RESEARCH STUDY PROTOCOL

PROTOCOL TITLE: **Transperineal ultrasound as a biofeedback tool for pelvic floor muscle therapy in postpartum patients.**

PROTOCOL NUMBER: **1**

VERSION NUMBER: **4**

VERSION DATE: **25th March 2025**

1 Table of Contents

1 BACKGROUND AND RATIONALE

Pelvic floor exercises (PFE) form the basis of recovery of the pelvic floor musculature after vaginal birth. Regular and effective PFE training has been demonstrated to reduce the risk of common pelvic floor disorders such as urinary and fecal incontinence, pelvic organ prolapse and sexual dysfunction[1]. However, in the postpartum period, effective pelvic floor muscle therapy is often overlooked with only 20% of postpartum women performing PFE on a regular basis[2]. One-on-one, supervised pelvic floor therapy with a trained physiotherapist can improve adherence to PFE. However, even when this group of women are evaluated, only 27% of them perform PFE in an effective manner[3].

The reasons for the poor adherence and effectiveness of PFE are multi-factorial. Lack of awareness of how to engage the pelvic floor muscles as well as what constitutes an effective contraction are the main barriers for effective therapy. A trained physiotherapist can make a digital assessment of pelvic floor muscle tone, however this assessment only provides indirect feedback to the patient. Verbal cues are often the only means of training and refining a patient's technique with PFE. What is needed is an objective, visual training tool that is available for evaluation by both physiotherapist and patient.

Biofeedback is the process by which a patient is able to control, train and modify voluntary body functions with aid of sensory feedback tools for the purpose of improving health and wellbeing[4]. Various biofeedback tools exist in medicine but in the context of pelvic floor physiotherapy, the use of transperineal ultrasound (TPUS) has gained popularity over the years due to its ability to clearly demonstrate the pelvic floor muscles and their interactions *(Fig. 1)*. TPUS has the advantage of being accessible, safe, easy to use and relatively non-invasive compared to other imaging modalities. It can be utilized in the outpatient (clinic) setting, providing real-time visualization of the pelvic floor and does not expose patient to potentially harmful ionizing radiation. Where available, many departments choose to utilize TPUS as an adjunct to pelvic floor muscle training. However, to date, no data exists which evaluates its effectiveness as a biofeedback tool in postpartum women. The primary aim of this study is to assess, under controlled conditions, whether the additional use of TPUS can serve as a useful biofeedback tool for postpartum patients during pelvic floor muscle therapy.

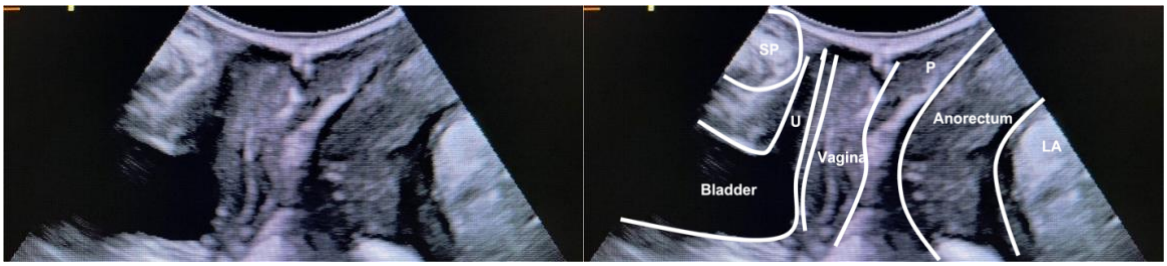


Figure 1: 2D mid-sagittal image of the pelvic floor at rest (Left) with corresponding anatomical overlay (Right). SP - symphysis pubis, U - urethra, P - perineum, LA - levator ani (puborectalis muscle).

2 HYPOTHESIS AND OBJECTIVES

Null hypothesis – transperineal ultrasound is not an effective biofeedback tool during pelvic floor muscle therapy.
Alternate hypothesis – transperineal ultrasound is an effective biofeedback tool during pelvic floor muscle therapy.

Primary outcome
Does visual feedback with transperineal ultrasound improve the effectiveness of pelvic floor muscle therapy in postpartum patients?

