Food, Pregnancy and Me: Exploring food insecurity in pregnancy in the UK

Submission date	No longer recruiting	Prospectively registered		
06/11/2024		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
07/11/2024	Completed Condition category	☐ Results		
Last Edited		Individual participant data		
15/10/2025	Pregnancy and Childbirth	[X] Record updated in last yea		

Plain English summary of protocol

Background and study aims

In the UK, we don't have much information about what food is eaten and how it is accessed during pregnancy. We would like to find out more about the food you eat, how you access food, any barriers you face in accessing food, and your health and wellbeing during your pregnancy. This information will help us to better understand whether pregnant women and people need more support to access the food and nutrients they need.

Who can participate?

Women who are pregnant and in their third trimester (29-40 weeks' gestation) may be invited to take part if they receive care at either Queen Elizabeth Hospital Gateshead or University Hospital Coventry and Warwickshire.

What does the study involve?

The first part of the study involves completing a questionnaire, either on paper or online. There are many things that affect what we eat and how we access food, lots of which are not in our control. For this research to find out what will help pregnant women and people who are struggling in the future, it is important that you answer the questionnaire honestly. We would like around 600 people to complete the questionnaire. To say thank you for your time, we will provide £20 supermarket gift vouchers.

We would also like to talk to around 40 people (20 each from Coventry and Gateshead maternity units) in more detail about their experiences accessing food during pregnancy. This is called a research interview. Participants in these interviews will receive an additional £25 voucher as a thank you for your time. When you complete your questionnaire for part one of this research, you will be asked if you are happy to be contacted about the interview.

What are the possible benefits and risks of participating?

There is no immediate benefit to you if you take part. However, you will receive a £20 voucher to thank you for taking the time to complete and return the questionnaire. You will need to complete the whole questionnaire to receive the voucher. If you miss any questions, the research team may contact you directly using the contact details you provide on the questionnaire, if you give permission for us to do so. There may be benefits to future pregnant

people if this research helps to find out what support pregnant people need to access food. There are no anticipated risks to taking part in this study.

Where is the study run from? Newcastle University, University of Birmingham & Lancaster University (UK)

When is the study starting and how long is it expected to run for? January 2023 to October 2025

Who is funding the study?

This study has been funded by the National Institute for Health and Social Care Research, School for Public Health Research (UK)

Who is the main contact? Professor Nicola Heslehurst, FPandMe@newcastle.ac.uk

Contact information

Type(s)

Principal investigator

Contact name

Prof Nicola Heslehurst

ORCID ID

https://orcid.org/0000-0001-8656-2319

Contact details

Population Health Sciences Institute Newcastle University Newcastle upon Tyne United Kingdom NE24AX +44 191 2083823 nicola.heslehurst@newcastle.ac.uk

Type(s)

Scientific

Contact name

Dr Kiya Hurley

ORCID ID

https://orcid.org/0000-0002-5084-5410

Contact details

University of Birmingham Birmingham United Kingdom B15 2TT +44 7483331986 k.hurley@bham.ac.uk

Type(s)

Scientific

Contact name

Prof Kate Jolly

ORCID ID

https://orcid.org/0000-0002-6224-2115

Contact details

University of Birmingham Birmingham United Kingdom B15 2TT +44 7745 914757 c.b.jolly@bham.ac.uk

Type(s)

Scientific

Contact name

Prof Heather Brown

ORCID ID

https://orcid.org/0000-0002-0067-991X

Contact details

University of Lancaster Lancaster United Kingdom LA1 4YW +44 1524 65201 h.w.brown@lancaster.ac.uk

Type(s)

Public

Contact name

Dr Zainab Akhter

ORCID ID

https://orcid.org/0000-0001-8878-5970

Contact details

Population Health Sciences Institute Newcastle University Newcastle upon Tyne United Kingdom NE24AX +44 1912083823 zainab.akhter@newcastle.ac.uk

Type(s)

Public

Contact name

Dr Eleanor Dyer

ORCID ID

https://orcid.org/0000-0002-4797-1459

Contact details

Population Health Sciences Institute Newcastle University Newcastle upon Tyne United Kingdom NE24AX +44 1912083823 eleanor.dyer@newcastle.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

326070

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 60504

Study information

Scientific Title

Food, Pregnancy and Me: Exploring food insecurity in pregnancy in the UK to inform future public health intervention needs

Study objectives

This study aims to explore the prevalence, experiences and health impact of FI in pregnancy in England to develop strategic recommendations for intervention strategies.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 04/04/2024, Newcastle & North Tyneside 1 Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 2071048384; newcastlenorthtyneside1. rec@hra.nhs.uk), ref: 24/NE/0027

Study design

Multi-centre observational cohort study and qualitative interview study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Food insecurity during pregnancy

Interventions

Questionnaires exploring diet quality, food security, mental health, and other health behaviours will be distributed to all women and pregnant people in their third trimester in two NHS Trusts in England

Intervention Type

Other

Primary outcome(s)

- 1. Maternal antenatal depression measured using the Edinburgh Postnatal Depression Scale in the third trimester of pregnancy
- 2. Infant preterm delivery (less than 37 weeks gestation) will be obtained from routine maternity records after delivery
- 3. An understanding of the experiences and support needs of food insecure pregnant people collected during interviews in the third trimester or after delivery

Key secondary outcome(s))

- 1. Maternal outcomes measured during pregnancy and delivery: gestational diabetes, preeclampsia, pregnancy induced hypertension, mode of delivery, induction, length of stay in maternity unit, maternal diet/nutrition measured using an adapted version of the Brief Diet Quality Assessment Tool
- 2. Child outcomes measured at birth and in the neonatal period: birthweight, large- and small-for gestational age, breastfeeding initiated/at discharge from maternity services, admission to special care baby units (and length of stay), Apgar score

Completion date

31/10/2025

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 15/10/2025:

- 1. Pregnant women and people
- 2. Age 16 years and above
- 3. In their third trimester of a viable pregnancy (28-40 weeks gestation)
- 4. Registered for maternity services at Queen Elizabeth Hospital Gateshead or University Hospital Coventry

Previous key inclusion criteria:

- 1. Women and pregnant people
- 2. Age 16 years and above
- 3. Pregnant and in their third trimester of a viable pregnancy (28-40 weeks gestation)
- 4. Registered for maternity services at Queen Elizabeth Hospital Gateshead or University Hospital Coventry

Participant type(s)

Population, Service user

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

Female

Total final enrolment

610

Key exclusion criteria

- 1. Under 16 years of age
- 2. Non-residents of the UK
- 3. Pregnant but less than 38 weeks gestation
- 4. Post-partum
- 5. Receiving care by maternity services other than those based at Queen Elizabeth Hospital Gateshead or University Hospital Coventry

Date of first enrolment

08/07/2024

Date of final enrolment

31/05/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Gateshead Hospitals NHS Trust

Queen Elizabeth Hospital Sherriff Hill Gateshead United Kingdom NE9 6SX

Study participating centre

University Hospitals Coventry and Warwickshire NHS TrustUniversity Hospital

University Hospital Clifford Bridge Road Coventry United Kingdom CV2 2DX

Sponsor information

Organisation

Newcastle University

ROR

https://ror.org/01kj2bm70

Funder(s)

Funder type

Government

Funder Name

School for Public Health Research

Alternative Name(s)

NIHR School for Public Health Research, NIHR SPHR, SPHR

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made 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?
<u>Protocol article</u>		07/05/2025	08/05/2025	Yes	No
Participant information sheet			07/11/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes