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ORIGINAL ARTICLE

Compliance with Uresta (CURE) study; a 12 month follow-up of 40 women

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Abstract

Introduction and hypothesis The Uresta bladder support is an effective management option for women with stress urinary incontinence (SUI), however, there is a lack of data assessing long-term compliance. The aim of this study was to assess compliance at 12 month follow-up in women using the Uresta bladder support for exercise related SUI.

Methods This was a prospective study advertised on social media, running clubs and gyms. Participants were fitted with a Uresta bladder support and followed up over a 12 month period. Power calculation recommended a sample size of 43. Ethical approval was obtained. Outcomes were assessed using the PUQ, ICIQ-FLUTS, UDI-6, IIQ-7, QUID and PGI-I questionnaires.

Results Forty-six women were recruited with an average age, BMI and parity of 42, 24 and 2.3 respectively. The most common activities were running (48%) and CrossFit (22%). Six participants withdrew after 2 weeks. Compliance was 90% at 12 months (n=40). Uresta insertion and removal was 'okay', 'easy' or 'very easy' for 86% and 75% respectively. Leakage was improved (n=13), greatly improved (n=12) or stopped (n=5) for 83% of participants, 75% were 'much better' or 'very much better' on the PGI-I scale, and 94% would recommend Uresta to a friend. There were no adverse events.

Conclusions The Uresta bladder support is a safe, effective, user-friendly management option for women who experience SUI during exercise with excellent long-term compliance. Further studies are required to identify predictors of successful fitting and efficacy, compare outcomes with different devices, and develop a validated questionnaire assessing SUI with exercise.

Keywords stress urinary incontinence · Uresta bladder support · compliance

Introduction

Stress urinary incontinence (SUI) has been shown to affect almost half of women who attend gyms or exercise classes [1, 2]. Women who continue to exercise or take part in sporting activities may describe discomfort, reduced levels of enjoyment, embarrassment and loss of confidence. Women who avoid exercise may develop weight gain as well as deterioration in general health and mental well-being [3].

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Vaginal devices are an appropriate management option for this cohort of women, especially those who wish to avoid surgery for incontinence. Vaginal devices are thought to prevent urinary leakage by providing mechanical support to the urethra and bladder neck [4]. They may be reusable or disposable and are designed for independent use. In the UK, vaginal devices are recommended as one of the first-line management options for SUI [5] however, evidence to support their use remains relatively weak [6]. In the UK, Contiform, Diveen, Efemia and Incostress incontinence devices are available on prescription and a plethora of other devices are available to purchase online. This can provide a challenge for patients and clinicians in terms of choosing or recommending a particular device.

The Uresta bladder support (Fig. 1) is a reusable rubber device that has been shown to be successful, cost-effective and user-friendly [7, 8]. The device has a

Fig 1. Uresta bladder support

narrow tip designed to allow easy insertion, and a small moulded handle at the base to assist removal. The device is designed to 'self-position' following insertion so that he wide base supports the urethra. A Uresta set includes three sizes (3, 4, or 5) with a smaller (size 2) or larger (size 6) available individually if required. Of 21 women successfully fitted in the Farrell et al study [7], 79% reported insertion as 'okay', 'easy' or 'very easy', 69% reported removal as 'okay', 'easy' or 'very easy', 66% were satisfied and 76% indicated they would continue using it after 1 year.

Lovatis et al investigated Uresta in a single blind randomised controlled trial [8]. Thirty-six women were randomised to Uresta or placebo (silastic ring in upper vagina). The primary outcome measure of 50% or greater reduction in pad weight was achieved in 67% in the Uresta group compared with 22% in the control group. Whilst this study confirmed objective effectiveness of the Uresta bladder support, the authors recommended further studies are required to assess subjective outcomes and long-term patient satisfaction. The aim of our study was therefore to evaluate subjective efficacy and long-term compliance with the Uresta bladder support in women who report SUI during exercise or sporting activities.

Materials and methods

This was a prospective study of the Uresta bladder support in women who reported SUI during exercise. The study was advertised through social media channels (Facebook, Twitter and Instagram) and posters in running clubs and gyms. The study protocol and consent process was approved by the regional Research Ethics Committee. The inclusion and exclusion criteria are listed in Table 1. Demographic characteristics were recorded including; age, parity, body mass index kg/m^2 (BMI), menopausal status, previous incontinence or prolapse surgery, previous trial of a vaginal device and previous pelvic floor muscle training (PFMT).

Participants were provided with a study information leaflet, completed a consent form, had a BMI calculation and completed baseline symptom questionnaires; ICIQ-FLUTS, urinary distress inventory (UDI-6), incontinence impact questionnaire (IIQ-7), and the questionnaire for urinary incontinence diagnosis (QUID). ICIQ-FLUTS is a validated questionnaire evaluating female lower urinary tract symptoms [9]. UDI 6 and IIQ-7 are validated questionnaires assessing the impact of incontinence on quality of life [10, 11]. QUID is a validated questionnaire used to distinguish between urge and stress incontinence [12].

Participants who met the inclusion criteria proceeded to a vaginal examination, performed by the senior author, to assess pelvic floor muscle strength (Oxford score) and to examine for evidence of atrophic vaginitis and pelvic organ prolapse which were exclusion criteria. Initial sizing and fitting was completed by the senior author. Correct positioning was confirmed by asking the participant to stand and perform a Valsalva manoeuvre. Participants were instructed on insertion and removal and asked to demonstrate this independently. Participants who were unable to self-manage the device were withdrawn from the study.

Participants were followed up after two weeks to assess for adverse events, compliance and success. If the device

Table 1 Inclusion and exclusion criteria

Inclusion criteria
• Significant stress incontinence during exercise (defined by a response of 'most of the time' or 'all of the time' to the ICIQ-FLUTS question 'Does urine leak when you are physically active, exert yourself, cough or sneeze?'
• Age over 18 years.
Exclusion criteria
• Significant urge incontinence (defined by a response of 'sometimes', 'most of the time' or 'all of the time' to ICIQ-FLUTS question 'Does urine leak before you can get to the toilet?')
• Body mass index ≥30 kg/m^2
• Previous incontinence surgery
• Previous prolapse surgery
• Pelvic organ prolapse (POP-Q stage 2 or greater)
• Atrophic vaginitis
• Unexplained vaginal bleeding or discharge

was not effective (PGI-I response 'no change', a little worse', 'much worse' or 'very much worse') participants were given the option of trialling a smaller (size 2) or larger (size 6) Uresta bladder support if appropriate, otherwise the participant was withdrawn from the study. Participants also completed the Pessary Use Questionnaire (PUQ), which although not validated, provides a succinct assessment of ease of use, subjective efficacy, and compliance for women using a vaginal device to manage SUI during exercise [7]. Participants successfully fitted at the 2-week review were followed up by telephone at 6 and 12 months. Symptom questionnaires were repeated at the 12-month review. The primary outcome measure was compliance at 12 months.

Power calculation was based on the study by Farrell et al where of 21 women successfully fitted with Uresta, 76% (16/21) were still compliant at 12 months. Assuming 76% is the true proportion of women who are compliant with Uresta after 12 months, and allowing for a false positive rate of 5%, 28 subjects would give 90% power to detect whether compliance at 12 months is more than 50%. Allowing for dropouts, the sample size of 28 was inflated by 15 to allow a 34% discontinuation of pessary use at baseline, as was seen in the study by Farrell et al, therefore, the total sample size required was 43. Questionnaire data is described as the median value plus interquartile range and comparison analysis described using the paired *t* test.

Participants did not receive any financial incentive to take part however they were provided with a free Uresta bladder support and offered travel vouchers to attend for assessments. The study design was not influenced by the supplier or inventor of Uresta and the research team did not receive any financial reward for conducting the study. The study was conducted in a private clinic. Funding for room hire and nurse chaperone, as well as a supply of Uresta bladder supports, was provided by the UK supplier of Uresta.

Results

Forty-eight women attended for initial assessment of whom two were excluded (BMI ≥30 kg/m^2). Characteristics of the 46 women recruited are summarised in Table 2. Six women were withdrawn at the 2-week review and successfully fitted

Table 2 Characteristics of the study participants (*n*=46)

Characteristics	
Age (years) *	42.2 (sd 7.5; range 30-57)
BMI (kg/m 2) *	24 (sd 3; range 19-29
Parity *	2.3 (sd 1.1; range 0-6)
Post-menopausal, *n* (%)	4 (9)
Previous pelvic floor muscle training, *n* (%)	39 (85)
Previous vaginal device, *n* (%)	11 (24)
Prolapse; POP-Q stage 1, *n* (%)	10 (22)
No prolapse, n (%)	36 (78)
Pelvic floor muscle strength (Oxford score), *n* (%)	
0	2 (4)
1	5 (11)
2	9 (20)
3	17 (37)
4	11 (24)
5	2 (4)
Type of exercise, *n* (%)	
Running	22 (48)
Running, gym classes, weights	12 (26)
Cross-fit	10 (22)
Not specified	2 (4)
Uresta size, *n* (%)	
2 (extra- small)	3 (17)
3 (small)	7 (15)
4 (medium)	23 (50)
5 (large)	10 (22)
6 (extra-large)	3 (7)

*Mean value

participants (n=40) were followed up at 6 and 12 months (Fig. 2).

Compliance at 6 and 12 months was 100% (40/40) and 90% (36/40) respectively. There were no adverse events.

Fig. 2 Uresta bladder support in situ

Responses to the pessary use questionnaire (PUQ) at the 12 month review (Table 3), showed that Uresta insertion was 'okay', 'easy' or 'very easy' for 86% of participants and removal was 'okay', 'easy' or 'very easy' for 75%. When using the Uresta bladder support, incontinence was 'improved' or 'better' in 83% (30/36), and cured in 14% (5/36). The majority of participants (94%) would recommend Uresta to a friend and 81% (29/36) felt more confident about not leaking in public (Fig. 3).

Responses to the validated symptom questionnaires (ICIQ-FLUTS, UDI-6, IIQ-7 and QUID) are summarised in Table 4. At the 12-month review, statistically significant reductions were observed in all questionnaires compared with baseline scores. The PGI-I questionnaire at the 12-month review indicated 75% of participants felt 'much better' or 'very much better'.

Discussion

Our study has demonstrated that the Uresta bladder support provides an effective management option for women who report SUI during exercise with 90% compliance at 12-month follow-up. Research on incontinence devices is limited and has typically focussed on clinical parameters such as pad tests, rather than long-term compliance and

Table 3 Pessary use questionnaire

Baseline assessment (n=36) (missing data n=4)					
Leaking with pessary	Not changed 4(11%)	Slightly improved 6(17%)	Improved 2(6%)	Greatly improved 13 (36%)	Stopped 11(30)
Inserting pessary	Very difficult 2(6%)	Somewhat difficult 6(17%)	Okay 12 (33%)	Easy 8(22%)	Very easy 8(22%)
Removing pessary	Very difficult 2(6%)	Somewhat difficult 7(19%)	Okay 8(22%)	Easy 11(30%)	Very easy 8(22%)
More confidence in public	Never 3(8%)	Rarely 2(6%)	Sometimes 6(17%)	Usually 6(17%)	Always 19(53%)
Plan to continue use	No 2(6%)	Yes 34(94%)			
Would recommend to a friend	No 2(6%)	Yes 34(94%)			
12 month follow up (n=36)					
Leaking with pessary	Not changed 1 (3%)	Slightly improved 5 (14%)	Improved 13 (36%)	Greatly improved 12 (33%)	Stopped 5(14%)
Inserting pessary	Very difficult 3(8%)	Somewhat difficult 2 (6%)	Okay 12 (33%)	Easy 15 (42%)	Very easy 4 (11%)
Removing pessary	Very difficult 4(11%)	Somewhat difficult 5(14%)	Okay 9 (25%)	Easy 13(36%)	Very easy 5(14%)
More confidence in public	Never 1(3%)	Rarely 2(6%)	Sometimes 4(11%)	Usually 15(42%)	Always 14 (39%)
Plan to continue use	No 2 (6%)	Yes 34 (94%)			
Would recommend to a friend	No 2(6%)	Yes 34 (94%)			

