



Protocol

EMPath: ExaMining the Experiences of Transgender Patients And
Their Healthcare Professionals at Milton Keynes University
Hospital

This protocol has regard for the HRA guidance and order of content

EMPatH

FULL TITLE OF THE STUDY

EMPatH: ExaMining the Experiences of Transgender Patients And Their Healthcare Professionals at Milton Keynes University Hospital

SHORT STUDY TITLE

The EMPATH study

PROTOCOL VERSION NUMBER AND DATE

Version 1.1 23.03.2025

RESEARCH REFERENCE NUMBERS

IRAS Number: 327106

SPONSOR'S Number: [Generated by the Sponsor. Enter if applicable](#)

FUNDER'S Number: [Generated by the funder. Enter if applicable](#)

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

Date:

...../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature:

.....

Date:

...../...../.....

Name: (please print):

.....

LIST of CONTENTS

GENERAL INFORMATION	Page No.
HRA PROTOCOL COMPLIANCE DECLARATION	i
TITLE PAGE	ii
RESEARCH REFERENCE NUMBERS	ii
SIGNATURE PAGE	iii
LIST OF CONTENTS	iv
KEY STUDY CONTACTS	v
STUDY SUMMARY	vi
FUNDING	vii
ROLE OF SPONSOR AND FUNDER	vii
ROLES & RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS	viii
STUDY FLOW CHART	ix
GLOSSARY OF TERMS	1
TABLE OF ABBREVIATIONS	2
SECTION	
1. BACKGROUND	3
2. RATIONALE	6
3. THEORETICAL FRAMEWORK	7
4. RESEARCH QUESTION/AIM(S)	8
5. STUDY DESIGN/METHODS	9
6. STUDY SETTING	10
7. SAMPLE AND RECRUITMENT	10
8. ETHICAL AND REGULATORY COMPLIANCE	12
9. DISSEMINATION POLICY	15
10. REFERENCES	17
11. APPENDICES	20

KEY STUDY CONTACTS

Chief Investigator	Dr. Julia Petty Associate Professor in Learning & Teaching Department of Nursing, Health and Wellbeing School of Health and Social Work
Study Co-ordinator	Thandiwe Rosemarysdóttir ar21aat@herts.ac.uk 07773 770513
Sponsor	School of Health and Social Work University of Hertfordshire College Lane Hatfield, Herts AL10 9AB
Joint sponsor(s)/co-sponsor(s)	Dr Julia Petty j.petty@herts.ac.uk
Funder(s)	Milton Keynes University Hospital NHS Foundation Trust Standing Way MK6 5LD
Key Protocol Contributors	
Committees	

STUDY SUMMARY

Study Title	EMPatH: ExaMining the Experiences of Transgender Patients And Their Healthcare Professionals at Milton Keynes University Hospital
Internal ref. no. (or short title)	EMPatH
Study Design	Appreciative Inquiry based interviews to elicit feelings and emotions experienced during that episode of care. Thematic analysis of the transcribed interviews.
Study Participants	Patients who identify as Trans* and have received an episode of care in MKUH in the last 18 months. Staff members who have cared for a Trans* patient at MKUH in the last 18 months.
Planned Size of Sample	20 (10 pairs)
Follow up duration	N/A
Planned Study Period	12 months
Research Question/Aim(s)	Does understanding the emotions and feelings experienced by Trans* patients and their healthcare professionals facilitate more positive experiences of healthcare?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
Mrs Antoanela Colda Head of Research and Development Milton Keynes University Hospital NHS Foundation Trust Standing Way MK6 5LD	Funding the course of study in its entirety Supporting the delivery of the study on-site at Milton Keynes University Hospital

ROLE OF STUDY SPONSOR AND FUNDER

The Sponsor is the University of Hertfordshire, School of Health and Social Work. This study is being undertaken as part of a PhD.

The Chief Investigator's supervisors support the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. They have the ability to terminate the study in case of unethical practice.

The Funder is Milton Keynes University NHS Foundation Trust. They are funding the study in its entirety. They have the ability to withdraw funding for the study. They also have the ability to prevent recruitment from their patients and staff, and to prevent sight of patient records.

ROLES & RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Steering Groups

Dr Rosemary Suttill (rosemary.suttill46@gmail.com) contributed to the plain English writing of the PILs, consent and assent forms.

Miss Mathilda Rose (contactable via Dr Suttill at rosemary.suttill46@gmail.com) contributed to the age-appropriate writing of the PIL and assent forms for the under-16s.

Patient & Public Involvement Group

PPI was carried out with one group of hospital staff and two groups of LGBTQ+ community members. Photo-elicitation and emotional touchpoints, and question and answer sessions were used to formulate the core question of "Are experiences of healthcare improved by making sure we speak the same language, and speak to the person not of the problem?"

