FEEL-GOOD study: Female Empowerment through Enhanced Living: a comparison of vaGinal continence devices and pelvic flOOr muscle training (PFMT) versus PFMT only for female stress urinary incontinence: a feasibility and pilot StuDy. Stage 2

PROTOCOL

A UK Collaborative Trial funded by the CSO

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Funder

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Signatures

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

Professor Mohamed Abdel Fattah (CI) 

Date: 18/09/2025

VERSION HISTORY

Amendment no.	Protocol version no.	Description of changes (*incl. author(s) of changes*)	Date of document
	Version 1	New Document	21 February 2025
	Version 2	*Minor amendment in section 7.2 -change of wording form pelvic organ prolapse to Stress Urinary Incontinence. And addition of wording about using a VCD at end of trial to section 3.2*	20 March 2025
4	Version 3	Addition of study website address, ISRCTN and REC number. Revision to the exclusion criteria including an alternative clinical assessment of prolapse to accommodate centres where the POP-Q is not routinely used (trial summary, section 4.3.1). We are also including information about a supply of Contrelle Activgard ® VCD for use in centres where participants might experience difficulty in obtaining a VCD otherwise (section 3.2 and 4.11)	28 May 2025
8	Version 4	Option of Trial team managing Contrelle stock for centres experiencing limitations in storage capacity (section 3.2 and 4.11). We are also amending the alternative clinical assessment for prolapse (exclusion criteria) to clarify that the most prolapsing point is within the vagina and does not extend beyond the introitus. (trial summary, section 4.3.1). The study end date has been updated following the approval of a no cost extension by the funder	18/09/2025

TABLE OF CONTENTS

TRIAL SUMMARY

Trial title	FEEL-GOOD study: Female Empowerment through Enhanced Living: a comparison of vaGinal continence devices and pelvic flOOr muscle training (PFMT) versus PFMT only for female stress urinary incontinence: a feasibility and pilot StuDy
Short title	FEEL-GOOD study
Rationale	Urinary incontinence (UI) is common and debilitating, affecting >6million UK women over age of 40 years, causing embarrassment, low self-esteem, social isolation, and reduced productivity. Management of UI in women has an estimated annual cost of £358million for the NHS. Self-inserted vaginal continence devices (VCDs) provide mechanical support to the continence mechanism to help achieve continence. VCDs can potentially lead to additional improvement in women's quality of life (QoL) and reduced strain on the NHS if surgery can be avoided. A recent systematic review and meta-analysis updated to 1st August 2024 showed statistically significant results favouring VCDs (RR 4.10, 95% CI 2.04 to 8.25). However, all RCTs were small (maximum n=72), with high risk of bias. Three were single-centred and two were funded by the device company. High drop-out rates were noted in these studies. Despite the lack of robust evidence, VCDs have been widely used in clinical practice according to our recent NHS survey. NG210 reiterated the lack of evidence on the clinical and cost-effectiveness of VCDs and recommended a trial to evaluate *"How effective is a pessary or intravaginal device combined with pelvic floor muscle training for managing pelvic floor dysfunction, compared with pelvic floor muscle training alone?"* A definitive trial to gather such evidence is likely to be complicated and expensive. It is not clear from the current literature whether women will be willing to participate; accept randomisation; adhere to the treatment pathway and remain within follow-up. Working closely with our PPI partners "Women Voices" and "Bladder Health-UK", we co-developed a two-stage preliminary study. We aim to explore the perspectives of women and clinicians regarding VCDs and to assess the feasibility of conducting a definitive trial.
Trial design	A feasibility and pilot RCT embedded qualitative study
Eligibility criteria	**For the feasibility and pilot RCT:** **Inclusion Criteria** Women aged 18 years or over with clinically diagnosed stress predominant UI and deemed by their clinician to be suitable for VCDs, and willing to self-manage VCDs. **Exclusion criteria:**

	Women will be excluded from the trial if they have one or more of the following: • Vaginal prolapse more than POP-Q Stage 2a (POP-Q= Pelvic Organ Prolapse Quantification score). For centres where POP-Q is not routinely used, clinical assessment of the most prolapsing point will be considered an acceptable alternative method of assessment for exclusion. Patients would be eligible if the most prolapsing point is still inside the vagina and does not extend beyond the introitus. • Neurogenic bladder • Urgency predominant UI • Evidence of active pelvic or vaginal infection, • Vaginal ulceration, • Allergy to silicone or rubber • Known vaginal cancer • Current pregnancy or within 6 months postpartum • Completed full course of supervised Pelvic Floor Muscle Training and has been discharged by the physiotherapist within the last two years • Contraindications to vaginal devices: o Current vaginal infection or irritation o History of Toxic Shock Syndrome o Pelvic surgery in the last 6 months o Ongoing therapy for pelvic malignancy o Current urinary infection o Problems with manual dexterity which could cause insertion or removal issues. • Women lacking capacity to consent • Inability to understand the PIL, consent and/or questionnaires in English. **For the embedded qualitative component:** • For women: the same inclusion/exclusion criteria as described above for the feasibility and pilot RCT will apply. • For Health Care Professionals: clinicians, physiotherapists and specialist nurses in the pilot sites who are involved in the care of women with stress predominant UI are eligible; this includes HCPs who currently do or do not offer VCDs.	
Interventions	VCDs plus supervised PFMT versus supervised PFMT only	
Randomisation and blinding	Women will be randomised 1:1 to receive VCDs plus supervised PFMT or supervised PFMT only. Non-blinded	
Planned sample size	74 women	
Duration of trial	24 months	
	Objectives	Main Outcome measures
Primary	To establish the feasibility to deliver a definitive RCT comparing the clinical and cost effectiveness of VCDs plus supervised PFMT to supervised PFMT only in management of stress	The feasibility of participant recruitment within the proposed time scale (I.e. achieve >/= 80% of the target recruitment within 6 months).

	predominant UI (SUI) in women.	
Secondary	1. To establish the facilitators and barriers for recruitment (and specifically randomisation) for women and healthcare providers for a definitive RCT.	A. Understanding of attitudes and preferences of women and HCPs regarding VCDs as a management option for SUI, B. Identification of potential factors impacting on the trial participation (e.g. randomisation/ follow up and recruitment; uncertainty, preference and trust in HCPs and researchers) and decisional regret). C: Ethical and pragmatic issues impacting on the pilot RCT conduct/management and the fidelity of intervention delivery and adherence.
	2. To establish the relevant outcomes for a definitive randomised controlled trial (RCT) from women's and healthcare professionals (HCPs) perspectives.	Identification of key outcomes that matter to women as well as clinically important outcomes for HCPs.
	3. To establish a reliable sample size and recruitment projection for a definitive RCT, the adherence of participants to the proposed treatments, response rates to questionnaires, and loss to follow-up rate.	A. The participants' adherence rates: i) for VCDs: 70% of women wearing the VCDs as instructed by their clinicians and ii) for PFMT: attending 70% of their individualised planned program appointments); B. The retention rate I.e. achieve 80% retention at 6 months follow-up); C. The rates of missing data; patient-reported success rates and adverse events of VCDs; use of self-funded vs NHS prescribed VCDs; waiting times for physiotherapy, The above will enable establishing reliable recruitment projection and refining our pre-defined progression criteria for a definitive RCT.
Embedded qualitative study	The qualitative study embedded in the trial, informed by Theoretical Framework of Acceptability and INCLUDE Framework and the FEEL GOOD study stage 1 findings, aims to identify attitudes and preferences of women and healthcare professionals HCPs (Clinician, physiotherapist	

	and nurses) regarding VCDs as a management option for SUI, key outcomes of importance from both women and for HCPs perspectives, and ethical/practical issues impacting on trial participation and provision of trial. Qualitative study will involve one-to-one semi-structured interviews with 9-15 women and focus groups with 8-10 HCPs from across the participating sites. All interviews and Focus group data will be coded inductively and deductively, and the analysis organised using - Framework' analysis approach.
Statistical methods	The number of eligible participants, number of individuals who consent, and number recruited will be presented both in tables and graphs using count and percentage. The number and percentage of recruited participants who decline their allocated intervention, withdraw consent and fail to provide outcome data will also be presented in tabular form. For the various outcome measures, the appropriate linear model will be used to obtain a treatment effect and 95% confidence interval. A repeated measures analysis corrected for baseline will be used where appropriate.
Co-ordination	Local: by local research teams Central: by Trial Office in Aberdeen (Telephone 01224 438103, 01224 438405). Overall: by the Project Management Group and overseen by the Trial Steering Committee and the Data Monitoring Committee.

LAY SUMMARY

Urinary incontinence (UI) is common and debilitating, affecting >6million UK women over age of 40years, causing embarrassment, low self-esteem, social isolation, and reduced productivity. First-line treatment is pelvic floor muscle training (PFMT), but currently one in three women still proceed to surgery.

Vaginal continence devices (VCDs), worn inside the vagina, support the bladder to help achieve continence. Guidelines recommend VCDs are used when PFMT is not effective on its own. Combining VCDs with PFMT might be more effective for treating UI than PFMT alone, improving quality of life (QoL) and reducing the need for surgery. VCDs are widely used, despite little evidence about their benefits, risks and whether they provide value-for-money.

Providing such evidence requires a complex and expensive clinical trial. A preliminary study is needed to ensure that such study is feasible and can be conducted successfully. Working closely with our PPI partners "Women Voices" and "Bladder Health-UK", we co-developed a two-stage preliminary study. Stage-1 explores women's and clinicians' views on VCDs and a potential larger clinical trial, using interviews and focus groups. Stage-2 uses stage-1 findings to undertake a small version of the potential larger clinical trial. 74 women with UI from four-six UK hospitals will take part: 37 will receive PFMT alone and 37 PFMT plus VCD, with equal chance of being in either group. We will collect information on women's symptoms and QoL before and after treatment (at 3 and 6 months). The results will help us design a clinical trial to fill the gap in evidence about effectiveness of VCDs combined with PFMT.

GLOSSARY OF ABBREVIATIONS	
AE	Adverse Event
AR	Adverse Reaction
CHaRT	Centre for Healthcare Randomised Trials
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CTU	Clinical Trial Unit
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
GP	General Practitioner
HRQoL	Health Related Quality of Life
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
IVR	Interactive Voice Response (randomisation)
NHS	National Health Service
NHSG	National Health Service Grampian
NRES	National Research Ethics Service
PI	Principal Investigator
PIL	Patient Information Leaflet
PMG	Project Management Group
PPI/PPIE	Patient and Public Involvement/and Engagement
PQ	Participant Questionnaire
QA	Quality Assurance
RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
TMF	Trial Master File
TSC	Trial Steering Committee
UK	United Kingdom
UKCRC	United Kingdom Clinical Research Collaboration
UoA	University of Aberdeen

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Trial Office Team

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2 CHaRT Director

3 Trial Manager

4 Data Co-ordinator

5 Senior Trial Manager

6 Senior IT Manager

7 Trial statistician

Project Management Group (PMG)

This group is comprised of the grant holders along with representatives from the Trial Office central trial team (trial manager, data co-ordinator, senior trial manager, senior IT manager, statistician).

Trial Steering Committee (TSC) Members

The membership of this committee comprises independent members along with the Chief Investigator (CI) (Professor Abdel Fattah) or a nominated delegate. The other FEEL-GOOD grant-holders and key members of the central office (e.g. the trial manager) may attend TSC meetings. Membership and the terms of reference are documented in the TSC Charter and filed in the TMF.

