

Legacies and Futures: Measuring the roles of resilience and vulnerability in pregnancy and birth outcomes

Submission date 11/05/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/03/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Patients using reproductive health services, like care during pregnancy (called antenatal care), are most often assumed to be heterosexual married women whose gender matched their sex assigned at birth (i.e., cisgender). Due to these assumptions, pregnancy care procedures are based on a sweeping assumption of who becomes pregnant and gives birth. This assumption is based on the pregnant person's gender and/or sexual orientation. As a result of this assumption, parents who are lesbian, gay, bisexual, queer, intersex, asexual, and/or transgender (LGBTQIA+) can experience stress in the form of stigma, prejudice, and discrimination (i.e. "minority stress"). In the United Kingdom, there are 525,000 LGBTQIA+ potential gestational parents who may face this type of stress while receiving pregnancy care. That means that there is a preventable higher risk for pregnancy and birth complications caused by increased stress during pregnancy and daily life. These complications include macrosomia, pre-term birth, and low-birth weight. Preventable stress, also called minority stress, links to this increase in health problems outside of pregnancy as well. Since minority stress influences patient/parents' health, it is also called a risk or vulnerability. Resilience, or the ability to overcome stress and discrimination, can sometimes help improve health outcomes. However, little is known about which types of resilience can be helpful for LGBTQIA+ parents given their unique experiences of minority stress.

The planned observational study will investigate the ways in which experiences of minority stress and resilience in pregnancy care are associated with parent health and birth outcomes.

Who can participate?

A sample of pregnant parents from maternity wards in and around London. Participant recruitment will focus on LGBTQIA+ pregnant parents. A matched comparison sample of cisgender, heterosexual pregnant parents will also be recruited to take part from the same maternity.

What does the study involve?

Participants will take part in an online panel survey (completed twice) that will be linked to each patient/participant's electronic health records to create a quantitative dataset. From the full

sample, a smaller group of patient/parents from University College London Hospital will be invited to complete an at-home journal activity which will provide qualitative data on their experiences of minority stress and resilience. Results from this study can be used to inform LGBTQIA+ guidelines, training, and help make reproductive healthcare more inclusive.

What are the possible benefits and risks of participating?

There are no direct personal health benefits to participating in this study. You may find that thinking through the questions is interesting and provides new perspectives on your lived experiences, but this will vary for each participant. By taking part in the study, you will be helping to improve what is known about pregnancy and childbirth among diverse communities in a way that should help to improve guidelines and policies.

There are no known risks for participating study, since there are no changes to your pregnancy care. The topics that will be covered in the survey questions are similar to topics discussed in everyday conversations that you might have with family and friends. These may also include topics covered by the news and social media as well. There will be a brief description of the questions you will be answering at the start of each section.

When answering questions in the surveys about your daily life you may experience uncomfortable emotions or discontent. We suggest taking your time with the survey, taking it in a safe and comfortable space. There are recommended points to take a break within the survey in case you do need to step away and come back at a later time.

For privacy purposes, we recommend using an individual email address for communication and survey reminders. Additionally, while completing the surveys you may also wish to position yourself where no-one is able to see your screen. After completing each survey, you may wish to clear your browser history if you are concerned about it being on the computer you used.

Where is the study run from?

University College London Hospital (UK)

When is the study starting and how long is it expected to run for?

September 2019 to March 2024

Who is funding the study?

Economic and Social Research Council (UK)

Who is the main contact?

Kate Luxion, stnvkll@ucl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Ms Kate Luxion

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Integrated Research Application System (IRAS)

264198

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 46939, Grant Codes: ES/P000592/1, IRAS 264198

Study information**Scientific Title**

Legacies and futures: gestational parents' experiences with vulnerability and resilience as it influences parent and neonatal health

Study objectives

What role(s) do resilience and vulnerability play in the health and wellbeing of LGBTQ+ gestational parents, as compared to their cisheterosexual peers, during their antenatal care?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/02/2022, Central London REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 207 104 8221; londoncentral.rec@hra.nhs.uk), ref: 21/LO/0551

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Mental health around reproductive health and childbirth