LGBTQ+ sessions were arranged via Q:Alliance (jay@qalliance.org.uk)

Staff sessions were arranged via the MKUH Business Partners (thomas.dunkley@mkuh.mhs.uk)

PROTOCOL CONTRIBUTORS

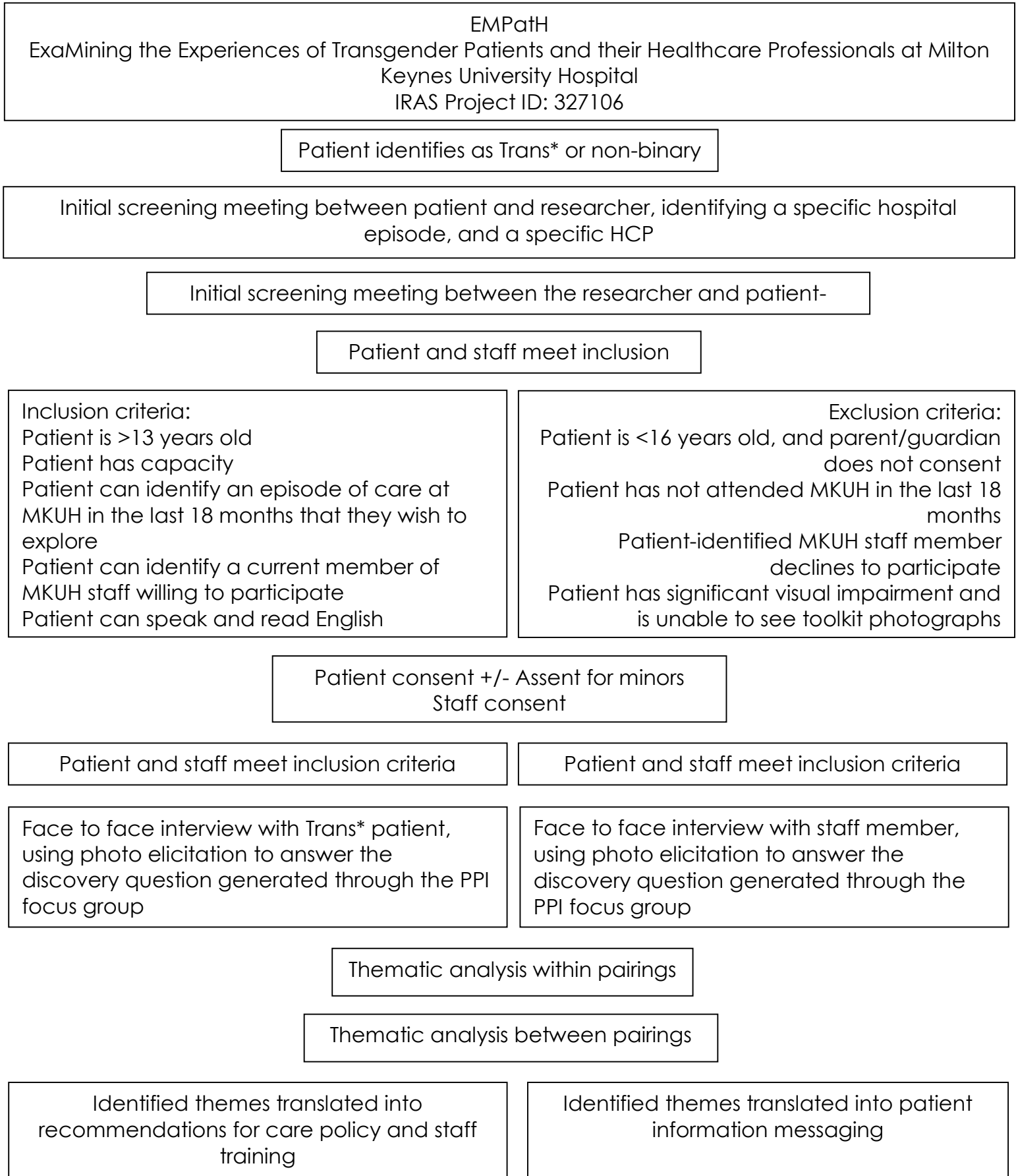
The Sponsor is the University of Hertfordshire, School of Health and Social Work. This study is being undertaken as part of a PhD.

The Chief Investigator's supervisors support the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. They have the ability to terminate the study in case of unethical practice.

The Funder is Milton Keynes University NHS Foundation Trust. They are funding the study in its entirety. They have the ability to withdraw funding for the study. They also have the ability to prevent recruitment from their patients and staff, and to prevent sight of patient records.

KEY WORDS: Transgender, Patient Experience, Staff experience, Hospital-based care

STUDY FLOW CHART



STUDY PROTOCOL

EMPatH: ExaMining the Experiences of Transgender Patients And Their Healthcare Professionals at Milton Keynes University Hospital

GLOSSARY OF TERMS

Transgender people are those who have been assigned one sex at birth, but who identify as a different sex.

Gender non-conforming people are people who do not identify themselves as any particular sex.

Gender fluid people are those who do not feel their sex is fixed to a certain point on the spectrum, and may change from time to time, feeling more masculine at one time, and more feminine at others, or neither.

Inter-sex babies are born with both male and female gonads. Previously, doctors may have made an early decision about which sex to “enforce”. More recently, this intervention happens less frequently, and children may continue to grow with both sets, and be free to choose their sex later on in their lives.

Table of Abbreviations

Ai	Appreciative inquiry
Trans*	Umbrella term incorporating all those who do not conform to the gender identity binary
CI	Chief Investigator
CV	Curriculum Vitae
ED	Emergency Department
GCP	Good Clinical Practice
GIDS	Gender Identity Development Service
GNC	Gender non-conforming
GP	General Practitioner
GRA	Gender Recognition Act
GRC	Gender Recognition Certificate
HCA	Health Care Assistant
HCP	Healthcare Professional
IRAS	Integrated Research Application System
ISF	Investigator Site File
LGBTQAI+	Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Asexual, Intersex, and others who do not conform to the gender identity binary
MKUH	Milton Keynes University Hospital
MKUHFT	Milton Keynes University Hospital Foundation Trust
NB	Non-binary
PI	Principal Investigator
R&D	Research and Development
REC	Research Ethics Committee
SAE	Significant Adverse Event
SOP	Standard Operating Procedure
TNB	Transgender and Non-binary
UH	University of Hertfordshire
UK	United Kingdom

1 BACKGROUND

Empath is a single-site, open prospective study of the experiences of Trans* patients and their healthcare staff during a specific hospital attendance at MKUH.