Secondary outcomes
a. Are postpartum patients who have trained with visual biofeedback more likely to continue to perform pelvic floor muscle therapy than those who do not train with visual biofeedback?
b. Do postpartum patients who train with visual biofeedback continue to perform effective pelvic floor muscle contractions 3 months after pelvic floor muscle training.
c. Does pelvic floor contraction strength improve after 3 months of pelvic floor muscle therapy with visual biofeedback compared to those who did not receive visual biofeedback.

3 EXPECTED RISKS AND BENEFITS

The only intervention performed in this study is the addition of transperineal ultrasound (TPUS). Ultrasonography is the use of high frequency sound waves to create an image of underlying structures. It has been utilized for decades and provides detailed images used for diagnostic purposes. It is extremely safe as it does not involve the use of ionizing radiation. Some data suggest that high energy ultrasound (which will not be used in this study) may produce heat effects of human tissue, however these effects have no known consequences on fetal nor maternal health[7]. This study intends to recruit postpartum (and therefore, non-pregnant) women therefore what little potential risk there is, is substantially reduced in this study population. Transperineal ultrasound has a similar safety profile to all other ultrasound-based imaging modalities with no reported adverse effects from its use [8]. Overall, despite the excellent safety profile this study will continue to use ultrasound at the lowest required energy setting for the minimum amount of time.

The major benefit of this study is that it can potentially introduce a tool to objectively measure the effectiveness of pelvic floor muscle contractions. This can be beneficial both to the patient and the clinician who is treating them. Patients will be able to use visual cues to help train and refine their technique resulting in better outcomes. Clinicians can offer bespoke guidance to aid recovery and prevent progression of pelvic floor disorders. For future clinicians it can also be used as a training tool and can help remove subjectivity and therefore the potential for error from clinical practice.

4 STUDY POPULATION

4.1 List the number and nature of subjects to be enrolled.

This study is a single-site, prospective randomized controlled trial of female postpartum patients attending a specialized pelvic floor assessment clinic. Sample size calculations estimate that a total number of 94 participants are required (47 in each arm) to demonstrate a difference between the study group and the control group and therefore reject the null hypothesis (see Section 8.1).

4.2 Criteria for Recruitment and Recruitment Process

Recruitment of potential participants will occur in the outpatient setting. Postpartum patients attending the specialized pelvic floor assessment clinic will be screened, and if they meet the eligibility criteria will be offered an opportunity to participate. Participation in the study will be voluntary and go alongside the patient's normal clinical care. Informed, written consent will be obtained and each of the participants will have the right to withdraw from the study at any point.

4.3 Inclusion Criteria

- Female participants
- Aged 21 – 45 years old.
- Within 4 months of a singleton, vaginal delivery.

4.4 Exclusion Criteria

- Currently pregnant
- Over 4 months since vaginal birth.
- Previous caesarean delivery.
- Previous pelvic floor surgery (eg. pelvic floor repair, continence surgery, cervicetomy, cosmetic pelvic floor procedures)
- Neurological disorder affecting muscle contraction (eg. Guillan-Barre syndrome, motor neuron disease, multiple sclerosis)

5 STUDY DESIGN AND PROCEDURES/METHODOLOGY

5.1 Methodology

This is a prospective, randomised controlled study and will be conducted through five stages:

Stage 1: Recruitment and randomisation.
Stage 2: Assessment.
Stage 3: Preliminary analysis and Interim report.
Stage 4: Follow up assessment.
Stage 5: Final analysis.

5.1.1 Stage 1: Recruitment and Randomisation

Postpartum patients who attend the pelvic floor assessment clinic will be screened for eligibility to the study. The study team will be responsible for screening and recruiting the participants based on the aforementioned inclusion/exclusion criteria. If eligible, the potential participant will be approached by a member of the study team and provided with a Participant Information Sheet and Consent Form. If they agree, they will be recruited to the study and will be allocated a study identifier number (SIN). A member of the study team will take written consent from the participant. English will be the default language of use; however, interpretation will be available in both Chinese, Malay and Tamil if required. Each participant will be asked to complete the pre-study questionnaire. Participants will be randomized into two different arms for the study (control arm and study arm). Equal numbers are required in each arm and therefore randomization will be performed using a computer randomizer set to distribute SINs into two equal groups.

