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

| Submission date | Recruitment status | Prospectively registered |
|-------------------|--------------------------|--|
| 06/11/2024 | No longer recruiting | [X] Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 07/11/2024 | Ongoing | Results |
| Last Edited | Condition category | Individual participant data |
| 08/05/2025 | Pregnancy and Childbirth | [X] Record updated in last year |

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

Study website

https://sphr.nihr.ac.uk/food-pregnancy-and-me/

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

326070

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital, Medical and other records

Study type(s)

Other

Participant information sheet

See study outputs table

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 measure

- 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

Secondary outcome measures

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

Overall study start date

01/01/2023

Completion date

31/10/2025

Eligibility

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

Age group

Adult

Lower age limit

16 Years

Sex

Female

Target number of participants

605

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

30/04/2025

Locations

Countries of recruitment

England

United Kingdom

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 Trust

University Hospital Clifford Bridge Road Coventry United Kingdom CV2 2DX

Sponsor information

Organisation

Newcastle University

Sponsor details

Faculty of Medical Sciences Newcastle upon Tyne England United Kingdom NE1 7RU +44 191 208 6338 susanne.lewis@newcastle.ac.uk

Sponsor type

University/education

Website

https://www.ncl.ac.uk/

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

Publication and dissemination plan

We plan to publish the study protocol in a peer-reviewed open access journal. We also plan to have five journal articles using reporting outputs from this study. All will be published open access. These will be:

- 1. Food insecurity prevalence
- 2. Food insecurity impact on maternal nutrition and diet quality
- 3. Food insecurity impact on maternal and child health outcomes
- 4. Economic analysis
- 5. Qualitative research with women experiencing food insecurity

Intention to publish date

01/12/2025

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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| Participant information sheet | | | 07/11/2024 | No | Yes |
| <u>Protocol article</u> | | 07/05/2025 | 08/05/2025 | Yes | No |