHS Trust are joint Data Controllers, 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 Officers here www.bristol.ac.uk/secretary/data-protection and www.nbt.nhs.uk/about-us/information-governance/privacy-policy-data-protection.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/AKAK8992.

Primary conflicts of interest: Stephanie J MacNeill is a member of HTA General Committee.

Tamsin Greenwell is a consultant for Boston Scientific and Abbvie; she is/has been a speaker for Abbvie, Axonics, Boston Scientific and Medtronic; ESGURS board member [European Association of Urology (EAU)], and member of the EAU Urethral Stricture Guidelines Committee; has received institutional grants/sponsorship to run the annual Female Urology and Urogynaecology Masterclass at University College London Hospitals (UCLH) from Abbvie, Axonics, Boston Scientific, June Medical, Laborie, Mediplus, Medtronic, Pierre Fabre, UroMedica and Vesica Urology; has received sponsorship from Medtronic for a Neuromodulation Fellow at UCLH (now replaced by the Medipoints system); has received an education grant from Laborie for an ICS-approved urodynamic study course at UCLH. She is current Chair of the United Kingdom Continence Society.

Hashim Hashim is a speaker for Astellas and Medtronic; a committee member of BAUS FNUU; an associate editor of Neurourology and Urodynamics and BJUI Compass journals. Has received institutional grants to run Medtronic courses on sacral neuromodulation and has received speaker fees from Medtronic for mentorship and lecturing. Hashim Hashim is chair of the ICS mesh complications working group and CI for NIHR UNBLOCS trial, co-applicant on PURSUIT, CATHETER II, TRIUMPH, and FUTURE.

Wael Agur has received trainer and speaker fees from CR Bard, Contura, NHS Ayrshire & Arran, and the London Medical Education Academy; sponsorship from Boston Scientific and Neomedic; expert fees from NHS Scotland and various law firms in the UK, Ireland, the USA, and Australia in relation to mesh litigation; and institutional research support as principal investigator for the SIMS Pilot, PROSPECT, and VUE studies, and as cochief investigator for PURSUIT study. Wael Agur was also a member of an All Party Parliamentary Group on surgical mesh.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Publications

Agur W, Pope C, Greenwell T, Athene Lane J, White A. Treating women with recurrent stress urinary incontinence: a Hornet's nest still needing proper clinical evidence. *Eur Urol* 2021;**79**:6–7.

Clark L, Fitzgerald B, Noble S, MacNeill S, Paramasivan S, Cotterill N, *et al*. Proper understanding of recurrent stress urinary incontinence treatment in women (PURSUIT): a randomised controlled trial of endoscopic and surgical treatment. *Trials* 2022;**23**:628.

Pope C, Cotterill N, Drake MJ, Fitzgerald B, Greenwell T, Jha S, *et al*. The importance of overcoming the challenges in delivering the Proper Understanding of Recurrent Stress Urinary Incontinence Treatment (PURSUIT) study. *Continence* 2022;**1**:100020.

Trial registration

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This synopsis provided an overview of the research award Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in women (PURSUIT): A Randomised Controlled Trial of Endoscopic and Surgical Treatment. For other articles from this thread and for more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/17/95/03).

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List of abbreviations

AE	adverse event
AUS	artificial urinary sphincter
BTC	Bristol Trials Centre
CI	chief investigator
CEA	cost-effectiveness analysis
CONSORT	Consolidated Standards of Reporting Trials
CUA	cost–utility analysis
DMC	Data Monitoring Committee
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
HCP	healthcare professional
HRQoL	health-related quality of life
ICIQ-UI-SF	International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form
ISC	intermittent self-catheterisation
ISRCTN	International Standard Randomised Controlled Trial Number
MUT	mid-urethral tape

NICE	National Institute for Health and Care Excellence
PAG	Patient Advisory Group
PGI-I	Patient Global Impression of Improvement
PI	principal investigator
PIL	participant information leaflet
PISQ-IR	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-IUGA Revised
POP	pelvic organ prolapse
PPI	patient and public involvement
PURSUIT	Proper Understanding of Recurrent Stress Urinary Incontinence Treatment
QALY	quality-adjusted life-year
QoL	quality of life
QRI	QuinteT Recruitment Intervention
QuinteT	Qualitative Research Integrated within Trials
RCT	randomised controlled trial
RN	research nurse
SUI	stress urinary incontinence
TMG	Trial Management Group
TSC	Trial Steering Committee

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Appendix 1

Appendix for *Protocol*.