The Transgender, Gender-Diverse and non-binary (Trans*) population is an increasingly visible community with unique healthcare needs. It is a demographic found across society, many of whom also suffer inequalities within society, culture, and healthcare.

Overall, acceptance of Trans* people in single-sex spaces and in public services is increasing (Morgan et al, 2020). However, attitudes in the general population towards Trans* people are mixed. Some people who do not consider themselves transphobic are not against transphobia per se but still exhibit transphobic attitudes in certain circumstances (National Centre for Social Research, 2019). Negative and ambivalent attitudes are not limited to the cis-gender (those whose gender identity matches their assigned gender), straight community, but are also seen amongst lesbian and gay communities (Wang-Jones et al, 2018). The Trans* community is the subject of polarizing debate, which has been accused of being “about shutting down freedom of expression and stifling discussion” (Doward, 2020). Intersectionality among Trans* people (where multiple social categories such as race and sexuality interconnect) increases the degree of “otherness” e.g., those who are poor, of colour, Trans*, and disabled are lower in the societal hierarchy than those who are rich, white, cis, and able-bodied (Hill and Ritz, 2021). This intersectionality can compound the effect of barriers experienced by each societal group, increasing the marginalisation of Trans* people, and further reducing their access to healthcare.

The Government Equalities Office (GEO) (2018) tentatively estimates that there are approximately 200,000-500,000 Trans* people in the UK. Since 2004 when the Gender Recognition Act came into effect, 4,910 trans people have been issued a Gender Recognition Certificate (GRC) (GEO, 2018). In 2021 the National Census included the question “Is the gender you identify with the same as your sex registered at birth?”, a move that has been welcomed by many in the Trans* community as a positive step. Of the 45,651,748 respondents, this data identified 262,113 over 16-year-olds whose gender identify is anything other than “the same as sex registered at birth”.

EMPatH

There is no current national Trans* monitoring information standard (LGBT Foundation, 2021) and this lack of accurate data on the size of the UK Trans* population, annual numbers of hospital visits made by them, or the specific hospital services they accessed, hampers research into their experiences in hospital.

Without accurate figures, it is difficult for service commissioners to plan for the needs of Trans* people (House of Commons Women and Equalities Committee, 2019) and in the absence of a baseline, budgets cannot be set, training cannot be put in place, and outcomes cannot be measured. For example, there is no understanding of the incidence of cervical cancer rates in Trans* men (Berner et al, 2021). This lack of data and understanding contributes to the ongoing failure to address the needs of Trans* people.

There is an increasing body of literature focusing on the experiences of Trans* patients, the majority coming from Primary Care and mental health care, or generically "healthcare", rather than focusing on hospital care.

Requiring hospital care can make anyone feel vulnerable and anxious, but for Trans* patients, the experience can be even more difficult. Trans* people fear being misgendered in hospital (Brighton and Hove LGBT switchboard, 2015) and may be unable to access sex-specific care (e.g., a trans* man needing cervical screening) (Berner et al, 2021) as their documented gender may not match their physical body. Many Trans* people do not have confidence in healthcare providers. Barriers include a lack of trans-healthcare related knowledge, and discrimination from healthcare professionals (Allison et al, 2021, Chisolm-Straker, 2017, White and Fontenot, 2019), discriminatory attitudes, and widespread unconscious bias among health staff (Somerville, 2015). Like all patients, Trans* people also need care for health concerns that are not related to their sex, gender, or anatomy, but inappropriate curiosity, ignoring, or failing to consider, specific needs (GEO, 2018), previous experience of, or anticipated, stigma and discrimination (Berner et al, 2021), and a lack of attention to the patient voice, (Carlile, 2020) are all factors that can prevent access to appropriate, safe, and dignified healthcare. Issues such as invisibility, erasure and negation of identity (Kerr et al, 2021, Hoffkling et al, 2017) misgendering and using the wrong name (von Vogelsang et al, 2016), and care providers being unwilling, unable,

EMPath

or refusing, to provide care (Lee et al, 2022, Kosenko et al, 2013) create negative experiences of healthcare.

Trans* patients report being subject to gender insensitivity (Callander et al, 2019, Kosenko et al, 2013) enacted stigma (White and Fontenot, 2019), expressions of stereotypical attitudes (Kerr et al, 2021, von Vogelsang et al, 2016) verbal abuse, and forced care (Kattari et al, 2021(b), Kosenko et al, 2013). This victimisation increases with increased intersectionality (Kattari et al, 2021(a), Kattari et al, 2021(b)) and negative experiences are greater for non-binary patients than Trans* men (Markovic et al, 2021).

Literature on the healthcare experiences of Trans* patients identifies consistent themes, both negative and positive. Whilst much of the literature comes from America, a similar picture is seen in Canada, and in Europe. Healthcare staff receive little or no specific training (Mikulak et al, 2021), such as how to clarify gender pronouns (Parameshwaran et al, 2017), or how to recognise and accommodate Trans* patients in sex-segregated areas (Snelgrove et al, 2012). These issues may occur because of healthcare workers' lack of understanding and knowledge (Allison et al, 2021, Chisolm-Straker, 2017, von Vogelsang et al, 2016). Additionally, Western-centric health policies that exclude queer, postcolonial or national identity perspectives (Sekoni et al, 2022), racial disparities and intersectional insensitivity (White and Fontenot, 2019) compound the barriers faced by individuals who belong to multiple social groups.

