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)
Can ED docs' uncertainty tolerance affect patient health/resource use

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)*

☑ 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.

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 administering questionnaires/interviews for quantitative analysis or mixed methodology study

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)
Can ED docs' uncertainty tolerance affect patient health/resource use

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Can Emergency Doctors' Tolerance of Uncertainty Impact on Patient Outcomes and Resource Use? A Multi-Site, Multi-Level, Retrospective Cohort Study

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Prof	Rebecca	Lawton
Post	Professor		
Qualifications	PhD		
ORCID ID			
Employer	University of Leeds		
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Work Telephone			
* Personal Telephone/Mobile	01274383465		
Fax			

** 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
	Mrs	Jane	Dennison
Address	Bradford Institute for Health Research		
	Bradford Royal Infirmary, Duckworth Lane		
	Bradford		
Post Code	BD9 6RJ		
E-mail	jane.dennison@bthft.nhs.uk		
Telephone	01274382575		
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):	BTHFT 2595
Sponsor's/protocol number:	N/A
Protocol Version:	1
Protocol Date:	19/01/2021
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.*

One essential skill of emergency doctors is to quickly, but safely, identify and satisfy treatment needs of individual patients, while managing patient flow. Importantly, this relies on deciding who needs treatment, and who may be diverted elsewhere – often a decision with risks. Optimal ED decision making in requires doctors to balance risks; a balance moderated by the degree to which doctors can tolerate uncertainty in their decisions.

Research in other specialties show that doctors who dislike uncertainty make more risk-averse decisions, for example by ordering more diagnostic tests/referring more patients. These doctors may be likely to use more vital NHS resources which may be better directed elsewhere. One primary aim of this study is to assess whether uncertainty

tolerance impacts resource use in emergency medicine too. Another is to assess whether uncertainty tolerance is associated with patient outcomes. This is because uncertainty tolerance may not be wholly positive; it may increase high-risk decision making which may incur patient harm, e.g. a patient may be inappropriately diverted.

In a retrospective cohort study, we will recruit A&E doctors in 5 emergency departments, before having them complete a questionnaire designed to assess uncertainty tolerance (+ other factors, e.g. burnout/demographics). Collaborators at each site will then identify recent patients our recruited doctors have assessed and extract anonymised data about the episodes, including patient demographics, whether the patient was admitted, what tests/treatments were ordered, patients' length of stay if admitted, and readmissions. Models will assess whether doctor-level uncertainty tolerance is associated with these patient health/resource use outcomes, adjusted for certain site-level (e.g. busyness), doctor-level (e.g. experience) and patient-level (e.g. comorbidity status) factors.

In an embedded study, we will also interview consenting doctors to get their views on what helps them cope with uncertainty, with the aim of informing a future intervention to help moderate uncertainty tolerance

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, R&D office 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

All elements of this project were either developed or scrutinised by a large number of both clinical and non-clinical researchers, including several emergency doctors, a GP, an expert in decision-making, multiple health psychologists, an occupational therapist, a work psychologist, and more. This includes members of the research team, but also those external to the project in our grant steering group, and an independent pathologist/data scientist. As such, there have been many discussions, debates and iterations of the protocol. The final protocol is thus well informed and has been thought through from many angles, perhaps most importantly from the perspective of feasibility and utility.

The purpose of the study is well defined (outlined in detail in the following 'PURPOSE AND DESIGN OF THE RESEARCH' section, particularly item A12) and justified. All researchers involved in the development of the project agree unanimously that this study has the chance to 1. identify a key point of intervention to help reduce resource use (i.e. by helping staff increase uncertainty tolerance), 2. Inform the development of that intervention (i.e. by looking at demographics/psychological attributes associated with uncertainty tolerance, plus discussing methods of coping with it in interviews), and 3. Identify whether such an intervention may be unduly risky (i.e. if high uncertainty tolerance is associated with increased patient harm, if for instance, such doctors may make particularly risky decisions).

In designing the main study, we were acutely aware that we did not have the resources to conduct a full prospective cohort study with many follow-up measurements, and large numbers of recruited doctors and patients. We pragmatically opted to take a retrospective approach using routinely collected data, with a large number of patient's data matched to a smaller number of doctors. The design thus poses minimal burden on doctors as they only have to complete a single questionnaire pack, which will boost our recruitment rate. It also ensures that we can obtain a large number of patient's data by extracting data from medical records instead of having to recruit patients directly.

Recruitment
Doctors will be recruited by local expert ED clinician collaborators at each site, who will be their colleagues. This circumvents any issues around securing site access from the central research team, as well as meaning the research team will have no access to doctor participant personal information (i.e. as the initial approach will be made by colleagues who already have access to this data). These local collaborators will also extract patient data. Patients will not be recruited directly - a select few, identified as being treated by the participating doctor, will be identified in the relevant records and unidentifiable details of their care episode extracted. As these extractors are a member of the patients' care team and because we will not take identifiable information (e.g. name, address), no explicit patient consent is necessary.