Role of the Trial Sponsor and Funder

The Sponsor has responsibility for the initiation and management of the study as defined by the UK Policy Framework for Health and Social Care Research v3.3 07/11/17. Specific responsibilities delegated to another party are formally agreed and documented by the Sponsor.

The funder has oversight of the study through regular reports from the trial office. The funder appoints the independent members of the Trial Steering Committees and receives minutes from these. The funder is made aware of all outputs from the study but does not have a role in the decision to publish results from the study. In any publications, the funder is acknowledged, and appropriate disclaimer used to indicate that the views expressed are those of the author(s) and not necessarily those of the funder.

FEEL-GOOD study: Female Empowerment through Enhanced Living: a comparison of vaGinal continence devices and pelvic flOOr muscle training (PFMT) versus PFMT only for female stress urinary incontinence: a feasibility and pilot StuDy

1. INTRODUCTION

1.1 Background

Urinary incontinence (UI) is a common and debilitating condition that affects over 6 million UK women over the age of 40 years[1]. UI leads to embarrassment, low self-esteem, social isolation, and reduced productivity. It is more common as women age hence the numbers are likely to increase. Management of UI in women is costly: with an estimated annual cost of £358million for the NHS[2] and in-addition £273million out-of-pocket expenses for women[2]. All values reported are inflated from source studies to 2022[3]. A landmark study (September 2023)[4] showed that UI affect 55-60 million people in Europe with an estimated healthcare costs of €40billion in 2023.

NICE guidance (NG123) recommends pelvic floor muscle training (PFMT) as first line treatment for women with UI (done regularly for 16 weeks under physiotherapy supervision)[5]. However, NG123 also highlights that PFMT sometimes fails and one third of women proceed to surgery. The lifetime risk for UK women by age 80years undergoing pelvic floor surgery is 12.2%[6].

The public debate and concerns over the use of mesh in treatment of female UI and their suspension in Scotland (in 2014 followed by the rest of the UK 2018) led to an increased emphasis on the alternative non-surgical treatment options. This was further accentuated by the COVID-related long surgical waiting lists.

Self-inserted vaginal continence devices (VCDs) are relatively new. They provide mechanical support to the lower urinary tract continence mechanism and may also enhance the benefits of PFMT in the longer-term[7]. PFMT programmes require individual motivation to adhere to a daily regime and continued practice, however it takes time for the PFMT to achieve notable improvement in UI[8]. VCDs in their own right can provide women with relatively rapid results to improve their QoL. In-addition, encouraging them to adhere to the PFMT program. It is also hypothesised that VCDs may help women to better identify the pelvic floor muscles they need to contract which can also improve PFMT outcomes. Hence, it is proposed that VCDs can potentially lead to additional improvement women's quality of life (QoL), earlier improvement in their symptoms and reduced strain on the NHS if surgery rates can be reduced.

1.2 Rationale for the trial

The latest Cochrane review on VCDs (2014)[9] concluded that VCDs might be better than no treatment, but the evidence was inconclusive. We updated the literature review to 1st August 2024. Five RCTs (n=168 participants)[10-14] compared VCDs with placebo or no treatment and used the objective pad test as primary endpoint. Our meta-analysis showed statistically significant results favouring VCDs in achieving negative pad test (RR 4.10, 95% CI 2.04 to 8.25). Caution is required as all RCTs were small (maximum n=72), with high risk of bias. Three[11,12,13] were single-centred and two[10,14] were funded by the VCD manufacturer company. One further 3-arm RCT[15] published in 2010 compared one type of vaginal pessaries (continence dish/ring) versus PFMT only versus pessary plus PFMT (n=446). At 3-month follow-up. patient reported success rate was significantly better in the combined PFMT and pessary group than pessary alone (p=0.02) but not better than PFMT alone. However, the study evaluated an old technology completely different to the current VCDs and had high drop-out rates (40%). Pessaries were designed for treatment of prolapse and later enhanced with bladder neck support for UI.

Despite the lack of robust evidence on their benefits, risks, and cost-effectiveness, VCDs have been widely used according to our recent NHS survey (details below).

The recent NICE guideline, NG210 (2021)[16] on pelvic floor dysfunction prevention and non-surgical management recommends VCDs for women with SUI who have failed other conservative measures. But NG210 reiterated the lack of evidence on the clinical and cost-effectiveness of VCDs and recommended a trial to evaluate *"How effective is a pessary or intravaginal device combined with pelvic floor muscle training for managing pelvic floor dysfunction, compared with pelvic floor muscle training alone?"*

A definitive RCT to gather such evidence is likely to be complicated and expensive. It is also not clear from the current literature whether women will be willing to participate; accept randomisation; adhere to the treatment pathway and remain within follow-up. It is also unclear if clinicians would be willing to participate in such RCT. No preliminary studies have been carried out.

We conducted a survey of practice of 64 hospitals currently collaborating in our NIHR funded RCTs for management of SUI in women (SIMS[17] and FUTURE RCTs[18]). This showed:

- Response rate 81%(n=52 gynaecologists/ urologists)
- 70% of respondents recommend trying a VCD in women with SUI:
  - Clinicians view VCDs as reversible, rapid acting and a potentially successful conservative management option for SUI.
  - Clinicians report good acceptability by their patients and some patients are willing to buy VCDs themselves.
  - The reasons for not utilising VCDs are equally divided between the current lack of evidence of their clinical and cost-effectiveness and/or the fact that VCDs are not recommended in NG123. For some (n=3), they had individual experience of lack of efficacy.
- 90% agreed with NG210 on the uncertainty regarding the effectiveness of VCDs, and the importance of the proposed research question.
- 88% would participate in a Pilot RCT if funded.
- There is uncertainty among responding clinicians:
  - whether women will accept randomisation if they perceive they were denied VCDs that may help their UI, and
  - Regarding patients' compliance and whether they adhere to combined PFMT and VCDs for the duration of 16 weeks and beyond.

In the FEEL-GOOD study, we propose to explore the perspectives of women and clinicians regarding VCDs and to assess the feasibility of conducting a definitive trial.

1.3 Assessment and management of risk

The CI and TSC will ensure that adequate systems are in place for monitoring the quality of the study (compliance with GCP) and appropriate expedited and routine reports of adverse events, to a level appropriate to the risk assessment of the study.

Trial participants will be informed of possible benefits and known risks (including known complications) of both interventions in the trial by means of a Participant Information Leaflet (PIL), discussion with the local Research Nurses and the wider clinical team. Both interventions: pelvic floor muscle training (PFMT) and Vaginal Continence Devices (VCDs) are routinely used within the NHS. We do not anticipate that participants will run additional risks by participating in the FEEL-GOOD study. They will sign a consent form approved by the Ethics Committee. They will be consented to participating in the study – being randomised and followed up within the study; and optionally to be contacted in the future about this and other related research. Potential participants who are not willing to be randomised will not be recruited to the pilot RCT; but will still be invited to take part in a qualitative interview (see section 8.6).

2. TRIAL AIM AND OBJECTIVES

The aim of this study is to determine the feasibility to deliver a definitive RCT comparing the clinical and cost-effectiveness of Vaginal Continence Devices (VCDs) and Pelvic Floor Muscle Training (PFMT) compared PFMT only in the conservative management of stress-predominant urinary incontinence (SUI) in women.

The objectives include:

1. To establish the facilitators and barriers for recruitment (and specifically randomisation) for women and healthcare providers for a definitive RCT.
2. To establish the relevant outcomes for a definitive RCT from women's and healthcare professionals' (HCPs) perspectives.
3. To establish a reliable sample size and recruitment projection for a definitive RCT, the adherence of participants to the proposed treatments, response rates to questionnaires, and loss to follow-up rate.

Research question: Is it feasible to deliver a definitive RCT comparing the clinical and cost effectiveness of VCDs plus supervised PFMT to supervised PFMT only in management of stress predominant UI (SUI) in women.

3. TRIAL DESIGN

This is a sequential exploratory mixed methods, non-blinded study comprising: a qualitative study (stage-1) and a multicentre, combined feasibility and pilot, randomised controlled trial (stage-2) with embedded qualitative component. **This protocol is for stage 2 only.** The protocol for stage 1 is a separate document, that has already received separate approvals via the University of Aberdeen School Ethics Review Board (SERB reference number: 2758089) and currently is in stage of preliminary data analysis. Figure 1 shows the overview of the study.

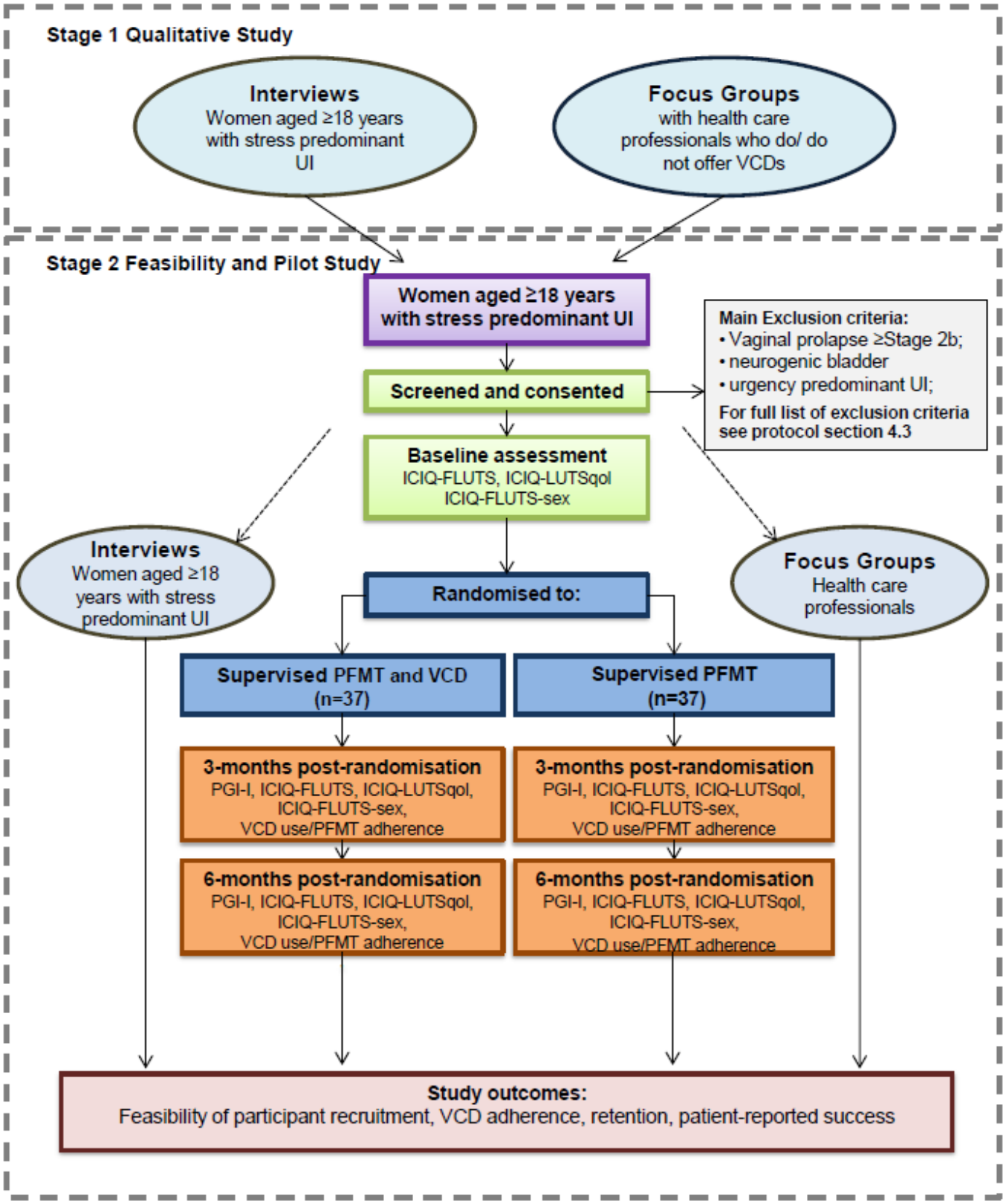
3.1 Interventions to be evaluated

The interventions being compared are: 1) Vaginal Continence Devices (VCDs) and supervised PFMT and 2) supervised PFMT-only. Women will be randomised 1:1 to receive VCDs plus supervised PFMT or supervised PFMT only.