Interventions

The design is a cohort study that involves both quantitative surveys and qualitative patient journals. There are two points that participants will be asked to use an online survey platform from their home: once during pregnancy and once after birth. Participants will consent to use of their patient records and be informed how that information is being used for the study. These surveys are estimated to take 30-45 minutes each, with the ability to pause and return to complete. A concurrent sub-study at UCLH will gather additional consent for these activities. In both instances the consent will be recorded digitally, meeting the MHRA standards, and kept separate from the other data once data collection is complete. The data collected via the surveys will then be analysed using Structural Equation Modelling (SEM) and the journals data will be assessed using narrative analysis to review the concepts of vulnerability and resilience as latent variables.

The order of event are:

1. Study Invitation using patient records (i.e., recruitment)
2. Screener questionnaire
3. First Online Survey at Home (while pregnant; recruitment for #3)
4. Journal sent to relevant participants
5. Second Online Survey at Home (roughly 1-month postpartum)
6. Journal collected from participants (reminder to submit with #4)
7. Data analysis (qualitative and quantitative, integrated)

Parent health will be measured using allostatic load which is assessed by using data from routine antenatal tests extracted from patient records throughout the pregnancy. Consent covers additional tests and notes as relevant (e.g. complications, pre-existing conditions, etc.). Infant health will be measured through routine tests and measurements done at birth. Consent covers additional details as relevant (e.g. loss, complications, skin-to-skin, etc.).

Intervention Type

Other

Primary outcome(s)

1. Resilience and vulnerability measured using psychometric scales in two online surveys, once during pregnancy and once postpartum
2. Parent health measured using allostatic load which is assessed using data from routine antenatal tests, including blood pressure, body mass index, blood sugar, urinalysis, and fundal height extracted from patient records throughout the pregnancy.
3. Infant health measured through routine tests and measurements including height, weight, gestational length, Apgar score, length of gestation, and head circumference at birth.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

30/03/2024

Eligibility

Key inclusion criteria

1. Primary Sample Characteristics:

1.1. Legal adult of reproductive age (18 - 49 years)

1.2. Identifies as a lesbian, gay, bisexual, queer, and/or transgender

1.3. Currently pregnant and receiving antenatal care at registered study site - (regardless of sex /gender designation)

2. Secondary Sample Characteristics:

2.1. Matched case to primary sample participant

2.2. Identifies as cisgender and heterosexual

2.3. Currently pregnant and receiving antenatal care at a registered study site

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

49 years

Sex

All

Key exclusion criteria

1. Any pregnant persons under the age of 18 years

2. Pregnant individuals using site locations for Urgent Care, A&E, non-antenatal services only

Date of first enrolment

15/04/2022

Date of final enrolment

30/09/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University College London Hospital

University College London Hospitals NHS Foundation Trust

250 Euston Road

London

United Kingdom

NW1 2PG

Study participating centre

The Royal London Hospital

Barts Health NHS Trust

80 Newark Street

London

United Kingdom

E1 2ES

Study participating centre

Worthing Hospital

University Hospitals Sussex NHS Foundation Trust

Lyndhurst Road

Worthing

United Kingdom

BN11 2DH

Study participating centre

Guys Hospital

The Guys and St Thomas NHS Trust

St Thomas Street

London

United Kingdom

SE1 9RT

Study participating centre

Homerton University Hospital

Homerton Row

London

United Kingdom

E9 6SR

Study participating centre

St Marys Hospital

Imperial College Healthcare NHS Trust

The Bays

South Wharf Road

London

United Kingdom

W2 1BL

Study participating centre

Kings College Hospital

King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre

Kingston Hospital NHS Foundation Trust

Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre

Royal Free Hospital

Pond Street
London
United Kingdom
NW3 2QG

Study participating centre

Watford General Hospital

West Hertfordshire Teaching Hospitals NHS Trust
Trust Offices
Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre

The Whittington Hospital

Whittington Health NHS Trust
Magdala Avenue
London
United Kingdom
N19 5NF

Sponsor information

Organisation

University College London

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Research council

Funder Name

Economic and Social Research Council

Alternative Name(s)

Economic and Social Research Council (ESRC), ESRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.3	22/02/2022	08/04/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes