Management of Urinary Incontinence in Athletic Women: The POsITIve Feasibility Study

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Abstract

Objectives: To investigate the feasibility and acceptability of conducting a future trial of physiotherapy to manage urinary incontinence (UI) in athletic women.

Design: Feasibility study with nested qualitative interviews.

Setting: Community clinics: university and private.

Participants: Adult women who i) lived locally, ii) provided informed consent iii) self-reported UI iv) exercised at high/moderate intensity for over 150 minutes and over three times a week.

Interventions: Up to seven sessions of tailored physiotherapy delivered over 6-months. Despite some variation in prescription and progression, all programmes included elements of pelvic floor muscle training undertaken in clinic and at home.

Main outcome measures: Recruitment, eligibility of those screened, consent, data completion and attendance rates: assessed to determine feasibility of progression to a definitive trial. The acceptability of specific outcome measures, the intervention and of randomisation within a future trial was also examined.

Results: Direct recruitment of athletic women from sporting venues was feasible and acceptable. Most women not only consented to an intimate examination as part of the assessment but described this as an important part of the intervention. Attendance rates and data completion was generally high but the return of 3-day fluid charts was poor: this was also reflected in comments by participants that these were difficult to incorporate into daily life. The addition of a smartphone app to aid motivation and monitoring was welcomed but further education in its use may enhance compliance.

Conclusions: Direct recruitment from sporting venues was acceptable and feasible. Women valued assessment and treatment for UI.

Contribution of the Paper

- Recruiting athletic women directly from their sporting venue is both acceptable and feasible
- Inclusion of an intimate examination within the research is not a deterrent to women
- Women value the opportunity to access treatment for incontinence despite their history of ‘managing’ the condition

Keywords: urinary incontinence, female athletes, pelvic floor, physical activity, feasibility

Clinical Trial Registration Number: NCT03986411

Background

Urinary Incontinence (UI), involuntary loss of urine, is common, affecting nearly 40% of UK women [1]. Definitions include stress UI (SUI), association with impact or coughing and sneezing, urgency UI (UUI), association with increased desire to void, and mixed UI (MUI), a combination of both [2]. It is associated with obesity, childbirth and ageing [3] and yet the prevalence in young nulliparous female athletes is reported to be twice that of sedentary counterparts [4]. There is, as yet no definitive causation for the high rates of UI in the athletic population. However, suggestions are that impact and increased intra-abdominal pressures related to sport may weaken the pelvic tissues [5], yet some investigations report stronger pelvic floor muscles (PFM) in athletes [6] and others agree that the PFM are stronger but lack endurance [7].

There is robust evidence to support pelvic floor muscle (PFM) rehabilitation in the management of UI [8], and the National Institute of Health Care and Excellence (NICE) guidelines recommend 3-months supervised PFM training as treatment of SUI [9]. It is not yet known what the optimum PFM rehabilitation in the athletic population is despite consensus regarding the high prevalence of UI in this group [10-12], and there is little evidence to date regarding optimum management [13]. In the absence of a definitive aetiology, we propose that athletes with UI require specialist assessment and tailored PFM training (PFMT). We report results from a mixed-methods study (The POsITIve Study) [14] to investigate the feasibility of conducting a future trial to explore the physiotherapeutic management of UI in athletic women. We present data regarding recruitment methods, information about consent procedures, outcome measures, the acceptability of the intervention and the

retention of participants. This study will determine whether conducting a future definitive appropriately powered study in this area is feasible.

Methods

Design

The protocol has been published [14]. This was a feasibility study with nested qualitative interviews: a red, amber, green (RAG) format was developed to facilitate the decision for each objective on whether to progress to a future trial (Figure1).

Quantitative objectives	**Qualitative analysis**
Numbers recruited	Recruitment process
Proportion of those screened who were eligible	Intervention
Proportion of eligible participants who consented	Outcome measures eg questionnaires and fluid charts
Proportion of those enrolled who consented to intimate examination	Venues
Proportion of scheduled appointments attended	SqueezyCX smartphone app
Proportion of questionnaires returned at 3-months and 6-months	Prospect of randomisation in a future trial
Proportion of Fluid charts returned at 3-months and 6-months	

Figure 1 Objectives to determine the feasibility of progression to future trial

1) *Feasibility study*

Participants and recruitment

Inclusion criteria	**Exclusion criteria**
Female	New to sport or exercise within the last year
Adult	Pregnant or less than 1 year post-natal
Taking part in moderate to vigorous exercise for 150' or over and more than three times per week	Physiotherapy or continence advice within the last year
Self-report symptoms of Urinary Incontinence	Existing neurological conditions that may cause UI
	De nuevo oestrogen or anticholinergic treatment within the previous 3 months

Definitions

Urinary incontinence: leaking of urine associated with increased abdominal pressure such as impact, coughing, and/or sneezing, leaking associated with urinary urgency and will also include increased urinary urgency and/or frequency such that it is bothersome to the woman.

Moderate to vigorous exercise: defined by the UK Chief Medical Officers' report [15] page 10

Table 1 Summary of inclusion and exclusion criteria

Intervention

Explanation of the study procedures and the intervention was incorporated into an initial appointment, where consent was taken, questionnaires, log of sports-activity, 3-day fluid volume charts (FVC) and a sample pot for an MSU were given. At the second appointment, subjective assessment of obstetric and medical history and objective assessment of the PFM, via digital vaginal examination (DVE) was performed by an experienced specialist pelvic health physiotherapist (KGC). A tailored plan, derived from the assessment was agreed with each participant by the physiotherapist (KGC). This included elements of PFM training [16], both within the clinic and at home. Education both general and specific to their symptoms was given verbally and re-enforced within a standardised leaflet, based on the definition of physiotherapy in this area [16]. To aid compliance and to monitor adherence to the

programme, participants were offered the opportunity to download a smartphone 'app', 'SqueezyCX' [17].

Baseline measures to be repeated at 3-months and at 6-months
Short Urinary Distress Inventory (UDI 6) [18]
International Consultation on Incontinence Modular Questionnaire Female Lower Urinary Tract Symptoms Long Form Module (ICIQ-LUTS-lf) [19]
3-day Fluid Volume Chart (FVC)
Digital Vaginal Examination (DVE) of pelvic floor muscles to grade power and endurance via the modified oxford scale
Electromyography (EMG) to record PFM activity in standing for control and endurance

Table 2 Outcome measures recorded at baseline:2nd appointment and repeated at 3-months and 6-months

2) Interviews

Recruitment

Participants completing the feasibility study were invited for a semi-structured interview, to explore the acceptability of a range of factors (Figure 1). Initial written consent taken and further consent for recording taken at the start of the interview.

Procedure

Interviews were conducted by one researcher (FN), not involved in other aspects of the research. To ensure consistency, interview questions were developed initially between two researchers (FN and KGC), discussed within the research team and piloted with a PPI member of the steering group. Based on PPI feedback, the schedule was modified to include lay terms such as 'leaking'.

Emergent themes were noted and used to shape the semi-structured interviews going forward. To increase validity and minimise investigator bias, an investigator triangulation [20] was adopted involving other study researchers in the

analytical process. Interviews were digitally recorded, anonymised, transcribed in full and then checked for accuracy by the researchers.

Data Analysis

Descriptive statistics were used to analyse quantitative measures.

Transcriptions from the interviews were uploaded into the qualitative software package NVivo 12 and analysed using the framework approach [21]. Two researchers (FN and KGC) analysed the data independently before agreeing the resultant themes.

Impact of the COVID-19 pandemic

In March 2020, face-to-face contact for research was halted due to the COVID-19 pandemic and adaptions were made to encompass virtual contacts within the feasibility study and for interviews. Further ethical approval was obtained and all subsequent contact with participants was via video-link or telephone: consent was taken by email. It was not possible to continue with DVE or EMG. Questionnaires and fluid charts were adapted to be used digitally if the participants wished. Those that preferred to continue with paper versions were sent these by post with a return envelope.

Direct recruitment via gyms and sports clubs was no longer possible, and no further participants were recruited after this point. Three participants chose not to continue with the study: one citing COVID as the reason.

Results

Recruitment commenced in September 2019 and ceased 31st May 2020 (extended by 2-months due to COVID). Data collection ended 30th November 2020.

1) Feasibility Study

See Figure 2 for recruitment, consent, attrition and data completion.