There are different VCDs brands used in clinical practice and some of them can be obtained on NHS prescription (for example Contiform®, Contrelle®, Diveen®, Efemia®). The choice of VCDs will be according to the hospital's standard practice and as a shared decision by women and their HCPs. All types of VCD will be permitted in the study, provided they are CE marked. See section 3.2 for further information.

Both groups will be referred to the physiotherapist for supervised PFMT. An individualised PFMT plan will be designed as per the patient's goals and the standard practice in the collaborating hospital. They will have the option of face to face or telephone appointments as per standard of care in the collaborating hospital. See section 3.3 for further information.

Figure 1: study overview



ICIQ-FLUTS[R] International Consultation on Incontinence Questionnaire - Female Lower Urinary Tract Symptoms long form; ICIQ-FLUTS[R]-sex International Consultation on Incontinence Questionnaire – Female Sexual Matters; ICIQ-LUTSqol[R] lower urinary tract symptom related quality of life; PGI-I patient global impression of improvement; PFMT pelvic floor muscle training; VCD vaginal continence device

3.2 Vaginal Continence Devices

Vaginal continence devices are mechanical pessaries made of silicone (Incostress®, Efemia®), santoprene (Contiform®, Diveen®), elastomer resin (Uresta®) or medical foam (Contam®, Contrelle Activgard®). They are designed to support the continence mechanism: bladder neck, urethra and pelvic floor muscles. Manufacturers advertise them as a self-inserting device; however, it is unclear from the evidence whether they are easy to insert or not. Their effectiveness is also unclear.

There are different brands in the market with various shapes; however, they share a comparable mechanism of action. They are designed to be self-inserted, similar to the steps involved in the insertion of a tampon. These brands offer a starter pack with different sizes. Women are encouraged to use the starter pack first to find the size that can comfortably sits in the vagina while reducing stress urinary incontinence. Once the correct size has been identified, they can be prescribed (or purchase) the specific size accordingly.

Since some of these devices are single-use only (Contam®, Contrelle Activgard®), they ought to be changed daily. The Diveen® brand can be used twice before needing to be replaced. With regular use, other devices can last up to 30 days (Contiform®) or up to three months (Efemia®).

Vaginal continence devices can be used only when necessary, such as during physical activity. Most, however, are marketed for usage for 12–16 hours per day. Most devices designed for non-single use advise removing it at night so that it can be cleaned and allowed to dry overnight. However, one manufacturer (Contiform®), states that their device can be used continuously for five days before needing to be removed to be cleaned and dried. Within the study, we will recommend use as described by the manufacturer.

The choice of VCDs in our study will be according to the hospital's standard practice and as a shared decision by women and their HCPs with any type of VCD permitted, provided they are CE marked. If one VCD type fails or falls, the woman and her clinician will be able to decide to try other type(s) of VCDs. Self-funded VCDs will also be permitted provided they are CE marked. We will record the type of VCD used.

Following an approach by a Viveca Biomed Limited, the sponsor has an agreement with this company for the provision of a six (6) month supply of the Contrelle Activgard ® VCD free of charge for a maximum of 38 Study Participants for use exclusively in connection with the Study. These VCDs will be available in centres where the participants might experience difficulty obtaining the VCD (for example because they cannot get it on prescription from the hospital or their GP). The company will provide the Contrelle Activgard ® VCD direct to the centres, and the centres will identify the most appropriate way to supply the VCD to the participants. The company will not receive any participant details or study data.

Where centres have limited storage capacity or shipping resources the trial office in Aberdeen can assist with storage and distribution as directed by the centre. The trial office will retain their VCD stock and post VCDs directly to participants in the VCD arm, as requested.

VCDs are designed for self-insertion. However, if needed, and as per standard clinical practice, women will be trained by their HCP in insertion and removal. This could be the practice nurse in their own GP surgery, a nurse or member of the clinical team at the hospital or the physiotherapist at time of PFMT.

Women allocated to PFMT only will be given the opportunity to discuss and try a VCD at the end of the study according to local standard clinical practice.

If women are in the PFMT and VCD and want to continue with the VCD at the end of the trial they will discuss with their local clinical team.

3.3 Pelvic Floor Muscle Training (PFMT)

PFMT is a programme of exercises designed to improve pelvic floor muscle strength, power, endurance, relaxation or a combination of these. It is the first line treatment for women with stress and mixed urinary incontinence as recommended in the NICE guidelines (NG123).

In order to create a training effect on the pelvic floor muscles, PFMT entails the consistent practice of repeated voluntary muscle contractions with adequate exercise progression. A PFMT program aims to improve muscle strength, volume, and structural support. It increases contraction endurance; improves resting tone; improves muscle recruitment through improved nerve function and muscle fibre properties; and improve cognitive awareness of body posture and the difference between a relaxed and an unrelaxed pelvic floor.

Furthermore, during physical activities that raise abdominal pressure and cause UI, a PFMT program teaches how to contract and relax the pelvic floor muscles to enhance coordination and functional use in obstructing the urethra.

The fundamental physiological principles must be followed in order to increase muscle strength and endurance: specificity (muscles must be trained with exercise or physical activity that as closely mimics the necessary functional movement as possible), overload (muscles must exert more effort than usual until exhaustion), maintenance (exercises must continue in the longer term), and reversibility (exercise benefits will reverse if they are not performed regularly).

As part of the training regimen, the NICE guidelines (NG123) recommend performing at least eight vaginal contractions, three times a day, for treatment of stress or mixed urinary incontinence. However, the number of muscle contractions required may vary depending on the patient's objectives and the findings at the time of vaginal examination. Typically, the individualised PFMT strategy calls for working the pelvic floor muscles till exhaustion and then increasing the frequency gradually.

Women in both groups of our study will be referred to the physiotherapist for supervised PFMT. An individualised PFMT plan will be designed as per the patient's goals and the standard practice in the collaborating hospital. They will have the option of face to face or telephone appointments as per standard of care in the collaborating hospital.

4. TRIAL RECRUITMENT

4.1 Trial population

Women aged 18 years or over with stress predominant UI who have been referred to the collaborating gynaecology, urology or urogynaecology within hospitals across the UK. We aim to recruit and randomise 74 women (37 in each arm).

For the purposes of this trial, the term 'women' includes all people with a vagina and assigned female sex at birth.

Setting: secondary and tertiary care acute hospital settings across the UK. NHS Grampian will be the clinical co-ordinating centre and house the Chief Investigator (CI)

Women will be approached and recruited by HCPs in UK hospitals in Scotland and England representing diverse geographical and socio-economic characteristics. The hospitals will be chosen to represent the practice in the UK and will include a mix of urban and rural, tertiary and secondary care and serve ethnically and socio-economic diverse populations. Each unit will have at least one participating healthcare professional who is comfortable prescribing VCDs.

4.2 Selection of participants

As standard practice, HCPs will assess patients likely to require treatment for SUI. A log will be documented of all potentially eligible participants to record reasons for non-inclusion in the trial to inform the CONSORT diagram.

Screening logs at each site will be used to record details of potentially eligible patients as an aid to monitoring possible participant inclusion.

4.3 Inclusion and exclusion criteria

4.3.1 For the feasibility and pilot RCT:

Inclusion criteria:

Women aged 18 years or over with clinically diagnosed stress predominant UI and deemed by their clinician to be suitable for VCDs, and willing to self-manage VCDs.

Exclusion criteria:

Women will be excluded from the trial if they have one or more of the following:

- Vaginal prolapse more than POP-Q Stage 2a (POP-Q= Pelvic Organ Prolapse Quantification score) For centres where POP-Q is not routinely used, clinical assessment of the most prolapsing point will be considered an acceptable alternative method of assessment for exclusion. Patients would be eligible if the most prolapsing point is still inside the vagina and does not extend beyond the introitus.
- Neurogenic bladder
- Urgency predominant UI
- Evidence of active pelvic or vaginal infection,
- Vaginal ulceration,
- Allergy to silicone or rubber
- Known vaginal cancer
- Current pregnancy or within 6 months postpartum
- Completed full course of supervised Pelvic Floor Muscle Training and has been discharged by the physiotherapist within the last two years
- Contraindications to vaginal devices:
    - Current vaginal infection or irritation
    - History of Toxic Shock Syndrome
    - Pelvic surgery in the last 6 months
    - Ongoing therapy for pelvic malignancy
    - Current urinary infection
    - Problems with manual dexterity which could cause insertion or removal issues
- Women lacking capacity to consent
- Inability to understand the PIL, consent and/or questionnaires in English.

We have applied minimal exclusion criteria as possible to ensure generalisability of the results. Women with >stage 2a prolapse are not suitable for VCDs as they may require a different type of pessary for management of prolapse which cannot be mutually inserted with VCDs.

Co-enrolment

Participants will be permitted to take part in other non-interventional studies. Those enrolled in the active intervention phase of another interventional trial should be excluded from FEEL-GOOD, but if they are in the long-term follow-up up phase of any other interventional trial, they are eligible for FEEL-GOOD.

4.3.2 For the embedded qualitative component:

Inclusion and exclusion criteria for the qualitative component are described in section 8.

4.4 Identifying and approaching participants

We are recruiting women from secondary and tertiary care hospitals. Across all sites, a study poster may be displayed as a resource to support recruitment.

There are varied local procedures and patient pathways at the participating hospitals. Therefore, the timing and mode of approach to patients and the consent process will vary to accommodate both the needs of the patients and the variations between sites.

Where possible, patients likely to meet the eligibility criteria will be identified by screening the outpatient clinics by the HCPs, research nurse (RN) or a designated team member (with permission to access clinic lists as part of standard of care). Depending on local centre procedures, The Invite Letter and Patient Information Leaflet (PIL) may be sent together with clinic appointment letters or sent separately to potentially eligible patients., This will ensure that they have ample time for consideration before being approached by the research team at the clinic. *A member of the usual care team (which may include embedded research nurses) may contact the participant by telephone around two weeks after the initial approach to answer any questions they have about the study.*

At the clinic, the HCPs/ research nurse (RN) will explain the study to the patient and answer any queries. If the patient wishes to take part, they can complete the consent form and baseline pack during their clinic appointment. Alternatively, the participant may take the consent form and baseline pack for completion at home and send back to the site using pre-paid post. If they prefer to complete the consent form and baseline questionnaire in person, arrangements can be made for a separate appointment at the clinic to facilitate this.

Women who do not receive a copy of the PIL in advance of their clinic appointment, can be provided a copy at their clinic appointment. They can have as much time as they require to consider participation. They may decide to participate during the appointment – this is acceptable if they have had sufficient time to read the PIL and make an informed decision. However, they may wish to have more time to think about participation. In such cases, if the woman agrees to be contacted at home, she will receive a telephone call from the local RN to discuss any queries. If the woman agrees to participate in the study at that stage, they will have the option to complete the consent form and the baseline questionnaire at home and send back to the site using a pre-paid envelope. Alternatively, arrangements can be made for a separate appointment at the clinic if the participant prefers, and written consent is obtained. They will receive the baseline questionnaire during this appointment.

