WARWICK
MEDICAL SCHOOL

GP-MATE
GP Management After Transition Events

Participant Information Leaflet – Patient/carer Interview (IPC)

Study Title

General **P**ractice **M**anagement **A**fter **T**ransition **E**vents (**GP-MATE**) - Developing an intervention to assist older patients' communication with their GP practice after discharge from hospital in order to improve patient safety

Investigators

Dr Rachel Spencer, (Associate Professor of general practice) who is based at the University of Warwick, is responsible for this project.

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. If you have any questions, would like any further information, or want to discuss participating further, please call us on 02476151193.

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it AND/OR for future research. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details and details from your patient-held copy of our intervention. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for

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the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study on secure University of Warwick servers.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients, by asking one of the research team, by sending an email to r.spencer.2@warwick.ac.uk, by ringing us on 02476151193 or emailing the sponsor's data protection officer on: infocompliance@warwick.ac.uk. Find out more technical information about patient data and research here: http://www.hra.nhs.uk/patientdataandresearch.

Who is organising and funding the study?

The study is being co-ordinated and sponsored by the University of Warwick and is led by Dr Rachel Spencer. The study is funded by the National Institute for Health Research Advanced Fellowship (Award number 301328).

What is the study about?

We would like you to take part in this study that is developing a communication tool for older patients who have been discharged from hospital to better enable them to interact with their general practice. We aim to make and test an approach ('GP-MATE') to assist older patients and their carers to discuss with their GP practice their care after coming home from hospital. This is to make care safer and prevent mistakes from occurring. Older patients and their carers have a key role to play in preventing these errors and harms. GP-MATE will be designed to help them take a more active role in their general practice care after coming home from hospital. It will help empower them to do so with greater success.

What would taking part involve?

You have important experiences of being discharged from hospital (or of caring for somebody who has been discharged) that you can share with the research team. We want to focus on older people as we think they have the most to gain from our work. As part of the study your GP practice has been using the GP-MATE communication tool and you perhaps already received a copy of it. If you used GP-MATE, we are interested in how you used it and what you thought about it. If you didn't use it, we are interested in the reasons why. The entire study runs over four years and will finish in 2025. The interviews you are taking part in will be conducted in 2023/4. You will be participating for around an hour's time in total.

If you are happy to proceed a member of the study team will be in touch by phone or email (please tell us your preference on the expression of interest form). We will discuss where you prefer the interview to take place and talk through consent procedures. At a time and place of your choosing we will audio record an interview with you (and your carer if applicable). This can be done over video conferencing if this method suits you. We will talk for up to 45 minutes but you can stop at any time if you feel unwell or unable to continue or just need to take a break. At a later date, you will be given the option to see a written transcript of the interview and comment on it.

Do I have to take part in the study?

No. It is up to you to decide whether you want to take part. You are free to change your mind and withdraw from the study at any time and you do not have to give a reason why. Your future care with your general practice team will not be affected by taking part in the study.

What are the possible benefits of taking part?

You will be helping others' by telling your own experiences. You will help: other patients and carers; general practice staff (including your own general practice); hospital teams; other researchers looking to promote patient voices.

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

We do not believe there are any major risks to taking part in this study. An experienced GP (the study lead) will closely supervise one research assistant and either one of us will conduct the interview. If there are any concerns, we can chat with you after the interview. As the study lead is a GP, she will be able to deal with any concerns about your clinical care that might come up in the interview and there will be a procedure in place to relay information to your clinical team if it is necessary for the safety of your care.

Expenses and payments

There are no payments for taking part in the study and we do not anticipate any expenses for those who take part.

Will my details be kept confidential?

All information that is collected during the study will be kept confidential at all times and held in compliance with the Data Protection Act 2018. All electronic data will be stored in a secure format. We will always ensure that any material that may identify who you are, has the identifiable data removed before there is any analysis of the data. Study documentation and data will be archived for at least ten years. The only reason we would break confidentiality would be in an emergency. If your own health, or somebody else's health, was in danger, we would contact your GP. Any audio recording of interviews will be transcribed by a third-party transcription service or a member of the research team contracted to work on the research project. On all occasions we will ensure that any material that may identify who you are is removed before there is analysis of the transcripts. We may use written quotations from the transcripts in academic presentations or publications based on this research. In the future we may use the anonymous transcripts for other research. We might agree to share these with other, carefully selected, researchers; any such sharing will be closely monitored by the University.

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 in order to undertake this study and will act as the 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 identifiable contact information about you 2 years after the study finishes.

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. 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 your consent at the outset of this research project.

Research data will be **pseudonymised** as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data and will be replaced with a participant number. The key to identification will be stored separately and securely to the research data to safeguard your identity. We will be unable to withdraw your pseudonymised audio recording from analysis after 2 weeks from the date of interview.

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. 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 your consent at the outset of this research project. 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.

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

You are free to change your mind and withdraw from the study at any time and you do not have to give a reason why. Please note, that if you withdraw from the study, it will not be possible to withdraw your data after 2 weeks following the interview because it will have entered the transcription process. 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?

We will present the findings in a study report and in health and medical journals. You will not be identified in any of the publications. The study team will make sure that you know about the results by sending you a brief summary of the study findings.

Who has reviewed the study?

Any research that involves the NHS and patients is subject to review by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and given favourable opinion by East of England - Essex Research Ethics Committee, Reference 21/EE/0227. It has also been reviewed by the Confidentiality Advisory Group who have deferred a decision until after we have undertaken our co-production process.

Who can I contact if I need more information?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have any concerns about this study, please contact the Chief Investigator of the study. If you have any questions about the study, or your involvement in it, either now or in the future, do please contact the study team using the details below:

Dr Rachel Spencer (Chief investigator and study co-ordinator)
Unit of Academic Primary Care,
Warwick Medical School,
University of Warwick, Coventry,
CV4 7AL

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Email: r.spencer.2@warwick.ac.uk
Telephone: 02476151193

Who should I contact if I wish to make a complaint?

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
Tel: 02476 575733
Email: researchgovernance@warwick.ac.uk

Thank you for taking time to read this information leaflet and for considering the study.

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