5.1.2 Stage 2: Assessment

Assessment of participants is divided into two parts. The first part involves the gathering of clinical data such as demographic, pregnancy, and symptom information. This is obtained through their electronic medical record (using only the Citrix application), as well as eliciting symptoms history verbally from the participant. A clinical examination for uterovaginal prolapse is performed and a digital examination to assess pelvic floor muscle tone, known as the Modified Oxford Scale (MOS), is recorded in the standing position[5]. This assessment forms part of the usual care for each of the participants and can therefore be performed by any qualified member of their clinical care team. After this assessment, study participants are provided with a

specially designed hard-copy questionnaire to complete which is relevant to the aims of the study. This is to ascertain the participants knowledge of, and exposure to pelvic floor muscle therapy.

The second part of the assessment is conducted by a member of the study team specialized in transperineal ultrasound of the pelvic floor and pelvic floor muscle training techniques. Each participant is asked to undress from the waist down and lay supine for the examination. A chaperone is present and dignity is maintained throughout.

Participants will be encouraged to "squeeze the muscles" of their perineum and several attempts will be given to each participant to achieve this. Verbal feedback will be given by the assessor after each attempt to be sure the participant is activating their pelvic floor muscles and not co-activating their abdominal or gluteal muscles.

Transperineal ultrasound is then performed for all participants. Preparation of the probe involves applying a single-use, non-latex probe cover around a GE™ RAB2-5-MHz 3-dimensional volume transducer with generous amounts of ultrasound conducting gel placed inside and outside the probe cover. The transducer is placed upon the participant's perineum, in the mid-sagittal plane, and acquisition of images in conducted through a Voluson™ S10 ultrasound system. An acquisition angle of 85° is set and the machine is configured to the "Pelvic Floor" setting.

Participants in the control arm will have the ultrasound screen turned away from them with only the assessor having access to it. One 3d static image of the pelvic floor at rest will be obtained. The assessor will then ask the participant to perform a pelvic floor muscle contraction where a 4d dynamic image of the pelvic floor will be obtained. Three attempts at pelvic floor muscle contraction will be made for each participant. During this time the assessor will provide no feedback nor encouragement to the participant.

Participants in the study arm will have the ultrasound screen turned towards them in a way that both the assessor and participant can view it. A simple demonstration of the pelvic anatomy will be given to the participant outlining the orientation of the image as well as the basic pelvic structures such as positions of the bladder, vagina and rectum. As in the control group, the assessor will obtain the same static 3d image of the pelvic floor at rest as well as three dynamic 4d images during a pelvic floor contraction. Unlike the control group, the participant will be able to visualize in real-time the dynamic movement of their pelvic floor. They will be permitted to adjust/strengthen their technique between attempts based on these visual cues.

Upon completion of the assessment, all participants will have a follow up visit arranged in 3 months. This appointment usually forms a standard part of their clinical care and will be utilized to perform the follow up assessment. Participants who wish to continue to take part in the study will be informed that they will have the opportunity to repeat the assessment again during their follow up visit and will be encouraged to continue to perform pelvic floor muscle therapy in the interim.

5.1.3 Stage 3: Preliminary analysis and Interim report

This stage is performed by the study team only and does not require the involvement of the participants. Ultrasound data sets will be evaluated by a member of the study team who is blinded to the clinical data as well as to the study arm that the data set belongs to. The following describes the measurement parameters which are relevant to the study.

a. Antero-posterior (AP) pelvic hiatal diameter.

This is defined as the distance between the inferior edge of the symphysis pubis and the greatest apogee of the puborectalis muscle. The measurement can be obtained in both the mid-sagittal as well as the transverse (axial) planes *(Fig. 2)*. However, care must be taken to orientate the 3d/4d image to reflect the correct plane of viewing regardless of the method of measurement.

It is well established that the AP hiatal diameter is a very good indicator of pelvic floor muscle contraction. Based on a previous study, a proportional change in AP hiatal diameter of >15% corresponds well with a normal pelvic floor muscle contraction[6]. This cut-off value will be utilized to determine the adequacy of contraction.

b. Transverse diameter
This is defined as the maximal diameter between the inner edge of the levator ani muscles and is measured solely in the transverse plane. As with AP diameter, changes in transverse diameter are associated with effective muscle contractions, albeit to a lesser extent[6]. The transverse diameter can be a useful adjunct to the AP diameter as it provides assurance that that a pelvic floor contraction is effective.

c. Pelvic hiatal area
This is the defined as the area enclosed anteriorly by the symphysis pubis, laterally by the levator ani and posteriorly by the puborectalis. This measurement can only be obtained in the transverse plane and conventionally measured along the axis subtended by the symphysis pubis and greatest apogee of the puborectalis.