The above arrangements can be individualised for each centre.

All participants will have the option to complete the consent form electronically rather than completing a hard copy. Details of the consent discussion, including discussion date, will be recorded on the Trial inclusion CRF.

4.5 Non-recruited participants

The following anonymised information will be monitored and collected for all potentially eligible participants

- Year of birth
- Ethnicity (if recorded in the medical notes)
- Date of consultation when approached about the trial
- Reason for not participating if willing to give a reason

4.6 Informed consent

Good Clinical Practice (GCP) guidelines will used to guide informed consent from participants. The Patient Information Sheet will advise potential participants of all aspects of the trial, including the possible risks and their responsibilities. The Research Team will answer any queries as required and participants will be given ample time to consider participation.

Women who cannot give informed consent (e.g. due to lack of capacity) will not be eligible for participation. Following informed consent, if a participant loses capacity, the consent given when capable remains legally valid. In these case, identifiable data collected with consent will be retained and used in the study but no further data will be collected or research procedures carried out.

Patients who are not able to read or write (but who have capacity and who can speak English sufficiently to understand the information being provided orally) can agree to take part in the trial. In such cases, the trial team will provide them with literature about the trial and read and discuss this information with the potential participant. There should also be a discussion about the support networks that the patient has to facilitate their participation in the trial (for example help to complete questionnaires). If the potential participant is fully informed and wishes to take part in the trial, they will be asked to sign or make their mark on the consent form. Their agreement to take part in the trial should be witnessed by someone independent from the research team who will record this in writing by adding their signature to the consent form; this will be supplemented with a file-note documenting the event.

The application for approval is made via the NHS National Research Ethics Service. The Research Ethics Committees will agree and confirm the procedures to seek and gain informed consent from eligible potential participants. The participant's authorisation will be sought to inform their general practitioner of their involvement in this trial. As part of the consent process, women will be asked if they would be happy to be approached about taking part in an interview (this will be optional).

When informed consent is received in person, this should be received by an appropriately trained individual who is listed on the delegation log. Consent forms that are returned by post are checked, signed and dated with the date of receipt by someone who is listed on the delegation log with appropriate delegated responsibilities.

Participants will be provided with a fully signed copy of the consent form; where it is not possible to provide this to them in a face-to-face appointment, a copy will be posted to them.

A copy of consent forms completed in person or by post will be uploaded by the local site team to the trial website for retention by the trial office in the Trial Master File (TMF). (If e-Consent is completed, the trial office will download a copy from the trial database.)

4.7 e-Consent

For participants who opt to consent using an e-consent form, they will do this via the secure web-based trial management system provided by CHaRT. If this option is preferred, participants will be asked to provide their email address which will be entered into the secure web-based trial management system. Participants will be sent a verification email with a link to verify their email. Once the email address is verified, participants will be automatically emailed the PIL and a link to the participant e-consent form for their unique study number. The e-consent form will be identical to the approved paper version of consent form, with the approved PIL version number and date automatically populated. The participant will be asked to provide their signature online via a signature box using a finger tracing via a touch screen or using a mouse.

When a participant provides consent via the e-Consent system, the local study team will be notified by the trial database. Completed e-consent forms will be checked, and electronically counter-signed by someone listed on the delegation log with appropriate delegated responsibilities. The countersignature will only be recorded after discussion has taken place with the participant about the study and any questions have been answered. Only once both participant and person receiving

consent signatures are present will informed consent be considered to have been obtained. Participants will be sent a copy of the e-consent form for their own records and a copy will be downloaded from the study website and retained in the investigator site file and TMF.

Should participants who are sent the study information choose not to take part in the study, their email address will be deleted (as an automated process) from the trial management system after 3 months.

The trial management system used to record e-consent has a clear audit trail with tracking of all inserts or updates made. Database interactions logged against a user and date/time and the audit trail can be downloaded and analysed at any time by authorised users.

Regardless of how consent is received, details of the consent process and discussion, including discussion date, will be recorded on the Eligibility and Inclusion CRF. To document the consent process, site staff can place a copy of this in the medical records. A copy of the consent form should also be placed in the medical records.

Informed consent must be obtained before any study related procedures are performed.

4.8 Randomisation and allocation

Eligible participants, who have signed the informed consent form, will be randomised to one of the two study groups in a 1:1 allocation ratio. A randomisation application hosted by CHaRT will be used for this purpose. This is available 24 hours a day by means of a web-based randomisation application. Random allocation will use a stratification algorithm based on:

- collaborating centre
- type of urinary incontinence (pure Stress Urinary Incontinence or stress-predominant mixed urinary incontinence)

The type of urinary incontinence will be as per the HCP assessment at the time of review at the clinic.

Consenting patients will be randomised to VCDs plus PFMT or to PFMT-only as close as possible to receiving the interventions. Participants in the VCD plus PFMT arm will be prescribed and/or start using their VCDs at the time (or as close as practically possible) to their first physiotherapy appointment.

A person with delegated authority will access the web-based system. The trial is not blinded - at randomisation, an email will be sent to the collaborating site research team, including the PI, and the trial office, informing them of the allocation.

4.9 Follow-up procedures

At baseline, participants will be asked for their contact preferences for questionnaires. If they select email or text messaging, the email and/or mobile number will be verified automatically via the study website. Once an email address is verified, those selecting email as their preference will have a link to the questionnaire emailed to them. Those selecting post as their preference will have the questionnaire posted to them. Once an email number is verified, those selecting text messaging as their preference will have a link to the questionnaire texted to them.

The trial office will be responsible for entering all questionnaire data returned by post into the study website.

Questionnaires will be administered to all participants who were randomised in the study, regardless of their compliance to the randomised treatment unless they have opted out of questionnaire follow-up.

If questionnaires are returned as non-deliverable, attempts will be made by site staff or staff at the Trial Office to trace the participant via the local sites and/or the GP.

Consenting Participants will be asked, at baseline, to complete the baseline questionnaire which includes questions on participants' demographic details, their general health and relevant medications. It also comprises validated questionnaires for symptom severity of UI and its impact on quality of life (QoL) and sexual function: International Consultation on Incontinence Questionnaire - Lower Urinary Tract Symptoms Questionnaire (ICIQ-FLUTS), disease specific QoL questionnaire (ICIQ-LUTSqol) and the International Consultation on Incontinence Questionnaire Female Sexual Matters Associated with Lower Urinary Tract Symptoms (ICIQ-FLUTSsex).

The above questionnaires will also be completed at 3- and 6-months post-randomisation. In addition, participants will be asked to complete the Patient Global Impression of Improvement (PGI-I), a validated single-item tool assessing women's perception of improvement. They will also be asked to report any side effects, further treatment received for UI, adherence to PFMT and use of VCDs, as well as reasons for non-adherence. The questionnaires will also collect information on frequency and duration of VCDs use, and types of VCDs used by participants.

We will use various methods to collect the outcomes (paper/electronic) according to participants' choice, to maximise response rates. Non-responders will receive two reminders; the first is by their preferred method of contact (postal, text message, email) and the second reminder will be a postal one-page short questionnaire. For non-responders after this second reminder, we will use an automated text/interactive voice recognition application to collect information on how their incontinence has been in the last two weeks compared to when they joined the study (the single question in section 5 of the follow-up questionnaire). We have selected this question to focus this data collection on as this is the most likely primary outcome for a larger future trial. This data collection will apply to participants who have supplied us with their mobile phone number and consent to contact them via phone. Initially the system sends the participant a text identifying the study and asking the participant to complete the primary outcome question via the link provided. If the participant chooses not to use the link to respond, the IVR will attempt to call the participant. The IVR message will be played if the call is answered, and women will be asked to confirm that they are the participant. If they confirm they are the participant, the IVR will read the question and women will be able record their response. If the call is not answered, no message will be left. This data collection system has been successfully implement in a previous study (SIMS).

The qualitative study embedded within the pilot RCT is described in section 8.

4.10 Change of Status/Withdrawal procedures

Women will remain on the trial unless they opt to withdraw consent or if they are unable to remain for a clinical reason. Participants are free to withdraw from the study at any time. A research team member will complete the "change of status form" which includes the participant's instructions on what parts, or whole, of the study they may wish to withdraw from. Unless a participant specifically declines, the research team will continue to gather relevant data from their healthcare records. All other changes in status except for formal withdrawal of consent will mean the participant is still followed up for all study outcomes whenever possible. All data collected up to the point of complete withdrawal is retained and used in the analysis.

Participants who do not receive their allocated treatment or receive the other (non-allocated) intervention or discontinue their treatment are not considered withdrawals and will be followed-up for all trial outcomes unless they request otherwise.

Women who request that no further questionnaires are issued (i.e. completing questionnaires) will be followed up for other trial outcomes unless they are complete withdrawals.

Participants for whom any outcome data are available are included in an intention to treat analysis.

4.11 Administration arrangements post recruitment

Following trial entry, the trial office will, with participant's consent:

- Advise the participant's General Practitioner in writing that a patient has enrolled in the trial. GPs are requested to contact the Study Office if one of the participants moves, becomes unwell so that they cannot continue in the study or dies, or any other notifiable event or possible serious adverse event ensues. Alternatively, the GP may be contacted by the staff at the Study Office.

The site research team will:

- Organise a VCD for those women randomised to PFMT plus VCD. The VCD can be prescribed in primary or secondary care. If the standard of care is to prescribe in primary care, the site research team will contact the General Practitioner to prescribe the VCD – they will use their standard of care NHS letter to request this (rather than a study approved letter). If the standard of care is to prescribe in secondary care, the site research team will organise this. In centres where participants might experience difficulty in obtaining a VCD through NHS prescription (GP or Hospital), a supply of Contrelle Activgard® VCDs can be made available by Viveca Biomed Limited under a supply agreement (see section protocol section 3.2). These will be made available to the centre to supply to participants should the clinician/ participant make a shared decision this is the VCD of choice. If a centre's Contrelle stock is managed by the Trial Office, the research team must inform the Trial Office of the appropriate Contrelle VCD size and amount to be dispatched to the participant. Alternatively, women can self-fund a device – in these cases, no prescription is required – VCDs are available to purchase without prescription.
- File a copy of the consent form in the hospital notes along with information about the trial, provide one copy to the patient, file the original copy in the local site file and, if consent was received as hard copy, send one copy to the Study Office in Aberdeen
- Enter trial data regarding the participant into the FEEL-GOOD trial website.
- Maintain trial documentation at site.
- Return copies of trial documentation when requested by the Trial Office in Aberdeen to aid quality control.
- Refer the patient to the physiotherapy department so they can be added to their waiting list for assessment.

5. OUTCOME MEASURES

5.1 Primary outcome measure

The primary outcome is the feasibility of participant recruitment within the time scale (i.e. achieving 80% of the target within 6 months); see table 1.

5.2 Secondary outcome measures

Secondary outcomes include adherence rates (for VCDs, this is 70% of women wearing the VCDs as instructed by their clinicians. For PFMT, this is women reporting attendance to 70% of their individualised planned program appointments).

Other secondary outcomes include retention rate (achieve 80% at 6 months follow-up); rates of missing data; patient-reported success rates and adverse events of VCDs; use of self-funded VCDs; waiting times for physiotherapy, establishing reliable recruitment projection and refining our pre-defined progression criteria for a potential future RCT.