A lack of institutional infrastructures that support gender-affirming care (Nair et al, 2021), such as specific Trans* healthcare related resources (Squires et al, 2022, Rolle et al, 2021), gender-neutral restrooms (Grimstad et al, 2020), patient registration forms that give options beyond the male/female binary, (Macdonald et al, 2019) and a welcoming clinical environment (Baldwin et al, 2018) sends the message to patients that their needs have not been prioritised.

It is important to recognise, however, that not all Trans* patients' experiences are negative. Positive experiences are created when staff use inclusive language (Rolle et al, 2021, Baldwin et al, 2018), show respect (von Vogelsang et al, 2016), and

demonstrate training and an understanding of Trans* patients (Chisolm-Straker et al, 2017).

There are few studies examining healthcare staff feelings and attitudes to caring for LGBTQ patients (Domogauer et al, 2021) either in hospital or in wider healthcare.

There are a number of areas where Trans* peoples' health is poorer than that of other sectors of society. Trans* people are more at risk of mental health problems, including self-harm, bullying, suicide attempts and successful suicide, yet find accessing mental health services difficult (GEO, 2018). Differentiate a & b By engaging in more risky sexual behaviours such as unprotected sex, or sex on drugs and alcohol, than their cis-gender peers, Trans* people are at greater risk of sexually transmitted infections, unplanned pregnancies, and future infertility (Nahata et al, 2020). Home circumstances may be unstable due to discrimination and lack of acceptance, potentially leading to homelessness, which is both more hazardous to Trans* people, and harder to escape from (The Albert Kennedy Trust, 2015). Trans* people experience higher rates of domestic abuse than the general population (Stonewall, 2018, ONS, 2016), and are increasingly subject to Trans* identity hate crimes (Home Office, 2019). These factors can contribute to worse mental than physical health (Polonijo et al, 2020) vulnerability, avoidance of healthcare (Hobster and McLuskey, 2020) and health attendance-related anxiety (Rolle et al, 2021, Thompson-Blume et al, 2021) for Trans* people.

2 RATIONALE

Provision of Trans* healthcare is complicated by existing disciplinary divisions of responsibilities within medicine (Snelgrove et al, 2012), few health professionals identifying Trans* healthcare as an interest area, and specialist health services for Trans* people being limited to major cities (Berner et al, 2021). LGBT+ inclusion, including the education of staff in the health service, lacks strategic, organisation-wide drive (House of Commons Women and Equalities Committee, 2019), adding to the "postcode lottery" of appropriate healthcare availability.

The needs and experiences of vulnerable people, including Trans* people, are least understood, and require extra investigative work. Examining the experiences of Trans* patients is important to understand their perspectives, and to identify where their care

EMPath

can be improved. This may be in managing any complex care needs, addressing any feelings of vulnerability, or ensuring privacy, dignity and confidentiality is maintained.

The examination of patient experience only became part of the approach to quality with Lord Darzi's Next Stage Review (Department of Health, 2008) and it now serves as a framework for the human experience of healthcare (Wolf et al, 2021). A good experience of treatment, care, and support, along with clinical effectiveness and patient safety, is essential to an excellent health service (NHS Improvement, 2018) and can affect clinical outcomes and safety (Doyle et al, 2013).

3 THEORETICAL FRAMEWORK

The Empath study is a qualitative, appreciative inquiry into the experiences of Trans* patients and the hospital staff who deliver their care. The study is qualitative to help to address some of the challenges of investigating the social world (Bleiker et al, 2019) by seeking an experiential understanding of complex interrelationships between key participants, making new, significant, distinctions, leading to improved understanding of the of the cases being studied (Aspers and Corte, 2019) of how hospital attendances are experienced by the participant groups.

Recruitment will take place in MKUH, a medium-sized District General Hospital (DGH). The participants will be identified using pseudo-anonymised numbers. The study will be carried out over 5 years and part of a Professional Doctorate in Health and Social Care at the University of Hertfordshire. Recruitment will take place over 2 years.

The results of this study have the potential to contribute to a greater understanding and empathy between Trans* patients and healthcare staff in MKUH. This may reduce the number, and severity, of negative experiences on the part of both groups. These are not being measured as part of the Empath study, but it is anticipated that this will lead to a reduction in stigma, and delayed access to care by Trans* patients, thus improving health outcomes, reducing moral injury, and personal and professional discomfort in staff. The output will inform training and policy at MKUH regarding the care of Trans* patients, conscientious objection by staff, support of hospital staff, patients and visitors, and the infrastructure of patient electronic care records.

4 RESEARCH QUESTION/AIM(S)

Does understanding the emotions and feelings experienced by Trans* patients and their healthcare professionals facilitate more positive experiences of healthcare?

4.1 Aim

To explore the experience of a hospital attendance at Milton Keynes University Hospital (MKUH) from the dual points of view of a Trans* patient, and their healthcare professional, to identify what is happening in the environment of the care event that contributes to a good experience.

4.2 Objectives

To identify discrete healthcare events involving the care of Trans* patients.

To identify the patient, and a healthcare professional involved in that event.

To interview dyads consisting of a Trans* patient and their healthcare provider about an identified hospital attendance to identify the feelings and emotions elicited by the event.