Inclusion / exclusion
This is detailed in A17-1 and A17-2, repeated here:

We will recruit emergency doctors in each participating ED from specialty trainee year 3 and above for two main reasons. First, doctors who have committed to the specialty may be more likely to be representative of those in it or who choose it. Second, they are of seniority whereby they are less likely to defer their decisions to others. If it were the

case that a large proportion of doctors did defer their decisions to their seniors, we would not be able to accurately study the link between that doctor's characteristics and their treatment decisions.

For sampling patients from each doctors treatment history, we have two inclusion criteria:

1. The data extracted must not come from a patient currently admitted (e.g. an inpatient) or a patient seen by the treatment doctor in under the last 30 days This is mainly because we would not then be able to assess these patients' post-treatment episode outcomes. This may also partially offset the fact that doctors' knowledge about the study may influence their decision-making (i.e. the Hawthorne effect), depending on the speed from doctor-level data to patient-level data collection.

2. Patients must have presented with any of the following complaints: abdominal pain, chest pain, vomiting, and back pain. These conditions were chosen based on their perceived level of uncertainty in management. Indeed, a collaborating consultant A&E doctor first generated a shortlist of 14 complaints that they deemed most conducive of uncertainty. We then conducted an anonymous survey of 10 A&E doctors who chose their top 5 from the shortlist. The resulting inclusion complaints are those (in order) which received the most endorsements.

Consent
As above, doctors will be consented 1. for participating in the main study (i.e. the retrospective cohort study), and if they express an interest for 2. participating in the aforementioned embedded qualitative study (i.e. aiming to understand methods of dealing with uncertainty). Informed written consent will be obtained from doctors and they may withdraw from the study. Patients will not be consented - their data will be unidentifiable and extracted by a member of their care team at each collaborating site.

Risks, burdens and benefits
There are likely minimal risks to doctors participating; they will just complete a questionnaire wherever they want, in a format they want, and if interested, will participate in an interview in a format of their choice. Of course, both may be distressing, given the topics discussed. As such we have as members of our team psychologists with clinical experience to offer them, as well as the support of a consultant occupational therapist, both either either remotely (e.g. online) or face to face as appropriate. Patients will not be exposed to any risks.

Benefits include 1. helping advance the state of the art on this topic - including helping inform an intervention that may potentially benefit colleagues in the future, and 2. receiving feedback and support on their uncertainty tolerance which is a professional development opportunity (detailed in the next section).

Confidentiality
Doctor and patient data will be kept confidential and secured stored. More detail is provided in later sections of this form.

Conflict of interest
There are no commercial or other conflicts of interest amongst the research team.

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
- [x] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research

☑ Questionnaire, interview or observation study

☐ Randomised controlled trial

☑ Other (please specify)

Measure development/psychometric assessment.

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

Main study

To establish whether there is an association between emergency doctors' tolerance of uncertainty and patient outcomes and resource use.

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

Main study

Develop a comprehensive self-report measure of emergency doctors' uncertainty tolerance based on Hillen et al. (2017) and assess its psychometric properties.

Assess whether the relationship between uncertainty tolerance and patient outcomes/resource use is moderated by the complexity of patient episodes.

Identify characteristics (i.e. correlates) of highly uncertainty tolerant doctors such as coping, traits, confidence, job satisfaction and experience of adverse events. (Potentially useful for developing targeted intervention).

Embedded qualitative study

Conduct interviews with a sample of participating doctors to provide developmental feedback on their self-assessment results, but also to to seek their views about coping strategies they currently use in dealing with uncertainty, and what a useful intervention to moderate their uncertainty might look like.

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

A previous study by this research team (Lawton et al. 2018) showed that amongst emergency doctors, tolerance of uncertainty – as measured on the validated Physician's Reactions to Uncertainty questionnaire (Gerrity et al. 1990; 1995) - was highly and significantly associated with risk aversion. Further, it was found that tolerance of uncertainty partially mediated the effects of clinical experience on risk aversion, such that more experience was related to more tolerance and fewer risk averse decisions. It was suggested that, through experience, doctors transition from 'system 2' decision making, where judgments are based on slower, more analytical reasoning, to 'system 1' where judgments become a function of a 'sense' or 'feeling'. Through past experiences, doctors may be able to apply their tacit knowledge to their current situation – such that they identify 'patterns' and similarities amongst cases, and come to appropriate decisions quickly, using informed heuristics. While indicating that higher uncertainty tolerance may be a positive thing (i.e. by reducing risk aversion) Lawton et al. (2018) has some key limitations:

First, and perhaps most importantly, it is still unknown whether uncertainty tolerance is wholly positive; it is conceivable that lower risk aversion may actually lead to more patient harm – as they may be exposed to more risks.

Second, the study only assessed doctors' hypothetical behaviour; they were required to rate their predicted actions, in response to vignettes. This may not represent their behaviour in practice.

Third, it was cross-sectional; thus, the study could not capture temporal dynamics in measuring uncertainty tolerance – i.e. their responses on the tolerance measure may have influenced their risk decisions.

Lastly, recent research has highlighted that the use of the Physician's Reaction to Uncertainty measure (Gerrity et al. 1990; 1995), while validated, may be insufficient. Indeed, it has been highlighted that many past measures fail to encapsulate many features (i.e. responses to and sources of uncertainty) of uncertainty tolerance, and thus may not assess what they intend to. This is a large problem where the phenomenon of interest is a latent construct and cannot be observed directly.

In response to the above limitations, the present study was designed to advance the literature in several key ways.

First, we aim to assess the degree to which uncertainty tolerance in ED can impact on actual clinical decisions – such as the decision to admit patients, or the ordering of diagnostic tests. This would give some indication of the magnitude of excess resource use associated with uncertainty intolerance.

Further, the relationship between uncertainty tolerance and patient outcomes, such as (re)attendance at A&E upon diversion, adverse events amongst diverted patients, or the incidence of short hospital stays, will be assessed; allowing some indication of whether low risk aversion negatively effects patient safety, and whether high aversion leads to inappropriate decisions to admit.

We also aim to develop a new, more holistic measure of uncertainty tolerance in response to identified deficiencies in previous measures (Hillen et al. 2017).

It is also hoped that the study will allow the team to identify key correlates of uncertainty tolerance – such as personality characteristics, demographics, experiences and so on – to identify moderators of the trait, and potentially modifiable intervention targets to safely reduce resource use.

Lastly, it is intended that a subset of recruited doctors will agree to participate in interviews with the research team, in which we will get their views on the best strategies to help them deal with uncertainty - primarily to inform the development of future interventions to moderate their uncertainty tolerance, which have hitherto not been designed or trialed (to the research team's knowledge).

Overall, based on the above, this study may allow us to identify a key point of intervention to moderate uncertainty tolerance to mitigate resource use, and inform the development of that intervention. By assessing patient health outcomes, this will also give some idea of whether such an intervention is appropriate - again, it is conceivable that high uncertainty tolerance may not be wholly positive (if it leads to many risky decisions that cause patient harm).

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.*

Main study

Design
This will be a multi-centre, correlational, retrospective cohort study. Doctors will be contacted and asked to complete self-report measures of tolerance of uncertainty (TofU) and other variables. Patients will not be contacted; patient-level data will be taken from the electronic records of a sample of each participating doctor's previous patients. Thus, this study has a multi-level structure with a larger sample of patients nested within a smaller sample of doctors.

Setting
Doctors recruitment and patient record data extraction will be conducted at several A&E hospital departments across the county of Yorkshire, UK, including: Bradford, Airedale and Leeds (West Yorkshire, pop. 2.3mill), and Barnsley and Sheffield (South Yorkshire, pop. 1.4m).

Population
We aim to recruit 50 doctors across our sites, and extract 10 patients worth of data from their treatment histories (500 patients).

Procedure/recruitment
To reduce the burden on doctors to participate, we aim be as unobtrusive as possible; asking them to complete just one baseline self-report questionnaire pack. The process will be:

1 Initial approach by ED clinician collaborators at each site will approach potential doctors meeting the inclusion criteria (ST3 grade and higher) to introduce the study.
2 If eligible doctor is interested in the study, our clinician collaborator will provide them with an information sheet and consent form.
3 The interested doctor will be given time to consider taking part and can discuss any issues and questions with the local clinician collaborator or with the research team, if required.
4 If the doctor consents to take part then the signed consent form, detailing their participation in the main questionnaire study or both the main questionnaire study and the embedded interview study will be provided to the local clinician collaborator.

5 Consenting doctors will be provided a physical questionnaire pack by the local clinician collaborator OR if they prefer will provide email contact details to the research team in order to get a link to the digital version.
6 If participating in the embedded interview study, the participant contact email details will be provided to the study team so they can be contacted at a later date to organise the interview.

Local collaborators will extract patient data onto our digitised patient data extraction forms from the trust computers at each participating A&E department. Patients will not be contacted directly but we will advertise the study in various ways (e.g. posters, leaflets) at each site. We will also ensure to extract pseudo-anonymised data (i.e. no names, addresses) which will be stored on encrypted trust computers.

Measures
Doctor-level measures
The final questionnaire is 65 items long and takes ~10-20 minutes to complete. It consists of three sections assessing: 1. Demographics, 2. Uncertainty tolerance and 3. Personality and work life factors (e.g. risk aversion, burnout, experience of patient safety incidents). This questionnaire has gone through various iterations following completion by A&E doctors and discussion amongst the researcher team. To control for extraneous factors and to assess the association between demographic variables and other measures, doctors will self-report their: age, gender identity, clinical hours worked in A&E per week, length of time worked in A&E, year of doctor qualification, and grade.

We provide a detailed outline of how we came to develop our tolerance of uncertainty measure in the protocol submitted with this application.

Patient-level measures
Our patient data extraction form was designed in a collaborative manner within our research team. The latest iteration of the form was made following edits and feedback from data extractors who participated in a piloting of the form at 4 sites (Barnsley: 6 patients, Sheffield: 6 patients, Bradford: 10 patients, Airedale: 4 patients).

Our form assesses: patient age, gender, site, mode of arrival, initial complaints, diagnosis, and health status (based on triage scores, extractor-graded ASA score, and free text listed comorbidities). We also included a 2-item extractor-judged measure of the complexity of the decision to admit/discharge. This is to assess whether the complexity of the patient episode moderates the effects of tolerance of uncertainty on our chosen outcomes (i.e. the hypothesis that the effects of uncertainty tolerance may only materialise when cases are complex). We also included an important item to assess contamination; that is, whether there was any written evidence in the patient notes that the treating doctor deferred their decision to admit each patient, or likewise for the order of treatment and tests. If it were the case that their decisions were not 100% theirs, this would obscure the correlation between uncertainty tolerance and our outcomes.

Site-level factors
We may be able to extract site-level factors to control for extraneous factors, at least at some sites. This includes department busyness at the time of doctor decision making. All site-level data will include no identifiable information, and will be taken from publically accessible datasets.

Embedded qualitative study

At the point of initial recruitment, all doctors recruited will be invited to take part in a second stage involving a debrief/interview (anticipated to be approximately 1 hour). This will be an opportunity to receive confidential, developmental feedback on their self-assessment results with a psychologist, but also acts as a research forum for the researcher to seek their views about coping strategies they currently use and what a useful intervention might look like. We anticipate that 40-60% will agree to take part in this second stage.

After data have been extracted and coded and data for each doctor are available within the main study, a follow up session will be arranged with those doctors who consented to the debrief/interview. This will take place in a convenient location for the clinician which has privacy.

Again, the follow-up session will be conducted by a psychologist and will serve two functions.

In the first part of the session the psychologist will provide clinicians with feedback on all their self-report measures, indicating where their scores place them in relation to other participants - on average. There will an opportunity to discuss the results confidentially, in a supportive climate.

In the second part of the session, the psychologist will ask the clinician about their experience of coping with uncertainty, specifically how do they currently cope with it and what interventions might support them to do this more confidently/comfortably. The second part of the session will be audio-recorded using an encrypted voice recorder, transcribed verbatim and analysed using thematic analysis.

The key research questions will be:
How do low, medium and high scoring clinicians cope with uncertainty?

Do low, medium and high scoring clinicians cope with uncertainty differently? If so, how do their coping strategies differ?

What type of intervention do low, medium and high scoring clinicians believe would support them?

Is there a difference in low, medium and high scoring clinicians with respect to the type of intervention they believe would support them? What are these differences?

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?

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

Give details of involvement, or if none please justify the absence of involvement.
We will involve the Sheffield Emergency Care Forum and PSTRC patient panel as a means of involvement. We will update each group on progress with the study at their regular meetings and get feedback on the direction/management as well as disseminating the finding to this group initially.

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: 100	Years

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

Doctor inclusion criteria
Doctors from ST3 level of trainee through to consultants will be included in the study. An ST3 threshold of trainee is chosen as this has been judged to be the to be the level that trainees commit to a long term career in emergency medicine, but crucially this is also a grade where doctors consistently make autonomous decisions about patient management, without deferring to senior clinicians. It is crucial that the individual doctor' measures of tolerance of uncertainty can be compared with their autonomous patient management decision making in order to test the hypothesis and objectives of the study.

Patient inclusion criteria
For sampling patients from each doctor's treatment history, patients must have presented with any of the following complaints: abdominal pain, chest pain, vomiting, and back pain. These conditions were selected as presentations whose management was characterised by a high degree of uncertainty. Indeed, a collaborating consultant A&E doctor first generated a shortlist of 14 complaints that they deemed most conducive of uncertainty. We then conducted an anonymous survey of 10 A&E doctors who chose their top 5 from the shortlist. The resulting inclusion complaints are those (in order) which received the most endorsements.

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

Patient exclusion criteria
The data extracted must not come from patient seen by the treating doctor within the last 30 days. This is mainly because we would not then be able to assess these patients' post-treatment episode outcomes. This may also partially offset the fact that doctors' knowledge about the study may influence their decision-making (i.e. the Hawthorne effect), depending on the speed from doctor-level data to patient-level data collection.

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
Questionnaire completion	1	N/A	10-20 mins	Each doctor will complete the questionnaire pack wherever they wish, either electronically or physically (on paper).
Doctor consent	1	N/A	2 mins	Each doctor will provide informed consent wherever they wish, either electronically or physically (on paper).
Doctor interview	1	N/A	~60 mins	A member of the research team will interview doctors who consent to an interview. This will take place either remotely (e.g. on the phone) or at the doctor's place of work in a private space. This will be at the doctor's discretion.

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

Doctors will only have to be 'in' the study for the duration of time it takes them to complete a questionnaire pack. A reasonable estimate would therefore be 2 weeks. For doctors who wish to participate in a ~60 minute interview, this will be longer, as we will have to arrange a date and time to interview them. A reasonable estimate would be around 4-6 weeks.

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.

There are minimal risks and burdens to participants; participants who take part will only have to complete a 10-20 minute questionnaire pack, and if they wish, take part in a longer interview. They can complete the questionnaire wherever they wish either electronically or physically, and have as long as they wish to decide to take part (within the recruitment phase of the study). They may also opt to have either a face to face or remote interview. Interviews will take place outside of normal working hours so there will be no impact on clinical staffing levels.

