ISRCTN17628275 https://doi.org/10.1186/ISRCTN17628275

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

Registration date
08/04/2022

Overall study status
Completed

Last Edited
27/03/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Study website
http://www.homepages.ucl.ac.uk/~stnvkll/

Contact information

Type(s)
Scientific

Contact name
Ms Kate Luxion

ORCID ID
http://orcid.org/0000-0002-3093-3683

Contact details
Thomas Coram Research Unit
27-28 Woburn Square
London
United Kingdom
WC1H 0AA
+44 20 3108 4358
stnvkll@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
264198

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
https://www.homepages.ucl.ac.uk/~stnvkll/PIS.html and https://www.homepages.ucl.ac.uk/~stnvkll/PIS_Sub.html

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 measure
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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
23/09/2019

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

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
49 Years

Sex
Both

Target number of participants
Planned Sample Size: 800; UK Sample Size: 800

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
England

United Kingdom

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

Sponsor details
UCLH/UCL Joint Research Office, part of the Research Directorate
4th Floor
West 250 Euston Road
London
England
United Kingdom
NW1 2PG
No telephone contact available
uclh.randd@nhs.net

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
There is a plan to, at minimum, publish in peer-review journals, along with conference presentations. Topics will include both the quantitative and qualitative findings, alongside the theoretical and methodological details. Formats and dates are tentative due to the study being on-going.

Intention to publish date
31/03/2025

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?
Protocol file	version 3.3	22/02/2022	08/04/2022	No	No
HRA research summary			28/06/2023	No	No