4.3 Outcome

To identify what is happening when feelings and emotions are positive, and how this can be transferred across the hospital.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

5.1 PICO table

P: Population	Patients who identify as Trans* and have received an episode of care in MKUH in the last 6 months. Staff members who have cared for a Trans* patient at MKUH in the last 6 months.
I: Intervention	Appreciative inquiry based interviews to elicit feelings experienced during that episode of care
C: Comparator	Inter- and intra-group analysis
O: Primary Outcome	Themes describing the feelings of the participants during the episode of care

5.2 Data collection

Appreciative inquiry-based interviews will be carried out by the Principal Investigator. These are to elicit feelings and emotions experienced during that episode of care. The Core Question for the Ai interviews has been co-created with PPI groups.

Data will be recorded on a personal recording device which will be transferred to secure, and password protected account.

5.3 Data analysis

The interview recordings will be transcribed by the Principal Investigator. Once transcribed, the anonymised transcript along with fieldnotes, will be kept securely on the University of Hertfordshire Microsoft OneDrive and the raw data audio files deleted. Thematic analysis of the transcribed interviews will be done by the Principal Investigator in accordance with Braun and Clarke (2006).

6 STUDY SETTING

Empath is a single-site, open prospective study. Participants will be identified by gatekeepers at MKUH and LGBTQ+ support organisations in Milton Keynes. They may also respond in person to advertising within the hospital and LGBTQ+ support organisation meeting sites.

Interviews will be conducted at MKUH, in a quiet room away from the main hospital or in a dedicated room in Milton Keynes Library. The setting of the data collection is important. It must be a location where all participants feel safe, comfortable, and able to express themselves without fear of being overheard. It needs to ensure that participants' confidence in the researcher is gained and maintained.

Transcription will take place at the home of the Principal Investigator, directly onto the University of Hertfordshire OneDrive, in a password protected file. The PI will be the sole password holder.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Inclusion criteria: Trans* patient

- Is >13 years old
- Has attended MKUH as a patient in the last 18 months
- Identifies as Trans*
- Has capacity
- Is willing to give consent (or assent if under 16 years)
- Is willing and able to take part in an Appreciative Inquiry interview

Inclusion criteria: Staff participant

- Is a current member of staff at MKUH
- Has been selected by the Trans* patient to form the case duo
- Is willing to give consent
- Is willing and able to take part in an Appreciative Inquiry interview
- Is able to conduct interviews in English without an interpreter

7.1.2 Exclusion criteria (Trans* patients, and staff)

- Is \leq 13 years old
- Is >16 years old and whose responsible adult does not consent to the young person participating
- Inability to consent
- Previous recruitment into the study
- Patient in custody or prison

7.2 Sampling

7.2.1 Size of sample

Purposive sampling is the most appropriate for the scope of this study. It is anticipated that the sample size will be small, reflecting the small percentage of the population who identify as Trans*. However, anecdotal evidence shows that there are a number of patients who have been cared for in the hospital. This indicates that the patient group should be available in the hospital to invite to take part in the study.

7.2.2 Sampling technique

Participants will be purposively sampled from across Milton Keynes University Hospital (MKUH) and LGBTQ+ support organisations in Milton Keynes. Pairs of participants (the Trans* patient and the HCP who delivered their care) will be interviewed separately, using the core question.

Gatekeepers will be required at all recruitment sites for the protection of potential participants. Potential staff and Trans* patient participants who respond personally to advertising will not require gatekeepers.

7.3 Recruitment

7.3.1 Sample identification

The study will be advertised across the hospital, in staff areas and in patient areas. It will be verbally presented at senior nurse meetings, medical meetings, and therapies team meetings for dissemination across the clinical staff via the Weekly Trust newsletter.

Awareness within staff teams will serve to prepare staff in case they are identified by Trans* patient participants. It will also prepare them in case they are approached by Trans* patients requesting further information. Information will include the inclusion and exclusion criteria to avoid unnecessary identification of the patient's gender identity. Staff will also be asked to assess the capacity of the Trans* patient to give consent or assent.

Advertising will invite Trans* patients to contact the researcher directly via a QR code, or to speak to their healthcare practitioner for referral. The QR code will link to the Participant Information Leaflet.

Advertising will also be posted on social media, where permitted by the account holder, on sites supporting Trans* people across Milton Keynes. Permission will be sought from the MKUH communications team to advertise the study on the hospital internet and intranet sites.

All communications will stress the importance of maintaining the confidentiality of the Trans* patients. They MUST NOT be directly identified to the researcher without prior consent. Discussion between staff and potential Trans* patient participants should not be documented in the patient's electronic record without their consent.

Advertising resources will note that no payments are available to any participants.

7.3.2 Consent

Once the potential participant is in contact with the researcher, valid informed consent will be requested. This conversation between the researcher and the participant will cover:

- The content of the Patient Information Leaflet
- The objectives of the study
- The method of data collection
- Any potential risks, and where to seek help in case of distress
- How data will be stored
- How confidentiality will be maintained
- Participants will be given the opportunity to ask questions
- It is voluntary to take part in research
- Declining or withdrawing from research will not have negative consequences for the participants.
- Participants who wish to withdraw from the study will have their raw data recordings deleted, along with their transcripts. If data has already been integrated into the thematic analysis, it will not be possible to withdraw the data.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Empath participants will be recruited from NHS patient groups. Thus, the appropriate regulatory framework is applied to ethical approval. Additionally, participants may be vulnerable as they identify as Trans*, and may be under 16 years old.

(See also Protocol Appendix 4) To ensure participant safety and dignity, Participant Information Leaflets clearly state that information divulged in study interviews will be kept confidential and pseudonymised, unless there is concern for the safety of the participant or those around them. As the interviews may revisit difficult memories, signposting to support services is provided. Participants under 16 years of age may, if they wish, have their responsible adult present during the interview.