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

If Yes, please give details of procedures in place to deal with these issues:

There is a small possibility that the questionnaires or interviews, because they include questions about burnout, confidence, resilience and exposure to patient safety incidents, may be upsetting for participants. Furthermore, one element of our follow-up interviews (with consenting doctors) will be to support their learning and understanding of tolerance of uncertainty by discussing with them their own score on this measure and considering this in relation to the norm for their peers. This will need to be handled carefully and it is not within our remit to make value judgements about whether high levels of tolerance of uncertainty are good or bad. Indeed one of the aims of the project is to establish what the relationships are between tolerance of uncertainty and patient outcomes. We have developed our protocol in a collaboration with a consultant occupational therapist, and our embedded interview study design was put together by a psychologist with clinical experience. All of our interviews will either be by a clinical or organisational psychologist with counselling experience, or under their guidance. If doctors are visibly distressed at any point during the interviews, they will be asked if they wish to withdraw from the study, and will be able to without reason. They will be offered further support as necessary, or will be signposted to appropriate services.

We will specifically request that doctors do not disclose details of patient safety incidents that have not previously been reported. There is no need for them to do this within the interviews.

If the local clinician collaborator is made aware of concern about a participating doctors wellbeing e.g high burnout, they will notify their line manager who can then signpost the doctors to the most appropriate support services in the department/trust.

If the research team consider there to be an immediate threat to the safety of patients and others, they will inform a senior member of staff within the institution.

The research team have experience of working within the NHS. Should any concerns arise, the researchers will be able to contact an experienced supervision team for advice and support.

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

Benefits include 1. helping inform an intervention that may potentially benefit colleagues in the future, 2. receiving feedback and support on their uncertainty tolerance which is a professional development opportunity, 3. An opportunity to participate in a research study, which will be beneficial for their professional development and is an important part of their clinical role (doctors will receive a certificate of participation for their portfolios).

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

There is a potential for research team to collect questionnaire data from study sites (EDs), if it is physically administered. Also will carry out interviews at the study sites. These visits will be facilitated by the local ED clinician collaborators and therefore any risks to researchers will be negligible.

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 social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

Doctor collaborators at each site will identify relevant patient records and extract them from routine electronic medical records at each site. The doctor collaborators already have access to the patient records as part of their day to day job role, and will use a purpose-designed data extraction form designed for this study to extract relevant data (this can be seen in the protocol submitted with this application). This form does not capture items such as the name, NHS number or address of the patients. The research team will not have access to medical records or identifiable information. They will receive only the data as extracted on the data extraction form per patient.

Participating doctors will be approached in person or via email and recruited by their colleagues, who are already collaborators on this project. As outlined previously:

1 Initial approach by ED clinician collaborators at each site will approach potential doctors meeting the inclusion criteria (ST3 grade and higher) to introduce the study.
2 If eligible doctor is interested in the study, our clinician collaborator will provide them with an information sheet and consent form.
3 The interested doctor will be given time to consider taking part and can discuss any issues and questions with the local clinician collaborator or with the research team, if required.
4 If the doctor consents to take part then the signed consent form, detailing their participation in the main questionnaire study or both the main questionnaire study and the embedded interview study will be provided to the local clinician collaborator.
5 Consenting doctors will be provided a physical questionnaire pack by the local clinician collaborator OR if they prefer will provide email contact details to the research team in order to get a link to the digital version.
6 If participating in the embedded interview study, the participant contact email details will be provided to the study team so they can be contacted at a later date to organise the interview.

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:
In order to identify patients based on the inclusion criteria, electronic medical records will have to be examined which naturally includes identifiable information. This will only be done by our local ED clinician collaborators, who will be doctors employed at each emergency department and thus part of the patients' care 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.*

Again, extraction/identification will only be done by our local collaborators, who will be doctors employed at each emergency department and thus part of patients' care team.

No data will be extracted/documented for patients that do not meet the inclusion criteria. For patients that are eligible, we have a data extraction form that records only psuedo-anonymised information (e.g. no names, addresses, NHS numbers).

Whilst not obtaining direct consent from patients we will put up posters in the departments about the study giving patients the opportunity to opt-out

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

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

Doctor participants will be approached in person or via email/telephone by our local ED clinician collaborators at each site.

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.

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

Our doctor participants will provide informed consent in writing or electronically, though the patients whose data is being extracted will not. The latter, which would require us trying to follow-up over 500 patients post-care episode which would not be feasible given our budgetary and time constraints.

All patient data will be extracted only by individuals employed at the emergency department - and thus a part of the patients care team. Extracted data will not include any NHS numbers, genetic, biometric, names, addresses or any other identifiable items, meaning it will be anonymised. The central research team will thus not be able to easily trace patients based on their data, nor intend to try. We will also blind our analyst to sites.

Whilst we are not obtaining direct consent from patients we will put up posters in the departments about the study

giving patients the opportunity to opt-out

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

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
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:

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

Data from patients' notes will be entered onto our data extraction forms by participating doctors locally, either electronically on an Excel spreadsheet or editable .pdf, or on paper. Electronic data will be emailed from the local collaborating site to the research team at the bradford institute for health research from one NHS email to another (which will ensure the information is transferred securely and safely). Paper data will be picked up physically from each site by a member of the research team at the bradford institute for health research.

Doctor questionnaires, again, will either be completed electronically on an editable .pdf or Excel spreadsheet, or completed on paper. Doctors will email or physically give their completed questionnaire to the local site collaborator, who will send that through to the research team at the bradford institute for health research after removing any identifiers (i.e. names replaced with a random number pseudonym) before destroying the original copy.

All electronic files will be downloaded to a password protected Trust computer and kept in password protected folders. All physical files will be kept securely locked away in one member of the research team's bradford institute for health research office. Once transferred into software or file types amenable to analysis, the original files will be destroyed for both electronic and physical data.

The analysis-ready data files will be kept for 15 years before being destroyed in compliance with the Bradford Teaching Hospital NHS Foundation Trust protocol for long term data storage.

Consent forms received by email will be saved in a password protected folder on a Trust computer. Any hard copy consent forms will be kept in a locked filing cabinet. Again, these will be collected by local collaborators and sent in one batch at the end of the recruitment phase.

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.*

Our patient data extraction form includes no items that could directly identify the patients, such as names or addresses. Their data will be assigned a random number ID by the local collaborator at each site, so we can match them to doctor questionnaires.

Again, doctor questionnaires will either be completed electronically on an editable .pdf or Excel spreadsheet, or completed on paper. Doctors will email or physically give their completed questionnaire to the local site collaborator, who will send that through to the research team at the bradford institute for health research before destroying the original copy (this will not have any doctor identifiers on it, just a random ID).

The local collaborator will, however, keep a record of the doctor's names so they can assess their patients' notes, though, depending on whether the doctor has or has not consented to our follow-up interview/feedback session, they will destroy this information as soon as the study is over (they need to keep a record of the pseudonym-to-name pairs during the study in case a doctor wishes to withdraw from the study) - which will be given the same identifier as that on the sent doctors questionnaire, enabling 1-2-1 matching by the research team.

For doctors who do consent to a follow-up interview, they also be explicitly consenting to the research team having on record their name and questionnaire responses. This is because one element of the interview is discussing where they fall in relation to their colleagues on uncertainty tolerance scores. Interviews with doctors will be audio recorded on an encrypted device and then transcribed. The doctors' name will not be recorded on audio recordings, transcripts of interviews or written report of the findings. the voice recording will be downloaded onto a secure file located at bradford institute for health research and that once the recording has been transcribed and checked it will be deleted.

The research will be conducted in accordance with the principles of Good Clinical Practice (GCP), as applicable under UK regulations and the UK Policy Framework for Health and Social Care Research (HRA, 2020). The lead researcher and Site Specific collaborators will follow the guidance on confidentiality set out in the NHS Code of Practice on Confidentiality (DoH, 2003).

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.*

All of the information we collect will be securely stored at the Yorkshire Quality and Safety Research Group at the Bradford Royal Infirmary. The anonymised data will be looked at only by the research team and by other responsible individuals at the sponsor organisation or regulatory authorities for the purpose of auditing and/or monitoring. All information will remain confidential. If our interviews are transcribed by an external organisation, an appropriate agreement will be in place to protect participant confidentiality.

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?

All quantitative and qualitative data (in the form of anonymised transcripts saved as Word documents) will be analysed by the lead researcher with help from others in the research team on a Trust computer in Bradford Institute for Health Research.

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

Title	Forename/Initials	Surname
Dr	Luke	Budworth

Post	Research Fellow
Qualifications	BSc, MSc, PhD
Work Address	Bradford Institute for Health Research Bradford Royal Infirmary, Duckworth Lane Bradford
Post Code	BD96RJ
Work Email	luke.budworth@bthft.nhs.uk
Work Telephone	07450896824
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

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

Years: 15
Months: 0

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.*

As detailed in A37/38 Analysis-ready data will be stored on password protected trust PCs in password protected folders in a member of the research team's bradford institute for health research locked office.

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

A50-1. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
This is not a clinical trial or an effectiveness study, and it is not eligible for the CRN portfolio because it is fully funded and conducted within an Applied Research Collaboration (i.e. within another NIHR structure), therefore ISRCTN is not an appropriate platform to register it.

The study will be registered on https://www.protocols.io/. This is a free platform for sharing and publishing other types of protocols.

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:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ 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
- ☐ Other (please specify)

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

No identifiable information will be published. Only anonymised, aggregated data will be presented.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
We will inform all our doctor participants of the results, and welcome them to feedback on their thoughts on the

findings. When a draft report of findings is available we will create a short summary document in lay language and formatted to a wider audience aimed at patients too.

