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| IRAS ID: | 333799 | Sponsor Reference No.: | RG-0385-24 | Version no.: | V1.2 | Version Date: | 25-Apr-2024 |
|----------|--------|------------------------|------------|--------------|------|---------------|-------------|



Building an evidence base for the use of advice and guidance (BADGER)

PARTICIPANT INFORMATION SHEET: Primary Care Clinicians

Version 1.2, dated 25-Apr-2024, IRAS: 333799

We are inviting you to take part in a research project called BADGER. Before you decide whether or not to take part it is important for you to understand why the research is being undertaken and what it would mean to you if you were to take part.

Please take time to read the following information carefully and discuss it with others (such as friends and family) if you wish.

1. What is the purpose of this research?

The use of Advice & Guidance (A&G) has been promoted as a way of alleviating compound pressures on the NHS, yet there is little evidence of how A&G alleviates these pressures nor what best practice may look like. The BADGER study aims to build such an evidence base through exploring the experiences of using the A&G pathway from the perspectives of patients, clinicians and healthcare commissioners. We aim to measure the impact of A&G on the healthcare system in terms of quality of care, satisfaction with the process, and service utilisation.

We aim to interview 20 primary care clinicians to explore their views and experiences of using A&G, including how patients perceive it, and their views on how the A&G process may be improved. Patients, Secondary care Specialists and healthcare commissioners will also be interviewed as part of the study.

2. Why have I been invited?

You have been invited to participate in an interview because you work in a participating GP practice and have been identified by your local Clinical Research Network (CRN) as a clinician who regularly uses A&G.

3. Do I have to take part?

No, taking part in this research is **completely voluntary**. It is up to you to decide if you want to volunteer to take part in the research or not. If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study

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|----------|--------|------------------------|------------|--------------|------|---------------|-------------|
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|----------|--------|------------------------|------------|--------------|------|---------------|-------------|

up to a week after the interview without giving a reason, at which point any data collected will be destroyed.

4. What will taking part involve?

You are invited to take part in one interview which will last no longer than one hour. To take part, we will ask you to agree to being audio or video recorded. During the interview you will be asked about your views relating to the A&G process. There are no right or wrong answers. The interview will be arranged for a mutually convenient time and conducted over video call (MS Teams) or phone call.

The interview will be recorded and the recording transcribed. We may publish direct quotations from the interview transcript which will be anonymised to reduce the chance of you being identified. You will be reimbursed £90 for your time.

5. What are the possible disadvantages, burdens and risks (if any) of taking part?

There are no obvious disadvantages or risks of taking part, and participants can choose how much information to share with the interviewer regarding their experiences. The time burden of the interview will be approximately one hour.

6. What are the possible advantages or benefits (if any) of taking part?

There are no direct benefits to you in taking part in an interview; however, some people enjoy the opportunity to discuss their views. The insights we gain will help us to better understand the ways in which A&G is used and experienced by Primary Care Clinicians, which may have future healthcare benefits in terms of recommendations of best practice.

7. Expenses and payments

Participants will be paid £90 to participate in the study.

8. What if something goes wrong?

If you have a concern or complaint about any aspect of this research project, in the first instance you should contact the researcher(s) who will do their best to answer your questions. Their contact details are found at the end of this document.

If you remain unhappy and wish to complain formally, you can do this by contacting the research Sponsor at research.governance@keele.ac.uk

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

9. What will happen if I don't want to carry on with the research?

Even if you agree to take part and have given your consent, you are still free to withdraw at any time without giving a reason.

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|----------|--------|------------------------|------------|--------------|------|---------------|-------------|
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|----------|--------|------------------------|------------|--------------|------|---------------|-------------|

Once the interview has been conducted, you may withdraw up to one week after the interview at which point all data collected from you will be destroyed. If you withdraw after this time period, your data will remain on file and will be included in the final study analysis.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at www.hra.nhs.uk.

10. Will my taking part in this research study be kept confidential?

The information you provide during the research will be dealt with in the strictest confidence. The data, which identifies you, will be kept securely on a password protected research folder on the university system.