Methods for data collection and analysis

Inclusion criteria:

- Adult women (≥ 18 years) with bothersome SUI symptoms after primary SUI surgery (including bulking injections).
- Urodynamics to confirm recurrent or persistent SUI.
- Patient willing to consider interventional therapy.
- Patient willing to be randomised and willing to give consent.

Exclusion criteria:

- Predominant urgency incontinence.
- POP more than or equal to stage II.
- Relevant neurological disease, such as multiple sclerosis, Parkinson's disease or spina bifida.
- Being treated for gynaecological or bladder cancer.
- Unresolved mesh exposure from previous vaginal surgery.
- Current pregnancy.
- Urethral diverticulum.
- Recent pelvic surgery.
- Participation in another study that might influence results or increase patient burden.
- Unable to give informed consent/complete assessments.
- Previous AUS surgery.

Potentially eligible women were given the applicable PILs, and site staff discussed the study with them after at least 24 hours, obtaining consent, if eligible, and interested in participating.

Endoscopic bulking injections are also known as bladder neck injections and are done with a cystoscope to guide injection of bulking agents to the urethra under direct vision, to enhance its ability to close effectively. Sites used their usual urethral bulking agent (e.g. Bulkamid®, Deflux® and Macroplastique®), and repeat injections were permitted.

The interventions offered in the surgery arm were:

- Autologous fascial sling: a strip of the patient's own tissue (fascia) placed to compress the urethra.
- Colposuspension: the anterior vaginal wall is repositioned to support the urethra.
- AUS: an implanted cuff is used to compress the urethra. The compression can be released by pressing on a component in the vaginal labium, allowing the woman to pass urine.

The type of surgical intervention received by participants in the surgical treatment arm was decided following discussion between the patient and their surgeon, as per usual local practice. MUTs were not offered, due to restrictions in their use. In the event of a change in the restrictions, the rules relevant at the time were to be used.

Standard clinical assessments were done in accordance with NICE NG123 guidance,[30] including urodynamics. As well as diagnosing the type of incontinence, the tests were used to ascertain what type of surgery would be suitable for each participant if she entered the 'surgical' treatment arm at the subsequent randomisation.

For any patients requesting to cross over from their randomised treatment allocation to the alternative, the

crossover treatment was delayed until after the primary outcome was recorded at 1 year, though in practice the timing of any crossover intervention could not be imposed. Participants were able to withdraw from involvement in the trial, without affecting their usual care.

Primary outcome measure

The primary outcome was the patient-reported outcome measure of continence using the ICIQ-UI-SF[4] at 1 year post randomisation.

Secondary outcome measures

- Longer-term clinical subjective measure of continence at 6 months and 2 and 3 years post randomisation (ICIQ-UI-SF).
- Improvement of symptoms at 1, 2 and 3 years post randomisation [Patient Global Impression of Improvement (PGI-I) questionnaire].[31]
- Procedure/operative assessment measures collected at the time of intervention and at 6 months post intervention: procedure/operation time, estimated blood loss, hospital stay, return to normal activity.
- Assessment of sexual health at 1, 2 and 3 years (PISQ-IR).[32]
- The safety of each intervention adverse events (AEs) and the likelihood of retreatment assessed at intervention, 6 months post intervention, and 6 months and 1, 2 and 3 years post randomisation.
- Cost-effectiveness from NHS and societal perspectives at 1 year post randomisation in terms of QALYs and ICIQ-UI-SF at 1 year, and from a secondary care perspective in terms of QALYs at 3 years post randomisation. QALYs were calculated from EuroQol Group's five-dimension health status questionnaire EQ-5D-5L.[33]
- Secondary care resource use was abstracted from Trust electronic systems (or Hospital Episode Statistics) at 1 and 3 years post randomisation. Other resource use was collected by questionnaires at 6 months and 1 year post randomisation.
- Patient experiences of the intervention at 6 months, 1 year and 3 years post intervention (qualitative interviews with patients).
- Clinician views of the intervention at, or around, baseline (qualitative interviews with clinicians).

A local RN or trained delegate (or member of the central trial team) randomised patients using the online or telephone randomisation system. Randomisation was done after eligibility was confirmed, written consent obtained, and the patient had at least 24 hours to consider the study information and had any questions answered. Once a participant was randomised, they were 'enrolled' in the study and were added to the appropriate procedure of waiting list (as per usual local clinical practice) to enable treatment to proceed.