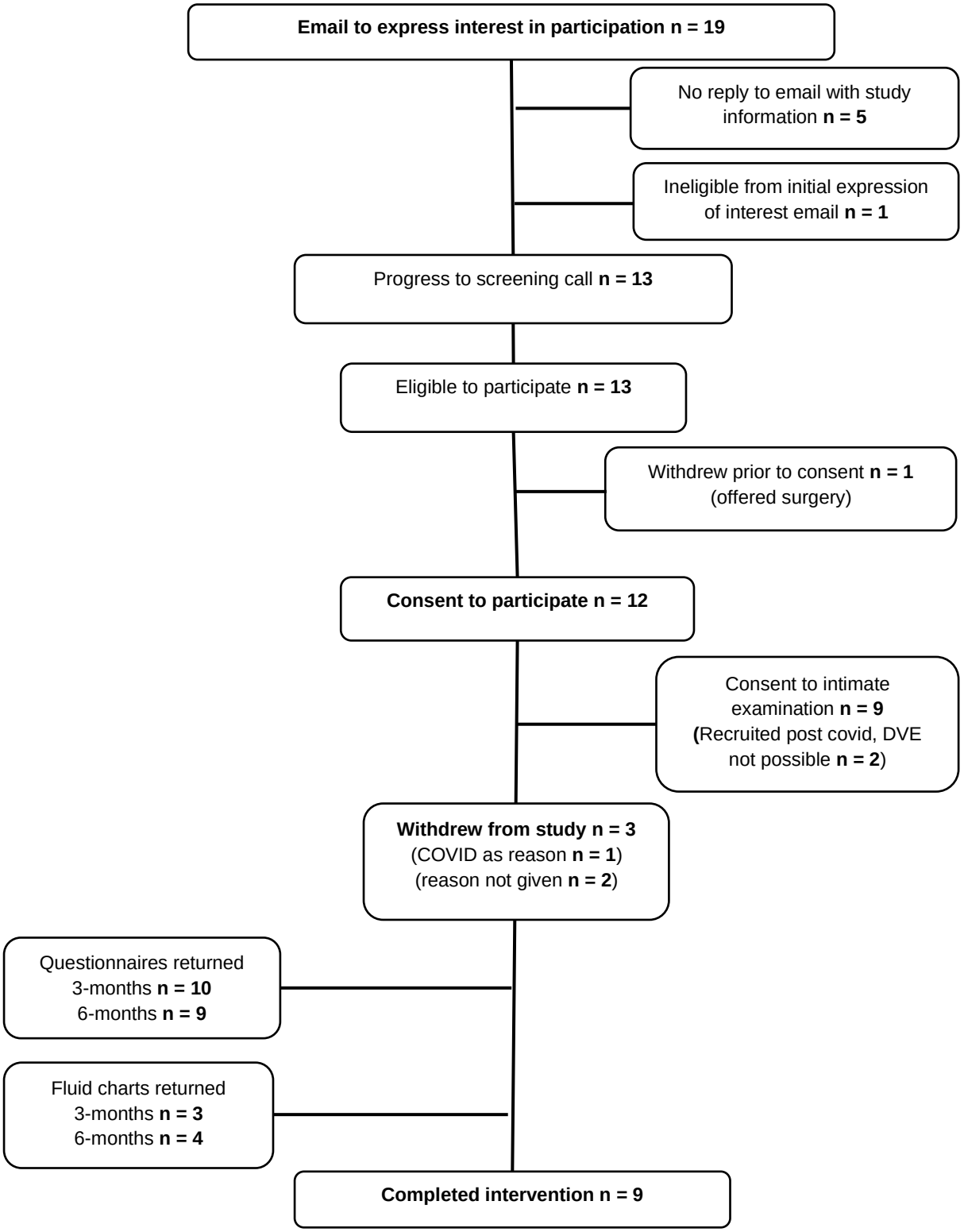

Figure 2 Flow chart of recruitment, consent, attrition and data completion throughout the feasibility study

Table 3 illustrates characteristics of participants.

Characteristic		
Mean age in years (S.D.) **Range**	47.6 (9.8) 33 to 62	
Stage of life n (%)	Pre-menopause Menopausal Post-menopause	5 (46) 4 (36) 2 (18)
Mean duration of symptoms in years (S.D.) **Range**	12.6 (8.1) 2 to 24	
Parity n (%)	Nulliparous Parous CS (4), Forceps (2), NVD (14)	2 (18) 9 (82)
Sport, weight bearing or non-weight bearing* n (%)	Weight bearing Running (4), Triathlon (1), Impact classes (3) Non-weightbearing Cycling (1), Swimming (1), Kayak (1)	 8 (73) 3 (27)
Urinary Incontinence Symptoms n (%)**	Mixed Urgency Stress	6 (55) 3 (27) 2 (18)

* Weight bearing and non-weight bearing sports are as defined in Groothausen et al [22]

** definitions of UI (4)

Urgency related UI: leaking associated with increased urgency or desire to void

Stress UI: leakage associated with physical exertion such as sports, coughing and sneezing

Mixed UI: a combination of the symptoms of UUI and SUI

CS – Caesarean Section, Forceps – assisted forceps delivery, NVD – normal vaginal delivery

Table 3 Characteristics of participants

Outcome measures

- Questionnaires UDI 6 and ICIQ-FLUTS-lf

See Table 4 for baseline, 3-months and 6-months results.

Outcome Measure	Baseline n = 11	3-Months n = 10	6-Months n = 9
UDI-6 (Higher scores reflect increased level of 'bother' with respect to symptoms)	Mean 31.1 (sd = 13.9) Range 12.5 - 50.0	Mean 18.6 (sd = 6.9) Range 8.3 - 29.0	Mean 12.0 (sd = 6.1) Range 4.2 - 25.0
ICIQ-FLUTS-LF (Higher scores reflect increased severity of symptoms and reduced QoL)	Mean 66.6 (sd = 21.8) Range 42.0 - 107.0	Mean 38.9 (sd= 26.0) Range 7.0 - 81.0	Mean 23.9 (sd = 14.0) Range 8.0 - 51.0

Table 4 Results of the questionnaires returned at Baseline, 3-Months and 6-Months

Both questionnaires reported on quality of life (QoL) or how 'bothersome' symptoms were. Higher results imply reduced QoL or increased 'bother'. All participants returned questionnaires as directed at each time point. Of those offered questionnaires and fluid charts in digital format 60 % (n=9) chose this option.

- FVC

All patients completed their baseline 3-day FVC but the return at subsequent time points was greatly reduced at 3-months (18%) and at 6-months (36%). Due to the low return rate, this data is not reported.

- Use of the 'SqueezyCX app'

Participants were offered the use of 'SqueezyCX 'a smartphone app both to motivate and to monitor adherence to PFM training. Ten participants downloaded the app, all reported using it and saving their results. However, the number of registered

users reduced to five by 6-months and mean adherence, initially 49% (n=10), reduced to 22% (n= 5) at 6-months.

2) Interviews

Of the nine participants who completed the feasibility study, six were interviewed: one did not wish to be interviewed and two, who agreed, did not return consent, despite prompting. Duration of interviews ranged from 26 to 34-minutes (M = 30, S.D.= 3.5,). Although all reported symptoms of UI lasting several years, (M = 14.2, S.D. = 7.8), only one had previously sought professional help. Four reported MUI, two UUI and one SUI.

Key themes from the interviews are presented under the headings: Recruitment; Intervention and intimate examination; Outcome measures; Venues; SqueezyCX App; Acceptability of being randomised into a future trial; Effects of UI on sport and life.

i. *Recruitment*

Direct targeting of participants via gyms and sports clubs was regarded as acceptable and appropriate. The majority felt their condition was not serious enough to bother their GP with, despite longevity of symptoms. Some further felt that, in agreeing to participate in the study, they were less likely to be turned away than if they had presented to their GP.

> ‘I’ll just put up with it [UI] because the embarrassment of going to see the doctor and imagining the doctor saying, you’ve had children, what do you expect … I thought it’s obviously I’m not going to get turned away at this point, am I?’ (PS302)

UI was seen to be a ‘normal’ consequence of ageing or parity, the presence of incontinence products in the supermarkets was seen to support this belief.

> ‘There’s just rows of incontinence pants in the supermarket and you think oh, is that what my future is?’ (PS305)

Expectations of recovery were low however and participants were pleasantly surprised at the success of the intervention.

> ‘I thought give it a whirl and I’ve got a bit of an issue, see what’s out there. I never expected to find out really the reason that she thought was the problem.’ (PS301)

ii. Intervention and Intimate Examination

All of those interviewed described the intervention as ‘valuable’. The tailored advice and progression were particularly regarded as a positive point, and the intimate examination was believed an essential aspect of the assessment. No-one reported embarrassment, and it was perceived to be a key part of identifying their problem.