Data which would identify you will not be passed to anyone outside the research team without your express written permission. The exception to this is authorised representatives from the research Sponsor (Keele University) who may need to access data (for example for audits) to fulfil their responsibility to ensure the research is being carried out correctly, and any regulatory authority which has the legal right to access the data for the purposes of conducting an inspection, audit or enquiry. These agencies treat your personal data in confidence.

Keele University will keep the information you provide for 10 years after the research has finished. This is normal in research of this nature.

The recorded interviews will be transcribed by an external company who has a confidentiality agreement with the university. The transcribed (written) copy will not contain any information that might identify you. The anonymous information will be used in reports, publications and presentations. It will not be possible to identify you in any of these.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

11. What will happen to the information collected about me during the research project / study?

All data will be stored securely in the password protected research folder on the university system.

Information collected on paper records, such as consent forms and the reply slip, will be uploaded to the password protected research folder on the university system and the paper record destroyed.

Your personal information (name, postcode, contact details) will be destroyed at the end of the study.

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|----------|--------|------------------------|------------|--------------|------|---------------|-------------|
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|----------|--------|------------------------|------------|--------------|------|---------------|-------------|

Interview video or audio recordings will be uploaded to the password protected research folder on the university system and the recordings deleted from the device. The recordings will be kept until the end of the study and then deleted.

Interview transcripts will be uploaded to the password protected research folder on the university system. The anonymous transcripts will be kept for 10 years.

Access to these data are restricted to relevant members of the study team for research purposes and for audit purposes outlined above.

In line with Keele Medical School's policies, all research data (your anonymised interview transcript) will be securely stored for 10 years after completion of the study; after this time all data will be destroyed.

12. What will happen to the results of this research?

The data, when made anonymous, may be presented at academic conferences, or published as a project report, academic dissertation or in academic journals or book. It could also be made available to any commissioner or funder of the research.

Anonymous data, which does not identify you, will be publicly shared at the end of the project and made open access. A licence will be applied to this publicly shared data. This will allow anyone else (including researchers, businesses, governments, charities, and the general public) to use the anonymised data for any purpose that they wish, providing they credit the University and research team as the original creators. No restrictions will be placed on the shared anonymised data, allowing its reuse for both commercial and non-commercial purposes.

The raw data will be retained for a minimum of 10 years. When it is no longer required, the data will be disposed of securely.

13. 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, contact details, ethnicity, age, job role, and gender. People will use this information to do the research or to check your records to make sure that the research is being done properly.

14. What are your choices about how your information is used?

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.

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

You can find out more about how we use your information:

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- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from [Research participants - Keele University](#)
- by asking one of the research team
- by sending an email to research.badger@keele.ac.uk or
- by ringing us on [phone number].

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer (dpo@keele.ac.uk) who will investigate the matter. 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, <https://ico.org.uk/make-a-complaint/>).

16. Who is organising and funding the research?

The research project / study is being led by Dr Claire Burton and other researchers at Keele University and is sponsored by Keele University. It is funded by NIHR. None of the researchers or study staff will receive any financial reward by conducting this study, other than their normal salary.

17. How have patients and the public been involved in this research?

Patients and the public have been involved throughout the development of this project. The study team includes a member of the public, and our public and patient involvement group meets regularly to help inform the study. Their input has been instrumental in co-creating all patient facing documents, and they will help us share the findings of the study.

18. Who has reviewed the study?

All research carried out within the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This research project has been reviewed and given a favourable ethical opinion by North East – Tyne & Wear South Research Ethics Committee (IRAS reference: 333799).

Contact for further information

If you have any questions or would like any further information, please contact the research team by email: research.badger@keele.ac.uk or phone: 01782 731750.

If you have any general questions about taking part in research, you can also contact can contact NHS England on Tel: 0300 311 2233, email: england.contactus@nhs.net

Thank you

Thank you for taking time to read this information sheet and for considering volunteering for this research. If you do agree to participate your consent will be sought; please see the accompanying consent form.