Due to the nature of the interventions, participants and those administering the interventions were not blinded to group allocation. Nor were the supporting clinical and site staff, to ensure relevant data collection. The senior statistician co-applicant was blinded throughout the trial. The second trial statistician performed all disaggregated analyses according to a pre-specified statistical analysis plan and attended closed DMC meetings as required. The health economist(s) was blinded when cleaning data, but unblinded when conducting the analysis. Other members of the study team were blinded to aggregate data, but not necessarily to individual participant data.

A RN, or other delegated site staff member, completed a study-specific case report form at each appropriate study time point. Data were entered directly into a password-protected REDCap (Vanderbilt University, Nashville, TN, USA) database.[29] All research data will be retained in a secure location for at least 5 years after the end of the trial. At the end of the archiving period, data will be destroyed by confidential means, with the exception of a final trial data set, which will be made available for data-sharing purposes. The approval of North Bristol NHS Trust as owner of data and study sponsor, as well as the CI, will be sought prior to destruction of the data.

Statistical methods for primary and secondary outcomes

The following section summarises the intended analysis plans that were based on obtaining a complete data set. All analyses and reporting will be in line with CONSORT guidelines.[5] Primary analyses will be performed on the intention-to-treat basis, analysing women in the groups to which they were randomised. Descriptive statistics will be used to summarise characteristics of patients and compare baseline characteristics between groups. Means and SD will be used for continuous outcomes or medians and IQRs if required for skewed data. Categorical variables will be summarised using frequencies and proportions. Patient-reported outcome scores based on standardised questionnaires will be calculated based on the developers' scoring manuals and missing erroneous items will be handled according

to these manuals. Secondary analyses will adjust for any prognostic variables showing a marked imbalance at baseline (ascertained using descriptive statistics). The patient-reported outcome measure, ICIQ-UI-SF, at 1 year post randomisation is the primary outcome. Comparisons between treatment arms will be made using a multivariable linear model with random effect for site to account for within-site correlation. The model will adjust for baseline ICIQ-UI-SF scores. The underlying assumptions of the model will be checked, and analyses adjusted accordingly. The primary analyses will be based on the observed data, and a sensitivity analysis will be conducted, where missing data are imputed using appropriate methods based on patterns of missingness.

For secondary outcomes, continuous measures will be studied in the same manner as the primary outcome, and ordered categorical variables will be studied using ordinal logistic regression. Where outcomes are measured at multiple time points post randomisation, repeated measures analyses will be used to examine whether treatment effects are sustained, diminished or emerged later. These will be investigated formally by introducing an interaction term between treatment arm and time. All models will adjust for the outcome at baseline. Surgical outcomes will be described using descriptive statistics for those women allocated to the surgical arm, and no formal comparisons will be made between surgeries. An independent DMC will review confidential accumulating data at its discretion, but at least annually. No interim statistical analyses by study arm are planned.

All primary analyses will adjust for the outcome as measured at baseline. Secondary analyses will adjust for any prognostic variables demonstrating marked imbalance at baseline as determined using descriptive statistics.

A small number of pre-defined subgroup analyses will be done to assess whether the difference in ICIQ-UI-SF at 1 year between the two treatment arms differed according to baseline characteristics, including age. Effect modification will be assessed by including an interaction term in the regression model, and formal tests of interaction will be performed.

Trial management

A TMG had responsibility for the day-to-day management of the trial and reported to the TSC, which had an independent chair plus three additional independent members (a clinician, a statistician and an independently nominated PPI representative). Terms of reference for the TSC were reviewed and agreed by all members of the committee. A DMC monitored accumulating trial data for quality, completeness and patient safety. The DMC had an independent chair, two other independent members with expertise in trials and statistics, and gynaecology and urology and the CI. Responsibilities and reporting mechanisms of the DMC are detailed in the DMC charter.[34] The study was monitored in accordance with the sponsor's monitoring standard operating procedure, in line with the UK Policy Framework for Health and Social Care Research.

Adverse events

Adverse event data were collected and assessed throughout an individual's participation in the study as secondary outcomes. The PI at each participating site (or appropriate delegate) was responsible for categorising whether AEs were serious, expected and related. Serious and non-serious AEs, reported by the participant or research teams, were reported in accordance with the Good Clinical Practice guidelines and the sponsor's research-related AE reporting policy. Events that could be expected during/after any surgery, or within this patient population, are listed below:

- anaesthetic complications, for example, stroke or cardiac events, such as myocardial infarction
- operative injury to adjacent structure
- fistula
- return to theatre
- intensive therapy unit (ITU) admission
- new urinary tract symptoms
- urinary tract infection
- wound infection
- POP
- urinary retention/catheterisation (ISC and indwelling)
- pain
- implant exposure (tape, AUS)
- incisional hernia
- deep-vein thrombosis/pulmonary embolism
- bleeding/haematoma/blood transfusion
- chest infection
- new sexual problems, for example, dyspareunia
- other infections (sepsis, septicaemia, abscess, respiratory)
- inflammation, for example, osteitis pubis
- death.

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Appendix 2

Appendix for *Statistical analysis*.

TABLE 11 Summary of opened sites

Site	Date open to recruitment	Number of women consented	Number of women randomised	Number withdrawn (post randomisation)	Number receiving allocated intervention
North Bristol NHS Trust	January 2020	6	6	0	4
Birmingham Women's and Children's NHS FT	February 2020	4	4	0	3
NHS Ayrshire & Arran	February 2020	3	3	1	1
Sheffield Teaching Hospitals NHS FT	November 2020	1	0	0	0
Cambridge University Hospital NHS FT	January 2021	3	3	0	2
South Tees Hospitals NHS FT	July 2021	0	0	0	0
Stockport NHS FT	September 2021	0	0	0	0
Mid and South Essex NHS FT	October 2021	2	2	0	1
Bedfordshire Hospitals NHS FT	October 2021	2	2	1	0
Royal Cornwall Hospitals NHS Trust	November 2021	0	0	0	0
Liverpool Women's NHS FT	December 2021	0	0	0	0
Bradford Teaching Hospitals NHS FT	December 2021	1	1	0	0
East Lancashire Hospitals NHS Trust	January 2022	0	0	0	0
Northern Care Alliance	March 2022	0	0	0	0
Leeds Teaching Hospitals NHS Trust	March 2022	2	2	0	0
Total	15	24	23	2	11

FT, foundation trust.

TABLE 12 Reasons for ineligibility among women with recurrent SUI assessed by clinical staff (*n* = 192)

Exclusion criteria	Number of women excluded (% of those excluded)
Predominant urgency incontinence	48 (25.0)
POP more than or equal to stage II	37 (19.3)
Relevant neurological disease	7 (3.6)
Being treated for gynaecological or bladder cancer	0 (0)
Unresolved mesh exposure from previous MUT	1 (0.5)
Current pregnancy	0 (0)
Urethral diverticulum	3 (1.6)
Recent pelvic surgery (within the last 6 months)	6 (3.1)
Participation in another study	0 (0)
Previous AUS surgery	0 (0)
Does not want to be randomised	22 (11.5)
Unable or unwilling to give informed consent	0 (0)
Unable or unwilling to complete assessments or trial procedures	8 (4.2)
Other[a]	60 (31.3)
Total	192

a This category incorporates a range of responses, including 'no reason given' (*n* = 16), 'overactive bladder' (*n* = 13), 'unable to have further bulking if randomised' (*n* = 2), 'gastric bypass planned' (*n* = 2) and 'does not want treatment at this time' (*n* = 3). For each of the following, one woman had these exclusion criteria: 'reduced bladder capacity, detrusor overactivity', 'poor voiding and detrusor overactivity', 'surgery not required', 'urodynamics showed isotonic D.O. (detrusor overactivity)', 'had previous diagnosis of isotonic detrusor overactivity', 'patient receiving treatment elsewhere and wants to remain there', 'D.O. on urodynamics', 'mixed incontinence on urodynamics', 'urodynamics not done', 'very mild stress incontinence', 'lives abroad', 'opted for bulking', 'not suitable for SUI treatment at this time', 'opted for colposuspension', 'awaiting mesh removal', 'recurrent urinary tract infections', 'clinician discretion', 'repair of childbirth injury', 'interstitial cystitis', 'MUI (mixed urinary incontinence) and OAB (overactive bladder)', 'urethral cyst', 'pessary/cystoscopy', 'rectocele stage II' and 'Fenton's procedure'.

