Study Protocol

What does research impact mean to participants?

Full title: What does research impact mean to participants? Interview study to explore participants' views on the impacts of healthcare research

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Main Sponsor: Imperial College London
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STUDY COORDINATION CENTRE: Imperial College London

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Protocol authorised by:

Name & Role	Date	Signature
Dr Lisa Newington, Chief Investigator	19/05/2021	
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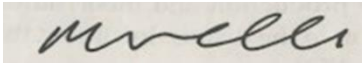
Prof Mary Wells, Co-Investigator	22/05/2021	

Study Management Group

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Study Management: Research team (as above)

This protocol describes the study 'What does research impact mean to participants?' and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to collaborators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Clinical Queries

Clinical queries should be addressed to Dr Lisa Newington (details above) who will direct the query to the appropriate person.

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

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Funder

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GLOSSARY OF ABBREVIATIONS

AE	Adverse event
AHP	Allied Health Profession(al)
CI	Chief Investigator
GCP	Good Clinical Practice
ICHT	Imperial College Healthcare NHS Trust
IRAS	Integrated Research Application System
NHS	National Health Service
NIHR	National Institute for Health Research
NMAHPP	Nursing, Midwifery, Allied health professions, Healthcare Science, Psychology and Pharmacy
PIC	Participant identification centre
PIS	Participant information sheet
RGIT	Research Governance and Integrity Team
SAE	Serious adverse event

KEYWORDS

Nursing, Midwifery, Allied Health Professions, Healthcare Science, Psychology, Pharmacy, Research Impact, Clinical Academic, Clinical Research, Qualitative Research, Framework Analysis

STUDY SUMMARY

TITLE What does research impact mean to participants? Interview study to explore participants' views on the impacts of healthcare research

DESIGN Qualitative interview study

AIMS To explore research participants' views on the impacts of research involvement, specifically for research that has been led by healthcare professionals outside medicine

ANALYSIS METHOD Framework analysis

POPULATION Current and previous research participants/patient research advisory group members who are/have been involved in research led by healthcare professionals outside medicine

ELIGIBILITY Research involvement in past 3 years

DURATION 16 months

1. INTRODUCTION

1.1. BACKGROUND AND SUMMARY

Healthcare research is commonly associated with clinical trials, led by clinical doctors. Yet, clinicians from other healthcare professions also need to make sure they are delivering evidence-based care for their patients. This involves conducting research to answer questions that are relevant and important for clinical care within their field.

The aim of this study is to explore research participants' views on the impacts of research involvement, specifically for research that has been led by healthcare professionals outside medicine. These include nurses, midwives, allied health professionals, pharmacists, healthcare scientist and psychologists (abbreviated to NMAHPPs). The term 'impact' has not been pre-defined; this will be determined as part of the study.

Recruitment has two parts: i) National Institute for Health Research records and established networks will be used to identify NMAHPP researchers across the UK; and ii) these individuals will share the invitation to take part with their existing research participants and patient advisory group members.

One-to-one interviews will be conducted to explore participants' experiences of being involved in research, including the associated personal and broader impacts (both positive and negative). Interview transcripts will be analysed to identify common, unique and differing themes.

The findings will contribute to the development of a framework to capture the impact of NMAHPP research that incorporates items that are meaningful to research participants. This framework will be developed and refined through discussion with patients, researchers, clinicians and hospital managers. The findings will also contribute to the ongoing national discussion on clinical academic careers for healthcare professionals outside medicine.

1.2. RATIONALE FOR CURRENT STUDY

Imperial College Healthcare NHS Trust (ICHT) has a strategic plan to increase research activity among healthcare professionals outside medicine [1], a goal that is recognised nationally [2]. Along with increasing research activity, there is also the need to capture and evaluate its impact. Our recent NIHR Imperial BRC funded research explored the perceived impacts of research activity among research-active nurses, midwives, allied health and other healthcare professionals outside medicine (NMAHPPs) [3–5]. The identified impact themes contained several proposed benefits to patients, including: increased access to evidence-based management; improved care pathways and service delivery; and driving changes in the local culture to promote patient-focused care. However, these proposed impacts were reported by clinicians, and it is not known how patients/research participants perceive such research activity.

When capturing and evaluating the impact of research, it is important to consider the types of impact that have been identified as meaningful to participants as well as those perceived as valuable to researchers or healthcare organisations. The 2019 national Research Participation Experience Survey found that 90% of respondents reported a good experience of taking part in a research study, however the survey predominantly collected quantitative data, which did not allow in-depth exploration of the factors contributing to this response [6]. As research activity increases among NMAHPPs, there is the potential that patients might experience research fatigue, especially if research involvement is time consuming or does not lead to perceived benefits [7].

Existing literature on research participation primarily focuses on the reasons why patients did/did not agree to participate in, or complete, a research study [8–11]. This is valuable in informing optimal study designs, including processes to maximise recruitment and minimise loss to follow-up, however, to the best of our knowledge, the concept of participant-perceived research impact has not been previously explored outside feedback for individual research studies [12].

1.3. PATIENT AND PUBLIC INVOLVEMENT

This protocol was developed in collaboration with two patient and public advisors (before being transferred to the mandatory Imperial College London format). Both advisors participated in a virtual meeting to discuss the research question and study design, and provided valuable feedback and suggestions on the title, background summary, research funding application, qualitative interview design and participant information sheet. Patient and public involvement will be on-going throughout the study. Advisors will be invited to contribute to reviewing recruitment strategies, interpreting the preliminary findings and co-developing an impact capture framework.

2. STUDY OBJECTIVES

The aim of this qualitative interview study is to understand participants' views on the impacts of participating in NMAHPP-led research. This includes personal impacts to the individual, perceived impacts for others, opinions on what constitutes 'good' research, and how these aspects might be captured and evaluated. The findings will be triangulated with our existing work [3–5] and incorporated into the development of a tailored impact capture framework for NMAHPP research, which will be initially piloted at Imperial College Healthcare NHS Trust (ICHT).

3. STUDY DESIGN

Design: Qualitative interview study involving a single 1:1 interview with each participant
Duration: 16 months (November 2021 – February 2023)
Participants: Individuals who have been involved in NMAHPP-led research within the past 3 years
Sample size: 15-25 interviewees (final sample size to be determined by assessment of data saturation [13, 14])

3.1. DATA COLLECTION

This study uses a qualitative interview design, and each participant will take part in a single 1:1 interview led by the Chief Investigator. The interview format will be semi-structured, using a pre-piloted interview schedule informed by our current research [3, 4], and refined by discussion with the patient advisory group (Appendix F). Questions will be further refined as part of an iterative design to incorporate any additional topics identified in the initial interviews.

All interviews will be conducted remotely using telephone or video calls. The format will be determined by participant preference. A variety of video platforms will be offered, including Zoom, Microsoft Teams and Skype. Interviews will be audio recorded using the inbuilt recording function within the video platform and/or an external audio recording device and transcribed verbatim using an external transcription company (PageSix), who are bound by a confidentiality and non-disclosure agreement. Once the transcript has been reviewed and verified against the audio recording by the Chief Investigator, the audio file will be deleted.

Transcripts will be pseudo-anonymised to remove names, places and other potentially identifying characteristics, and will be stored using a unique participant identification reference. Participants will be offered the opportunity to review their transcript to check that they are happy with the content and level of anonymisation.

4. PARTICIPANT ENTRY

4.1. RECRUITMENT

4.1.1 Participant Identification Centres

NMAHPP clinical academics will be invited to contribute as Participant Identification Centres (PICs). Provisional agreement to participate as a Participant Identification Centre has already been granted by three sites and they have been included in the application for NHS ethics approval. Additional PIC locations will be added with approval via the ethics amendments process. It is anticipated that 10-20 PIC sites will be involved across the UK nations.

4.1.2 Participant recruitment

Potentially eligible participants will be identified by the collaborating NMAHPP clinical academics from their existing databases. No pre-registration evaluations are required. The

NMAHPP clinical academics (or member of the research team) will send a study invitation and flyer with a link to the participant information sheet to their current/previous research participants and/or patient and public advisory group members, ideally by email. This will only be possible where prior consent has been given by the participant to be contacted regarding future research. The invitation text, study flyer and participant information sheet are included in Appendices B-D. PIC sites will be asked to keep a log of the number of invitations sent to allow a general response rate to be calculated for the study. This will not be calculated at the level of individual PIC sites.

Interested individuals will be asked to contact the Chief Investigator by phone (study mobile) or email to register interest in the study or ask any questions. An additional open recruitment invitation will be advertised on Twitter if needed to boost recruitment (Appendix B).

Interested individuals will be asked to complete a screening questionnaire to confirm eligibility and provide background demographic data to enable purposive sampling. Purposive sampling criteria are outlined in Table 1 and the screening questions are provided in Appendix E. Screening will be completed using an Imperial College London Qualtrics form.

In the case of non-response after an initial expression of interest, up to three reminders will be sent before it is assumed that the individual no longer wishes to participate in the study. The format of the reminders could include email, text message or phone call.

Table 1. Purposive sampling criteria for interviewees

Sampling criterion	Categories
Clinical discipline of the research that they are/were a study participant	Nurse Midwife Allied health professional (art therapist, drama therapist, music therapist, chiropodist /podiatrist, dietitian, occupational therapist, operating department practitioner, orthoptist, osteopath, paramedic, physiotherapist, prosthetist/orthotist, radiographer, speech and language therapist) Healthcare scientist Pharmacist Clinical psychologist
Gender	Male Female Other
Type of participant	Research participant Patient/public involvement participant
Ethnicity (categories taken from the UK Office for National statistics guidelines [15])	Asian/Asian British Black/African/Caribbean/Black British Mixed/Multiple ethnic groups White/White British Other ethnic group
Age	18-30 31-45 46-60 61-75 Over 75
Geographical location	East of England London Midlands North East and Yorkshire North West South East South West Scotland Wales Northern Ireland

Recruitment and interviewing will continue until data saturation has been reached, i.e., when no new ideas are reported during the interview discussions, and no new codes are identified during the preliminary analysis [13, 14]. It is anticipated that 15-25 participants will be needed to reach data saturation, however this will be monitored during the study. Once it is believed that data saturation has been reached, an additional interview will be completed to either indicate that interviewing should continue or confirm data saturation.

4.2. INCLUSION CRITERIA

- Adults (aged over 18 years). In this instance, we want to explore the experiences of adult participants. It is anticipated that children and teenagers may report different experiences and reasoning for research involvement.
- Participated in research led by one of the NMAHPP disciplines within the past 3 years. This could be any type of study (for example, qualitative studies, observational cohort studies, randomised controlled trials etc). The NMAHPP disciplines are listed in full in Table 1. Research participation is defined as taking part in a study as either a research participant or as a patient/public research advisor. The period of 3 years was chosen to limit issues with recall.
- Able to provide informed consent to take part in a phone/video interview.
- Ability to take part in a 1:1 interview in English language. If a participant wishes to take part using a different language, including sign language, they will be able to request for a friend/family member to attend as an interpreter.

4.3. EXCLUSION CRITERIA

- Only participated only in research led by medical professionals (doctors and dentists).
- Participated in NMAHPP-led research more than 3 years ago.
- Aged under 18 years.
- Unable to provide informed consent to take part in a phone/video interview.
- Unable to take part in a 1:1 interview in English language (a friend/family member may be used as an interpreter, if appropriate, but this will need to be arranged by the participant).

4.4. WITHDRAWAL CRITERIA

Individual interviewees will be able to discontinue the interview at any time and withdraw their contribution from the study within 14 days of the interview. After this point, the anonymised interview transcript will be incorporated into the qualitative data analysis and it will not be possible to remove individual contributions.

5. ADVERSE EVENTS

It is not anticipated that any adverse events will occur. This is due to the nature of the research consisting of interviews. However, any questions concerning adverse event reported should be directed to the Chief Investigator in the first instance, then the sponsor. Imperial College London holds insurance policies which apply to this study.

Contact details for reporting adverse events to the sponsor:
RGIT@imperial.ac.uk

6. ASSESSMENT AND FOLLOW-UP

There will be no clinical assessment or follow-up of participants. The study design involves a single qualitative interview with each participant.

7. QUALITATIVE ANALYSIS

Interviews will be led by the applicant using a pre-piloted interview schedule informed by our current research [3–5], and refined by discussion with the patient advisory group (Appendix A). Questions will be further refined to incorporate any additional topics identified in the initial interviews. Interview transcripts will be analysed using Framework analysis to classify the key themes and sub-themes of impact that were described by participants, and to identify cases of disagreement [16]. Participants and patient advisors will be invited to provide feedback on the preliminary analysis, which will be used to develop the final themes/sub-themes.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study.

8. REGULATORY ISSUES

8.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the NHS Research Ethics Committee (Wales REC 5) and Health Regulator Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before interview invitations are sent to potential participants. The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2. CONSENT

Consent to enter the study will be sought from each participant only after a full explanation has been given, a participant information leaflet offered, and time allowed for consideration. Participants will be asked to complete an electronic consent form (Appendix F). Paper copies will be available for those who prefer a non-electronic format. For participants who are unable to complete a paper or electronic form, for example due to visual impairments, consent will be audio recorded using the same wording as the consent form. This will be recorded as a separate audio file from the interview. The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time before the interview without giving reasons and without prejudicing further treatment. Participants will also be able to withdraw from the study within 14 days of completing the interview.

8.3. CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

In accordance with the UK Data Protection Act (2018) and the General Data Protection Regulations (2018) all data will be confidential and used only for research purposes. All information will be stored electronically on an encrypted, password protected, Imperial College London computer (laptop). Identifying information (names, email addresses, phone numbers, screening responses, consent forms) will be kept separate from the interview transcripts, which will be identified only by a coded serial number. There will be no paper document storage. If the participant has chosen to complete their consent form as a paper version, this will be scanned and saved with the electronic versions and the paper form securely shredded.

Interviews will be audio recorded. The audio files will be securely deleted once transcription is completed and the accuracy checked. Transcription will be provided by an external transcription company (PageSix Transcription) who are bound by a non-disclosure agreement. Interview transcripts will be psuedonymised for analysis and storage (identified by the unique study reference number). This will remove references to names, places and other potentially identifying characteristics.

All study data will be kept securely and confidentially for 10 years in line with the Imperial College London data storage policy. It will not be possible to identify individual interviewees in any of the outputs from this research. Illustrative (anonymous) quotes will be used to support the analysis in publications and reports. These will be anonymous and only where the interviewee has provided consent.

8.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5. SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6. FUNDING

NIHR Imperial Biomedical Research Centre and Imperial Health Charity are funding this study. There is no payment for interviewees. Patient advisors will be reimbursed for their time at a rate of £20 per hour.

8.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated by the Chief Investigator, Dr Lisa Newington (l.newington@imperial.ac.uk).

10. PUBLICATION POLICY

Study findings will be discussed with the patient advisors and their input sought on how to best disseminate the results to the patient and public community. It is anticipated that this might include a short summary/blog for the ICHT website and other sources, however all recommendations will be explored. The study will be submitted for publication in a peer reviewed journal and disseminated through presentations at relevant healthcare forums and conferences.

The study findings will also be triangulated with our existing work [3, 4] to develop an impact assessment framework for NMAHPP research at ICHT. Preliminary development will be conducted by the research team. This will be further refined and co-developed with feedback from the patient advisory group and a small working group of research-active NMAHPPs and other key stakeholders (including professional and research leads). In addition, 2-4 extra patient/public advisors will be recruitment from interview participants who agreed to be contacted about other related research/activities. A future aim is for the research impact capture framework to be piloted at ICHT.

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12. APPENDICES

12.1 APPENDIX A – INTERVIEW SCHEDULE

Provided separately.

12.2 APPENDIX B – INVITATION TEXT

Text for recruitment email/social media post for researchers

Dear […]
We are running a qualitative interview study to explore participants' perspectives of healthcare research. Specifically, research led by non-medical healthcare professionals (nurses, midwives, AHPs, healthcare scientists, pharmacists and clinical psychologists). This follows on from our previous work exploring managers and research-active clinicians' perspectives of research impact [links for 3 papers: a systematic review and two papers exploring clinical academics and research impact].

We are looking for research-active clinicians from these groups to advertise our interview study to their past/present research participants and patient advisory group members (where consent has been provided for contact about future research). This would involve an initial mail out of our study invitation and participant information sheet [link to PIS], ideally by email, and a follow up approximately 2-6 weeks later. We hope you can help! Importantly, we are looking for current research participants/patient advisors, or those who were involved in a research study within the past 3 years.

We are based at Imperial College London and are looking for representatives from a variety of non-medical professions, located in different areas of the country. This study has been approved by [RGIT/IRAS details].

If you are interested in contributing to this project, or would like any additional information, please contact Lisa Newington on l.newington@imperial.ac.uk.
Many thanks in advance,

Twitter post for researchers

IMAGE – STUDY LOGO
Calling all UK research-active clinicians from professions outside medicine. We're interested in participants' views of research impact. Can you help advertise our study to your past/present research participants? Pls DM for details.
LINK - PIS

Text for recruitment email for researchers to send to their participants
Dear […]
Thank you for taking part in our study [name/description of study etc]/ Thank you for taking part in our patient/public advisory group for [name/description of study etc].

[I/we] would like to let you know about a study being run by healthcare researchers at Imperial College London.

Their study looks at research participants' views of taking parting in research. This would involve a one-off phone or video interview to discuss your experiences of being a research participant (or patient advisor) and your ideas of what makes good research.
[I/we] have attached an information sheet, which provides more details about the study [or link to PIS].

If you are interested in taking part, or have any questions about the study, please contact Lisa Newington on l.newington@imperial.ac.uk or 07866 997732.
Thank you!

Twitter post for participants
IMAGE – STUDY LOGO
Have you taken part in UK healthcare research led by nurses, midwives, allied health professionals (https://www.england.nhs.uk/ahp/role/), pharmacists, psychologists or healthcare scientists? If so, we're interested in speaking to you about your views of the impacts of research. Pls DM for details
LINK - PIS

12.3 Appendix C – Study flyer

Provided separately.

12.4 Appendix D – Participant information sheet

Provided separately.

12.4 Appendix E – Screening questions

Format: Qualtrics form (hosted by Imperial College London)

1. Please enter your name
   [free text]
2. Please provide an email address that we can use to contact you about this study
   [free text]
3. Please provide a phone number that we can use to contact you about this study
   [free text]
4. Would you prefer to be contacted by phone/email?
   [selection: phone/email/either]
5. What is your gender?
   [selection: male / female / other]
6. What is your age in years?
   [free text]
7. How do you describe your ethnicity?
   [selection: Asian/Asian British, Black/African/Caribbean/Black British, Mixed/Multiple ethnic groups, White/White British, Other ethnicity (please specify)]
8. Where do you live in the UK? Please select the region
   [selection: East of England / London / Midlands / North East and Yorkshire / North West / South East / South West / Wales / Scotland / Northern Ireland / Other (please specify]

9. What has been your healthcare research involvement in the last 3 years?
   [selection: study participant / patient or public advisor / I haven't been involved in healthcare research in the past 3 years]
10. Which hospital or university was responsible for the research you were involved in? If you are not sure of the name, please write the city or town where the research was based.
11. If you know the clinical discipline of the person or team leading the research that you were involved in, please select the discipline here. If you have been in more than one study, please pick the most recent:
    [selection: nursing / midwifery / art therapy / clinical psychology / drama therapy / music therapy / chiropody or podiatry / dietetics / healthcare science / occupational therapy / operating department practitioner / orthoptics / osteopathy / paramedic / pharmacy / physiotherapy / prosthetics or orthotics / radiography / speech and language therapy / medical doctor / surgeon / unsure]

Thank you for completing this screening information, and for your interest in our research. A member of the research team will be in contact will you shortly.

12.4 Appendix F – Consent form

Provided separately.