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A study evaluating a new digital tool for early pregnancy risk assessment in primary care

Submission date
05/07/2026

Recruitment status
No longer recruiting

Registration date
18/08/2026

Overall study status
Completed

Last Edited
21/07/2026

Condition category
Pregnancy and Childbirth

[_] 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
Some people have physical, mental health, or social circumstances that increase their chance of developing complications during pregnancy. Finding these risk factors as early as possible can help healthcare professionals provide the right care, support and referrals. However, many pregnant people do not have their first hospital maternity appointment until several weeks after they discover they are pregnant.
For many people, their GP practice is the first healthcare service they contact when they become pregnant. This study will evaluate a new digital tool called MpRisk, which is designed to help healthcare professionals identify people who may need additional support as early as possible. MpRisk reviews information that is already recorded in the patient's GP medical record and highlights factors that may increase the risk of complications during pregnancy. The tool is designed to support healthcare professionals and does not replace their clinical judgement or routine maternity care.

Who can participate?
Pregnant people aged 16 to 51 years who are registered with one of the participating GP practices and notify their GP that they are pregnant can take part. People who have chosen not to allow their GP data to be used for research (Type 1 Opt-out) will not be included.

What does the study involve?
Around 300 pregnant people will take part across five GP practices in London. Some practices will use MpRisk as part of their routine assessment when a pregnancy is reported, while the remaining practices will continue to provide their usual care without the tool.
Healthcare professionals using MpRisk will receive a summary of any identified pregnancy risks based on information already held in the patient's GP record. This may help them decide whether additional assessment, referral or support would be helpful. Clinical researchers will compare the two groups to see how well pregnancy risks are identified and will also ask healthcare professionals about their experiences of using the software.

What are the possible benefits and risks of participating?
The study may help identify pregnancy risks earlier, allowing healthcare professionals to offer more personalised care and support.

The risks are expected to be very low because MpRisk only analyses information that is already recorded in medical records. It does not replace routine care, and all clinical decisions remain the responsibility of the healthcare professional.

Where is the study run from?
The study is being carried out at five GP practices in London, England, and is sponsored by First 4 Health Group (UK)

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

Who is funding the study?
SBRI Healthcare (UK)

Who is the main contact?
Dr Kendra Wong, kendra.wong@nhs.net

Contact information

Type(s)
Principal investigator, Scientific, Public

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Type(s)
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Integrated Research Application System (IRAS)
343982

Study information

Scientific Title
Cluster controlled clinical trial evaluating a novel digital antenatal risk-assessment software for early identification of pregnancy risks in primary care

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/01/2025, London - London Bridge Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8222; londonbridge.rec@hra.nhs.uk), ref: 24/LO/0857

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Screening

Study type(s)

Health condition(s) or problem(s) studied
Pregnancy, with assessment of clinical, mental health, and social risk factors associated with adverse maternal and perinatal outcomes

Interventions
MpRisk is a digital antenatal risk assessment and clinical decision support software used at the point of pregnancy notification in primary care. When a pregnant individual notifies their GP practice of their pregnancy, the software analyses routinely collected demographic, clinical, mental health, and social information to identify and stratify individuals according to their risk of adverse maternal outcomes.

The software generates a risk profile to support healthcare professionals in the early identification of individuals who may benefit from enhanced assessment, referral, or tailored care. MpRisk is used alongside existing clinical pathways and local standard practice and does not replace routine antenatal care or clinical decision-making.

The purpose of the intervention is to facilitate earlier recognition of bio-psychosocial risk factors and support timely, needs-based care during pregnancy.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
1. Accuracy of pregnancy risk stratification measured using comparison with clinician review of participant medical records at completion of the initial pregnancy risk assessment

Key secondary outcome(s)
1. Healthcare professional experience of using MpRisk measured using semi-structured interviews independently conducted by a third-party evaluation partner using a predefined interview guide at the end of the study period

Completion date
29/08/2025

Eligibility

Key inclusion criteria
Pregnant individuals aged 16–51 years who are registered at the study site and are identified following notification of their pregnancy to their GP practice

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
16 Years

Upper age limit
51 Years

Sex
Female

Total final enrolment
300

Key exclusion criteria
Individuals with a recorded Type 1 Opt-out in their GP record are automatically excluded from the study

Date of first enrolment
03/01/2025

Date of final enrolment
04/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Church Road Health
1st Floor, The Centre Manor Park, 30 Church Rd
London
England
E12 6AQ

Study participating centre

Stratford Village Surgery
50c Romford Road
Stratford
London
England
E15 4BZ

Study participating centre
E7 Health
121 Woodgrange Rd
London
England
E7 0EP

Study participating centre
Glen Road Medical Centre
1-9 Glen Rd
London
England
E13 8RU

Study participating centre
Liberty Bridge Road Practice
Ludwig Guttman Centre
40 Liberty Bridge Road
Stratford
London
England
E20 1AS

Sponsor information

Organisation
First 4 Health Group

Funder(s)

Funder type

Funder Name
SBRI Healthcare

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available