The data management plan ensures that all physical and digital study information, including identifiers, interview recordings and interview transcripts, will be kept securely locked away, or on a secure server as appropriate.

8.1 Assessment and management of risk

- See Protocol Appendix 5 for Risk Management Plan

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC (researchers should check if they are required to gain a favourable opinion from the UK Health Departments Research Ethics Service NHS [REC](#)) or other REC approval) for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

Empath is NHS REC reviewed research. Therefore,

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- The Chief Investigator will produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

- Before participants are enrolled into the study, the Chief Investigator and Principal Investigator will ensure that appropriate approvals from participating organisations are in place. Empath has applied for
 - **Confirmation of Capacity and Capability from R&D, MKUH**
- For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D department at Milton Keynes University Hospital as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

Empath is NHS REC reviewed research. Therefore,

If the sponsor (University of Hertfordshire) wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid

EMPatH

notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments will be notified to the Research Ethics Committee (REC) and communicated to the R&D department at MKUH to assess whether the amendment affects the NHS permission for that site. Amendments that may be considered to be non-substantial for the purposes of REC will be notified to NHS R&D (e.g. a change to the funding arrangements).

When making an amendment:

- The Chief and Principal Investigators will be responsible for the decision to amend the protocol.
- The Chief and Principal Investigators will be responsible for deciding whether an amendment is substantial or non-substantial.
- The Amendment Tool will be completed and finalised
- This, along with all supporting documentation for the amendment via the NIHR online amendment submission link.
- Substantive changes will be communicated to relevant stakeholders via email, with a 35-day notice period to accept or decline the amendment.
- There will be an electronic amendment tracker in the Electronic Investigator Site File.

8.3 Peer review

The Empath protocol will be peer reviewed by appropriately experienced members of the Faculty from the School of Health and Social Work at the University of Hertfordshire.

8.4 Patient & Public Involvement (PPI)

The core question for the Empath study's Appreciative Inquiry-based interviews has been co-created by the researcher, and PPI contributors from the MKUH staff and Trans* users of LGBTQ+ support organisations in Milton Keynes. PPI groups will also be involved in dissemination of the results.

8.5 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

- Accidental protocol deviations can happen at any time. They will be appropriately documented on the relevant form and reported to the Chief Investigator and Sponsor immediately.
- Deviations from the protocol which are found to frequently recur are not acceptable. In this instance, the Chief Investigator will undertake immediate action and could potentially be classified as a serious breach and report to the REC as required.

8.6 Data protection and patient confidentiality

See Protocol Appendix 6

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The Data Custodian is the Principal Investigator, Thandiwe Rosemarysdóttir.

8.7 Indemnity

Professional indemnity will be provided by the University in its capacity as sponsor.

8.8 Access to the final study dataset

Only the Principal Investigator, Thandiwe Rosemarysdóttir, will have access to the complete raw dataset. Paper copies of the recruitment log, the single document that links study identification numbers with named individuals, will be kept locked in a tambour in the R&D office at MKUH. Electronic data will be stored on a secure drive at the University of Hertfordshire. This includes record of developing discussions of findings between the Chief and Principal Investigators and University supervisors.

There is no expectation of secondary analysis or any use of the dataset in future research.

9 DISSEMINATION POLICY

9.1 Dissemination policy

- The data arising from the study will be owned by the University of Hertfordshire
- On completion of the study, the data will be analysed and discussed and a Final Study Report prepared.
- The full study report can be accessed after completion of the course of study.

EMPatH

- The Principal Investigator has the right to publish the study findings. The Chief Investigator and supervisor will be named co-authors, as representatives of the University of Hertfordshire.
- The participants who confirm that they wish to be informed of the outcome of the study, either by provision of the publication, presentation, or email, etc. will receive the information, and their contact details will be securely retained for these purposes, with their consent.
- The study protocol and full study report will be made publicly available as a stored dissertation at the University of Hertfordshire.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The Principal Investigator has the right to publish the study findings. The Chief Investigator and supervisor will be named co-authors, as representatives of the University of Hertfordshire.