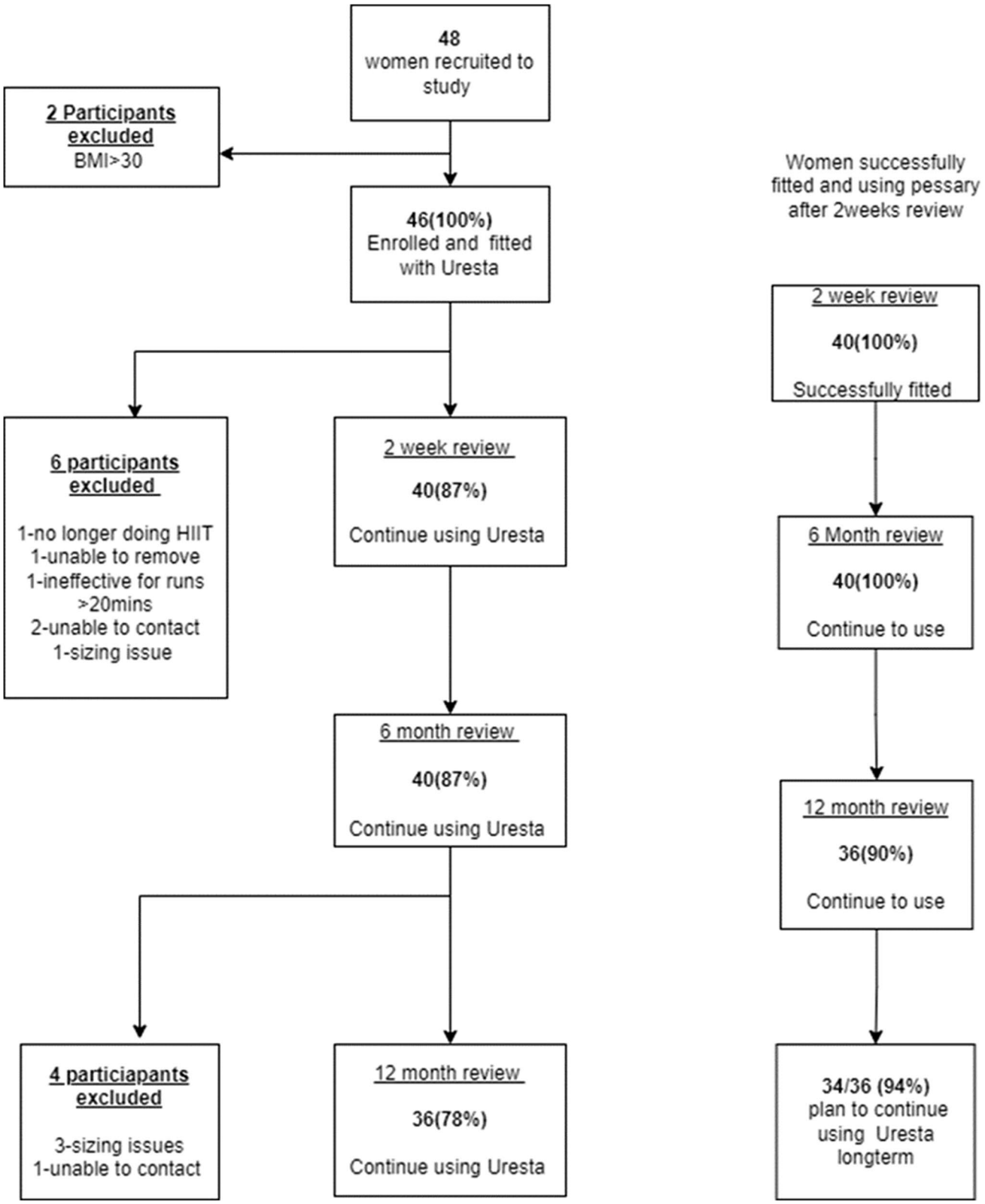

Fig. 3 Study flow chart

Table 4 Average outcome measures (PGI-I, ICIQ-FLUTS, UDI-6, IIQ-7, QUID)