5. Scientific and Statistical Review

A54-1. 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
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☐ Review by educational supervisor
- ☐ 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:
The protocol has been reviewed by a wide group of clinical and non-clinical colleagues, including multiple consultant emergency doctors, a consultant GP, a professor in decision-making, several psychologists, a consultant occupational therapist and more. These include individuals within our wider research team, but also those externally in our theme steering group.

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.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☑ Review by a statistician within the research team or multi−centre group
- ☑ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Luke	Budworth
Department	Bradford Institute for Health Research		
Institution	Bradford Royal Infirmary		
Work Address	Duckworth Lane Bradford		
Post Code	BD96RJ		

Telephone	07450896824
Fax	
Mobile	07450896824
E-mail	luke.budworth@bthft.nhs.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Based on several data extraction items on our patient data extraction form, our outcomes of resource use and patient outcomes include:

- Each doctor's patient admission rate.

- Patient adverse event rates, as indexed by i. (re)admissions within 7, 14 or 30 days, reattendance at the ED within 7, 14 and 30 days, and iii. 7, 14, 30 day mortality, amongst those not admitted following consultation with the doctor.

- Length of hospital stay if admitted.

- Number of tests/investigations/treatments by the treating doctor.

- Patient time in the ED, defined as the time from admission to discharge.

We will also liaise with health economists from within our funding grant in order to convert the above outcomes into financial outcomes.

A58. What are the secondary outcome measures?*(if any)*

N/A

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:	500
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
For the main study, we aim to recruit 50 doctors over our 5 sites and extract 10 patient's data per doctor (50 x 10 = 500). For the nested interview study, we aim to recruit as many doctors from the 50 as possible - with an estimate of around 20-30.

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.*

For our primary analyses (involving multi-level/hierarchical modelling), we opted to maximise the number of level-2 participants (i.e. doctors) following guidelines outlined in Gelman & Hill (2007). To achieve this, we are going to collaborate with 5 (mostly large) emergency departments to recruit 50 doctors across them. We will also extract 10 patient's worth of data per doctor, giving a total level-1 sample size of 500.

The power of multi-level analysis primarily rests on the level-2 (doctor-level) sample size, which is complicated here by the fact that we aren't just interested in controlling for within-cluster (i.e. doctor) variation and assessing patient-level effects at baseline and follow-up, but our primary hypothesis relates to doctor-level exposures at baseline predicting patient-level outcomes at follow-up. Given the complexity and vast number of assumptions necessary (particularly with a new primary predictor measure and outcomes without established parameters e.g. mean, SD) to conduct a multi-level power analysis simulation with the primary outcome analysis resting on a level-2 predictor on level-1 outcomes, the sample size for both levels was largely based on pragmatism.

For both levels, the chosen sample sizes are feasible within our time and budgetary constraints, though in comparison with many other similar studies (which have detected significant effects between psychological variables

and resource use), our sample sizes are comparatively large (e.g. Hautz et al. 2020, doctor n = 28, patient n = 473). This gives us assurance that moderate effects will be detected in a 'brute force' fashion. This is particularly true given that a previous study by the research team showed very large correlations between tolerance of uncertainty and hypothetical clinical behaviour (i.e. admission/deferral decisions), suggesting at least moderate correlations between uncertainty tolerance and actual clinical decisions.

Our study will allow future studies in the area to better estimate many parameters, such that more formal power analyses can be conducted - particularly those using our measure of uncertainty tolerance and similar outcomes.

A61-1. Will participants be allocated to groups at random?

○ Yes ◉ No

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.

As described above, our primary analyses (i.e. assessing the association between uncertainty tolerance and resource use/patient outcomes) will involve multi-level modelling. More specifically, we will investigate whether generalised models (e.g. Poisson models, logistic models) versus general (i.e linear) are necessary upon descriptive analysis of the raw data. We will analyse our data both in a univariable and multivariable (i.e. with covariates) models.

To assess whether case complexity moderates the primary associations of interest, we will enter case complexity ratings x uncertainty tolerance as an interaction term into our main models.

To assess the psychometric properties of our uncertainty tolerance questionnaire, we will conduct exploratory factor analyses, reliability analyses and exploratory network analyses.

To assess doctor factors associated with uncertainty tolerance, we will conduct simple correlations.

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
	Professor	Rebecca	Lawton
Post	Professor of Psychology in Healthcare		
Qualifications	BSc, PhD		
Employer	Bradford Teaching Hospitals FT		
Work Address	Duckworth Ln Bradford		
Post Code	BD9 6RJ		
Telephone	01274383465		
Fax			
Mobile			
Work Email	R.J.Lawton@leeds.ac.uk		

	Title	Forename/Initials	Surname
	Mr	Colin	O'Keeffe
Post	Theme Manager & Research Fellow		

Qualifications	BA, MA
Employer	Sheffield University
Work Address	School of Health and Related Research 30 Regent St, Sheffield City Centre
Post Code	S1 4DA
Telephone	01142220780
Fax	
Mobile	
Work Email	c.okeeffe@sheffield.ac.uk

