Participant Information Leaflet for parents

Study Title:	A FOCUS GROUP INTERVIEW LOOKING AT HOW YOU WOULD LIKE YOUR CHILD TO BE TREATED FOR GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)
Investigator(s):	Dr Simon Leigh & Dr Carla Toro

Introduction

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who is organising and funding the study?

The study is funded by Reckitt Benckiser, and is being conducted by researchers at the University of Warwick and the healthcare consultancy VISFO.

What is the study about?

Proton-pump inhibitors (PPIs) remain the leading evidence-based therapy for upper gastrointestinal disorders, including gastroesophageal reflux disease, heartburn, indigestion, dyspepsia, and peptic ulcer disease. Due to the high efficacy of PPIs in controlling the symptoms of upper gastrointestinal diseases, treatment often becomes ongoing and difficult to suspend. The aim of this research is to understand what good care for children suffering from GORD looks like from both a parental and healthcare provider (HCP) perspective, particularly among children where a therapeutic benefit may not be experienced. In addition, we aim to (1) explore how we as a scientific community may work towards reducing potentially avoidable PPI prescribing, understanding the concerns of HCPs and parents alike, and (2) understand the preferences of both parents of infants with GORD and HCPs towards the management of GORD.

What would taking part involve?

If you agree to take part, you will be asked to answer a series of questions about what you prefer with respect to the management of your child with GORD. You will be invited take part in a short 60-minute focus group (held digitally via Zoom) with other parents – no healthcare providers will be present. You will be asked to share your experiences of having a child diagnosed with GORD and your beliefs regarding their treatment.
You will also be asked some basic personal information questions which will be non-identifiable.

**All information will remain confidential, and we will not contact you again after the study.

You have no responsibilities to the study once you have completed the survey. The research is being carried out by a team from VISFO, and all responses will be audio recorded, stored and, analysed by a single researcher (Simon Leigh). Your responses will be held securely by VISFO in a password protected computer folder. Once the research is completed, your responses will be archived securely, again in a password protected folder. If you do provide personal details so that you may be contacted regarding study results, these too will be stored on a password protected computer. Anonymized transcripts of the focus groups (without personally identifiable information) will then be shared with Reckitt Benckiser Group plc. as sponsor of the research.

Do I have to take part?

No. Participation in this study is completely voluntary and choosing not to take part will not affect you, or your child in any way. You can also choose to withdraw your participation without giving a reason by contacting a member of the research team. Further details about withdrawing from the study are provided later on in this document.

What are the possible benefits of taking part in this study?

Your involvement in this study will help to better explain the needs of parents and their children when being treated for GORD.

What are the possible disadvantages, side effects or risks, of taking part in this study?

None. Your responses are anonymous and you are free to withdraw at any time without question.

Expenses and payments

You will be paid £60 for your involvement in this study, which will be provided to you via bank transfer.

Will my taking part be kept confidential?

Yes. No personally identifiable data will be collected. If you do wish to be contacted, your data will be held securely in a password protected computer folder. Once research is completed, responses will be archived securely, again in a password protected folder. We will only keep hold of email addresses for the purpose of arranging focus groups, after which these will be permanently deleted.

What will happen to the data collected about me?

As a publicly-funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study.

We will be using information from you, with VISFO acting as data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Warwick will keep information about you [for three years after the study has finished/ until 2026].

1) Research data will be **anonymous** from the point of the focus group commencing. As we are not collecting names or other identifiable information and linking these to the voices heard within the focus group, it will not be possible to withdraw your data after this point.

Data sharing

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe.

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 infocompliance@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

Participation is voluntary. You are free to withdraw at ANY TIME, and without explanation.

To safeguard your rights, we will use the minimum personally identifiable information possible and keep the data secure in line with the University's Information and Data Compliance policies.

What will happen to the results of the study?

The researchers aim to publish the results of this study in a medical journal. You will not be identifiable from the results of the study.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC).

Who should I contact if I want further information?

Dr Simon Leigh via email, using simon@visfo.health

Thank you for taking the time to read this Participant Information Leaflet