INVITATION TO COMPLETE THE IBRA RANDOMISATION ACCEPTABILITY SURVEY

Dear iBRA collaborators and colleagues,

Many thanks for your help with the iBRA study. iBRA has recruited over 2000 patients from over 50 centres in the UK making it the largest prospective evaluation of implant-based breast reconstruction (IBBR) in the world.

WHAT IS THE PURPOSE OF THE STUDY?

iBRA has demonstrated significant variation in the practice and outcomes of IBBR in the UK but data suggest that the short-term outcomes of reconstruction performed with different types of mesh (e.g. biological and synthetic meshes) may be similar at 3 months. Outcomes of prepectoral and subpectoral reconstruction may also be similar although the numbers of patients having pre-pectoral reconstruction is relatively small. There is therefore a need for further well-designed research to determine best practice in IBBR and improve outcomes for patients.

Randomised clinical trials (RCTs) provide the best quality evidence but previous RCTs in breast reconstruction have been unsuccessful as they did not involve reconstructing surgeons in designing a study that answered the most important questions in the most acceptable way.

The iBRA Steering Group would like to invite you to complete the following survey to help inform the design a large pragmatic RCT to determine which approaches to IBBR give the best outcomes for patients and are the most cost-effective for the NHS.

We would like to know where you feel the areas of uncertainty are in mesh-assisted implant reconstruction; what trial designs you think would be acceptable and you would be happy to randomise patients into; what outcomes we should use and finally how pragmatic the trial could be with regard to implant and mesh use and concomitant interventions such as use of drains and antibiotics.

WHY HAVE I BEEN INVITED?

You have been invited to participate as you offer patients IBBR as a treatment option or are involved in counselling patients considering surgery.

You and/or your unit do not need to have participated in the earlier phases of the iBRA study to complete this survey. We would like to include the views of as many breast and plastic surgeons and clinical nurse specialists as possible to inform a future trial.

WHAT WILL PARTICIPATION INVOLVE?

The survey should take no more than 20 minutes to complete.

We would also like to interview a sample of surgeons and specialist nurses completing the survey to explore their views in more detail.

Taking part in the interview study is completely optional and you can complete the survey only if you choose.

If you would be willing to be interviewed, please complete this section of the survey and we will contact you with further details.

We would be very grateful if you could also circulate the link to other colleagues and specialist nurses involved in implant-based breast reconstruction.

DO I HAVE TO TAKE PART?

Taking part is voluntary.

You can complete the survey only if you choose without agreeing to be interviewed.

Anonymised data will be made available on request to other researchers at the end of the study.

If you do not provide contact details, your responses will be completely anonymous, and it will not be possible to withdraw your data from the study.

If you have provided contact details, it is possible to withdraw your data after completing the survey if you wish.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study has been reviewed and given a favourable opinion by the University of Bristol Faculty of Health Sciences Research Ethics Committee (reference: 61501) and is funded by the National Institute for Health Research (NIHR) Research for Patient Benefit Programme.

If you would like to take part, please click on the link: https://is.gd/ibrasurvey

IF YOU HAVE ANY CONCERNS OR WOULD LIKE FURTHER INFORMATION

If you have any questions or queries about the study or would like to read a full copy of the study protocol, please do not hesitate to contact Miss Shelley Potter via e-mail (shelley.potter@bristol.ac.uk) or telephone (0117 9287218).

If you have a formal complaint or any concerns about this research, you may contact the University of Bristol's Research Governance team (research-governance@bris.ac.uk).

Many thanks in advance for your help in designing this important study

Best wishes

Miss Shelley Potter and Professor Chris Holcombe
On behalf of the iBRA Steering Group