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Prevent from home: young person and buddies' cardiovascular health improvement feasibility study

Submission date
27/11/2024

Recruitment status
Recruiting

Registration date
22/01/2025

Overall study status
Ongoing

Last Edited
18/03/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Heart attacks and strokes cause the greatest number of preventable deaths in the UK. People from ethnic minority groups and those with socioeconomic deprivation are most severely affected. Women who develop high blood pressure or diabetes during pregnancy are up to ten times more likely to develop these problems in later life. New medications (sodium glucose transport protein-2 inhibitors, SGLT2i) can prevent heart attacks, strokes and kidney disease, they also reduce weight, blood pressure, and blood sugar but we do not know if they can prevent high blood pressure and diabetes development.
Women find it very difficult to take part in research in the postnatal period, particularly those from ethnic minorities. We have spoken to patients with lived experience of pregnancies complicated by high blood pressure and diabetes, in addition to members of the public, and co-designed a study to ensure the design best supports postnatal participation.
This is a feasibility study of a randomised controlled trial which will compare outcomes of women (and their study-buddies) who take SGLT2i with women who do not, and explore different ways to support postnatal women taking part in maternity research.

Who can participate?
Part A:
Person aged 18 years and over with current pregnancy, or within 6 weeks of pregnancy, complicated by hypertension

Part B:
Postpartum person (including people not identifying as female) aged 18 years and over with previous pregnancy complicated by HDP and/or GDM

Study buddy:
Aged 18 – 60 years with one or more pre-CVD risk factors:
1. Pre-hypertension
2. Parent or sibling with diabetes /body mass index (BMI) >30 kg/m2 /age >25 years if African Caribbean, Black African, or South Asian) AND HbA1C ≥42-47 mmol/mol (6-6.4%)

OR
3. Postpartum person with a previous pregnancy complicated by HDP and/or GDM

What does the study involve?
The study involves:
1. Using ‘postpartum health champions’ to support women taking part in the study
2. Home-testing and digital data entry
3. Using ‘study-buddies’ (a friend or family member with pre-diabetes or borderline high blood pressure) to support
women taking part in the study, in addition to increasing awareness and reassurance about research

What are the possible benefits and risks of participating?
Participants may be apprehensive about taking the study medication 'off label' but the approaching team member and study PIL will endeavour to provide participants with all the information they require to make an informed decision as to whether they take part. This will include ensuring participants understand that participation is voluntary and that they can stop taking part at any point. The prescribing healthcare professional will explain the medication's side effects, as per usual practice.
The study has been designed (with PPIE embedded) to facilitate recruitment and reduce participant burden. For example by reducing in-person contacts to two visits, and all other monitoring completed at home with digital data entry. Testing devices such as weighing scales and BP monitors can be kept after the study has finished. Study-buddy and postpartum champions will work to support study participation. A £10 gift voucher will thank participants for returning samples collected at home.
All clinical interventions included as part of this study are routinely administered and will not have additional risks above usual clinical care.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
November 2024 to December 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Kate Bramham, kate.bramham@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ann-Marie Murtagh

Contact details
King’s Health Partners Clinical Trials Office
Floor 16, Tower Wing

Guy’s Hospital
Great Maze Pond
London
United Kingdom
SE19RT
+44 (0)20 71885732
QM.KHPCTO@kcl.ac.uk

Type(s)
Scientific

Contact name
Dr Jasmine Palmer

Contact details
The R&I Office
First Floor Coldharbour Works
245A Coldharbour Lane
London
United Kingdom
SW98RR
+44 (0)20 32991980
kch-tr.research@nhs.net

Type(s)
Principal investigator

Contact name
Dr Kate Bramham

Contact details
Weston Education Centre
10 Cutcombe Road
London
United Kingdom
SE5 9RJ
+44 (0)7776 210747
kate.bramham@kcl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1008673

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
3641PHYLLIS

Study information

Scientific Title
Prevent from home: young person and buddies' cardiovascular health improvement feasibility study (PHYLLIS)

Acronym
PHYLLIS

Study objectives
To undertake a feasibility study for a randomised controlled trial comparing sodium glucose transport protein-2 inhibitors (SGLT2i) and standard care in postpartum women with risk factors for cardiovascular disease, with peer support, co-recruitment (study-buddy) and remote monitoring.

Secondary process objectives:
1. To determine adaptations to meet the needs of different under-served communities
2. To explore the feasibility and acceptability of:
2.1. Recruiting peer-educator postpartum health champions
2.2. Co-recruitment of study-buddies
2.3. Novel community/home-based assessments of early endothelial dysfunction

Secondary clinical objectives:
To compare longitudinal changes in clinical parameters (including blood pressure, weight, cardiometabolic profile, anthropometric measures including waist, hip and upper arm circumference) for participants (and study-buddies) between study arms

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/01/2025, London - South East Research Ethics Committee (Health Research Authority, 2 Redman Place , London , E20 1JQ, United Kingdom; +44 (0)207 104 8222, +44 (0)207 104 8177, +44 (0)207 104 8263; londonsoutheast.rec@hra.nhs.uk), ref: 24/LO/0902