PGI-I	2 week review (*n*=40)	6 month review (*n*=40)	12 month review (*n*=36)			
Very much better, *n*(%)	14 (39)	10 (29)	11 (31)			
Much better, *n*(%)	9 (25)	13 (38)	16 (44)			
A little better, *n*(%)	9 (25)	6 (18)	5 (14)			
No change, *n*(%)	4 (11)	5 (15)	4 (11)			
A little worse, *n*(%)	0	0	0			
Much worse, *n*(%)	0	0	0			
Very much worse, *n*(%)	0	0	0			
Missing data, *n*	4	6	0			
Questionnaires	Baseline	IQR	12 month review	IQR	% reduction	*P* value
ICIQ-FLUTS score	13.1	5.25	8.9	5	32	<0.001
UDI-6 score	31..8	13	18.5	12.5	42	<0.001
IIQ-7 score	34.8	22.5	21.6	19	38	<0.001
QUID Urge score	4.8	5	2.6	6	46	<0.001
QUID Stress score	8.3	5	7	5	16	<0.001

patient reported outcomes. Recent studies on Contiform [13], Diveen [14] and Efemia [15] followed up participants for just 4 to 6 weeks. A study on Incostress [16] attempted to follow up participants at 3 and 6 months but struggled to do so, with a third of participants lost to follow-up. Our study is the first to report long-term compliance as a primary outcome measure. Of the 40 women successfully fitted at the 2 week review, just one patient (3%) was lost to follow-up at 12 months. This may be related to the final face to face consultation having been replaced with a nurse-led telephone follow-up. This protocol change was necessary due to the covid-19 pandemic which restricted face to face consultations. This may have been more convenient for participants than travelling voluntarily for a face to face consultation and may also have avoided potential reporting bias had the participants attended a face to face consultation at the final review.

We recruited participants with the predominant complaint of SUI during exercise through targeted advertisements on social media, running clubs and gyms, whereas other studies have recruited participants attending incontinence clinics [13–16]. Women recruited from hospital clinics are perhaps more likely to have co-existing pelvic organ prolapse, previous incontinence surgery or other health issues. Through targeted advertisements, and with strict inclusion and exclusion criteria, we recruited a cohort of women who we consider are ideally suited to an incontinence device.

We recruited women with a diagnosis of SUI based on response to the ICIQ-FLUTS questionnaire rather than urodynamic studies. This may be considered a limitation of the study, however we felt invasive testing was an unnecessary risk to participants. Furthermore, a placebo controlled randomised controlled trial, utilising urodynamic studies and pad testing, has previously confirmed objective efficacy with the Uresta bladder support [8].

We excluded women with stage 2 or greater pelvic organ prolapse or previous incontinence or prolapse surgery as previous studies have identified these as risk factors for incontinence device failure [7, 17]. We excluded women who reported significant urgency on the ICIQ-FLUTS questionnaire. Other studies have excluded patients with significant urgency based on clinical history [15] or with urodynamic studies [7, 18]. We excluded women with a BMI >30 kg/m^2 as obesity is a risk factor for SUI and we felt it reasonable to assume obesity may be a risk factor for incontinence device failure. To our knowledge, impact of obesity on incontinence device efficacy has not been reported.

Farrell et al [7] reported higher rates of fitting failure in women with higher parity. We observed a similar finding in that participants who had failed fitting had a higher average parity of 3 compared with participants successfully fitted who had an average parity of 2. Assessment of parity and mode of delivery as predictors of successful fitting warrants further investigation.

Whilst objective assessment of improvement is an important aspect of 'success' with incontinence devices, ease of insertion and removal is equally important. A device that is effective and easy to use is likely to have better long-term compliance than a device that is difficult to insert and remove. Furthermore, devices that are safe, effective, easy to use and available to purchase online, could potentially relieve burden on healthcare systems by empowering women to self-manage their condition. Farrell et al were the first to investigate ease of use using the Pessary Use Questionnaire (PUQ) in women using the Uresta bladder support [7]. They reported 78% of participants found insertion 'okay', 'easy' or 'very easy' and 69% found removal 'okay', 'easy' or 'very

easy'. In our study, participants reported similar experience; 86% reported insertion as 'okay', 'easy' or 'very easy' and 75% reported removal as 'okay', 'easy' or 'very easy'. In a study of the Diveen device, 100% of participants reported ease of insertion and removal as 'average', 'good' or 'excellent' after 4 weeks [14]. Diveen is inserted like a tampon and removed by pulling on a string which explains why no participants had any difficulty with insertion or removal. In a study of the Contiform device, Allen et al reported 20% of recruited participants were unable to be fitted with the device due to sizing issues and of those successfully fitted, 13.5% were withdrawn due to insertion or removal difficulties [13]. By comparison, of the 46 women recruited to our study, one was withdrawn due to difficulty with removal. In a recent study on Efemia, 85% of participants rated the device as 'easy' or 'very easy' to insert or remove although follow-up was just 6 weeks [15]. The potential relationship between ease of use and long-term compliance with incontinence devices should be assessed with comparative studies.

After 12 months of using the Uresta bladder support, incontinence was 'improved' in 83% and 'stopped' in 14% (Table 3) with significant improvements across all symptom questionnaires (Table 4). Overall, 75% of participants felt their condition was 'much better' or 'very much better' on the PGI-I scale. Comparison of efficacy with other studies is limited due to variations in outcome measures that have been used. The Contiform study, reported 54% were dry on a 24-hr pad test although no subjective assessment of satisfaction was reported and 1 in 5 participants opted to proceed with surgical management at the end of the study [13]. By comparison, in the Diveen study, there was no significant difference with pad test results between the treatment and control groups, although there was significant improvement in global score of quality of life using a 0 to 100 visual analogue scale [14]. This reinforces the argument that 'success' with incontinence devices should be a composite measure including objective assessment, patient acceptability and long-term compliance.

Pelvic floor muscle training (PFMT) is recommended first-line management of SUI (NICE) [5]. In our study cohort, 85% had previously tried PFMT and 25% had previously tried an incontinence device. A previous study has listed PFMT as an exclusion criteria [14] whilst other studies have not mentioned PFMT at all [8, 15, 16]. We would advocate incontinence devices should be integrated alongside, or following, a course of PFMT rather than considered a separate treatment option.

We used validated symptom questionnaires to assess subjective efficacy with the Uresta bladder support. A limitation of these questionnaires is that they do not specifically assess the impact of incontinence devices on SUI with physical activity or exercise. For example, the ICIQ-FLUTS question 11a and UDI 6 questionnaires enquire about SUI during exercise but the question is framed along with 'coughing and sneezing', rather than exercise only. The IIQ-7 [11] and QUID [12] questionnaires are more specific asking, 'has urine leakage affected your physical recreation such as walking, swimming or other exercise?' and 'do you leak when you walk quickly, jog or exercise?'. The Pessary Use Questionnaire [7], although not validated, assesses important aspects of experience with an incontinence device during exercise including ease of use, efficacy and compliance.

In conclusion, we have reported that the Uresta bladder support is a safe and effective management option for women who experience SUI during exercise with excellent long-term compliance. Future studies should identify predictors of successful fitting with incontinence devices and compare the efficacy, ease of use, compliance and cost-effectiveness between different devices currently available. Furthermore, development of a specific, validated questionnaire assessing impact of SUI with exercise and impact of incontinence devices would be a valuable resource for future research in this area.

Authors' contributions Campbell: Protocol/project development, data collection, manuscript writing.
Moran: Data collection, data analysis, manuscript writing.
Boyle: Protocol/project development, data collection, manuscript editing.
Gallagher: Data collection.

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Declarations

Conflicts of interest None.

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