10 REFERENCES

- Allison, M. K., Marshall, S. A., Stewart, G., Joiner, M., Nash, C., & Stewart, M. K. (2021). Experiences of transgender and gender nonbinary patients in the emergency department and recommendations for health care policy, education, and practice. *The Journal of emergency medicine*, 61(4), 396-405.
- Aspers, P., & Corte, U. (2019). What is qualitative in qualitative research. *Qualitative sociology*, 42, 139-160.
- Baldwin, A., Dodge, B., Schick, V. R., Light, B., Schnarrs, P. W., Herbenick, D., & Fortenberry, J. D. (2018). Transgender and genderqueer individuals' experiences with health care providers: what's working, what's not, and where do we go from here?. *Journal of health care for the poor and underserved*, 29(4), 1300.
- Berner, A. M., Connolly, D. J., Pinnell, I., Wolton, A., MacNaughton, A., Challen, C., ... & Richards, C. (2021). Attitudes of transgender men and non-binary people to cervical screening: a cross-sectional mixed-methods study in the UK. *British Journal of General Practice*, 71(709), e614-e625.
- Bleiker, J., Morgan-Trimmer, S., Knapp, K., & Hopkins, S. (2019). Navigating the maze: Qualitative research methodologies and their philosophical foundations. *Radiography*, 25, S4-S8.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, 3(2), 77-101.
- Brighton and Hove LGBT switchboard, 2015
- Callander et al, 2019
- Carlile, A (2020) The experiences of transgender and non-binary children and young people and their parents in healthcare settings in England, UK: Interviews with members of a family support group, *International Journal of Transgender Health*, 21:1, 16-32
- Chisolm-Straker, M., Jardine, L., Bennouna, C., Morency-Brassard, N., Coy, L., Egemba, M. O., & Shearer, P. L. (2017). Transgender and gender nonconforming in emergency departments: a qualitative report of patient experiences. *Transgender Health*, 2(1), 8-16.
- Department of Health, 2008 xxx
- Domogauer, J. D., Haseltine, M., Nelson, R., Charifson, M., Sutter, M., Chachoua, A., & Quinn, G. (2021). Faculty and Staff Cultural Awareness in the Care of LGBTQ Patients, A Single NCI-Comprehensive Cancer Center Experience. *International Journal of Radiation Oncology, Biology, Physics*, 111(3), e335.
- Doward, J. (2020) 'Polarised' debate on gender recognition is harming UK, says equalities chief' *The Guardian* 08 Aug. Available at <https://www.theguardian.com/society/2020/aug/08/polarised-debate-on-gender-recognition-is-harming-uk-says-equalities-chief> Accessed 24.9.2020 Doyle et al, 2013
- Government Equalities Office (2018) National LGBT Survey Summary Report. Available at <https://www.gov.uk/government/publications/national-lgbt-survey-summary-report/national-lgbt-survey-summary-report> Accessed 20.02.2020
- Grimstad, F. W., Stowell, J. T., & Gaddis, M. (2020). Survey of experiences of transgender and gender nonbinary patients during imaging encounters and opportunities for improvement. *American Journal of Roentgenology*, 215(5), 1136-1142.
- Hill, D., & Ritz, R. (2021). Genderism. In A. Goldberg, & G. Beemyn (Eds.), *The sage encyclopedia of trans studies* (Vol. 1, pp. 339-340). SAGE Publications, Inc., <https://www.doi.org/10.4135/9781544393858.n119> Accessed 13.4.2021

EMPath

Hoffkling, A., Obedin-Maliver, J., & Sevelius, J. (2017). From erasure to opportunity: a qualitative study of the experiences of transgender men around pregnancy and recommendations for providers. *BMC pregnancy and childbirth*, 17, 1-14.

Hobster, K., & McLuskey, J. (2020). Transgender patients' experiences of health care. *British Journal of Nursing*, 29(22), 1348-1353.

House of Commons Women and Equalities Committee (2019) Health and Social Care and LGBT Communities. First Report of Session 2019. Available at <https://publications.parliament.uk/pa/cm201919/cmselect/cmwomeq/94/94.pdf> Accessed 20.02.2020

Kattari et al, 2021 (a) Kattari, S. K., Bakko, M., Langenderfer-Magruder, L., & Holloway, B. T. (2021). Transgender and nonbinary experiences of victimization in health care. *Journal of interpersonal violence*, 36(23-24), NP13054-NP13076.

Kattari et al, 2021 (b) Kattari, S. K., Call, J., Holloway, B. T., Kattari, L., & Seelman, K. L. (2021). Exploring the experiences of transgender and gender diverse adults in accessing a trans knowledgeable primary care physician. *International Journal of Environmental Research and Public Health*, 18(24), 13057.

Kerr, L., Fisher, C. M., & Jones, T. (2021). "I'm not from another planet": The alienating cancer care experiences of trans and gender-diverse people. *Cancer nursing*, 44(6), E438-E446.

Kosenko, K., Rintamaki, L., Raney, S., & Maness, K. (2013). Transgender patient perceptions of stigma in health care contexts. *Medical care*, 51(9), 819-822.

Lee et al, 2022 ???

LGBT Foundation (2021) Pride in Practice LGBT Patient Experience Survey 2021. Manchester.

Macdonald, D. W., Grosseohme, D. H., Mazzola, A., Pestian, T., & Schwartz, S. B. (2019). "I just want to be treated like a normal person": Oral health care experiences of transgender adolescents and young adults. *The Journal of the American Dental Association*, 150(9), 748-754.

Markovic, L., McDermott, D. T., Stefanac, S., Seiler-Ramadas, R., Iabloncsik, D., Smith, L., ... & Grabovac, I. (2021). Experiences and interactions with the healthcare system in transgender and non-binary patients in Austria: an exploratory cross-sectional study. *International journal of environmental research and public health*, 18(13), 6895.

Mikulak, M., Ryan, S., Ma, R., Martin, S., Stewart, J., Davidson, S., & Stepney, M. (2021). Health professionals' identified barriers to trans health care: a qualitative interview study. *British Journal of General Practice*, 71(713), e941-e947.

Nair, J. M., Waad, A., Byam, S., & Maher, M. (2021). Barriers to Care and Root Cause Analysis of LGBTQ+ Patients' Experiences: A Qualitative Study. *Nursing Research*, 70(6), 417-424.

Morgan, H., Lamprinakou, C., Fuller, E., & Albakri, M. (2020). Attitudes to Transgender People: Research report: August 2020. Equality and Human Rights Commission.

Nahata, L., Chen, D., Quinn, G. P., Travis, M., Grannis, Nelson., Tishelman, A. C. (2020) Reproductive Attitudes and Behaviors Among Transgender/Nonbinary Adolescents *Journal of Adolescent Health*, 2020-03-01, Volume 66, Issue 3, Pages 372-374.

National Centre for Social Research (2019) British Attitudes Survey 36 Available at https://www.bsa.natcen.ac.uk/media/39358/5_bsa36_relationships_and_gender_identity.pdf Accessed on 20.07.2020 NHS Improvement, 2018

Office for National Statistics (2016) Intimate personal violence and partner abuse. Available at <https://www.ons.gov.uk/peoplepopulationandcommunity/crimeandjustice/compendium/focusonviol>

EMPatH

entcrimeandsexualoffences/yearendingmarch2015/chapter4intimatepersonalviolenceandpartnerabuse#heavily-victimised-groups-of-partner-abuse Accessed 20.02.2020

Parameshwaran, V., Cockbain, B. C., Hillyard, M., & Price, J. R. (2017). Is the Lack of Specific Lesbian, Gay, Bisexual, Transgender and Queer/Questioning (LGBTQ) Health Care Education in Medical School a Cause for Concern? Evidence From a Survey of Knowledge and Practice Among UK Medical Students. *Journal of Homosexuality*, 64(3), 367–381.

Polonijo, A. N., Gardner, A., Clinton, T., & Brown, B. (2020). Transgender and gender nonconforming patient experience in the Inland Empire, California. *Transgender Health*, 5(4), 267-271.

Rolle, L., Zayhowski, K., Koeller, D., Chiluzia, D., & Carmichael, N. (2022). Transgender patients' perspectives on their cancer genetic counseling experiences. *Journal of Genetic Counseling*, 31(3), 781-791.

Sekoni, A. O., Jolly, K., & Gale, N. K. (2022). Hidden healthcare populations: using intersectionality to theorise the experiences of LGBT+ people in Nigeria, Africa. *Global Public Health*, 17(1), 134-149.

Snelgrove, J. W., Jasudavisius, A. M., Rowe, B. W., Head, E. M., & Bauer, G. R. (2012). "Completely out-at-sea" with "two-gender medicine": a qualitative analysis of physician-side barriers to providing healthcare for transgender patients. *BMC health services research*, 12, 1-13.

Somerville, W., Kapten, S. W., Miao, I. Y., Dunn, J. J., & Chang, D. F. (2020). Identifying and Remediating Personal Prejudice: What Does the Evidence Say?. *Prejudice, Stigma, Privilege, and Oppression: A Behavioral Health Handbook*, 179-200.

Squires, L. R., Bilash, T., Kamen, C. S., & Garland, S. N. (2022). Psychosocial needs and experiences of transgender and gender diverse people with cancer: a scoping review and recommendations for improved research and care. *LGBT health*, 9(1), 8-17.

Stonewall (2018) LGBT in Britain. Trans Report. Available at <https://www.stonewall.org.uk/cy/node/61891> Accessed 20.02.2020

The Albert Kennedy Trust (2015) LGBT Youth Homelessness: A UK National Scoping of Cause, Prevalence, Response and Outcome. Available at <https://www.akt.org.uk/Handlers/Download.ashx?IDMF=c0f29272-512a-45e8-9f9b-0b76e477baf1> Accessed 20.02.2020

Thompson-Blume et al, 2021 ??

von Vogelsang, A. C., Milton, C., Ericsson, I., & Strömberg, L. (2016). 'Wouldn't it be easier if you continued to be a guy?'—a qualitative interview study of transsexual persons' experiences of encounters with healthcare professionals. *Journal of clinical nursing*, 25(23-24), 3577-3588.

Wang-Jones, T. S., Hauson, A., O., Ferdman, B., M., Kate Hattrup, Lowman, R., L., (2018) Comparing implicit and explicit attitudes of gay, straight, and non-monosexual groups toward transmen and transwomen, *International Journal of Transgenderism*, 19:1, 95-106

White, B. P., & Fontenot, H. B. (2019). Transgender and non-conforming persons' mental healthcare experiences: An integrative review. *Archives of psychiatric nursing*, 33(2), 203-210.

Wolf, Y., & Kwartin, S. (2021). Classification of transgender man's breast for optimizing chest masculinizing gender-affirming surgery. *Plastic and Reconstructive Surgery—Global Open*, 9(1), e3363.

11. APPENDICIES

11.1 Appendix 1- Required documentation

ar21aat EC1A Application for Ethics Approval of a Study Involving Human Participants

ar21aat EC1D NHS Protocol Registration Form

ar21aat Interview Core Question

ar21aat Empath advertising poster

ar21aat EC3 Patient

ar21aat EC3 Staff

ar21aat EC4 Child

ar21aat EC4 Parent_Guardian

ar21aat EC6 Adolescents

ar21aat EC6 Adult PIS

ar21aat EC6 Child

ar21aat EC6 Parent_Guardian

ar21aat DOI form

ar21aat SP1 form

Research CV – Thandiwe Rosemarysdóttir

Research CV – Dr Julia Petty

Research CV – Dr Cheryl Holman

11.2 Appendix 2 – Schedule of Procedures

11.3 Appendix 3 – Amendment History

11.4 Appendix 4 – Support and signposting letter

11.5 Appendix 5 – Harms, Hazards and Risks Form

11.6 Appendix 6 – Data Protection Impact Assessment

This is an official notification by a student of the University of Hertfordshire in respect of a study involving human participants.

Title of study: EMPaTH: ExaMining the Experiences of Transgender Patients And Their Healthcare Professionals at Milton Keynes University Hospital

Protocol Number: <applicant please enter the Protocol Number as displayed on your Ethics approval Notification>

Approving Committee:

The University of Hertfordshire Health, Science, Engineering and Technology Ethics Committee with Delegated Authority

If you have any queries concerning this document, please contact me Thandiwe Rosemarysdóttir, thandiwesuttill@hotmail.com or my supervisor Dr Julia Petty, j.petty@herts.ac.uk.