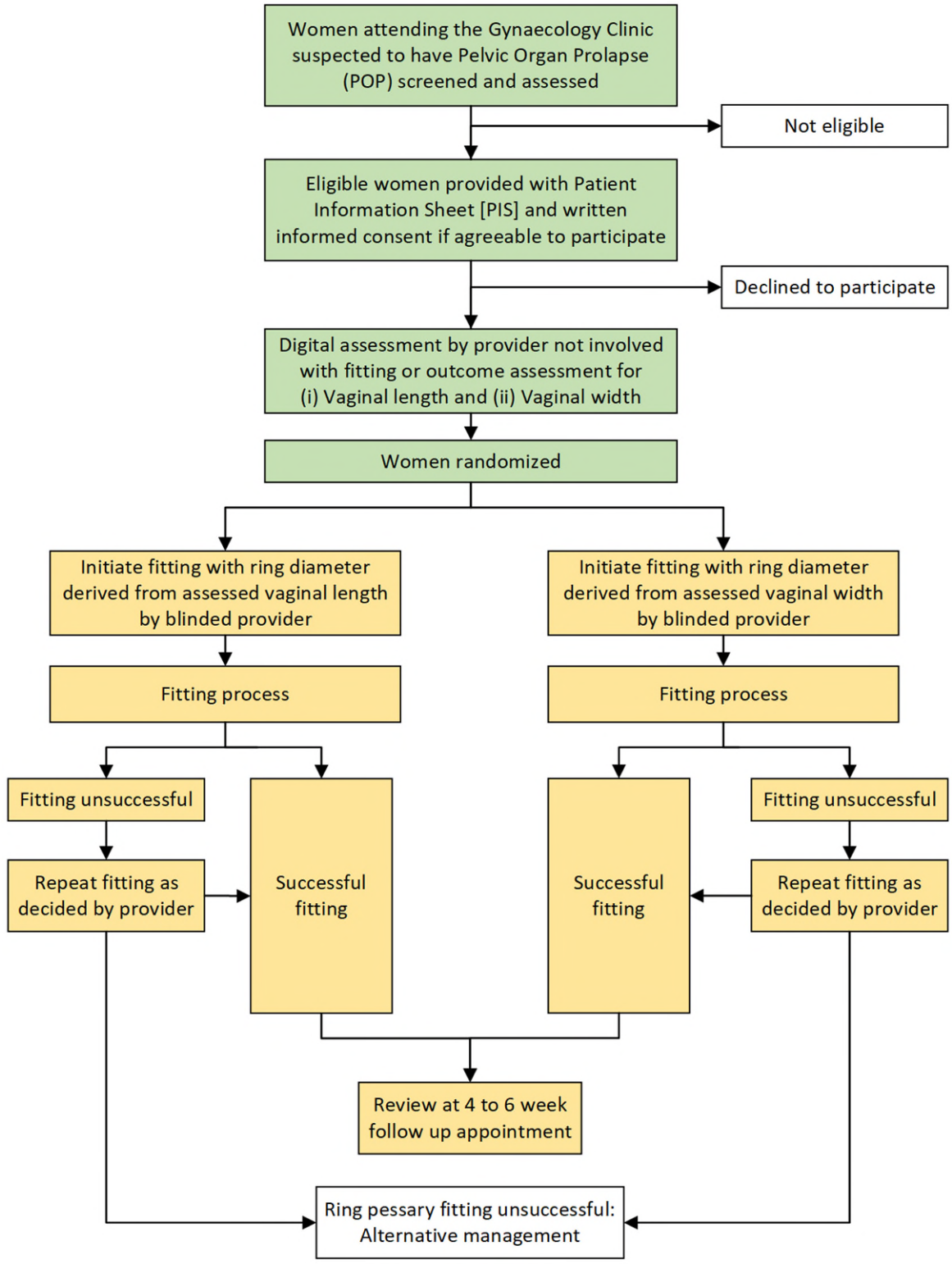
UNIVERSITY OF MALAYA MEDICAL CENTRE

TRIAL PROTOCOL [TP]

(Version 1.1 - 01/06/2024)

1. Women with suspected pelvic organ prolapse (POP) attending gynaecology clinic, PPUM, for their scheduled appointment will be assessed for recruitment suitability using the **Eligibility Assessment Form [EAF]**.
2. Women who fulfill both inclusion and exclusion criteria are provided the **Patient Information Sheet [PIS]** and a verbal explanation with regard to the trial participation.
3. Patients who agree to participate in the study will sign and date the **Informed Consent Form**.
4. If the patient does not agree to participate, they will be excluded from recruitment and subsequent care will be according to standard treatment protocols.
5. Participants' relevant details and characteristics will be transcribed onto the **Case Report Form [CRF]**.
6. A provider who will not be involved with pessary insertion or data collection will assess participants' stage of prolapse (using the Pelvic Organ Prolapse Quantification (POP-Q) system) and obtain (i) vaginal length and (ii) vaginal width measurements. These will be recorded onto the CRF.
7. Participants' symptom severity will be assessed using the 11 point 0 - 10 Numerical Rating Scale (NRS).
8. Participants are informed that they will be randomised into either of two trial arms :
   - Initiating ring pessary fitting with diameter derived from assessed vaginal length, or
   - Initiating ring pessary fitting with diameter derived from assessed vaginal width.
9. The provider will be handed a ring pessary blinded as to whether the pessary was sized from a vaginal length or width assessment to start the fitting process.
10. Once the initial fitting is successful, participants will be asked to rate their satisfaction with the process of getting the ring pessary fitted and the pain experienced with the first insertion of the ring pessary using the 11 point 0 - 10 NRS.
11. Participants will be allowed home and given a routine follow up appointment in 4 to 6 weeks to review if the ring pessary is still in place. Participants will be asked to rate their satisfaction with the ring pessary since the fitting, using the 11 point 0 10 NRS. Patients in the study who do not attend the routine follow up will be contacted by telephone to obtain the above information.
12. If the initial fitting is unsuccessful, subsequent fitting attempt will be with a ring size to be decided by the provider, who may decide to abandon the procedure after multiple fitting attempt for an alternative management.
13. Vulval inspection will be performed after successful fitting or abandonment to look for any laceration or bleeding.
14. Care providers' satisfaction with the first fitting, number of fitting attempts, ring pessary sizes used, and whether fitting was abandoned for an alternative management will be recorded onto the CRF.
15. Data entry and analysis will be done using SPSS Statistics Software.

TRIAL PROTOCOL



LEGEND

Performed by HCP 1

Performed by HCP 2