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The feasibility and implementation of the Psychosis Risk Prediction Algorithm

Submission date
05/12/2023

Recruitment status
No longer recruiting

Registration date
03/01/2024

Overall study status
Ongoing

Last Edited
10/03/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315320

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Screening

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

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
United Kingdom

England

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

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

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?
Participant information sheet	version 1.7		19/12/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.8	23/05/2023	19/12/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes