

Audio-recording the TOPSY STUDY “*Initial recruitment discussion*”

IRAS ID: 234662

Invitation

During your consultation you may be invited to take part in a UK wide study which aims to see if women who use a pessary for pelvic organ prolapse can self-manage their pessary care. The study is called the TOPSY study. You could be potentially eligible for the TOPSY study. We would like to audio record the discussion between you and the healthcare professional about the TOPSY study. We call this discussion the “*initial recruitment discussion*”. You can participate in the audio-recording even if you chose not to participate in the TOPSY study.

What is the purpose of the audio recording?

We are interested in understanding how the information about pessary care and specifically the TOPSY study is given to you and the reasons why people take part or not in the TOPSY study. It is hoped we can learn and teach all of the sites around the UK the best way to talk to women about the TOPSY study and make the recruitment process the best it can be. All recordings will be deleted when transcription and analysis is completed, and transcripts securely destroyed 5 years after completion of the study.

Do I have to take part?

No. It would help us if you do but is entirely your decision. You can withdraw at any time without giving a reason. If you **do not** want the “*initial recruitment discussion*” to be audio-recorded, you can still be given the information about the TOPSY study and your decision will not affect any medical care. Please take time to ask any questions you have about the audio-recording after reading this information leaflet. You can contact the study manager (details below) if you need any further information.

What will happen if I take part?

If you agree to take part, you will be asked to sign a consent form. By signing the consent form, you agree to the “*initial recruitment discussion*” being audio-recorded. This will take about 10-15 minutes.

What are the benefits/disadvantages of me taking part?

There will be no extra benefit to you in having the “*initial recruitment discussion*” audio-recorded but by doing so you will be helping our understanding of why people choose to take part in the TOPSY study or not. We do not anticipate any risks to you from the audio-recording.

What ethical and data permissions are in place?

West of Scotland Research Ethics Committee REC 03, your local hospital and your consultant have given approval for this study to be carried out.

What will happen to the results of the “*initial recruitment discussion*” audio-recording?

All recordings will be anonymised, transcribed and labelled with the TOPSY study number to ensure confidentiality. The results may help improve recruitment to the TOPSY study. The findings may be presented at conferences, meetings or in publications. Even if quotes of things you have said are used in reports, you will not be identifiable in any of the information presented.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION