Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
What does research impact mean to participants?

1. Is your project research?

- (●) Yes
- ( ) No

2. Select one category from the list below:

- ( ) Clinical trial of an investigational medicinal product
- ( ) Clinical investigation or other study of a medical device
- ( ) Combined trial of an investigational medicinal product and an investigational medical device
- ( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- ( ) Basic science study involving procedures with human participants
- ( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- (●) Study involving qualitative methods only
- ( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- ( ) Study limited to working with data (specific project only)
- ( ) Research tissue bank
- ( ) Research database

If your work does not fit any of these categories, select the option below:

- ( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [x] England

☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

○ Yes ◉ No

The NIHR Clinical Research Network (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
What does research impact mean to participants?

Please complete these details after you have booked the REC application for review.

REC Name:
PR Committee

REC Reference Number:
21/PR/0940

Submission date:
28/06/2021

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Interview study to explore participants' views of taking part in healthcare research

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Lisa	Newington
Post	Research Associate		
Qualifications	PhD, MSc, BSc(hons), MCSP, AHT (BAHT)		
ORCID ID	0000 0001 6954 2981		
Employer	Imperial College London		
Work Address	Education Building (corporate nursing) Charing Cross Hospital Fulham Palace Road, London		
Post Code	W6 8RF		
Work E-mail	l.newington@imperial.ac.uk		
* Personal E-mail	lnewington.pt@gmail.com		
Work Telephone	020 3311 7422		
* Personal Telephone/Mobile	07775563204		

Fax	00000000000

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
		Becky	Ward
Address	Research Governance and Integrity Team (RGIT)		
	Imperial College London and Imperial College Healthcare NHS Trust		
	Room 215, Level 2, Medical School Building, Norfolk Place, London,		
Post Code	W2 1PG		
E-mail	becky.ward@imperial.ac.uk		
Telephone	0207 594 9459		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	21CX6867
Sponsor's/protocol number:	N/A
Protocol Version:	1.0
Protocol Date:	17/05/2021
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	N/A

Additional reference number(s):

Ref.Number	Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language*

easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.

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' and research advisory group members' views on the impacts of their research involvement. Specifically for research that has been led by healthcare professionals outside medicine. These include nurses, midwives, physiotherapists, occupational therapists, other allied health professionals, healthcare scientists, pharmacists and psychologists (abbreviated to NMAHPPs). The term 'impact' has not been pre-defined; this will be discussed as part of the study.

Recruitment has two parts: National Institute for Health Research records and established social media networks will be used to identify NMAHPP researchers across the UK; these individuals will then 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 individual 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 ongoing national discussion on clinical academic careers for healthcare professionals outside medicine and will be used to inform impact capture strategies locally.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

PURPOSE AND DESIGN
This qualitative study has been designed to explore research participants' and patient advisors' views of being involved in research, including the personal and broader impacts. Specifically, we focus on research led by clinicians from non-medical healthcare professions.

The study was designed with input from two public advisors, who had previous experience as research participants, and was developed following our exiting work exploring research impact from the perspectives of research-active clinicians and managers [1,2].

Data will be collected through 1:1 interviews with the lead researcher. Interviews will be conducted by phone/video call, eliminating the risk of Covid-19 transmission and any risks that might otherwise be associated with lone working in a face-to-face context.

The interview topic guide was developed with input from the public advisors and refined following feedback from internal peer review as part of an application for funding. The interview schedule will be further piloted and refined as part of the iterative process of qualitative interviews.

RECRUITMENT
Recruitment has two stages. The first recruits NMAHPP researchers (nursing, midwifery, allied health professions, healthcare scientists, pharmacy and clinical psychology) using openly accessible NIHR records and social media networks. Provisional approval has been granted by the Healthcare Professionals in Research Facebook group and the Clinical Academic Research Implementation Network.

For the second stage of recruitment, the identified NMAHPP researchers will send study invitations to their participants/previous participants. This will only take place where prior permission had be granted to receive information about additional research opportunities. The current research team will not have access to any information about the potential interviewees at this stage.

Individuals who are interested in participating in a one-off interview will be invited to contact the lead researcher to register interest in the study. They will be asked to complete a short screening tool to aid purposive sampling.

The purposive sampling strategy will be used to ensure the inclusion of interviewees from the range of different backgrounds. At the first stage of recruitment, NMAHPPs will be sought to represent the different disciplines, and different research methods (clinical trials, cohort studies, cross-sectional surveys, qualitative research).

At the second stage of recruitment, interviewees will selected to represent different geographic areas, genders, age groups, and variation in both the type of research that they were involved in and the clinical discipline leading the research.

INCLUSION CRITERIA
Interviewees will have been involved in a research study led by an NMAHPP or NMAHPP team within the past 3 years. Because individuals will be asked to reflect on their experiences, this time point was chosen to limit issue with recall. Research participation may include as a study participant or as a patient advisor for a research study.

Only adults are eligible (aged >18 years). Research experiences and reasoning may be different for adults and teenagers or children. In this instance, we want to explore the experiences of adult participants. Future work should aim to understand the experiences of children and their families.

Interviewees will need to be able to provide informed consent to participate in the interview. In addition to the completed consent form, this will be explored through discussion with all interviewees at the beginning of the interview to establish that they understand the nature of the study and are happy to proceed with the interview. If the interviewee wishes to stop at anytime, the interview will be discontinued.

Interviews will be conducted in English language. Interviewees will be able to request for a friend or family member to attend as an interpreter, if they wish.

CONSENT
Individuals who agree to an interview will be asked to complete an electronic consent form after accessing the participant information sheet and asking any questions they have. A paper version will be made available for those who prefer to use this method. Audio consent will be offered, if requested, for individuals with visual impairment or who are otherwise unable to complete a written consent form.

Interviewees will be able to discontinue the interview at any time and will be able to withdraw completely from the study within 14 days of completing the interview. After this point, the psuedonymised transcript will be analysed and it will not be possible to completely exclude their contribution, however if the individual requests to be removed from the study, no quotes from this individual will be reported in resulting publications and reports.

RISKS AND BURDENS
The primary burden for interviewees is the time required to participate in the one-off interview. Potential interviewees are informed of the expected interview duration as part of the participant information sheet.

Participation in the interviews will not affect any of their medical care or other research involvement and no healthcare treatment or advice will be provided as part of the interview.

It is not anticipated that the content of the interviews will be distressing for interviewees, however if the interview appears distressed, they will be offered to opportunity to pause or discontinue the interview. If the interviewee reports concerns regarding symptoms or other health condition, they will be advised to contact their GP or the relevant study team, if their research participation is ongoing. If the interviewee reports any instances of potential research misconduct, this will be reported to the host research organisation.

CONFIDENTIALITY
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 the research purposes. All information will be stored electronically on an encrypted, password protected, Imperial College London computer. Identifying information (names, email addresses, phone numbers, screening responses, consent forms) will be kept separate from the pseudonymised interview transcripts. Transcripts will be identified only by a unique study reference code. Any potentially identifiable data within the transcript, such as names, locations, healthcare information etc, will be removed. A counter-signed copy of the consent form will be returned to the interviewee for their records.

Interviews will be audio recorded. The audio files will be 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 pseudonymised by removing references to names, places and other potentially identifying characteristics. Only the psuedonymised transcripts will be used for the analysis and will be stored securely following the method outlined above. It will not be possible to identify individual interviewees in any of the outputs from this research. Illustrative quotes will be used to support the analysis in publications and reported. These will be anonymous and used only where the interviewee has provided consent.

All study data will be kept securely and confidentially for 10 years in line with the Imperial College London data storage policy.

Contact with participants will be made using Imperial College email and a study mobile.

CONFLICTS OF INTEREST
The study team are research-active NMAHPP clinicians. Participants may be recruited from research studies where members of the study team are involved. All interviewees will be advised that the content of the interviews is confidential and will not affect their research participation.

REFERENCES
1. Newington L, Wells M, Adonis A et al. A qualitative systematic review and thematic synthesis exploring the impacts of clinical academic activity by healthcare professionals outside medicine. BMC Health Services Research 2021; 21:400 https://doi.org/10.1186/s12913-021-06354-y

2. Newington L, Alexander CM, Wells M. What is a clinical academic? Qualitative interviews with healthcare managers, research-active nurses and other research-active healthcare professionals outside medicine. Journal of Clinical Nursing 2021; online first https://doi.org/10.1111/jocn.15624

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

To understand and explore the perceived impacts of NMAHPP-led research from the perspectives of research participants and patient advisory group members.

Research participants are individuals who have consented to take part in a research study. Patient advisory group members are individuals who have contributed to aspects of the study design and management.

NMAHPP is defined as nursing, midwifery, allied health professions, healthcare science, psychology and pharmacy, and encompasses healthcare professions other than medicine and dentistry.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

To explore research participants' views of what makes 'good' research

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Nationally, there is a desire to increase research activity among healthcare professionals outside medicine [1]. 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 NMAHPPs [2–3]. 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 research 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 numerical data, which did not allow in-depth exploration of the factors contributing to this response [4].

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 [5].

Existing literature on research participation primarily focuses on the reasons why patients did/did not agree to participate in, or complete, a research study [6-8]. To the best of our knowledge, the concept of participant-perceived research impact has not been previously explored outside feedback for individual research studies [9].

The aim of this research 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 recorded and evaluated.

REFERENCES

1. Association of UK University Hospitals. Transforming healthcare through clinical academic roles in nursing, midwifery and allied health professions: A practical resource for healthcare provider organisations. 2016. https://councilofdeans.org.uk/2016/11/transforming-healthcare-thr ough-clinical-academic-roles-in-nursing-midwifery-and-allied-heal th-professions/

2. Newington L, Alexander CM, Wells M. What is a clinical academic? Qualitative interviews with healthcare managers, research-active nurses and other research-active healthcare professionals outside medicine. Journal of Clinical Nursing. 2020. doi:10.1111/jocn.15624

3. Newington L, Wells M, Adonis A et al. A qualitative systematic review and thematic synthesis exploring the impacts of clinical academic activity by healthcare professionals outside medicine. BMC Health Services Research 2021; 21:400 https://doi.org/10.1186/s12913-021-06354-y

4. National Institute for Health Research. Report of the research participation experience survey 2018/2019. 2019. https://www.nihr.ac.uk/documents/report-of-the-research-participa tion-experience-survey-20182019/12234#Survey_respondents

5. Clark T. "We're over-researched here!": Exploring accounts of research fatigue within qualitative research engagements. Sociology. 2008;42:953–70

6. University Hospital Southampton NHS Foundation Trust. Engaging for increased research participation: Key findings and recommendations. 2015. http://www.uhs.nhs.uk/Media/Southampton-Clinical-Research/Marketr esearch/Engaging-for-increased-research-participation-key-finding s-v2.pdf

7. Newington L, Metcalfe A. Factors influencing recruitment to research: Qualitative study of the experiences and perceptions of research teams. BMC Medical Research Methodology. 2014;14

8. Bertram W, Moore A, Wylde V, Gooberman-Hill R. Optimising recruitment into trials using an internal pilot. Trials. 2019;20:207. doi:10.1186/s13063-019-3296-5

9. MacNeill V, Foley M, Quirk A, McCambridge J. Shedding light on research participation effects in behaviour change trials: a qualitative study examining research participant experiences. BMC Public Health. 2016;16:91. doi:10.1186/s12889-016-2741-6

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

STUDY DESIGN
This study uses a qualitative interview design. The interviews will be semi-structured, meaning that a series of planned questions and prompts will be asked to each interviewee. However, the interview structure is not fixed and will also include the opportunity to discuss any other aspects as they arise.

Qualitative interviews were chosen to enable in-depth exploration of an individual's experiences, while also allowing identification of common and unique themes across all interviewees.

Interviews will be audio recorded and the written transcripts will be analysed by the research team using the Framework Method. This is a strategy that involves applying a code to each different feature of the interviewees' responses and grouping together similar codes to determine key themes and sub-themes.

STUDY PARTICIPANTS
It is anticipated that 15-25 interviews (15-25 study participants) will be needed to reach data saturation. That is where no new concepts are discussed by interviewees and no new codes are identified during the analysis. This will be monitored as the study progresses.

Eligibility criteria are:
1. Current or previous (past 3 years) involvement in research led by one or more NMAHPP healthcare professional. This includes involvement as a research participant and/or as a patient advisor.

2. Ability to take part in a 1:1 interview in English language, with the use of an interpreter if appropriate.

3. Aged 18 years or older. There is no upper age limit.

4. Able to provide informed consent to take part in a phone/video interview.

PATIENT AND PUBLIC INVOLVEMENT
Two patient advisors (who both had experience as previous research participants) were involved in the development of the study design, interview questions and participant information sheets. This took place using video meetings and independent review and feedback on draft versions of the study documents. Patient advisors will continue to be involved through out the study.

STUDY FORMAT
1. Previous/current research participants/advisors will be recruited via their research teams. This will involve an interview invitation letter and participant information sheet, which will be sent (either by post or email) to individuals who have agreed to be contacted about additional research opportunities.

2. Potential interviewees are invited to contact the lead researcher by phone or email to express an interest in taking part in the study, and/or to ask any questions. Interested individuals will be asked to complete a study screening form to check eligibility and collect basic demographic information. This will be used to aid the inclusion of individuals from different locations and with different types of research involvement and will be delivered using an online Imperial College London Qualtrics form.

3. A consent form (electronic or post based on interviewee preference) will be sent to those who agree to take part in an interview and the interview arranged at a date and time that is convenient.

4. Study participation involves a single 1:1 interview with the lead researcher. All interviews will be conducted by phone or video call (interviewee preference) and are expected to last 35-45 minutes. A variety of video platforms will be offered, including Zoom, Microsoft Teams and Skype. Interviews will be audio recorded using the integrated recording system within the video calling platform and/or an external audio recording device. Only audio recording is required for this study and no video files will be saved. The audio recording will be transcribed to provide a text version of the interview. Transcription will be conducted by an external company (PageSix Transcription) who are bound by a confidentiality and non-disclosure agreement.

ADDITIONAL INVOLVEMENT
Interviewees will also be given the option to participate in any of the following activities, if they wish. This will be indicated on the consent form.

1. Receive a copy of their interview transcript for review and comment. This is to ensure that the interviewee is happy with the content.

2. Receive a summary of the preliminary analysis for review and comment. This is to ensure that the proposed findings appear appropriate to the study participants.

3. Join an advisory group to contribute to the development of local research impact capture strategies as a follow-on from the current study.

4. Be contacted about the opportunity to be involved in future research.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research
- [x] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
The study protocol was developed in collaboration with two patient and public advisors. Both advisors participated in virtual meetings to discuss the research question and study design, and provided valuable feedback and suggestions on the title, plain-English abstract, research proposal, qualitative interview design, recruitment material and strategies.

Patient and public involvement will be on-going throughout the study. Advisors will be invited to contribute to interpreting the preliminary findings, co-developing an impact capture framework and assisting with dissemination.

We have funding to reimburse patient advisors for their time.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular

- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

1. Participated in NMAHPP-led research within the past 3 years (nursing, midwifery, allied health professions, healthcare science, pharmacy and clinical psychology). The allied health professions are: art therapy, drama therapy, music therapy, chiropody /podiatry, dietetics, occupational therapy, operating department practitioner, orthoptist, osteopathy, paramedic, physiotherapy, prosthetics/orthotics, radiography, and speech and language therapy. Healthcare research in all clinical areas and of all research types are included.

2. Aged 18 years or older. There is no upper age limit.

3. Able to provide informed consent to take part in a phone/video interview.

4. Able to take part in an English language interview, with the use of a friend/family member as an interpreter, if appropriate.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

1. Only participated in research led by medical doctors or dentists.

2. Participated in NMAHPP-led research more than 3 years ago.

3. Aged <18 years.

4. Unable to provide informed consent to take part in a phone/video interview.

5. Unable to take part in a phone/video interview in English language (a friend/family member may be used as an

interpreter, if appropriate).

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Receive and read interview invitation and participant information sheet	1	0	10 mins	Invitation will be emailed or posted by the NMAHPP research team.
Contact lead researcher to express interest in interview and complete screening information	1	0	15 mins	Potential interviewee will complete this information independently.
Complete interview consent form	1	0	3 mins	Interviewee will complete electronically, or using a pre-paid envelope.
Interview	1	0	45 mins	Lead researcher will conduct the interview by phone/video call. Interviewee will select the format.
Review transcript (only if the participant wishes)	1	0	1 hour	Lead researcher will email the transcript to the interviewee for review and comment. This will be read independently and the interviewee can respond by email/phone.
Review and comment on the preliminary analysis (only if the participant wishes)			45 mins	Lead researcher will email a summary of the preliminary analysis for review and comment. The interview can respond by email/phone.

A21. How long do you expect each participant to be in the study in total?

Study participation involves a one-off interview.

Interviewees will be offered the option to review their transcript and provide feedback/correction. This will occur within 1-2 months of the interview. Interviewees will also be invited to provide feedback on the preliminary study analysis, which will be within one year of the interview. Neither of these latter steps are requirements of study participation and each individual will be given the option to be involved as part of the study consent form.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

The primary burden for interviewees is the time required to participate in the one-off interview. Potential interviewees are informed of the expected interview duration as part of the participant information sheet.

Participation in the interviews will not affect any of their medical care or other research involvement and no healthcare treatment or advice will be provided as part of the interview.

It is not anticipated that the content of the interviews will be distressing for interviewees, however if the interview appears distressed, they will be offered to opportunity to pause or discontinue the interview. If the interviewee reports concerns regarding symptoms or other health condition, they will be advised to contact their GP or the relevant study team, if their research participation is ongoing. If the interviewee reports any instances of potential research misconduct, this will be reported to the host research organisation.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

There is no expected clinical benefit from taking part in this research. Interviewees may feel some personal benefit from contributing to research aimed at improving the experiences of future patients and research participants.

A26. What are the potential risks for the researchers themselves? *(if any)*

There is no potential risk to researchers. All interviews will be conducted remotely, avoiding any issues associated with lone working. The research team will not use their personal email addresses or mobile phone numbers as part of this study.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

There will be two stages to recruitment. Stage 1 will involve identification of NMAHPP clinical academic researchers who are willing to advertise the study among their current/recent research participants and patient advisors. These individuals will be identified from three sources:

1. NIHR record of current/previous award holders, where there are ~200 potentially eligible individuals (https://fundingawards.nihr.ac.uk)

2. Healthcare Professionals in Research Facebook group, a closed group consisting of >250 research-active NMAHPPs at doctoral/postdoctoral levels

3. Established NMAHPP research groups, including CARIN (Clinical Academic Research Implementation Network) and CHAIN (Contact, Help, Advice, Information Network). A purposive sampling strategy will be used to ensure that the identified NMAHPP clinical academics represent a range of clinical disciplines, academic levels and geographical locations. Sampling criteria are clinical discipline, academic level of the researcher, type of study, geographical location, type of healthcare setting.

Stage 2 will involve the identified clinical academics sending a study invitation 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 had been given by the participant to be contacted regarding future research. The study invitation will include the participant information sheet. Eligible individuals will be asked to contact the lead investigator (Lisa Newington) by phone or email to register interest in the study or ask any questions. An additional open recruitment invitation will be advertised on Twitter.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◉ Yes ○ No

Please give details below:

The NMAHPP clinical academic researchers will screen their own research database to identify individuals who agreed to be contacted about additional research opportunities. Study individuals will be sent to these individuals by their existing research team.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

Potentially eligible individuals are existing/previous research participants or patient advisory group members. Their data will have been stored in agreement with the original research protocol. Only those who agreed to be contacted about future research will be contacted. Invitations will be sent by their existing research team.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

The study will also be advertised by Twitter and where possible, regional NHS networks. The recruitment text has been included in the supporting information with this application. This is to support recruitment in the case of low response rates following the initial mail outs.

A29. How and by whom will potential participants first be approached?

Via an invitation email (or letter) sent by their existing research team or an open invitation via social media. This will include a copy of, or links to, the participant information sheet. Existing research teams will send out up to two invitations.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

After an individual has contacted the lead researcher to express interest in taking part in an interview, they will be provided with the study consent form (and an additional copy of the participant information sheet, if required). As the interviews are being conducted remotely, the planned consent format is via an electronic consent form, however a paper version will be available if the participant prefers. The consent form will be completed in advance of the interview. If the participant is unable to complete a paper or electronic form (for example, due to visual impairments), the consent form will be audio recorded before the interview as a separate audit file.

Verbal agreement to participate will also be re-confirmed before commencing the interview.

If you are not obtaining consent, please explain why not.

N/A

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

There will be no predetermined time period. Potential participants will be able to contact the lead researcher to express an interest in taking part at any time during study recruitment. It is anticipated that the recruitment period will run from 01/11/21 to 01/10/22.

If an individual expresses an interest in taking part up to three additional contacts (by email or phone) will be made by the lead researcher in the case of non-response.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Interviews will be conducted in English language. Interviewees will be able to request for a friend or family member as an interpreter if they wish. Unfortunately, we do not have funding to formally offer interpreter services, however if a situation did arise where this was needed, we would do our best to secure appropriate funding to enable the individual to provide consent and participate in an interview. This includes sign language in addition to spoken languages.

In the case of individuals with visual impairments an audio version of the participant information sheet will be provided on request and completion of the consent form will be audio recorded and saved in a separate audio file.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

○ The participant would continue to be included in the study.

○ Not applicable – informed consent will not be sought from any participants in this research.

◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Participation is a one-off interview. Written consent to participate will be collected in advance and verbally re-assessed at the start of the interview.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [ ] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:
Potential participants are invited to contact the lead researcher by Imperial College email or phone (study mobile). Details will only be saved if the individual agrees to participate in the study.

A37. Please describe the physical security arrangements for storage of personal data during the study?

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. A counter-signed copy of the consent form will be returned to the interviewee for their records. 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 deleted once transcription is completed and the accuracy checked. Transcription will be provided by an external transcription company who are bound by a non-disclosure agreement. Interview transcripts will be anonymised and only the anonymised version (identified by a reference number) used for the analysis. This ensures pseudonymisation.

All study data will be kept securely and confidentially for 10 years in line with the Imperial College London data storage policy.

Contact with participants will be made using Imperial College email and a study mobile.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Interview transcription will be completed by an external company (PageSix Transcription) who are bound by a confidentiality and non-disclosure agreement. After this initial transcription, the transcripts will be psuedonymised by the chief investigator, who will remove references to names, places and other potentially identifying characteristics. The chief investigator will also check for the accuracy of the transcript against the audio file, following which, the audio file will be securely destroyed.

The psuedonymised transcripts will be used for the analysis, with anonymous quotes used for the reports.

Transcripts will be stored securely following the method outlined above (A37). 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.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only the named research team will have access to the participants' personal data during the study: Dr Lisa Newington, Dr Caroline Alexander, Prof Mary Wells. Preliminary access may be granted as part of a formal Imperial College research audit process.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Anonymised interview transcripts will be analysed by the lead researcher and the small research team (Dr Caroline Alexander and Prof Mary Wells). These individuals are based in London, UK. In addition, a small number of research and healthcare students may be involved in the analysis as part of their training. These individuals will also be based in the UK, will only have access to the anonymised transcripts and will be supervised by the lead researcher.

Nvivo software will be used to support the analysis of the anonymised transcripts.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Lisa	Newington
Post	NIHR Imperial Biomedical Centre and Imperial Health Charity Postdoctoral Fellow		
Qualifications	BSc(hons), MSc, PhD MCSP, AHT(BAHT)		
Work Address	Education Centre Charing Cross Hospital Fulham Palace Road, London		
Post Code	W6 8RF		
Work Email	l.newington@imperial.ac.uk		
Work Telephone	07866997732		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
Research data will be stored for 10 years in accordance with Imperial College London policy. This will include personal data (names and contact details) to enable interviewees to be provided with information about publications and other research outputs, plus for other research opportunities to be sent where permission has been granted.

A44. For how long will you store research data generated by the study?

Years: 10
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Research data will be stored electronically on a secure Imperial College London server.
Data will be archived following the Imperial College London standard operating procedures at the Imperial Archiving facility.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
The research will be registered with Imperial College London. In addition, the approved research protocol will be published with the OSF repository, which allows open access.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of

publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [x] Internal report
- [x] Conference presentation
- [x] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [x] Other (please specify)

A summary of the research findings will be provided for study participants (where they have opted to receive this) and patient advisors. This will also be disseminated via Imperial College/NHS websites.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Interviewee demographics will only be presented in broad categories to prevent the identification of individuals. Transcripts will be anonymised to remove potentially identifiable features (names, places, medical details) before analysis and the research team will cross check all quotes before publication to ensure that anonymity is preserved.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
A summary of the research findings will be provided for study participants (where they have opted to receive this) and patient advisors. This will be in an electronic format and will be sent by email from the lead researcher at the end of the study. A paper version will also be available on request.

Additionally, publications and other research outputs will be shared with research participants. The time cale for this is not anticipated to extend past 3 years of study completion.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [ ] Review by educational supervisor
- [x] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
Funder peer review - Imperial Health Charity and NIHR Imperial Biomedical Research Centre. Reviewer comments and suggested amendments were incorporated into the final protocol and this ethics application.

Sponsor peer review - Imperial College London Research Governance and Integrity team review prior to sponsorship approval. Approval required before permitted to apply for NHS ethics approval via IRAS.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 25

Total international sample size (including UK):

Total in European Economic Area:

Further details:
It is anticipated that 15-25 interviews will be required to reach data saturation.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Interviewing will continue to data saturation. Data saturation will be defined in two parts. Firstly when no new topics are discussed during the interview, and secondly when no new codes are identified during the analysis [1,2]. Interviewing and preliminary coding will occur concurrently.

REFERENCES
1. Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, et al. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. Psychology and Health. 2010;25:1229–45

2. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. Quality and Quantity. 2018;52:1893–907

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Interviews will be analysed using the Framework Method [1]. The preliminary framework will be developed from our existing work and this will be expanded iteratively to include the different codes that are identified in the interviews.

The preliminary coding tree will be developed by the research team based on our existing research. This will also be discussed with the patient/public advisors. A minimum of two members of the research team will code the first 1-3 interviews and the coding tree will be refined, as appropriate. This will then be applied to the remaining interviews by the lead research, with additional refinements discussed among the research team.

Transcripts will be coded using NVivo (QRS). After coding, the lead researcher will develop preliminary themes and sub-themes to discuss the content of the interviews. These will be reviewed and modified by the research team, patient/public advisory group and interviewees (where they have consented to participate in this stage). Final themes and sub-themes will be approved by all stakeholders described above.

REFERENCES
1. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology. 2013;13:117

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Caroline M	Alexander
Post	Lead Clinical Academic for Therapies		
Qualifications	PhD, MSc, Grad Dip Phys, MCSP		
Employer	Imperial College Healthcare NHS Trust		
Work Address	Therapies, Charing Cross Hospital		
	Fulham Palace Road		
	London		
Post Code	W6 8RF		
Telephone			
Fax			
Mobile			
Work Email	caroline.alexander1@nhs.net		

	Title	Forename/Initials	Surname
	Prof	Mary	Wells
Post	Lead Nurse for Research		
Qualifications	PhD, MSc, BSc(hons), RGN		
Employer	Imperial College Healthcare NHS Trust		
Work Address	Corporate Nursing, Charing Cross Hospital		
	Fulham Palace Road		
	London		
Post Code	W6 8RF		
Telephone			
Fax			
Mobile			
Work Email	mary.wells5@nhs.net		

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	Imperial College London
Given name	Becky
Family name	Ward
Address	Research Governance & Integrity Manager, Room 215, Level 2, Medical School Building, Norfolk Place
Town/city	London
Post code	W2 1PG
Country	United Kingdom
Telephone	0207 594 9459
Fax	
E-mail	becky.ward@imperial.ac.uk

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation	
Given name	
Family name	
Address	
Town/city	
Post code	
Country	
Telephone	
Fax	
E-mail	

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- ○ Standalone project
- ○ Project that is part of a programme grant
- ○ Project that is part of a Centre grant
- ◉ Project that is part of a fellowship/ personal award/ research training award
- ○ Other

Other – please state:

Please give details of funding applications.

Organisation	NIHR Imperial Biomedical Research Centre and Imperial Health Charity
Address	Imperial Health Charity
	178-180 Edgeware Road
	London
Post Code	W2 2DS
Telephone	02038579847
Fax	
Mobile	
Email	grants@imperialcharity.org.uk

Funding Application Status: (●) Secured ( ) In progress

Amount: £64,902

Duration
Years:
Months: 16

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

NIHR Imperial Biomedical Research Centre and Imperial Health Charity Postdoctoral Research Fellowship. Awarded to Lisa Newington

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (●) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (●) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title	Forename/Initials	Surname
	Becky	Ward

Organisation	Research Governance and Integrity Team (RGIT)
Address	Imperial College London and Imperial College Healthcare NHS Trust
	Room 215, Level 2, Medical School Building
	Norfolk Place, London
Post Code	W2 1PG
Work Email	becky.ward@imperial.ac.uk

Telephone 0207 594 9459
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/11/2021
Planned end date: 28/02/2023
Total duration:
Years: 1 Months: 3 Days: 28

A71-1. Is this study?

- (●) Single centre
- ( ) Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?
( ) Yes (●) No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- [x] NHS organisations in England 1
- [ ] NHS organisations in Wales
- [ ] NHS organisations in Scotland
- [ ] HSC organisations in Northern Ireland
- [ ] GP practices in England
- [ ] GP practices in Wales
- [ ] GP practices in Scotland
- [ ] GP practices in Northern Ireland
- [ ] Joint health and social care agencies (eg community mental health teams)
- [ ] Local authorities
- [ ] Phase 1 trial units
- [ ] Prison establishments
- [ ] Probation areas

☐ Independent (private or voluntary sector) organisations
☐ Educational establishments
☐ Independent research units
☐ Other (give details)

Total UK sites in study: 1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◉ Yes ○ No

A73-2. If yes, will any of these organisations be NHS organisations?

◉ Yes ○ No

If yes, details should be given in Part C.

A73-3. Approximately how much time will these organisations expect to spend on screening records and/or provision of information to potential participants, and how will the costs of these activities be funded?

NMAHPP researchers will screen their databases of existing/previous research participants and send an invitation to participate. It is anticipated that this will involve an automated mail-merge function and will take approximately 60 minutes. A reminder invitation may be requested 2-6 weeks later, which will take approximately 30 minutes.

For small research studies, it may be quicker to hand search the participant database and compile a mailing list. The timing may be 60 minutes for the initial invitation and 10 minutes for the reminder.

We have no additional funding to support this activity, however NMAHPP contributors will be acknowledged in outputs of the research.

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

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. Data management will be supported and monitored by the Imperial College Faculty of Medicine Data Protection Team.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

Imperial College indemnity applies.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- ☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Imperial College indemnity applies.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- ☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- ☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- ○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name
IN1	○ NHS/HSC Site ◉ Non-NHS/HSC Site	Forename: Lisa Middle name: Family name: Newington Email: l.newington@imperial.ac.uk Qualification (MD...): PhD, MSc, BSc, MCSP, AHT(BAHT) Country: United Kingdom

Institution name: Imperial College London
Department name: MSk Lab, Surgery and Cancer
Street address: White City Campus, Sir Michael Uren HubBuilding
Town/city: London
Post Code: W12 0BZ
Country: United Kingdom

Participant Identification Centres

PIC Type	Centre	Individual(s)
○ NHS (England) ○ NHS (outside England) ◉ Non-NHS	University of Salford	Dr Yeliz Prior, Honorary Clinical Academic Lead E-mail: Y.Prior@salford.ac.uk
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS	MID CHESHIRE HOSPITALS NHS FOUNDATION TRUST	Dr Yeliz Prior, Senior Research Fellow E-mail: Y.Prior@salford.ac.uk
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS	IMPERIAL COLLEGE HEALTHCARE NHS TRUST	Dr Lisa Newington, Honorary Research Associate; Dr Caroline Alexander, Lead Clinical Academic AHP; Prof Mary Wells, Lead Nurse for Research E-mail: l.newington@nhs.net

◉ NHS (England) ○ NHS (outside England) ○ Non-NHS	ROYAL NATIONAL ORTHOPAEDIC HOSPITAL NHS TRUST	Anthony Gilbert, Clinical Academic Physiotherapist E-mail: anthony.gilbert@nhs.net
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS	UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST	Caroline Miller, Clinical Academic Physiotherapist E-mail: Caroline.Miller@uea.ac.uk

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Lisa Newington on 20/07/2021 10:48.

Job Title/Post:	Postdoctoral Research Associate
Organisation:	Imperial College London
Email:	l.newington@imperial.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Ms Becky Ward on 20/07/2021 16:10.

Job Title/Post:	RGM
Organisation:	RGIT Imperial College London
Email:	becky.ward@imperial.ac.uk