Table 1: proposed progression criteria for a future RCT

Proposed Progression criteria for an RCT	Red	Amber	Green
Participant recruitment	<60%	61 - 79%	≥80%
Participant Retention*	<60%	61 - 79%	≥80%
Adherence rates ▲	<50%	51 - 69%	≥70%

*number of participants completing the 6 month follow-up
▲number of women wearing the VCDs as instructed by their clinicians and for PFMT attending 3 out of the 5 appointments or 70% of their individualised planned program.

6. DATA COLLECTION AND PROCESSING

6.1 Measuring outcomes

A baseline questionnaire will be completed prior to randomisation. Follow-up questionnaires will be sent at 3 and 6 months post-randomisation. Table 2 summarises the sources and timing of outcomes measures.

Table 2: Outcome measures

	Baseline	3-months	6-months
Clinical assessment	○		
ICIQ-FLUTS (*International Consultation on Incontinence Questionnaire - Lower Urinary Tract Symptoms Questionnaire)*	○	●	●
ICIQ-LUTSqol *International Consultation on Incontinence Questionnaire - Lower Urinary Tract Symptoms Quality of Life Questionnaire*	○	●	●
ICIQ-FLUTSsex *International Consultation on Incontinence Questionnaire Female Sexual Matters Associated with Lower Urinary Tract Symptoms*	○	●	●
PGI-I		●	●
Adverse events		●	●

○ At clinic appointment or by post/ email
● By post, email, text – according to participant's preference

6.2 Baseline

The baseline questionnaires will collect information about participants' age, parity, smoking status, previous treatment, severity of urinary incontinence and ethnicity. As described, the following questionnaires are also included in the Baseline-pack: ICIQ-FLUTS, ICIQ-LUTSqol, ICIQ-FLUTSsex.

6.3 Follow-up

Participants will receive their follow-up questionnaires and any reminders according to their preference (see section 4.9).

6.4 Data processing

Data collected by the local sites will be entered by Research Nurses. Staff in the Trial office will work closely with local Research Nurses to confirm the data are as complete and accurate as possible. Postal follow-up questionnaires will be sent from and returned to the Trial Office in Aberdeen, where data entry will be done.

7. SAFETY

The FEEL-GOOD study comprises Pelvic Floor Muscle Training and the use of Vaginal Continence Devices for the management of female SUI. Adverse effects may occur related to either of these interventions.

7.1 Standard Definitions

Term	Standard definition
Adverse Event (AE)	Any untoward medical event affecting a clinical trial participant.
Serious Adverse Event (SAE)	Where any AE: • results in death; • is life threatening (i.e. the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe); • requires hospitalisation or prolongation of existing hospitalisation; • results in persistent or significant disability or incapacity; • is a congenital anomaly or birth defect; • is otherwise considered medically significant by the investigator.

Adverse events are not:

- Continuous and persistent disease or symptom, present before the trial, which fails to improve; such as voiding dysfunction, urgency, urgency urinary incontinence, pain or dyspareunia.
- Signs or symptoms of the disease being studied; or
- Treatment failure: persistence or recurrence of urinary incontinence.

Hospitalisations for treatment planned prior to randomisation and hospitalisation for elective treatment of a pre-existing condition will not be considered as an AE. Complications occurring during such hospitalisation will only be considered AEs or SAEs if they are likely to be related to the interventions or research procedures.

7.2 Trial specific considerations

Planned hospital visits for conditions other than those associated with urinary incontinence and/ or its treatment will not be collected or reported. Further UI treatment will be recorded as a secondary outcome measure, but will not be reported as serious adverse events.

In this trial, AEs that are potentially related to the trial procedures and interventions (VCDs, PFMT) will be recorded (see definition of “related” in section 7.5 below). **All serious related AEs will be recorded as SAEs.** Any deaths (any cause) will also be recorded as SAEs. We will not capture unrelated SAEs.

Due to the reporting and collection of these events as primary and secondary outcome measures, the following do not need to be reported as AEs or SAEs:

- Urinary symptoms
- Sexual dysfunction

Furthermore, pre-existing conditions and any pre-planned hospitalisations (e.g. elective surgery) not associated with clinical deterioration will not be classed as Serious Adverse Events.

Trial specific expected adverse events

The FEEL-GOOD trial involves interventions to treat stress urinary incontinence which are well established in clinical practice. Expected adverse events arising from PFMT and VCD usage are:

- pelvic or abdominal pain/ discomfort,

- low back pain
- vaginal pain/ discomfort/ irritation
- vaginal discharge/ ulceration or Smell,
- abnormal vaginal bleeding,
- bleeding during removal of the device
- urinary or vaginal infections,
- urinary retention requiring a catheter in the bladder
- VCD falling out
- VCD entrapment in the vagina requiring removal in theatre

7.3 Detecting AEs and SAEs

All relevant AEs and SAEs meeting the criteria for reporting in FEEL-GOOD (see section 7.2) must be documented from the time a participant consents to join the study until their last follow-up is complete. Follow-up questionnaires will ask about any AE/SAE occurrence. In-addition, participants will also be asked if they have been admitted to hospital and/or seen a healthcare professional.

7.4 Recording AEs and SAEs

Relevant adverse events will be recorded in the case report forms (CRFs) or questionnaires. The Investigator (or delegate) should record all relevant SAEs on the SAE form.

In addition, death for any cause (related or otherwise) is recorded on the SAE form. The Chief Investigator and the trial office are responsible for ensuring all notified relevant SAEs are reported to the Sponsor within 24 hours of becoming aware of the event and providing further follow-up information as soon as available.

Depending on severity of AE/SAE, it is the responsibility of the local Principal Investigator (or delegated medical personnel) to review appropriate documentation (e.g. hospital notes, laboratory and diagnostic reports) related to the event. The local PI (or the delegated medical personnel) should then record all relevant information in the CRF and if required on the SAE form.

The type and date of SAE will be collected as well as Investigator assessment of severity and causality and any investigation/ treatment required.

7.5 Evaluating AEs and SAEs

All adverse events will be assessed in respect of seriousness, relationship to study intervention, whether expected or unexpected, and therefore, whether constituting a Serious Adverse Event (SAE) by the local PI, CI or their deputies.

Assessment of Seriousness

The Investigator should make an assessment of seriousness as defined in Section 7.1.

Assessment of Causality

The Investigator must make an assessment of whether the SAE is likely to be related to any of the research procedures according to the following definitions:
- Related: resulted from any of the procedures required by the protocol, whether or not this procedure is the specific intervention under investigation and whether or not it would have been administered outside the study as normal care.
- Unrelated: where an event is not considered to be related to any of the research procedures.

Assessment of Expectedness

Expectedness will be assessed for events using the list of expected events listed in Section 7.2.

7.6 Reporting AEs and SAEs

Reporting responsibilities of centres
Once the local PI becomes aware that a relevant SAE has occurred in a trial participant, they must report the information to the Trial Office. The Trial Office will report to the Sponsor within 24 hours of becoming aware of the event as per the Sponsor guidance.

The SAE form must be completed as thoroughly as possible with all available details of the event and signed by the Investigator or designee.

If all the required information is not available at the time of reporting, the local PI must ensure that any missing information is provided as soon as this becomes available. It should be indicated on the report that this information is follow-up information of a previously reported event.

To report an SAE to the Trial Office, centre staff can either complete a hard copy of the SAE form and email it to the Trial Office or upload the SAE onto the trial website. If the SAE form is uploaded onto the trial website, the Trial Manager will be automatically notified.

Reporting responsibilities of the trial office
If, in the opinion of the local PI and/or the CI, the event is confirmed as being **serious but not related** the event does not require to be captured as a SAE.

If, in the opinion of the local PI and/or the CI, the event is confirmed as being **serious and expected**, expedited reporting to Sponsor is not required. Rather these will be summarised and reported to Sponsor, Funder, TSC and DMEC in their regular progress reports.

If, in the opinion of the local PI or the CI, the event is confirmed as **serious, related and not expected**, expedited reporting to Sponsor is required.

The sponsor will provide an assessment of the SAE. A Sponsor cannot downgrade an assessment from the PI or CI. Any disparity will be resolved by further discussion between these parties and documented in the TMF.

Regulatory reporting requirements
The CI or delegate reports any SAEs that are **serious, related and not expected** to the REC within 15 days of the CI becoming aware of it using the HRA SAE form.

7.7 Follow up procedures AEs/SAEs
After initially recording and reporting an SAE, the local PI is required to follow each participant as indicated by clinical practice. Follow up information on an SAE should be reported to the Trial Office as described above in the Section on 'Reporting responsibilities of centres'. The Trial office will notify the Sponsor about any follow-up information.

7.8 Pregnancy
Pregnancy is not considered an AE or SAE, however we will collect pregnancy information for trial subjects as part of the follow up questionnaires. If a participant becomes pregnant while participating in the trial, the details of the pregnancy should be reported to the treating clinician and research team as soon as the participant becomes aware and the participant will be withdrawn from the trial and her care will be provided by the centre. Notification of pregnancy during the trial will be reported in the change of status form.

8. EMBEDDED QUALITATIVE WORK

8.1 Overview

To address objectives 1 and 2, a qualitative study will be embedded within the pilot RCT. Informed by the results from the Stage-1 qualitative study on the possible challenges and the design/protocol of the pilot study (including proposed recruitment strategy and the outcomes to be collected), the Stage-2 qualitative work aims to identify:

- Attitudes and preferences of women and HCPs regarding VCDs as a management option for SUI,
- Issues impacting on the pilot (actual) trial participation (including treatment intervention and trial processes e.g. randomisation/ follow up and recruitment (uncertainty, preference and trust in HCPs and researchers) and decisional regret,
- Issues impacting on the pilot (actual) RCT conduct e.g. ethical issues (older adults and cognitive functioning), fidelity of intervention delivery and adherence, and
- Issues related to feasibility and measurement of key outcomes that matter to women as well as clinically important outcomes for HCPs

This qualitative study will involve one-to-one semi-structured interviews with women and focus groups with healthcare professionals (HCPs). The study will also involve audio-recordings of initial consultations between HCPs and potential participants where trial participation is discussed (these audio-recordings will be done in at least one recruitment site but it is not anticipated that all sites will be asked (or will agree) to this component of the study.

8.2 Theoretical Frameworks

The qualitative study will be informed by a theoretical framework of acceptability (i.e. the Theoretical Framework of Acceptability (TFA))[19]. The TFA (specifically developed to explore acceptability of healthcare interventions) will be used to inform a richer understanding of acceptability across core constructs for both the non-surgical intervention and for the potential trial. The project design, project materials, evaluation of the draft recommendations and the statement on feasibility of a future trial will also be informed by NIHR INCLUDE Framework[20].

8.3 Interviews with Women

One-to-one semi-structured interviews will be conducted to explore attitudes and preferences towards random allocation to different treatment options within the pilot trial evaluating VCDs and views on likely outcomes. Interviews will be conducted with between 9-15 women from across all sites. We also plan to interview women who decline to take part in the FEEL-GOOD pilot/feasibility trial to better understand reasons for this. We will aim to complete up to 5 such interviews pending their consent.

Eligibility criteria

The eligibility criteria for this interview component of the study are identical to those described for the feasibility and pilot RCT in section 4.3.1.

Participants' selection and sample size:

Consent to be contacted by the qualitative research team will be sought from participants in the FEEL-GOOD study at time of the main study consent process. Consent to be contacted will be an optional component of the main study consent form, with brief information contained within the PIL. As noted above, we would also like to interview women who decline to take part in the FEEL-GOOD study. Such women will be asked if they would consent to be contacted by the qualitative research team. In such cases, women will be asked to complete a separate consent to contact form, and sign and date the form to confirm that they are happy to be contacted.

Once consent to be contacted has been given, a participant information sheet for the non-trial participant interview component of the study will be given/sent to those individuals by the research nurse/study team.

The qualitative research team will answer any participant queries, ensure they are clear about what the study entails and arrange an appropriate time for interview. Potential participants will be informed that participation in the interview is voluntary and that they have right to withdraw from study at any time without providing a reason and the right to reschedule the interview at any time including during an ongoing interview. Potential interview participants will be asked to verbally confirm they consent to audio-recording prior to recording. If potential participants do not consent to the audio-recording, by default will not consent to the qualitative interviews. The audio-recording will commence only following verbal consent to continue. A script will be read to the participant to take fully informed verbal consent to the qualitative interview study and this will be audio-recorded. A verbal consent form is completed by the qualitative research team before the interview and a copy is provided to the participant. The audio-recording of the verbal consent is deleted after transcription. Consent to have the verbal consent transcribed by an external provider to the University will be sought as part of the consent process. Agreement to participate in the interview will be confirmed verbally at the start of each interview. The women who decline to be randomised but are interested to participate in the interviews will also be included in the embedded qualitative study.

Video conference or telephone interviews will be conducted as per participant preference by an experienced qualitative researcher. The interviews will be semi-structured and the topic guide will be informed by discussions between the study team, the scientific literature and key themes from Stage 1. Interviews will be audio-recorded in a separate audio-recording to the verbal consent and transcribed verbatim. Consent to record the interviews, to have the recordings of interviews transcribed by an external provider to the University and to use anonymised quotations from interview transcription for publication will be sought as part of the consent process. All interviews (including where video conferencing software (MS Teams) is used) will only be audio recorded by use of an encrypted digital recorder.

All women eligible to take part in the pilot RCT will be eligible to take part in the qualitative study if they are able to speak via MS Teams or phone call.

The research team will complete cultural competence and awareness training before beginning any qualitative work. They will also receive peer mentoring and feedback from the FEEL GOOD PPI group. The research team will remain responsive to input from the PPI group to maximise the design and enactment of the interviews.

Sampling: A purposive sampling frame informed by the NIHR INCLUDE project[20] has been used to inform the sample size and recruitment strategy for this study. The sample size is based on a combination of defined information power (narrow aim) including the diverse characteristics of the population to be sampled (e.g. age; medical frailty; ethnicity and socioeconomic status), a dense sample specificity, specific theory, experienced interviewer with background in this areas and a cross-case analysis strategy and previous experience and input from our PPI co-applicants. We will additionally set a priori recruitment and data check points for sample diversity. The intention in specifying initial analysis and recruitment checks is to increase confidence in the information power of the project and the contribution of new insights to the area in question.

Initially, 9 participants will be recruited and interviewed, and their data analysed. At this initial stopping point, we will reflect on the diversity of the sample and seek to increase diversity in the recruitment to the remaining interviews. A further 3 interviews will then be conducted and coded using both inductive and deductive coding. If new inductive themes are identified within this set of interviews, we will continue with another three interviews and so on until no new themes are identified.

The topic guide will be informed by findings from FEEL GOOD stage 1 qualitative study, discussions between the project team, and our PPI partner organisations, the scientific literature and by the two theoretical frameworks (TFA, INCLUDE).

8.4 Health Professional Focus Groups:

Focus groups will be conducted to explore attitudes and preferences towards the different treatment options within the pilot RCT evaluating VCDs and views on recruitment, RCT conduct and likely outcomes. Approximately 8-10 HCPs including those who currently do / do not offer VCDs, clinicians, physiotherapists and specialist nurses will take part in a focus group (using MS teams and MS whiteboard). The group of HCPs will be recruited from across all the sites, if possible, to reflect those likely to be involved in subsequent definitive trials.

Eligibility criteria

Clinicians, physiotherapists and specialist nurses in the pilot sites who are involved in the care of women with stress predominant UI are eligible; this includes HCPs who currently do or do not offer VCDs. HCPs who are directly involved in the study (i.e. listed on the study delegation log) are eligible, as are HCPs involved in patient care at the site (but not listed on the study delegation log). HCPs are eligible if they are able to speak via MS Teams or phone call.

Approaching HCPs

The Information Leaflet about this component of the study will be provided to eligible HCPs by the local PI or research nurse. If they are interested in taking part in a focus group, they will be asked to contact the qualitative researcher by telephone or email.

Sampling for HCP focus groups:

Purposive (non-probability) sampling will be used to ensure the diverse characteristics of the HCPs sampled (e.g. pilot RCT site, gender, ethnicity, role, years in practice).

Data Collection:

The qualitative researcher will arrange a suitable date/time for the focus group. Verbal consent will be recorded before the focus group and a copy sent to participants. Key demographic information will be collected as part of the focus group.

Focus group participants will be asked to verbally confirm they consent to audio-recording prior to recording. The audio-recording will commence only following verbal consent from all participants to continue. A script will be read to the participants to take fully informed verbal consent for the focus group and this will be audio-recorded. A verbal consent form is completed by the qualitative research team and a copy is provided to the participant. The audio-recording of the verbal consent is deleted after transcription. Consent to have the verbal consent transcribed by an external provider to the University will be sought as part of the consent process.

Focus groups will be audio-recorded in a separate audio-recording to the verbal consent and transcribed verbatim. Consent to record the focus group, to have the recordings of the focus group transcribed by an external provider to the University and to use anonymised quotations from the focus group for publication will be sought as part of the consent process. Focus groups (including where video conferencing software (MS Teams) is used) will only be audio recorded by use of an encrypted digital recorder.

All focus groups will be conducted by an experienced qualitative researcher (who also conducted the stage 1 qualitative study).

The topic guide for the focus group will be informed by the findings from the FEEL GOOD stage 1 qualitative study, discussions between the project team, and our PPI partner organisations, the scientific literature and by the two theoretical frameworks (see above).

8.5 Analysis

The data from interviews and focus groups will be professionally transcribed verbatim by a transcription company (NJC Secretarial) that is approved by University of Aberdeen.

All interview and focus group data will be coded inductively and deductively, and the analysis organised using an explicit, structured qualitative method - Framework' analysis (Smith and Firth 2011). This method employs a number of distinct but interconnected stages in a systematic process. The 5 key stages are: familiarisation of the data; identifying a thematic framework; indexing themes; charting; mapping and interpretation. NVivo (V 12) will be used to support the analysis of qualitative data.

8.6 Audio-recordings of recruitment consultations between HCPs and potential participants

We will aim to audio-record the initial consultations between HCPs and potential participants where trial participation is discussed in at least one recruitment site. We do not anticipate that all sites will be asked (or will agree) to this component of the study. Participation in this component of the study will be discussed during site set-up.

The aim of audio-recording the recruitment consultation is to explore trial decision-making by potential trial participants and clinical site staff (including Research Nurse(s)) involved in the trial. This will enable the trial team to systematically assess the content and presentation of study information by recruiters, the interactions between participants and recruiters, and provide evidence on which to develop appropriate recruitment strategies. This will also provide evidence about how potential participants can be better supported and informed when making a decision about participation. The audio-recordings will contribute to determining models of 'good practice' for consent discussions which can be used for site training.

<u>Sampling and recruitment</u>

All staff at the site(s) where the audio-recording component of the study is implemented who are involved in discussing FEEL-GOOD with potential participants will be asked to routinely record consultations in which the trial is discussed. As part of the FEEL-GOOD trial, potential participants will receive a participant information leaflet (PIL) explaining the trial in detail. To facilitate the audio recording study, a separate PIL will be given to participants at the same time, but before any discussion of the trial is initiated, explaining the purpose and the specific request to audio-record their recruitment consultations. Patients will not be obliged to participate in the audio-recording study and the decision will not affect their invitation to take part in FEEL-GOOD. Similarly, patients may agree to take part in the audio-recording study but then decline to take part in the FEEL-GOOD trial. Recruitment consultations will be recorded after an initial greeting and introduction to the consultation. If the participant indicates that they are happy for the recording to be started, this will be done. Immediately after this, the verbal consent script will be used to confirm the consent as part of the recording. If a participant does not want the recording to be started, it will not be started and the consultation will continue as planned (with no audio recording). If the participant declines to take part while the verbal consent script is being read, the audio recording will be stopped, and the file deleted. With regard to staff consent, staff information sheets about the recording process will be distributed and a one-off written consent from all staff involved in audio-recording (that covers all subsequent recordings captured throughout the study period) will be sought.

<u>Data collection</u>

Sites participating in this component of the study will be provided with encrypted devices to record the conversation. The audio recordings of recruitment consultations will be uploaded to a secure area of the study website. If for any reason the upload function is unavailable, a secure file transfer system, such as the University of Aberdeen ZendTo service, will be used. Once receipt of the recording has been confirmed by the qualitative researcher, the audio file held on the encrypted device will be deleted.

We will aim to achieve up to 5 such audio-recordings

Data management
All conversations within the recordings related to FEEL-GOOD pilot RCT will be transcribed for the purpose of analysis. Only conversations related to the FEEL-GOOD pilot RCT (where recruiters explain the design and details of the FEEL-GOOD pilot RCT, and patients decide whether or not to take part) will be transcribed for the purpose of analysis by a Sponsor approved third party professional transcription service (NJC Secretarial). When the transcript is returned from the transcription service, it will be checked for accuracy and the audio-file deleted. The transcript will be anonymised. Anonymised transcripts and will be held securely for 6 years in accordance with Sponsor requirements and data legislation.

Sample characteristics information will be collected for each of the audio recordings, including (but not limited to) information on: who was involved in the discussion (i.e. consultant, Research Nurse), duration of consultation, whether the participant consented, which treatment they were allocated to (as applicable), etc.

Data analysis
The transcripts of the consultations will be analysed using content and thematic analysis to elucidate reasons for imbalances in presentation, style and content of information provided by the recruiter, participation and engagement of the patient, and indications of the presence and origin of 'hidden challenges'. The analysis will focus on modifiable aspects of recruitment consultations e.g. eligibility of participants, exploration of preferences, discussion of uncertainty and balancing of options. Audio-recordings will also be analysed for discussions relating to trial follow-up procedures (i.e. completion of patient questionnaires) and the importance placed on commitment to the trial across the entire timeline. Feedback will be provided across all the sites on how to improve aspects of the informed consent process based on targeted analysis described above. Whilst we will continue to collect audio-recordings of consultations, the analysis of these will be triggered based on key diagnostics identified using the SEAR (Screened, Eligible, Approached, Randomised) framework.

As audio-recordings generated will be listened to and sent for targeted transcription (i.e. only transcribing sections relevant to improve trial process). Analysis will proceed alongside data collection. Analysis will focus on modifiable aspects of consultations e.g. eligibility of participants, exploration of preferences, discussion of uncertainty and balancing of options. Audio-recordings will contribute to determining models of 'good practice' for consent discussions. With regard to exploring aspects of trial retention, audio-recordings will also be analysed for discussions relating to trial follow-up procedures (i.e. clinic visits and completion of patient questionnaires) and the importance placed on commitment to the trial across the entire timeline. Feedback will be provided to all the collaborating sites on how to improve aspects of the informed consent process based on targeted analysis described above. The findings of this component will also feed into the larger trial that is planned.