Title	Forename/Initials	Surname
Professor	Suzanne	Mason

Post	Professor of Emergency Medicine
Qualifications	MBBS, FRCS, FFAEM, MD
Employer	Sheffield University/Sheffield Teaching Hospitals FT
Work Address	School of Health and Related Research 30 Regent St, Sheffield City Centre
Post Code	S1 4DA
Telephone	01142220694
Fax	
Mobile	
Work Email	s.mason@sheffield.ac.uk

Title	Forename/Initials	Surname
Dr	Luke	Budworth

Post	Research Fellow
Qualifications	BSc, MSc, PhD
Employer	Bradford Teaching Hospitals Foundation Trust
Work Address	Bradford Institute for Health Research Temple Bank House Bradford Royal Infirmary, Duckworth Lane
Post Code	BD9 6RJ
Telephone	
Fax	
Mobile	07450896824
Work Email	luke.budworth@bthft.nhs.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: (•) NHS or HSC care organisation ( ) Academic ( ) Pharmaceutical industry

Commercial status: Non-Commercial

- ◯ Medical device industry
- ◯ Local Authority
- ◯ Other social care provider (including voluntary sector or private organisation)
- ◯ Other

If Other, please specify:

Contact person

Name of organisation	Bradford Teaching Hospitals Foundation Trust
Given name	Jane
Family name	Dennison
Address	Research Management and Support Office, Bradford Institute for Health Research
Town/city	Bradford
Post code	BD9 6RJ
Country	
Telephone	01274382575
Fax	
E-mail	jane.dennison@bthft.nhs.uk

A65. Has external funding for the research been secured?

Please tick at least one check box.

- ☑ 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	National Institute for Health Research
Address	Richmond House 79 Whitehall London
Post Code	SW1A 2NS

Telephone
Fax
Mobile
Email

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

Amount: £8,999,752.00

Duration
Years: 5
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
NIHR Applied Research Collaborations

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
Mrs	Jane	Dennison

Organisation	Bradford Teaching Hospitals NHS Foundation Trust
Address	Bradford Institute for Health Research Temple Bank House Duckworth Lane, Bradford
Post Code	BD9 6RJ
Work Email	Jane.dennison@bthft.nhs.uk
Telephone	01274382575
Fax	
Mobile	

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

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

Yorkshire and Humber

For more information, please refer to the question specific guidance.

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

Planned start date: 01/03/2021
Planned end date: 01/01/2022
Total duration:
Years: 0 Months: 9 Days: 1

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

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

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 5

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:*

- ☑ NHS organisations in England 5
- ☐ 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: 5

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

○ Yes ◉ No

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

The study will be monitored and audited by the sponsors and the local R&D departments at each site.

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)

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)

All non-exclusively NHS research team members are university staff and thus have similar arrangements as detailed here: https://www.sheffield.ac.uk/finance/staff-information/help/insura nce/liability and https://www.leeds.ac.uk/insurance/liability.htm#:~:text=The%20Uni versity's%20public%20liability%20policy,the%20business%20of%20the %20University.

E.g. 'This policy provides cover for the employer in the event of claims brought by employees based on injury to their person suffered in the course of employment as a result of the fault of the employer. In the case of seconded staff, work experience placements and persons temporarily attached to the University, other employers or authorities may require confirmation or certificate of our insurance cover.'

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.

- [x] 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 Middle name Family name Email	Bradley Wilson Brad.Wilson@bthft.nhs.uk
	Organisation name	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	BSc, MD, FCEM
	Address	BRADFORD ROYAL INFIRMARY DUCKWORTH LANE BRADFORD	Country	United Kingdom
	Post Code	BD9 6RJ		
	Country	ENGLAND		
IN2	(•) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email	Susan Croft s.croft@sheffield.ac.uk
	Organisation name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	MBChB, MRCP, FCEM
	Address	NORTHERN GENERAL HOSPITAL HERRIES ROAD SHEFFIELD	Country	United Kingdom
	Post Code	S5 7AU		

Country	ENGLAND

IN3

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	LEEDS TEACHING HOSPITALS NHS TRUST
Address	ST. JAMES'S UNIVERSITY HOSPITAL BECKETT STREET LEEDS
Post Code	LS9 7TF
Country	ENGLAND

Forename	Kevin
Middle name	
Family name	Reynard
Email	kevin.reynard@nhs.net
Qualification (MD...)	MBChB, MRCP, FCEM
Country	United Kingdom

IN4

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	AIREDALE NHS FOUNDATION TRUST
Address	AIREDALE GENERAL HOSPITAL SKIPTON ROAD STEETON KEIGHLEY
Post Code	BD20 6TD
Country	ENGLAND

Forename	Sally-Anne
Middle name	
Family name	Wilson
Email	sally-anne.wilson@anhst.nhs.uk
Qualification (MD...)	MBChB, MRCP, FCEM
Country	United Kingdom

IN5

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	BARNSLEY HOSPITAL NHS FOUNDATION TRUST
Address	GAWBER ROAD BARNSLEY
Post Code	S75 2EP
Country	ENGLAND

Forename	Suzanne
Middle name	
Family name	Mason
Email	s.mason@sheffield.ac.uk
Qualification (MD...)	MBBS, FRCS, FFAEM, MD
Country	United Kingdom