This synopsis should be referenced as follows: Pope C, Cochrane M, Clement C, Liu Y, Paramasivan S, Noble S, *et al.* Challenges to overcome in a randomised trial for Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in women: the PURSUIT RCT [published online ahead of print July 2 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/AKAK8992

TABLE 13 Women's reasons for declining (*n* = 22)

Reason	Number of women reporting (% of those declining)
Wants a preferred treatment	14 (63.6)
No reason given	3 (13.6)
Lost to follow-up	2 (9.1)
Not interested in research	1 (4.5)
Referred for physiotherapy	1 (4.5)
Not wanted to travel if randomised to surgery	1 (4.5)

TABLE 14 Patient-reported outcome and resource use data completeness

	Time point			
Outcome	Baseline	6 months	1 year	2 years
Number of patients reaching follow-up	23	16	12	4
Number of questionnaires returned	23 (100%)	13 (81.3%)	10 (83.3%)	3 (75%)
ICIQ-UI-SF	23 (100%)	13 (81.3%)	9 (75%)	3 (75%)
EQ-5D-5L	23 (100%)	13 (81.3%)	10 (83.3%)	3 (75%)
PGI-I	[a]	[a]	9 (75%)	3 (75%)
PISQ-IR	19 (82.6%)	[a]	6 (50%)	3 (75%)
Community-based NHS resource use, patient out-of-pocket expenses and productivity losses	23	12	10	0
NHS secondary care	0	0	0	0
Qualitative interviews (*n* = 2 total)	1	1	–	–

a Outcome not collected at this time point.

Appendix 3

Appendix for *Health economics*.

TABLE 15 Resources collected and their valuation

Resources	Unit cost (£)	Source of unit cost
GP surgery visit	38.00[a,b]	Unit Costs of Health and Social Care 2022 Manual[35]
Continence nurse surgery visit	13.43[b,c]	Unit Costs of Health and Social Care 2022 Manual[35]
Visits to see urologist at a community urology services (i.e. outside of a hospital)	173.66[d]	2021/22 NHS National Cost Collection Data[36]
Other HCPs' surgery visit	13.43[b,c]	Unit Costs of Health and Social Care 2022 Manual[35]
GP home visit	95.24[a,b,e]	Unit Costs of Health and Social Care 2022 Manual[35]
Other HCPs' home visit	21.45[e,f]	Unit Costs of Health and Social Care 2022 Manual[35]
Online consultation in primary care	41.13[g]	Unit Costs of Health and Social Care 2022 Manual[35]
Online or telephone appointment with hospital consultant	131.69[d,g]	2021/22 NHS National Cost Collection Data[36]

a Excluding direct care staff costs.
b Including qualifications.
c For incontinence nurse and other HCP at GP surgery assume practice nurse costs. Duration is based on the assumption of a 15.5-minute consultation, as reported for a practice nurse in earlier unit cost series by Curtis and Burns (2015, p. 174).[37]
d Non-admitted, non-face-to-face, first consultation.
e Based on the assumption of a 11.4-minute home visit and 12 minutes of travel, as reported in earlier unit cost series by Curtis and Burns (2015, p. 176).[37]
f Assumed unit cost for Band 6 district nurse, Jones *et al.* (2022, p. 59).[35]
g Average for all initial primary care online consultations in Jones *et al.* (2022, p. 68).[35]

TABLE 16 NHS healthcare services resource use in the last 6 months because of urinary problems

Resource use	6 months	1 year
Mean number of packs of NHS-provided incontinence pads/pants	2.00 (6.92)	0
Number of patients who used an indwelling catheter for less than a month	1/12	0/10
Number of patients who used an indwelling catheter for 1–2 months	1/12	1/10
Number of patients who used intermittent catheter for less than a month	1/12	2/10
Number of patients who used intermittent catheter for 1–2 months	0/12	1/10
Number of patients prescribed any medication by GP because of urinary problems	4/12	3/10
Number of patients who used a prescription pre-payment certificate	0/12	0/10

TABLE 17 Patients' days off work in the last 6 months because of urinary problems

	6 months (n = 12)	1 year (n = 10)
Resource use	Mean (SD)	Mean (SD)
Days off work in the last 6 months due to urinary problems, not paid	0	0
Days off work in the last 6 months due to urinary problems, paid	0	1.20 (3.79)

Appendix 4

Appendix for *QuinteT Recruitment Intervention (QRI)*.

PURSUIT **Tips for recruitment and informed consent in the PURSUIT study**

This document includes tips and suggestions that can help with recruitment and informed consent to the PURSUIT study. These are drawn together from wider research by the QRI team and tailored to PURSUIT (some parts are drawn from data collected in PURSUIT). Phrases provided are suggestions that we hope you can adapt to suit your own style. The recruitment study team in PURSUIT would like to further customise the information with PURSUIT-specific data. To help us with this, **please record consultations with patients leading up to their study participation decision,** providing they are happy for you to do so. This gives us an insight into how study information is conveyed to patients and how they respond so we can feed back tips to recruiters and share good practice for effective recruitment.

Introducing the study

- Establish uncertainty and the need for the study early on.
  - E.g. *'We don't know whether endoscopic bulking injections or surgery is best for women with recurrent stress urinary incontinence so we're doing a study called PURSUIT to find out.'*
- Present the study confidently.
  - E.g. *'It's a national study aiming to answer an important question for the NHS that will determine the best type of treatment for future patients.'*
- Be mindful to convey and maintain equipoise throughout.
- Avoid the term 'trial' and use the more neutral term 'study' instead.

Balancing the procedures

- It works well to request patients to *keep an open mind* on the interventions until all information is heard.
- Emphasise that the treatments are well-established, common procedures.
  - E.g. *At [centre], both endoscopic bulking injections and surgery are well established, commonly performed, and good approaches for the treatment of recurrent stress incontinence, but there hasn't been a big reliable study comparing them to tell us which one is better.'*
- Present balanced information about both types of procedures.
  - Spend similar amounts of time discussing the benefits and drawbacks of each, and balance one against the other. Start with the procedure you are less familiar/comfortable with.
  - Avoid loaded terminology to explain the treatments *(e.g. 'gold standard', 'experimental', 'permanent', 'high success rates vs. low success rates', 'may not work/may not cure').*
- Engage with patients' concerns/preferences.
  - An indirect, open question early on will help elicit concerns or preferences *(e.g. What were your thoughts when you first heard about the study?').*
  - Gently find out the reasons why a patient prefers/is concerned about one option over the other. This will enable you to correct any misunderstandings, balance their views and ensure they understand both treatment options well enough to make an informed decision.
  - Remind the patient at the end of the discussion that regardless of which type of treatment they are allocated, they will be treated with the best possible care by an experienced doctor.

Explaining how treatment will be decided

- Explain the rationale for randomisation.
  - E.g. *'As we do not know which treatment is best, we need to compare them fairly to get a reliable answer. We use a process called randomisation to do this.'*
- It is best to avoid terms such as 'toss of a coin' or 'throw of the dice' or 'decided by a computer' to explain randomisation. Instead, explain that if the patient were to join the study, they would have an equal chance of having endoscopic bulking injections or surgery.
- Cover the key points: (1) we want to compare the two treatments as we don't know the best treatment option, (2) we want a fair comparison of treatment groups, (3) the process to achieve this is randomisation, as it produces comparable groups; it ensures the only difference between the two groups is that one group had endoscopic bulking injections and the other had surgery. It also means neither the patient nor the doctor can choose which one you have, and (4) you have an equal chance of receiving either endoscopic bulking injections or surgery.
- Explain that if they are randomised to the surgery arm, they will be able to decide alongside their doctor which of the surgical options is appropriate and acceptable to them.

Closing the consultation

- Ask the patient: '*what are your thoughts so far?*' This will enable you to further assess understanding, correct any misconceptions and balance views to ensure the patient is making a well-informed decision.
- Provide clear information on next steps whether or not the patient agrees to participate in PURSUIT.

FIGURE 4 Tips for recruitment.

Appendix 5

Appendix for *Qualitative interviews*.

Interview discussion topic guide

Baseline

- Background and general health.
- Health-seeking drivers.
- Previous treatment experience and perceptions of effectiveness.
- Product usage.
- Perspectives on both endoscopic and surgical treatment options – what would they like/expect to be offered.
- Expectations regarding outcomes; determinants of satisfaction.

Follow-up (3–6 months post treatment)

- Perspective on treatment received.
- Positive and negative aspects of the treatment, including pain, post-procedure recovery, associated symptoms, symptom improvement or deterioration, new onset symptoms.
- Return to activities and daily life impact.
- Product usage.

Long-term follow-up (12 and 36 months following delivery of the treatment)[a]

- Long-term perspective on treatment received.
- Symptom status
- Comparison with expectations, positive and negative aspects of the treatment.
- Product usage.
- Desire for further treatment.
- Requirement for coping strategies.
- Would they advocate the procedure?
- Satisfaction with symptom status.

FIGURE 5 Interview discussion topics. a, No interviews were conducted at the long-term follow-up point.