Defining an evidence base for the use of advice and guidance referrals

Submission date 10/06/2024	Recruitment status Recruiting Overall study status Ongoing	Prospectively registered	
		[X] Protocol	
Registration date 29/07/2024		 Statistical analysis plan Results 	
Last Edited 10/06/2025	Condition category Other	 Individual participant data [X] Record updated in last year 	

Plain English summary of protocol

Background and study aims

When a GP needs a specialist's input with the care of a patient, one option is to use Advice and Guidance (A&G). A&G is an electronic way for a GP to ask a consultant a clinical question and a specialist responds, usually within a few days. The response may be to send an appointment for the patient to see a specialist, try a treatment, or do a test. A&G was introduced to speed up access to a specialist opinion and cut waiting times for outpatient care. A&G became more important during the COVID-19 pandemic as it meant patients did not automatically need to travel to hospital. The use of A&G is now encouraged to help the NHS recover from the pandemic. There are very few studies telling us whether A&G has a better or worse effect on patient care than the usual referral system.

We will study the impact of Advice and Guidance on patients, healthcare workers and the healthcare system, in terms of:

- how often, why and when A&G is used
- views about its impact on the quality of care and patient satisfaction
- impact on how NHS services are used.

This will help us to work out whether A&G reduces waiting times and access to specialist care as planned, without making the quality of patient care worse. This will be done in comparison to the more traditional way of referring patients to be seen by a specialist in outpatients.

Who can participate?

We will interview patients who have had experience of the A&G process. We will also interview clinicians and commissioners who are involved in using A&G.

What will the study involve?

Interviews are likely to last between 30 and 90 minutes and will be one off events. There will be no follow-up interviews. Participants will be free to pause or stop their interview at any point without any expectation to continue. Interviewers are not able to provide clinical advice and will advise participants to seek support from their own clinical teams if needed. What are the possible benefits and risks of participating? By participating, patients will provide insight into and ideas about how A&G can be used effectively and safely in the care journey. Risks of being interviewed might include raising worries or concerns about healthcare.

Where is the study run from? The research team is based at Keele University (UK)

When is the study starting and how long is it expected to run for? June 2024 to May 2026

Who is funding the study? This study is funded by the NIHR HSDR (NIHR158681). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Who is the main contact? research.badger@keele.ac.uk

Study website https://www.keele.ac.uk/research/ourresearch/medicine/researchareas/primarycare/badger/

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 333799

ClinicalTrials.gov number Nil known

Secondary identifying numbers CPMS 58336, NIHR158681, IRAS 333799

Study information

Scientific Title

Building an evidence base for the use of ADvice and GuidancE Referrals at the primarysecondary care interface – a multistage mixed-methods study

Acronym BADGER

Study objectives

The overarching aim of the study is to measure the impact of Advice & Guidance (A&G) on patients, primary care clinicians, secondary care specialists, and the healthcare system in terms of quality of care, satisfaction with the process and service utilisation to understand how it works for whom, where, and why. The aim of the study was developed in partnership with our study lay co-applicant and Public and Patient Involvement and Engagement (PPIE) group who have experiences of A&G.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 13/06/2024, North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 207 104 8286; tyneandwearsouth.rec@hra.nhs.uk), ref: 24/NE/0110

Study design

Observational qualitative

Primary study design

Observational

Secondary study design

Qualitative study

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

Not yet available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

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Interventions

The BADGER study will interview up to 75 patient people. This will include 30 patients who have had Advice and Guidance used in their care, 40 clinical staff who use Advice and Guidance in their work in GP surgeries and hospitals (including doctors, nurses, pharmacists), and 5 healthcare commissioners. The interviews will ask participants about their experiences of Advice and Guidance, what works well and what doesn't, and how they see the future for Advice and Guidance.

Participants will be required to complete the consent form prior to the interview, either by returning a signed consent form to the team prior to interview, or immediately prior to the interview during the interview appointment. An opportunity for questions will be provided prior to the interview. Interviews will take place at a mutually agreed location, for example, in the homes or local public space for public participants, or remotely using a platform such as MS Teams.

Participants will be thanked for their time in line with current guidance.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

Semi-structured interviews will be conducted using topic guides co-developed by and in agreement with our PPIE group and collaborating stakeholders. Topic guides will explore patient interviewees' experiences and perceptions of the use of A&G during and after the consultation process, and aspects of an 'ideal' interaction between patients and health care professionals in relation to the use of A&G. Clinician participants will be interviewed around their own experiences and perceptions of the A&G process. Topic guides will be used flexibly to allow interviewers to explore any unexpected findings and enable comparison between accounts during analysis.

Interviews will be digitally recorded with consent. Audio-recordings of interviews will be transcribed and anonymised before analysis. A reflexive thematic analysis approach will be taken to obtain a rich and contextualised understanding of the strengths and weaknesses of the use of A&G in patient care at the primary secondary care interface.

Interviews are likely to last between 30 and 90 minutes and will be single events. There will be no follow-up/longitudinal interviews. Participants will be free to pause or stop their interview at any point without any expectation to continue. It will be made clear that interviewers are not able to provide clinical advice and will advise participants to seek support from their own clinical teams if necessary.

An inductive, reflexive thematic analysis will be carried out on the data following the principles outlined by Braun & Clarke. The data will be analysed within the participant groups, and as a complete dataset to holistically explore the experiences and interactions of the participants, and to identify any patterns and consistencies across the accounts.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/06/2024

Completion date

31/05/2026

Eligibility

Key inclusion criteria

1. Patients: Adult patients (18 years or over) registered at a participating practice with an episode of A&G recorded in their electronic health record in the last 3 months, and have capacity to consent to an interview.

2. PCCs: participants will be eligible if they currently work in the NHS and are users of A&G.

3. SCSs: participants will be eligible if they currently work in the NHS and are users of A&G.

4. Commissioners: participants will be eligible if they currently work in the NHS and are familiar with its use at Trust / local System level.

Participant type(s)

Patient

Age group

Adult

Lower age limit 18 Years

Sex Both

Target number of participants

Planned Sample Size: 75; UK Sample Size: 75

Key exclusion criteria

1. Patients: participants will be excluded if they do not have capacity to consent for themselves, or are unable to meaningfully communicate about their experiences in an interview. If English is not their first language, translation services will be used so as not to exclude due to language barriers.

2. PCCs, SCSs, Commissioners: participants will be excluded if they have no experience or knowledge of using A&G.

Date of first enrolment 01/07/2024

Date of final enrolment 31/03/2026

Locations

Countries of recruitment United Kingdom

Study participating centre NIHR CRN: North West Coast Royal Liverpool and Broadgreen University Hospitals NHS Trust Prescot Street Liverpool United Kingdom L7 8XP

Study participating centre NIHR CRN: West Midlands James House Newport Road Albrighton Wolverhampton United Kingdom WV7 3FA

Sponsor information

Organisation Keele University

Sponsor details

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Sponsor type University/education

Website http://www.keele.ac.uk/

ROR https://ror.org/00340yn33

Funder(s)

Funder type Government

Funder Name National Institute for Health and Care Research / HSDR

Results and Publications

Publication and dissemination plan

Sharing our understanding how A&G works for who, where, and why, and our resulting resources will be delivered throughout the project. Essential components of our outputs include highlighting 'quick wins' to enable rapid uptake to ease compound pressures, focus on health inequalities, fostering sustainable healthcare and adoption of future IT innovations. Outputs will enable optimization of the established A&G system, delivering practical, real-world solutions to primary care, specialist services and overarching Integrate Care Boards, patients and policy makers in how to make use of the system in a safe, effective, and efficient manner to reduce compound pressures on the NHS.

Intention to publish date

31/05/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Alice Faux-Nightingale (a.faux-nightingale@keele.ac.uk). Any subsequent requests for access to the data from anyone outside of the research team (e.g. collaboration, joint publication, data sharing requests from publishers) will follow the Keele University SOP data sharing procedure.

IPD sharing plan summary Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>	version 2.0	18/06/2024	10/06/2025	No	No