Changes in the pelvic hiatal area correspond well with clinical assessments, such as use of the MOS[6]. Care will be taken to ensure the correct plane is measured during rest and contraction and measurement of the area will be performed by tracing the inner outline using the trace function on the Voluson™ S10 ultrasound system.

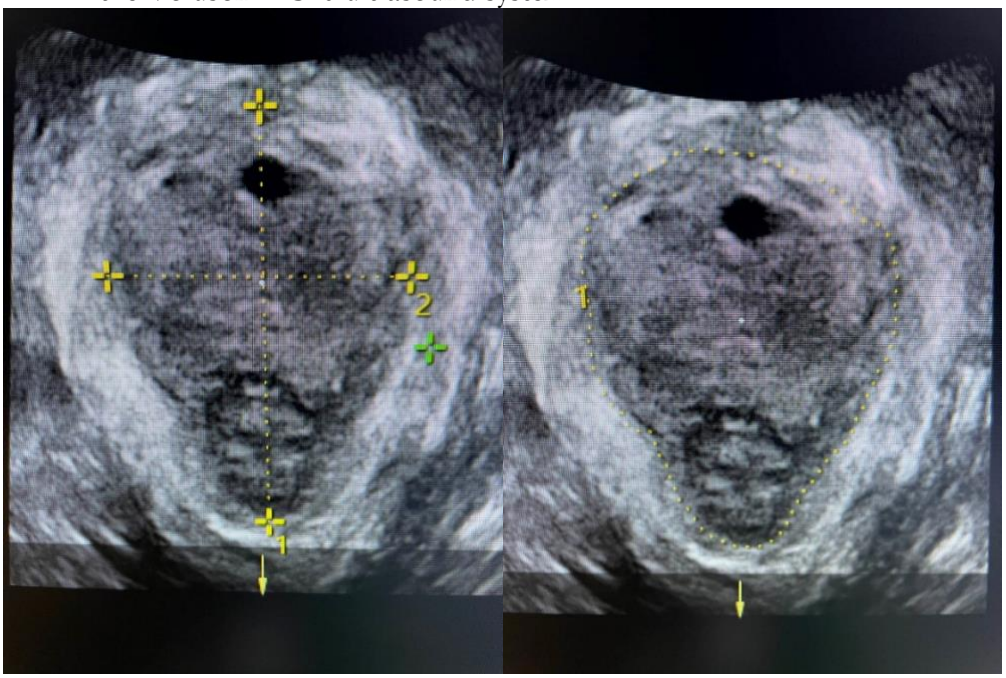


Figure 2: Pelvic hiatal measurements taken in the resting state along the transverse (axial) plane. Anteroposterior diameter (1), Transverse diameter (2). Right image - Genital hiatal area (1).

Preliminary analysis will be performed when the minimal sample size has been reached. Results of the analysis will form the basis of the studies' interim report. The interim report will ultimately aim to answer the primary hypothesis of the study- to determine if a significant difference is observed in pelvic floor muscle contraction between the study group and the control group. However, prior to this, several quality assurance checks will be performed. These quality assurance measures are described later (Section 7.1).

The interim report will also explore if there were any issues/adverse effects of the study and if so, whether this would warrant discontinuation of the trial. We do not anticipate any adverse physical effects of the study as the use of ultrasound is very safe. However, we do anticipate that some patients within the control group may wish to visualize their pelvic floor anatomy on ultrasound. As this would compromise the validity of the next stage of the study, we would be required to withdraw the participant from the study at this stage if they were to request this. We would be able to grant this request willingly at the end of the next stage as visualization after Stage 4 is complete will not compromise the results of the study.

5.1.4 Stage 4: Follow up assessment

This stage will occur 3 months after the initial assessment stage. Participants enrolled in the study will be invited back for a follow up review consisting of an assessment of any symptoms, adherence to PFMT and repeat ultrasound assessment of their pelvic floor muscle strength. As previously mentioned, the follow up stage is part of the standard clinical care for each patient and therefore the study will be done in parallel with their usual clinical care.

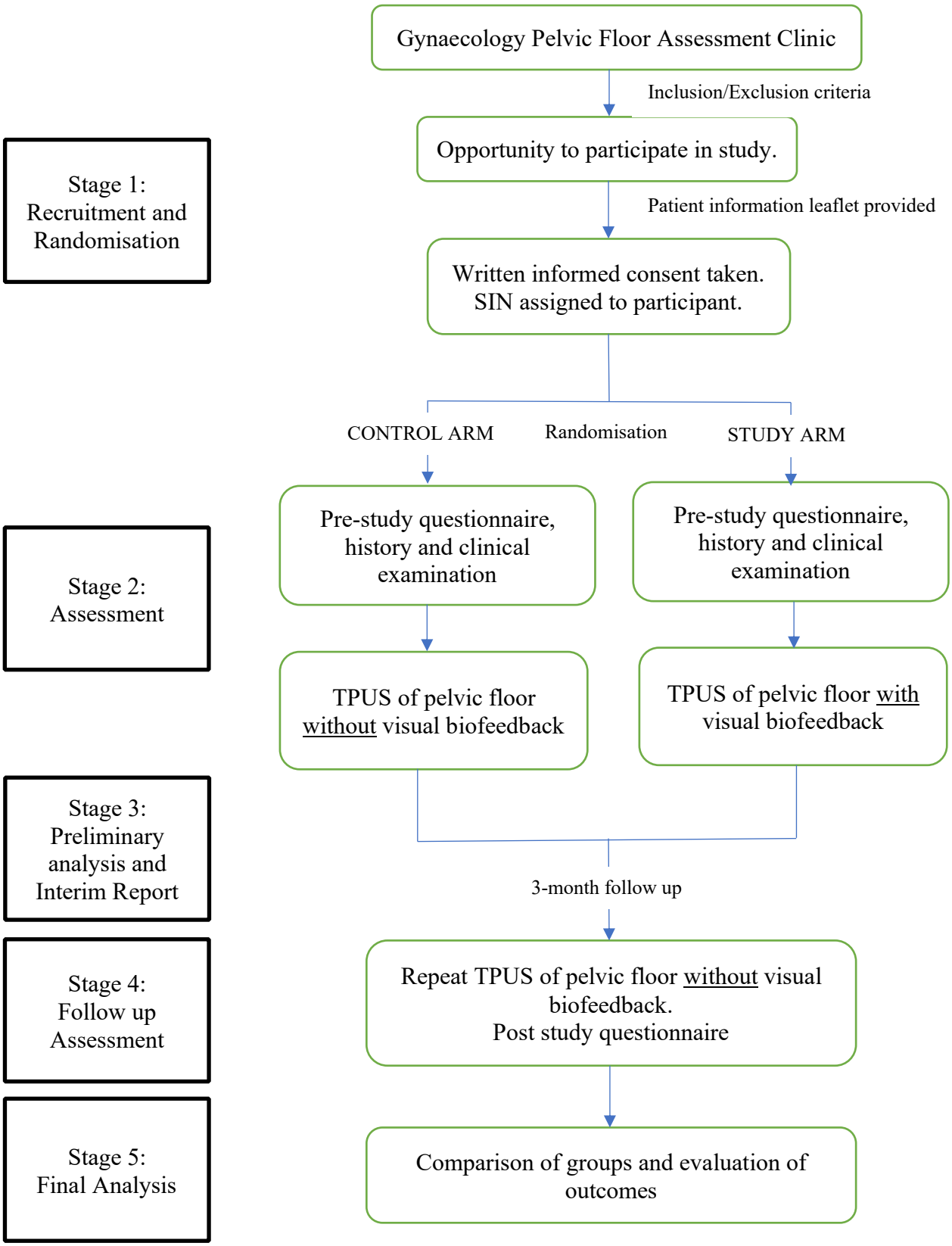
A similar method of assessment will be employed to the initial assessment, where a physical examination for uterovaginal prolapse and MOS grading are conducted. TPUS assessment will be done at rest, but when performing a pelvic floor muscle contraction, all participants will be blinded from visual biofeedback. Only the assessor will have access to the ultrasound screen and no verbal feedback or encouragement will be given during this time. As with the initial assessment three attempts at pelvic floor muscle contraction will be given to each participant with the best one being used for final analysis. The assessors themselves will be blinded to clinical data as well as the results of the previous assessment. Data will continue to be de-identified, using only the SIN as a reference to data sets.

The follow up will also be an opportunity to address any adverse effects or difficulties each participant may have experienced since the initial assessment. These will be thoroughly documented as part of the study results and will be managed appropriately by their clinical care team. The CIRB will be informed of any adverse event the participant suffers as a result of their participation in the study. Participant involvement will end at this stage. If requested, participants in the control arm, may view the images of the pelvic floor at rest and during contraction. Advice will be given to them on how to manage their pelvic floor symptoms and an opportunity for questions will be provided. Each participant will be encouraged to complete a post-study questionnaire outlining their experiences.