Study design
Open randomized controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypertension in pregnancy, gestational diabetes

Interventions
1:1 randomisation of postpartum individuals, who had pregnancies complicated by hypertensive disorders of pregnancy and/ or gestational diabetes, who have completed breastfeeding, to either 10 mg dapagliflozin once daily for 26 weeks, or standard care, with both arms offered additional support for participation in the form of remote monitoring, peer support or co-recruitment ("study buddy"). The follow-up period will be 52 weeks in total.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Dapagliflozin

Primary outcome(s)
The overall recruitment rate of postpartum participants with hypertension in pregnancy and/or gestational diabetes (number of participants per site per month, assessed at end of study). Determined from screening logs with eligibility criteria met and reasons for exclusion reported at the end of the study, defined as a database lock.

Key secondary outcome(s))
Process Endpoints:
1. Overall uptake and recruitment rate of study-buddies assessed at the end of the study. Determined from screening logs with eligibility criteria met and reasons for exclusion reported.
2. Longitudinal assessment of retention of postpartum participants and study buddies across both arms (assessed at end of study)
3. Number of blood pressures, weights, pregnancy test results, urine-dip results (at 26 weeks for each participant, total number assessed at end of study) from home results sent in by participants on the clinical portal (MyChart, or local patient electronic portal).
4. Number of returned blood and urine tests at 26 weeks
5. Acceptability and experience of all study activities: end of study survey with postpartum participants and study buddies at 52 weeks; focus group with postpartum participants, study buddies and health champions at 26 and 52 weeks*
6. Study resource use: contacts with health champions, time for health champion training, expenditure on printing (£), time (hours) on recruitment and data extraction, home testing kit use (at 26 weeks and 52 weeks)

Clinical Endpoints:
7. Adherence to daily SGLT2i (intervention arm) assessed either at 26 weeks by a member of the research team pill-counting, or by reviewing 4 weekly photographs of drug blister packs
8. Pregnancy rate during the study period (Part B) and pregnancy outcomes (pregnancy tests performed 4 weekly, overall pregnancy rates assessed at the end of the study) recorded in the Macro database
9. Longitudinal changes in BP and weight at 4 weekly intervals, and 26 and 52 weeks sent in by participants on the clinical portal (MyChart or local patient electronic portal) and recorded in the Macro database
10. Longitudinal changes in creatinine, HbA1C, lipid profile and liver function tests (Thriva) and albumin creatinine ratio (ACR) (Synnovis) at 2, 14, and 38 weeks from home testing recorded in the Macro database

11. Longitudinal changes in anthropometric measures (waist, hip and upper arm circumference), creatinine, cystatin, HbA1C, cholesterol and ACR at baseline, 26 and 52 weeks from onsite testing (Synnovis) recorded in Macro database

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Part A:
1. Person with current pregnancy, or within 6 weeks of pregnancy, complicated by hypertension
2. Able to provide written informed consent
3. Age ≥ 18 years
4. Body mass index >17 kg/m2

Part B:
Postpartum person (including people not identifying as female):
1. Previous pregnancy complicated by HDP and/or GDM (defined by NICE) ≤12 months
2. Able to provide written informed consent
3. Age ≥18 years
4. Completed breastfeeding
5. Body mass index >17 kg/m2

Study buddy:
1. Able to provide written informed consent
2. Age 18 – 60 years with ≥1 pre-CVD risk factor:
2.1. Pre-hypertension (systolic BP 120-139 mmHg and/or diastolic BP 80-89 mmHg)
2.2. Parent or sibling with diabetes or body mass index >30 kg/m2 AND age>40 years if White or age>25 years if African Caribbean, Black African, or South Asian AND Haemoglobin A1c ≥42-47 mmol/mol (6-6.4%)
OR
2.3. Postpartum person with a previous pregnancy complicated by HDP and/or GDM >12 months
3. Body mass index >17 kg/m2

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria

Part A:
Pregnant or postpartum person (including people not identifying as female) with:
1. Diabetes (Type 1 or 2)
2. Chronic kidney disease or heart failure and recommended routine SGLT2i
3. Liver disease (AST/ALT >2x upper limit of normal)
4. Allergy to dapagliflozin or its excipients
5. Hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption
6. Moving away from the study site within 12 months
7. Severe hepatic impairment
8. Contraindication to postpartum enalapril, amlodipine, nifedipine, or labetalol - including allergy
9. Planning pregnancy ≤6 months

Part B:
Postpartum person (including people not identifying as female) and study-buddies with:
1. Diabetes (Type 1 or 2)
2. Chronic kidney disease or heart failure and recommended routine SGLT2i
3. Liver disease (AST/ALT > 2x upper limit of normal)
4. Allergy to dapagliflozin or its excipients
5. Hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption
6. Pregnant, planning pregnancy within 6 months or breastfeeding (females of childbearing potential* with a positive pregnancy test at screening)
7. Moving away from the study site within 12 months
8. Severe hepatic impairment

Date of first enrolment
31/03/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
King's College Hospital NHS Foundation Trust

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes