

Study Title: GRACE

LearninG from women's expeRiences of Anal inContinenCE after vaginal birth

Chief Investigators: Dr Sarah Hillman and Professor Debra Bick

Participant Information Sheet

You are being invited to take part in a research study. Before you decide whether you would like to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully and ask us if there is anything that is not clear or if you would like more information.

This study involves..

Speaking to GPs about their experiences of caring for women that have anal incontinence following perineal injury during childbirth. We aim to explore key facilitators and barriers to the identification, support and treatment of anal incontinence by GPs, to inform the development of an e-Learning education resource for GPs and other health care professionals. In addition we will also be speaking to women about their experiences.

What happens if I agree to take part?

If you are interested in taking part please contact the study team. We will then discuss the study with you over the phone or by email. We will then organise a focus group of up to six GPs to talk either remotely (i.e. using Microsoft teams) or face to face (if coronavirus restrictions allow and this is the groups choice). At the start of the focus group we will take your consent by asking you to identify yourself and then replying to the consent questions. All focus

groups will be audio recorded (in addition focus groups conducted over Microsoft Teams will be video recorded) by the researchers with the permission of all focus group participants.

What does the study involve?

The focus group will be facilitated by researchers from Warwick Medical School. During the focus group, as well as your experience of caring for women with anal incontinence after childbirth, we will ask you about what you would find helpful to include in an online education resource for GPs we are developing. We anticipate the focus groups will take up to 120 minutes and we will aim to arrange it at a time that is convenient for all those attending.

What will I have to do?

If you would like to take part please contact Dr Jo Parsons and Dr Abi Eccles 02476 151404 or GRACE@warwick.ac.uk

What happens if I do not wish to take part in the study?

Participation in the study is entirely voluntary. If you do not wish to take part no further action is needed. If you agree to take part and then change your mind and you want to withdraw your data from the focus group, you need to tell the team within 2 weeks otherwise the transcript will have been transcribed and anonymised. If you tell us within two weeks of the focus group that you wish to withdraw your data, whilst we will remove all your verbal contributions to the focus group from the transcript, it will not be possible to completely remove your input as ideas are often discussed and developed by the whole focus group. You do not need to give us a reason for changing your mind. We will reply to confirm that your data will be removed securely and there will be no further contact from the research team.

What data will be collected?

We will collect your contact details. We will also ask you where you work, your gender and how many years you have been qualified as a GP. The interviews will be recorded and the recording may be sent for transcription (we use a company called APPEN that are approved by the University and meet our ethical and confidentiality standards). All anonymised data will be kept for 10 years, which is inline with the universities guidance. All audio/video recordings will be deleted after the focus groups are transcribed. Contact details will be retained for no longer than 12 months after the study is completed.

This data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to further consent at the outset of this research project.

Data Protection Privacy Notice

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using participant data must follow UK laws and rules. Universities may use participant data to do research to make health and care better.

The data controller for this project will be the University of Warwick. The Information and Data Compliance Team at Warwick will provide oversight of activities involving the processing of personal data, and can be contacted via GDPR@warwick.ac.uk. The Data Protection Officer for the University of Warwick is Rachel Gower. Your personal data will be processed for the purposes outlined in this notice. The legal basis that would be used to process your personal data is Article 6 (1b) a task in the public interest.

In addition to the legal basis for processing personal data, the University of Warwick must meet a further basis when processing special category data, including: racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, data concerning health, data concerning a natural person's sex life or sexual

orientation. The basis for processing your special category personal data is Article 9(2j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here:

<https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice> or by contacting the Legal and Compliance Team at GDPR@warwick.ac.uk.

Confidentiality

We will anonymise all the research data. All contact details will be kept securely on an encrypted database. No names of individuals or practices will ever be used in any of the output from this research.

What happens to the results of the study?

Results of the study will be used to create an online education resource for GPs and other healthcare professionals (hosted by the Royal College of General practitioners). Results will also be used in a publication for health care professionals and as part of an online resource for women.

Who is funding this study

This study is funded by the National Institute for Health research (NIHR) Research for Patient Benefit

Complaints

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services

University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

*An independent complaints service is
Patient Advice and Liaison Services (PALS)
Clifford Bridge Road, Coventry, Warwickshire, CV2 2DX
08000284203*

This study has been reviewed by Essex Research Ethics committee