5.1.5 Stage 5: Final analysis

The objective of the final analysis will be to assess if both the primary and secondary outcomes have been met. As with the preliminary analysis, participants are not required at this stage. Measurements of validated parameters will be obtained from each data set (initial and 3-month follow up) from each participant. These measurements as well as will be compared between time periods to assess if (a) postpartum patients continue to perform PFE; (b) are they still effective; and (c) is visual biofeedback more useful than no biofeedback.

5.2 CONSORT Flow diagram



5.3 Statistical analysis

Statistical testing will be performed using IBM SPSS statistics version 29.0 (IBM Corp. Armonk, NY). Interclass correlation coefficient with Bland-Altman plots will be produced for reliability analysis. Parametric tests will be conducted to compare the control group with study group.

6 SAFETY MEASUREMENTS

6.1 Definitions

Serious adverse event (SAE) in relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which:

- results in or contributes to death
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in or contributes to persistent or significant disability/incapacity or
- results in or contributes to a congenital anomaly/birth defect
- results in such other events as may be prescribed

Adverse event (AE) in relation to human biomedical research means any untoward medical occurrence as a result of any human biomedical research which is NOT serious. Adverse event can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease possibly/ probably/ definitely associated with the participant in the human biomedical research.

6.2 Collecting, Recording and Reporting of Serious Adverse Events (SAEs) to CIRB

The reporting requirements will be in accordance to the reporting requirements published on CIRB website at the time when the event took place.

Only related SAEs (definitely/ probably/ possibly) will be reported to CIRB. Related means there is a reasonable possibility that the event may have been caused by participation in the research.

The investigator is responsible for informing CIRB after first knowledge that the case qualifies for reporting. Follow-up information will be actively sought and submitted as it becomes available.

Related AEs will not be reported to CIRB. However, the investigator is responsible to keep record of such AEs cases at the Study Site File.

6.3 Data Safety Monitoring Plan

The principal investigator will be responsible for data monitoring and safety. It will be their responsibility to ensure that any SAEs and AEs are reported to the CIRB. Confidentiality of participants will be protected at all times with only the SIN being used to identify outcome data during the study. The study team will convene on a monthly basis to ensure the completeness of records and integrity of study data.

6.4 Complaint Handling

The patient information leaflet will provide contact information of the study team should a participant wish to lodge a complaint. The PI will be informed immediately of any complaints that arise and will be responsible for resolving them.

7 DATA ANALYSIS

7.1 Data Quality Assurance

Three stages of quality assurance will take place.

1. Ensure homogeneity of the study and control groups.
    - Statistical testing will be performed to ensure that the groups are well matched in reference to age, BMI, mode of vaginal delivery, and parity and that no confounding factors are present that can compromise the results of the study. This will be unlikely due to the nature of the randomization process, but formal assessment will nonetheless be performed.
2. Determine reproducibility of the ultrasound measurements.
    - An inter- and intra-observer variability analysis will be conducted. This will involve two trained urogynaecologists independently measuring pelvic diameters and areas on a sample of cases after which an interclass correlation coefficient can be calculated to assess inter-observer reliability.
3. Comparative analysis.
    - This is to ensure that strength of contraction measured by ultrasound corresponds well with those found on clinical examination using the Modified Oxford Scale. This will validify the use of the above ultrasound parameters as a clinical assessment tool.

7.2 Data Entry and Storage

Data collected from the study will be in the form of two linked sets:

1. Clinical and Demographic data
    - This is gathered from the history taking and electronic medical records (EMR) via the Citrix application. It includes data such as age, body mass index, mode of delivery, symptomology and findings on clinical examination.
    - Participant questionnaires. These will be hardcopy files completed in writing with only the SIN printed on them.
2. Ultrasound data
    - This is derived from the ultrasound images from each participant. It includes measurements made of the pelvic hiatus during rest and maximal contraction.

As previously mentioned, participants recruited to the study will be assigned a study identifier number (SIN). This SIN will be documented on their hospital EMR, which is only accessible by members of the patient's clinical care team. Clinical and demographic data lifted from the EMR from each participant will contain de-identified data and will be stored only on the hospital's secure network. Data files will be password encrypted with only members of the study team having access to them. These measures will ensure that it will not be possible to retroactively access patient-identifiable information using the SIN. However, should the need arise, the clinical care team who is managing the patient could potentially request the data with authorisation from the study team.