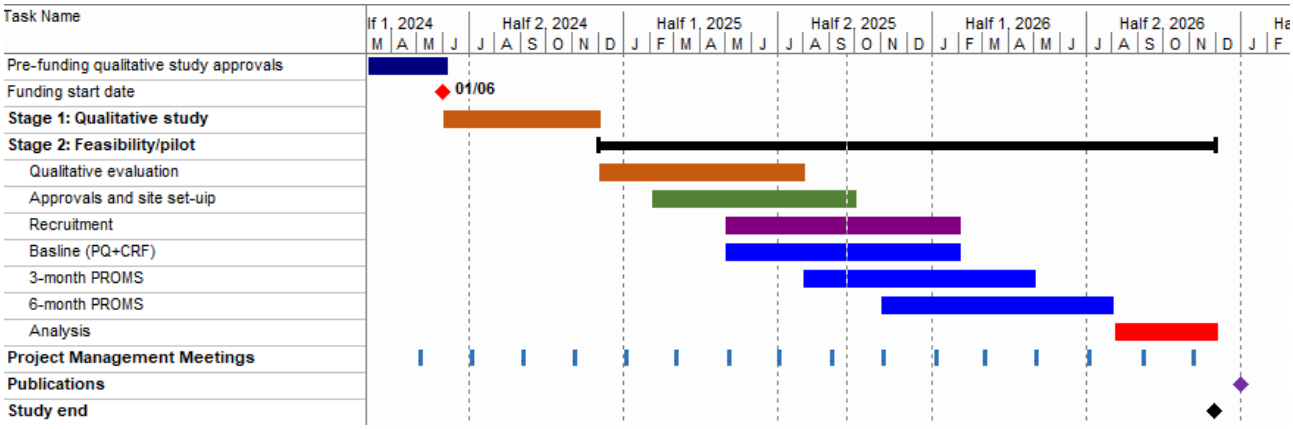
9. SAMPLE SIZE AND PROPOSED RECRUITMENT RATE

9.1 Sample size and recruitment rate
A sample size of 60 women will be sufficient to identify any potential problems in feasibility which have a 5% probability of occurrence, with 95% confidence. A pilot study of this size will also give a precise estimate of the standard deviation for a small effect size in a future phase 3 effectiveness trial with 90% power and two-sided 5% significance.[21,22]

We aim to recruit a total of 74 women to allow for 20% attrition based on our previous RCTs in this field (SIMS[17] and OPAL[23]). In our detailed survey of practice in 64 potential collaborating centres, recruitment estimates ranged from 8 to 50 participants per month. We used a conservative estimate

of 4-6 centres, each recruiting 3-4 per month per centre, to achieve our target of 74 participants over a 6-month recruitment period.

9.2 Gantt chart



10. STATISTICAL ANALYSIS

The statistical analysis is outlined fully in a separate statistical analysis plan. All main analyses will be based on the Intention-to-Treat (ITT) principle. Analysis will take place after full recruitment and follow-up is complete. The focus will be on tabulated and associated graphical summaries of the key indicators of success of the pilot.

We will report data in line with the Consolidated Standards of Reporting Trials (CONSORT) 2010 extension statement for Pilot and Feasibility trials showing attrition rates and loss to follow-up.

As the primary outcome is the feasibility of achieving 80% of the target within 6 months it is a simple summary of the number of participants recruited and there is no uncertainty on this count. The number identified as eligible is also an exact number as are the numbers who drop out from receiving the intervention, withdraw consent and fail to provide follow-up data. These numbers can be used to calculate the percentage of eligible participants who enter the trial, adhere to their allocated intervention and also estimate the loss to follow-up percentage. Confidence intervals will be obtained for these percentages too.

The success rate from the PGI-I, adverse events will be summarised with count and percentage while the specific UI outcomes and waiting time for physiotherapy will be summarised with mean and standard deviation. The UI outcomes and PGI-I success rate will be compared using the appropriate linear regression model with adjustment for the baseline outcome where possible to obtain a treatment effect and 95% confidence interval. Adverse event rates will be compared between the groups using the appropriate linear model to obtain a relative risk.

10.1 Integration of data

The findings from Stage1 qualitative study will be used to generate an initial set of deductive codes (grounded in the Theoretical Framework of Acceptability) and inductive codes relating to recruitment, randomisation and study outcomes to inform the design of Stage 2 Pilot RCT. Deductive content coding and inductive generation of new sub-codes will then form the first stage of analysis of the Stage 2 data. This will then be followed by matrix driven coding to complete the integrated analysis of Stage 1 and Stage 2 data. NIVIVO will be used to support rigour.

11. ORGANISATION: TRIAL MANAGEMENT AND OVERSIGHT ARRANGEMENTS

11.1 Trial office in Aberdeen

The Trial Office is in the Centre for Healthcare Randomised Trials (CHaRT) based within the Health Services Research Unit, University of Aberdeen and provides day to day support for the clinical centres. The Trial Manager in ChaRT and the NRS Fellow (MD) will take responsibility for the daily transaction of study activities. The data co-ordinator will provide clerical support to the trial, including organising all aspects of the postal questionnaires (tracking, mailing, and entering returned data using the trial web data entry portal). The CHaRT Quality Assurance Manager will supervise that CHaRT's standard operating procedures for trials are being followed, including adherence of the appropriate principles of GCP.

At the centres, the recruitment coordinators/ research nurses will be responsible for all local processes involved in identifying, consenting, and randomising the participants, along with facilitating the delivery of the intervention.

The FEEL-GOOD Study Office Team will meet regularly during the course of the study to ensure streamlined running and trouble-shooting.

11.2 Local organisation in sites

The local PI and research nurse in each site are responsible for all aspects of local organisation including identifying, consenting, and randomising participants as well as completing and maintaining appropriate documentation and notifying any challenges or unexpected changes during the trial. They will be responsible for ensuring that study data is collected for baseline assessments, gathering and recording participant study data on study specific Case Report Forms and will log all the details onto the remote web-based data capture system as soon as practical after completion. The local PI will return all study documents to the study office in Aberdeen when requested

Appropriate members of the local team are knowledgeable about the Protocol and will have appropriate Good Clinical Practice (GCP) training if applicable. Those members of the local team who are carrying out their routine activity as part of the study (for example physiotherapists involved in delivering PFMT) are not required to have GCP training. They can be added to the delegation log if they wish to be included. The local team is also responsible for notifying SAEs to the Trial Office (see section 7).

11.3 Project Management Group (PMG)

The trial will be supervised by the FEEL-GOOD Project management Group (PMG). This consists of the grant holders and representatives from the Trial Office. The PMG will meet/teleconference every 3 months on average. In addition, the PMG will also meet at the annual Trial Steering Committee meeting.

11.4 Trial Steering Committee (TSC)

A Trial Steering Committee (TSC), with independent members, oversees the conduct and progress of the trial. The TSC Charter documents the terms of reference of the TSC, the template for reporting and the names and contact details of members of the TSC. This Charter is filed in the Trial Master File (TMF).

11.5 Patient and Public Involvement (PPI)

We undertook an extended PPI focus group session, at the conception of the proposal and integrated their valuable suggestions. We worked closely with Women's Voices (RCOG) and Bladder Health-UK in the co-development of this proposal. They will form a patient advisor group (PAG) to drive our PPI partnership and play an active role in the design, recruitment, delivery, analysis and dissemination of the study. Both our PPI partners have patient representatives from diverse

backgrounds including age, ethnicity and socio-economic status. The PAG will ensure the research is centred on the needs of the women with UI through co-designing the patient interview questions and the HCP focus group questions. The PAG will also identify and support two members of the PAG to act as peer advocates. Our PPI will be part of the Project Management Group. All PPI will receive any training they need and will be reimbursed in line with NIHR guidance and the RCOG PPI tariff.

With the PPI members we will develop a public dissemination strategy that use a range of methods and formats including newsletters, podcasts, infographics, etc. The patient community will be informed by study newsletter and infographics, and the broader public via our PPI partner organisations' channels of communication e.g. social media, and advocacy events.

12. RESEARCH GOVERNANCE, DATA PROTECTION AND SPONSORSHIP

12.1 Research Governance

CHaRT is a fully registered Clinical Trials Unit with specific expertise in running multicentre RCTs. The study will be run under the auspices of CHaRT based at the Aberdeen Centre for Evaluation, University of Aberdeen. This supports compliance with Research Governance and the principles of GCP, and provides centralised trial administration, database support and statistical analyses.

The PMG will ensure via TSC that adequate systems are in place for monitoring the quality of the trial and that reports are prepared to a level suitable to the risk assessment of the trial.

12.2 Data protection

Data collected during the research will be kept strictly confidential and accessed only by trial team members. Data may be looked at by individuals from the Sponsor organisation or NHS sites where it is relevant to the participant taking part in this trial.

The trial staff involved with this project will comply with the requirements of the UK Data Protection Laws. The HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the PIL.

The CI and trial staff based in Scotland will also adhere to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate trial staff.

Computers used to collate the data will have limited access measures via usernames and passwords.

Remote access to the network will be subject to robust authentication, and VPN (Virtual Private Network) connections to the network are only permitted for authorised users, ensuring that use is authenticated, and data is encrypted during transit across the network. No personal data will be downloaded or stored on local hard drives. All data input/access will be via the VPN and/or secure website.

Published results will not contain any personal data that could allow identification of individual participants.

The CHaRT senior IT development manager (in collaboration with the CI) manages access rights to the data set. Participants are allocated an individual trial number which is used to identify questionnaires and case report forms.

We anticipate that anonymised trial data may be shared with other researchers to enable international prospective meta-analyses. Consent will be sought for this.

12.3 Sponsorship
The University of Aberdeen is the sponsor for the trial.

13. ETHICS AND REGULATORY APPROVALS
Research Ethics Committee and appropriate NHS R&D approvals will be obtained prior to the commencement of recruitment. The trial will be conducted according to the principles of Good Clinical Practice provided by Research Governance Guidelines and any appropriate NHS R&D approvals will be obtained. The End of Trial declaration, and a final report are submitted to the Sponsor and the REC within the timelines defined in the regulations.

13.1 Protocol compliance and amendment
The Investigators will conduct the trial in compliance with the Protocol given favourable opinion by the NHS Research Ethics Committee. Any amendment to the Protocol or other approved documents will be reviewed by Sponsor (and funder where appropriate) before application to REC and R&D unless in the case of urgent safety measures when the Sponsor is notified as soon as possible. Sponsor will advise if an amendment is substantial / non-substantial and which review bodies need to receive it. Any deviations from the Protocol will be fully documented.

14. MONITORING AND AUDIT
The trial is monitored to ensure that it is being conducted as per protocol, adhering to Research Governance, the principles of GCP, and all other appropriate regulations. The approach to, and extent of, monitoring is specified in the trial monitoring plan and is appropriate to the risk assessment of the trial. Investigators and their host institutions are required to permit trial related monitoring and audits to take place by the Sponsor and/ or regulatory representatives, providing direct access to source data and documents as requested.

14.1 Risk assessment
An independent risk assessment has been carried out by the sponsor.

15. FINANCE AND INSURANCE

The trial is funded by a grant awarded by the Chief Scientific Office (CSO). The necessary clinical trials insurance is provided by the University of Aberdeen.

16. END OF TRIAL

The end of follow-up for each participant is defined as the final data capture on that individual. The end of the trial is defined as the end of funding.

The end of the trial will be reported to the Sponsor and REC within 90 days, or 15 days if the trial is terminated prematurely. If terminated prematurely, the Investigators will inform participants and ensure that the appropriate follow up is arranged for all involved, if appropriate.

A summary report of the trial will be provided to the Sponsor and REC within one year of the end of the trial. An end of trial report should also be issued to the funders at the end of funding.

