

# The feasibility and implementation of the Psychosis Risk Prediction Algorithm

<b>Submission date</b> 05/12/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/01/2024	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 10/03/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Psychosis is a mental illness. Symptoms include hallucinations and strange, fixed thoughts, called delusions. Psychosis can be devastating for sufferers and their families and outcomes are often poor with many people becoming ill again after recovery. Only about 20% of people with psychosis are in paid employment and many have a poor quality of life. Physical health is also poorer with a life expectancy 15-20 years shorter than average. Treating psychosis costs the NHS about £2 billion per year. The best way to improve outcomes is to ensure that people who are at risk of psychosis receive specialist care quickly. However, being able to identify people at risk of psychosis has proved difficult.

Most people enter specialist mental health care via their GP, but GPs report difficulties in detecting the warning signs of psychosis. Also, people do not always see the same GP when they visit their surgery and so small changes in their mental health can be missed. A computer tool, called P risk has been developed using a very large data set of GP records to teach the computer to spot who is likely to develop psychosis. P Risk has already proven to be accurate and can predict who will get psychosis about 80% of the time. However, it is not yet known if it will work in the real world on GP computers, or what patients, their families, GPs and mental health staff think about it. This information is needed before P Risk can be used in GP surgeries. This study aims to examine if it is feasible and acceptable to practitioners, patients, and carers to implement a psychosis risk prediction algorithm in primary care.

### Who can participate?

As part of the qualitative work, we will conduct interviews with GPs, clinicians working in the Early Intervention Services, and patients (aged 18+ years old) who have consulted their GPs over the last six months for non-psychotic symptoms (e.g. depression or problems with sleep) and their carers.

### What does the study involve?

In this study, the team will: 1) work with the company that provides software for GP computers to make sure that P Risk works on their computers 2) work out the accuracy of P Risk in clinical practice, and 3) explore practitioner, patients' and carers' views on how P Risk should be used in practice and how its results should be communicated between practitioners and between

practitioners and patients. This information will help us develop the next stage of our work, which will investigate whether P Risk is effective at helping GPs identify people at risk of developing psychosis.

What are the possible benefits and risks of participating?

Whilst there are no individual benefits from taking part in the study, participants will make an important contribution to the P Risk research project. As a thank you for their time, we will offer patients and their carers an online shopping voucher.

There is a small chance that some patients taking part in the interview may become distressed when talking about their own experiences. The researchers running the interviews will be trained to manage this situation if it occurs. If the researcher is concerned about the mental well-being of the patient, they will advise the patient to contact their GP or mental health clinician as soon as possible.

Where is the study run from?

1. University of Bristol (UK)
2. University College London (UK)

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

March 2022 to March 2026

Who is funding the study?

NIHR RfPB Biomedical Research Centre (UK)

Who is the main contact?

Sarah Sullivan, sarah.sullivan@bristol.ac.uk

### **Study website**

<https://prisk.blogs.bristol.ac.uk/>

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

Dr Sarah Sullivan

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## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

315320

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

2022 - 1178 version 0.8, 23.05.2023, IRAS 315320, CPMS 53885

## Study information

**Scientific Title**

The feasibility and implementation of a Psychosis Risk Prediction Algorithm (P Risk) for use in primary care

**Acronym**

P Risk

**Study objectives**

To determine the operationalisation and acceptability of using P Risk in real-world clinical situations

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 15/03/2023, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +4 (0)207 104 8290; gmeast.rec@hra.nhs.uk), ref: 22/NW/0289

**Study design**

Multi-centre observational study

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

GP practice, Medical and other records

**Study type(s)**

Screening

**Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Early Identification of people at risk of psychosis in Primary Care Services

## **Interventions**

This is a multi-centre observational study. The study aims to: i) demonstrate whether P Risk can be implemented in primary care data systems; ii) investigate the accuracy of P Risk using real-world primary care data systems; and iii) investigate the acceptability of P Risk to practitioners, patients, and carers.

### **Study design:**

Work package 1: Conversion of the P Risk statistical algorithm into a code that is compatible with EMIS medical records software. The P Risk algorithm will be run on the historical EHRs of every patient over the previous 5 years to investigate any 'bugs' in the functioning of P Risk in EMIS software.

Work package 3: Investigate the accuracy of P Risk in real-world data by calculating the sensitivity (true positives) and specificity (true negatives) of P Risk (number of diagnoses of psychosis correctly picked up by P Risk) against the gold standard of a coded psychosis diagnosis

Work package 4: In-depth interviews will be held with GPs and focus groups/individual interviews will be held with those on whom it would be used and those affected by it (patients and their carers), to explore their views on the acceptability and potential value and implications of using P Risk in general practice. As P Risk may alter referrals from general practice to Early Intervention Teams (EITs), interviews will also be held with EIT staff to assess their views of P Risk, and their thoughts about GPs making referral decisions informed by P Risk and whether they would accept referrals on this basis.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Coded incident diagnosis of First Episode Psychosis (FEP) or an At-Risk Mental State (ARMS) recorded in primary and/or secondary care EHRs measured using medical records at one timepoint
2. Patients' and clinicians' views on the acceptability and potential value and implications of using P Risk in general practice measured using interviews with GPs and focus groups/individuals at one timepoint

## **Secondary outcome measures**

1. Whether the P Risk threshold for high, medium or low is optimal
2. Calibration in two subsamples of patients measured using a coded diagnosis of psychosis at one time point:
  - 2.1. Afro-Caribbean ethnicity
  - 2.2 Older women (50-65 years of age)), where there is evidence that they are at increased risk

## **Overall study start date**

14/03/2022

## **Completion date**

31/03/2026

## **Eligibility**

## **Key inclusion criteria**

Work package 1:

1. GP practices which use EMIS clinical records software
2. All GP practices in the Bristol, North Somerset and South Gloucestershire CCG (BNSSGCCG) region use EMIS software

Work package 3:

GP practices which use EMIS clinical records software.

Work package 4:

1. GPs from BNSSG and the London area
2. Clinicians from the Early Intervention Services within Avon and Wiltshire NHS Foundation Trust and the London area, who provide assessments for people at risk of psychosis
3. Patients who consulted their GP within the last six months for non-psychotic mental health problems
4. Patients' carers

## **Participant type(s)**

Patient, Health professional, Carer

## **Age group**

Mixed

## **Lower age limit**

18 Years

## **Upper age limit**

80 Years

## **Sex**

Both

## **Target number of participants**

Work package 1: Population One Primary Care Network (PCN) in Bristol, North Somerset and South Gloucestershire CCG (BNSSGCCG) region. Sample Size: 4 GP practices with approximately 64,000 patients registered. Work package 3: All BNSSGCCG GP practices. Sample size: Approximately 1 million patients whose GP electronic health records are linked to secondary care mental health electronic health records. Work package 4: between 10-12 GPs, 6-8 EIT clinicians, between 16-32 patients in up to 4 focus groups (or ~15 patients in individual interviews), between 8 and 16 carers in between 2-4 focus groups (or 6-8 carers in individual interviews)

## **Total final enrolment**

29

## **Key exclusion criteria**

Work package 1:

There are no participant exclusion criteria

Work package 3:

Any patient with an existing coded diagnosis of psychosis either in primary or secondary care EHRs or any recorded prescription for anti-psychotic medication at a dosage appropriate for psychosis

Work package 4:

Inability to provide informed consent

**Date of first enrolment**

16/03/2023

**Date of final enrolment**

31/12/2023

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bristol, North Somerset and South Glos. CCG**

17 Marlborough Street

Bristol

United Kingdom

BS1 3NX

**Study participating centre**

**London CCGs**

London

United Kingdom

N1 1TH

**Study participating centre**

**Avon and Wiltshire Mental Health Partnership NHS Trust**

Bath NHS House

Newbridge Hill

Bath

United Kingdom

BA1 3QE

**Study participating centre**

**Barnet, Enfield and Haringey Mental Health NHS Trust**  
London  
United Kingdom  
N15 3TH

**Study participating centre**  
**Tavistock and Portman NHS Foundation Trust**  
The Tavistock Centre  
120 Belsize Lane  
London  
United Kingdom  
NW3 5BA

**Study participating centre**  
**Central and North West London NHS Foundation Trust**  
Trust Headquarters  
350 Euston Road  
Regents PLACE  
London  
United Kingdom  
NW1 3AX

**Study participating centre**  
**Camden and Islington NHS Foundation Trust**  
St Pancras Hospital  
4 St Pancras Way  
London  
United Kingdom  
NW1 0PE

## **Sponsor information**

**Organisation**  
University of Bristol

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England  
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**Sponsor type**

University/education

**Website**

<https://bristol.ac.uk/>

**ROR**

<https://ror.org/0524sp257>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Research for Patient Benefit Programme

**Alternative Name(s)**

NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in open-access high-impact journals, targeting primary and secondary care researchers. These articles will be promoted via Twitter, through departmental newsletters and websites, and mailing lists, such as those used by the University of Bristol, the Society for Academic Primary Care and the NIHR School for Primary Care Research (SPCR). Study outputs will also be presented at national and international primary care and mental health conferences. Blogs written by team members summarising findings will be posted online and promoted via Twitter. The PPI group will advise on how best to disseminate findings to different audiences. All participants will be sent a summary of the findings.



## Intention to publish date

28/02/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Paul Roy (quantitative data) (paul.roy1@nhs.net) or Daniela Strelchuk (qualitative data) (daniela.strelchuk@bristol.ac.uk). Data will become available after publishing the paper for a period of 5 years. Anonymous data will be shared with other researchers. Data will be shared via secure data transfer. Consent has been obtained from interviewees (from the qualitative work) to share the information collected anonymously with other researchers).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 1.7		19/12/2023	No	Yes
<a href="#">Protocol file</a>	version 0.8	23/05/2023	19/12/2023	No	No