For ultrasound data, images acquired from each participants assessment will be stored on the ultrasound machine only. The images will be tagged to the SIN so only the study team is able to link the demographic

and clinical data with data collected from the ultrasound images. No identifiable information will be stored on the ultrasound machine.

Electronic data will only be stored on hospital computers under the login credentials of the study team. These are password encrypted computers and, as data will be stored on the study team's virtual drive, access to data will only be available to members of the study team. Written, hardcopy data (participant questionnaires, consent forms) will be kept in a single, locked filing cabinet that can only be accessed by member of the study team.

8 SAMPLE SIZE AND STATISTICAL METHODS

8.1 Determination of Sample Size

Effective pelvic floor muscle contractions are observed in 27% of women who undergo pelvic floor muscle training [2] while other biofeedback methods have demonstrated an improvement of up to 58%[3]. For our primary outcome measure, to demonstrate equivalence to other biofeedback tools, a minimum sample size of 78 participants will be required (Power 80%, alpha 0.05). This calculation is based upon two independent groups with a dichotomous primary outcome measure (i.e effective pelvic floor muscle contraction or not) Taking into account a potential 20% dropout rate, a further 16 participants will be required - 94 participants in total (47 in each arm).

8.2 Statistical and Analytical Plans

a. General considerations
   Both groups will be evaluated for homogeneity. Parametric t-tests and Chi-squared analysis will be used to determine if groups are well matched. Bland-Altman plots with interclass correlation coefficients will be used to determine if there is any significant degree of inter and intra-observer variability between ultrasound measurements.
b. Safety Analyses
   The study presents very little physical risks to participants. A safety review will nonetheless be conducted during the preliminary analysis. All reportable SAEs and AEs will be compiled and a determination will be made as to whether to continue the study or not.
c. Interim Analyses
   The interim analysis will focus on the primary outcome of whether adding visual biofeedback with TPUS improves the effectiveness of PFMT. Details of the interim analysis were outlined in Section 5.1.3.

9 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator(s)/institution(s) will permit study-related monitoring, audits and/or IRB review and regulatory inspection(s), providing direct access to source data/document.

10 QUALITY CONTROL AND QUALITY ASSURANCE

Data will be evaluated for quality on a monthly basis. In addition to ensuring participant homogeneity, ultrasound measurement reliability and comparative analysis, data sets will be monitored for completeness and validity. Adherence to the study protocol will be ensure through regular data reviews by the study team and it will be the responsibility of the PI to ensure the data entries are accurate.

11 ETHICAL CONSIDERATIONS

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the Good Clinical Practice and the applicable regulatory requirements.

This final Study Protocol, including the final version of the Participant Information and Consent Form, must be approved in writing by the Centralised Institutional Review Board (CIRB), prior to enrolment of any patient into the study.

The principal investigator is responsible for informing the CIRB of any amendments to the protocol or other study-related documents, as per local requirement.

11.1 Informed Consent

Written, informed consent will be obtained from all participants prior to enrolment into the study. Consent will be taken only by members of the study team. Provisions will be made for translation for non-English speaking participants. Vulnerable populations and those lacking capacity to provide consent will not be recruited to the study. All study team members will abide by GCP guidelines and comply with the ethical principles that have their origin in the Declaration of Helsinki.

11.2 Confidentiality of Data and Patient Records

Confidentiality of participants will be maintained throughout the study. All participants are assigned a SIN upon enrolment and any data gathered will be deidentified.

12 PUBLICATIONS

All publication related decisions will be discussed amongst the study team members with the PI giving final approval of decisions.

13 RETENTION OF STUDY DOCUMENTS

Records for all participants, including CRFs, all source documentation (containing evidence to study eligibility, history and physical findings, laboratory data, results of consultations, etc.) as well as IRB records and other regulatory documentation will be retained by the PI in a secure storage facility. The storage will be in accordance with the SingHealth CIRB guideline on Retention of Research Data and Records and will be stored for a minimum period of 6 years after completion of the study. The records will be accessible for inspection and copying by authorized authorities.

14 FUNDING AND INSURANCE

This study is self-funded and will be insured under the National Clinical Trial Insurance Policy.

15 REFERENCES

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