17. DATA HANDLING, RECORD KEEPING AND ARCHIVING

17.1 Source data

If hard copy and/or electronic CRFs are completed from medical records, the medical record is considered to be the source document.

For any patient reported data captured on a hard copy CRF, the CRF is considered to be the source document. If the patient reported data is completed directly onto the eCRF, the eCRF is considered to be the source document.

For CRF data, if the eCRF is considered to be the source document, in order to maintain a copy of the data that is independent from the sponsor copy, sites will be encouraged to print or save a copy of the data within the eCRF. The study website will provide this facility.

For all case report forms, there is an electronic record (as part of the study website) which indicates whether the case report form was completed online (no paper copy) or not. This will allow identification of the source document.

If participants complete paper copies of the questionnaires, these are considered to be the source document. If participants complete online versions of the questionnaire, the online record is considered to be the source document.

17.2 Data management

Clinical data will be entered into the database by the designated team members working in each recruitment site, together with data from questionnaires completed at clinic. Questionnaires returned by post to the trial office will be entered there. Staff in the trial office will work closely with local team members to ensure that the data are as complete and accurate as possible. Extensive range and consistency checks will further enhance the quality of the data.

The sponsor is responsible for archiving the trial data appropriately. All essential data and documents (electronic and hard copy) are retained for a period of at least 6 years after close of trial according to the funder requirements and relevant Sponsor and CHaRT archiving SOPs. Electronic data will be archived by the University of Aberdeen. Research sites will archive hard copies of consent forms, along with any CRFs and baseline questionnaires completed as hard copy. The trial office (University of Aberdeen) will archive follow-up questionnaires completed as hard copy.

18. SATELLITE STUDIES

It is recognised, that the value of the trial may be enhanced by smaller ancillary studies of specific aspects. Plans for these will be discussed in advanced with the PMG and, if appropriate, with the TSC. Depending on the nature of the satellite trial, the Sponsor may consider this to be a non-substantial or a substantial amendment to the REC approval for the FEEL-GOOD trial, or to require REC approval as a project in its own right. R&D management approval may also be required. In such situations, the sponsor will be contacted for advice.

19. AUTHORSHIP AND PUBLICATION

Please refer to the Appendix 1 (authorship policy) for full details on authorship.

To safeguard the integrity of the main trial, reports of explanatory or satellite studies will not be submitted for publication without prior arrangement from the PMG and TSC.

19.1 Other Dissemination

Once the main trial findings have been published, a lay summary of the findings will be sent to participants.

Trial findings will also be disseminated to professionals involved in the trial, including GPs of participants, PIs at sites, site staff, etc.

More detailed plans for this dissemination will be considered and developed with input from PPI partners through the duration of the trial and will be finalised as part of the close-out plans.

REFERENCE LIST

1. National Institute for Health and Clinical Excellence (2006). Urinary incontinence; full guideline. CG40 [accessed January 2013]. URL: http://guidance.nice.org.uk/CG40/Guidance/pdf/English
2. Perry, S. *et al*. (2000). An epidemiological study to establish… The Leicestershire MRC Incontinence Study. J Public Health Med. 2000Sep;22(3):427-34. doi: 10.1093/pubmed/22.3.427.
3. Ioe.ac.uk.(2019).CCEMG-EPPI-v.1.4.: https://eppi.ioe.ac.uk/costconversion/default.aspx.
4. https://urologyweek.org [Accessed 23 Sep. 2023].
5. National Institute for Health and Care Excellence (2019). Urinary incontinence and pelvic organ prolapse in women: management. [NICE guideline No.123].
6. Abdel-Fattah, M. *et al.* (2011) Primary and repeat surgical treatment for female pelvic organ prolapse and incontinence in parous women UK. BMJ Open. doi: 10.1136/bmjopen-2011-000206.
7. Northern (NHS) Treatment Advisory Group (2022). Decision Summary: Vaginal devices for female urinary stress incontinence. https://ntag.nhs.uk
8. Bø, K. (1995) Pelvic floor muscle exercise for the treatment of stress urinary incontinence: An exercise physiology perspective. Int Urogynecol J6,282–291. https://doi.org/10.1007/BF01901527
9. Lipp, A. *et al*. (2014) Mechanical devices for urinary incontinence in women. Cochrane Database of Systematic Reviews. DOI: 10.1002/14651858.CD001756.pub6
10. Cornu, J. *et al.* (2012) 75NC007 device for noninvasive stress urinary incontinence management in women: a RCT. Int Urogynecol J. doi: 10.1007/s00192-012-1814-z.
11. Glavind, K. (1997) Use of a vaginal sponge during aerobic exercises in patients with stress urinary incontinence. doi: 10.1007/BF02765595. PMID: 9609334.
12. Nygaard, I. (1995) Prevention of exercise incontinence with mechanical devices. J Reprod Med. 1995 Feb;40(2):89-94. PMID: 7738934.
13. Lovatsis, D. *et al.* (2017) Short-term Uresta efficacy (SURE) study: a randomized controlled trial of the Uresta continence device. Int Urogynecol J. doi: 10.1007/s00192-016-3090-9.
14. Jonasson, A. *et al.* (2021) A Vaginal Inlay for Reduction of Stress Urinary Incontinence: Outcome of a RCT and Four User Acceptance Studies, Advances in Urology, doi: 10.1155/2021/8822186
15. Richter, H. *et al.* (2010) A Trial of Continence Pessary vs. Behavioral Therapy vs. Combined Therapy for Stress Incontinence. Obstet Gynecol. doi:10.1097/AOG.0b013e3181d055d4.
16. National Institute for Health and Care Excellence (2021). Pelvic floor dysfunction: prevention and non-surgical management. [NICE guideline No. 210]. https://www.nice.org.uk/guidance/ng210
17. Abdel-Fattah, M. *et al.* (2022) Single-Incision Mini-Slings for Stress Urinary Incontinence in Women. N Engl J Med. 2022 Mar 31;386(13):1230-1243. doi: 10.1056/NEJMoa2111815.
18. Abdel-Fattah, M. et al. (2021) (FUTURE study): a superiority RCT to evaluate effectiveness of invasive urodynamic investigations in management... doi: 10.1186/s13063-021-05661-3.
19. Sekhon, M. *et al.* (2017). Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC 17(1). doi:10.1186/s12913-017-2031-8
20. NIHR (2020). INCLUDE project. www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435
21. Viechtbauer W, *et al*. A simple formula for the calculation of sample size in pilot studies. Journal of Clinical Epidemiology. 2015;68:1375-9.
22. Whitehead A, *et al.* Estimating sample size for pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. Statistical Methods in Medical Research. 2016;25:1957-073.
23. Hagen, S. *et al.* (2020) Effectiveness of pelvic floor muscle training with and without electromyographic biofeedback for UI in women: multicentre RCT. doi: 10.1136/bmj.m3719.

APPENDICES

Appendix 1: AUTHORSHIP POLICY FOR FEEL-GOOD TRIAL

1. DEFINING AUTHORSHIP

Authorship of published or presented papers is based on the following criteria.[1]

i. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

ii. Drafting the work or revising it critically for important intellectual content; AND

iii. Final approval of the version to be published; AND

iv. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-author.

2. PRINCIPLES OF AUTHORSHIP

The following principles of authorship have been derived from editorial publications from leading journals[2,3] and are in accordance with the rules of the International Committee of Medical Journal Editors (ICMJE)[1].

All contributors must fulfil the criteria detailed in section 1: DEFINING AUTHORSHIP in order to qualify for authorship.

Contributors who meet fewer than all four of the criteria for authorship listed above should not be listed as authors, but they should be acknowledged. For example, participation solely in the acquisition of funding, collection of data or technical editing, language editing or proofreading the article is insufficient by itself to justify authorship[1]. Those persons may be acknowledged and their contribution described. See section 3: ACKNOWLEDGEMENTS.

a. Preferred CHaRT authorship

Where possible, all CHaRT trials should publish using all the named contributors who qualify for authorship in the by-line i.e. Jane Doe, John Doe, John Smith and Ann Other.

However, there may be situations where this is not possible, for example if the journal limits the number of authors. In such circumstance, group authorship may be appropriate using by-lines similar to “The FEEL-GOOD trial group” or “Jane Doe, John Doe, John Smith, Ann Other and the FEEL-GOOD trial group”. The article should carry a footnote of the names of the people (and their institutions) represented by the corporate title. For some journals the journal will provide instructions on how to ensure the names of the collaborators appear on PubMed or equivalent.

Group authorship may also be appropriate for publications where one or more authors take responsibility for a group, in which case the other group members are not authors but may be listed in the acknowledgement (the by-line would read 'Jane Doe *for* the Trial Group')[2]. Again, the article should carry a footnote of the names of the people (and their institutions) represented by the corporate title.

b. Determining authorship

These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion numbers (ii) or (iii). Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript[1].

Tentative decisions on authorship should be made as early as possible[3]. These should be justified to, and agreed by, the Project Management Group (PMG). Any difficulties or disagreements will be resolved by the Trial Steering Committee (TSC).

c. Ordering of authors

The following rules may help with the ordering of authors, particularly for publications with individual authorship:

i. The person who has taken the lead in writing may be the first author.
ii. The senior author may wish to be the last named author.
iii. Those who have made a major contribution to analysis or writing (i.e. have done more than commenting in detail on successive drafts) may follow the first author immediately; where there is a clear difference in the size of these contributions, this should be reflected in the order of these authors.
iv. All others who fulfil the four authorship criteria described in Section 1: DEFINING AUTHORSHIP may complete the list in alphabetical order of their surnames.

3. ACKNOWLEDGEMENTS

All those who make a contribution to a publication, but who do not fulfil the criteria for authorship, such as interviewers, data processors, staff at the recruiting sites, secretaries and funding bodies, should be acknowledged by name, usually in an 'Acknowledgements' section specifying their contributions. Because acknowledgment may imply endorsement by acknowledged individuals of a trial's data and conclusions, authors are advised to obtain written permission to be acknowledged from all acknowledged individuals[1].

The acknowledgements should also reflect any agreed acknowledgements (for example with suppliers) that were documented in supply agreements (or equivalent).

4. DISCLAIMERS

All papers arising from CHaRT should include any appropriate disclaimers. For the current disclaimer please see Q-Pulse.

Authors should also ensure they include the trial funder's disclaimer: refer to the funders' website for details. Be aware that other disclaimers may also be required.

5. QUALITY ASSURANCE

Ensuring quality assurance is essential to the good name of the trial group. All reports of work arising from the FEEL-GOOD trial, including conference abstracts, outputs describing methodological aspects of the trial, and any outputs describing results from the trial, should be peer reviewed by the PMG. The PMG will be responsible for decisions about submission following internal peer review. Submission may be delayed or vetoed if there are serious concerns about the scientific quality of the report. If individual members of the group are dissatisfied by decisions, the matter may be referred to the TSC.

It is hoped that the adoption and dissemination of this policy will prevent disputes that cannot be resolved by informal discussion. However, any member of the trial team with a concern about authorship should discuss it with the relevant Chief Investigator, TSC, Line Manager or Programme Director as appropriate.

REFERENCES

1. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Developed by members of the ICMJE, the document is revised regularly and the current version (updated Jan 2024) is available at (www.icmje.org/#authors)
2. Huth EJ (1986). Guidelines on authorship of medical papers. *Annals of Internal Medicine*, **104**, 269-274.
3. Glass RM (1992). New information for authors and readers. Group authorship, acknowledgements and rejected manuscripts. *Journal of the American Medical Association*, **268**, 99.