> ‘I think that’s one of the reasons why I went for it [intimate examination] really because you can Google, can’t you, things to do and exercises and whatever but it’s until you’ve had a sort of examination by an expert you don’t know whether you’re doing the right thing or not, so yes, it was what I expected’ (PS302)

> ‘I could feel what was happening with my muscles because we had the internal. And I think the internal was the golden moment for me.’ (PS306)

iii. Outcome measures

All participants found the questionnaires straightforward and quick to complete. Despite the comprehensive nature of the longer questionnaire, some felt that questions clarified their symptoms. One participant remarked that being asked about symptoms she did not experience was an incentive to work hard to prevent further deterioration in her own symptoms.

> '…make sure I keep doing my exercises, so I don't end up having those symptoms' (PS305)

There was less enthusiasm regarding the FVC, however, which were regarded as difficult to complete particularly outside the home.

> 'I think to do that in a work environment is just a non-starter basically.' (PS303)

iv. Venues

Both the university and private physiotherapy clinic used were acceptable to the participants. It was suggested that the main issue was proximity to the home or workplace rather than site specifics.

> 'It was worth it, but I think there might be people who have different circumstances who couldn't make the journey across the city. So, if it was the sort of thing that was available in different locations that would have been even better.' (PS204)

v. SqueezyCX App

Participants were all positive regarding the 'App' as a motivator for completing their home exercises although, some felt that it was less useful once a routine was established. It was anticipated that the 'App' would facilitate monitoring of adherence to home exercise programs and, while all claimed to have saved

their sessions, this was not reflected on the platform. Some however, noted that the belief that the physiotherapist was monitoring them was a strong motivation for compliance.

> ‘I think I had to sort of say that I’ve done them and completed them, so it sounds ridiculous …… but at least she saw that I’d done them, and I wasn’t lying.’ (PS301)

vi. Acceptability of being randomised in a future trial

Half of those interviewed volunteered because they wanted to be involved in research and to help others, so would still volunteer for a study where there was a possibility of being in the control group. Others felt, however, that this would have removed any incentive, although agreed that an option for the intervention later, e.g., in a wait-list control trial, would have been acceptable.

> ‘if you thought actually, I’m just going to be part of the control group and not get any intervention then, no, I wouldn’t do it.’ (PS303)

vii. Effects of UI on sport and life

All the interviewees described their symptoms as being minor and predominantly related to their sport. Yet, it became apparent that aspects of UI did have a wider impact. Common issues mentioned were reduction of fluid intake and anxiety regarding urgency during meetings or on car journeys. Of note was the worry associated with running when not in sportswear:

> ‘things like just sprinting across the park when one of the kids had fallen over, that sort of thing, could make me have a little leak. …… And I was a bit more conscious of it when I wasn’t out on my own in running gear, ……. just wearing jeans at the park and it would have been more embarrassing.’ (PS304)

One interviewee expressed anxiety regarding the possible progression of her symptoms.

> ‘I’ve started having dreams about wetting myself in public and things. But it’s not anything that’s actually happened’ (PS305)

Feasibility of Progression

Objectives within the feasibility study were given a RAG rating (Table 5)

Progression Criteria	Measurement	Result	RAG rating
Recruitment	Numbers recruited	19	G
Eligibility	Proportion of those screened who were eligible	13/14 = 93 %	G
Initial Consent	Proportion of eligible participants who consented	12/13 = 92 %	G
Consent to Intimate Examination	Proportion of those enrolled who consented to an intimate examination	9/12 = 75 %	G
Attendance	Proportion of scheduled appointments attended	56/60 = 93 %	G
Data Completion (Baseline n = 11)	Proportion of questionnaires collected at 3-month review	10/11 = 91 %	G
	Proportion of questionnaires collected at 6-month review	9/11 = 81 %	G
	Fluid charts collected at 3-month review	3/11 = 18 %	R
	Fluid charts collected at 6-month review	4/11 = 36 %	A

Table 5 Table illustrating RAG rating of objectives assessed for progression to a future trial

Although the majority of objectives were met (green ratings), one was amber (fluid chart return at 6-months) and one was red (FVC return at 3-months).

Regarding objectives around acceptability of the intervention and processes, it was clear that the recruitment process, the intervention, completion and content of the questionnaires, choice of venues and the use of the SqueezyCX app were all regarded positively. However, the FVCs were reported as being difficult to incorporate within daily life, reflected in the return of these in the study at both time points. In addition, several participants felt that, had they been allocated the control group in an RCT, this would have deterred them from participation.

Discussion

Results from the feasibility study and interviews indicate that a future RCT to investigate physiotherapy to manage UI in athletic women is feasible and that the proposed intervention was acceptable to participants. However, prior to scaling this up for an RCT there should be some modifications to the original protocol:

- Outcome measures: ICIQ-FLUTS-lf alone, (FVCs would be retained at baseline as directed by NICE [8] but would not be used as a research outcome measure)
- The SqueezyCX app was useful for motivation, but participants should be actively encouraged to continue recording throughout, to monitor compliance
- Any future RCT may need to consider concerns regarding the lack of intervention within the control group, e.g., consideration of a wait-list control design.

We wanted to recruit participants from outside NHS clinics as we knew that women often feel that UI is too trivial to seek treatment for [23]. This was further

confirmed by our participants who, despite reporting symptoms for many years, had not previously sought professional help. Recruitment from sporting venues was an appropriate method for recruitment and it was further noted that there was an increase in numbers after each new advert placement and there was particular interest after researchers presented directly within gym classes. In a larger study this suggests repeated adverts should be circulated throughout recruitment. There were no further participants recruited to the study after the gyms were closed due to COVID which likely effected the overall study numbers.

During protocol development, there was concern that the intimate examination as part of the assessment may be a deterrent to participation. Recent evidence indicated that women report these as embarrassing, or traumatic [24]. However, the consent rate for the DVE would suggest that this is not an issue as, before the pandemic, all who were offered an intimate examination agreed. Furthermore, interviews suggested that this was regarded as a positive aspect of study involvement. Given that participants valued the intimate examination it may be that the halt on face-to-face contact was a disincentive to recruitment and to continuing the intervention.

Data collection with respect to the questionnaires was good, with data returned at each time-point. Despite the length of ICIQ-FLUTS-lf, it was not considered to be problematic to complete and was seen as helpful in that it highlighted specific issues and served as an incentive to prevent deterioration of their condition. The FVCs, however, did not have a good return rate at either 3-months or 6-months. Some participants felt that the charts were difficult to complete outside the home. We would recommend that, although these are a valuable clinical tool and recommended within NICE guidelines [9], they are less useful as a research

outcome measure: a 7-day voiding diary to note incontinence episodes may be useful to provide an objective marker. Although this is not validated, this could be considered within a future study. Within the original protocol, we planned to assess pelvic floor muscle function via DVE and EMG as additional outcome measures, however due to the pandemic, face-to-face contact was only an option for four participants at 3-months and for no-one at 6-months. Consequently, we were not able to report meaningful results regarding the use of these outcome measures. In a future trial if DVE to assess PFM function was to be included as an objective marker it would be necessary that assessors should be independent of the intervention and blinded.

In order that the study could monitor compliance with home exercise programmes, the participants were offered the opportunity to download the 'SqueezyCX' app. Use of a smartphone app to measure adherence to a protocol has been recommended [25]. While all those interviewed reported completing and saving their exercises regularly, the adherence levels recordings did not support this. Adherence and data recording decreased throughout the process. It was noted by some that after establishing their exercise routine, using the app was less valuable. Although regarded by all as a good motivator, if incorporated within a future trial a potential strategy to improve compliance would be to re-enforce the importance of recording and saving data. It may be that including a compliance diary would be more reliable and this should be discussed with the PPI group before designing a future study.

All participants were offered the intervention, and despite participants' low expectations of success, this was an incentive to taking part. In an RCT, where one arm would not receive the intervention, some participants remarked that this would

be a disincentive. This issue may need to be considered in a future trial, perhaps by incorporating a wait-list control [26].

Conclusion

The investigation of the management of UI in athletic women is an under-researched area. We have shown that it would be feasible to recruit and deliver a trial of the physiotherapeutic management of urinary incontinence in this group however, several key amendments to the design have been identified. Women greatly valued the opportunity to access treatment for these symptoms.

Key Messages

- Recruiting athletic women directly from their sporting venue is both acceptable and feasible
- Inclusion of an intimate examination within the research is not a deterrent to women
- Women value the opportunity to access treatment for incontinence despite their history of 'managing' the condition

Ethical Approval

This study has been reviewed and approved by the University of Nottingham, Faculty of Medicine and Health Sciences Research Ethics Committee (Ethics reference number 280-1904). All participants gave informed consent either written, by email or recorded digitally.

Trial Registration: NCT03986411. Registered 14th June 2019

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Conflict of Interest

None declared.

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