

# Early Youth Engagement in First Episode Psychosis (EYE-2) Randomised Controlled Trial

<b>Submission date</b> 07/05/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/09/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Around 7,500 young people in England develop psychosis every year. It is a severe mental health problem that generally starts in people aged 14-35 and has long-term effects. People who experience psychosis die up to 25 years earlier than the general population from suicide and physical health problems. The financial cost to society is high: £11.8 billion per year. Early intervention in the first 3 years of psychosis can improve long-term outcomes so that people have fewer symptoms and hospital admissions, better health, and reduced suicide risk. A 3-year Early Intervention in Psychosis (EIP) service also saves £5,000 per person per year just by reducing hospital admissions, and saves £15 for every £1 spent on EIP services. However, at least a quarter of all young people drop out of services in the first 12 months, leading to greater risk of poor health and more long-term service use. Families also struggle more. Ensuring that young people receive a service quickly is a current NHS priority, but there are no interventions to improve engagement with services. This study is about improving services for people who have a first episode of psychosis so that more people want to stay with the service and benefit from its support. The first Early Youth Engagement (EYE) project developed a new approach with young people, their parents and Early Intervention in Psychosis (EIP) staff. The EYE approach addresses the issues that can put people off services, like the way staff talk with them; how much family & friends are included, and how much it helps with their goals, treatment choices and preferences. The EYE approach includes a website, booklet series co-written with young people, and other resources to support young people and families; and a training programme for staff in how to work flexibly, honestly and openly using key, well established "motivational" techniques to help young people achieve their goals. In the pilot study, more young people were engaged with the new approach at 12 months. Service users and carers said it helped with isolation, trust, personal goals, better communication with the service, shared decision making with staff, and family involvement. The aim of this study is to build on what was learnt, and to test whether the new EYE-2 approach helps young people to stay engaged with services, and whether it saves money, in more NHS services around the UK. It will develop a toolkit to support other services that want to introduce the approach.

### Who can participate?

Young people aged 14-35 in 20 EIP services in Manchester, London, Norfolk-Cambridge, Hampshire and Thames Valley

What does the study involve?

EIP teams are randomly allocated to one of two groups. Half of the teams deliver the EYE-2 approach and the other half work as usual. EYE-2 resources will be adapted for people from ethnic minorities and the researchers will evaluate how the intervention is delivered and resources are used to ensure the best outcomes. The measure of success is whether more young people stay engaged in the service for longer. The study also tests whether they have better mental health, work experience, social life, recovery, service satisfaction, and whether the approach saves money.

What are the possible benefits and risks of participating?

The findings will help to decide whether the EYE-2 treatment is helpful and affordable for use in EIP services, so they can offer the best service. There are no immediate advantages to taking part in the study but some people enjoy taking part in these types of project, where they can share their views and experiences. It is possible that talking about their health, work or services might make them feel upset, or talking for this long might make them feel tired. Participants can take a break or stop at any time during the interview, without having to give a reason. If they have any concerns, they can talk to their friends, family, an independent person, or a researcher.

Where is the study run from?

1. South London and Maudsley NHS Foundation Trust
2. Southern Health NHS Foundation Trust
3. Greater Manchester Mental Health NHS Foundation Trust
4. Oxford Health NHS Foundation Trust
5. Cambridgeshire and Peterborough NHS Foundation Trust
6. Norfolk and Suffolk NHS Foundation Trust
7. Berkshire HealthCare NHS Foundation Trust
8. Central and North West London NHS Foundation Trust

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

June 2018 to January 2022

Who is funding the study?

Health Services and Delivery Research Programme (UK)

Who is the main contact?

Prof. Kathryn Greenwood

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## Contact information

**Type(s)**

Scientific

**Contact name**

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**Contact details**

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

238744

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

CPMS 37742

## **Study information**

### **Scientific Title**

The Early Youth Engagement in first episode psychosis (EYE-2) study: pragmatic cluster randomised controlled trial of implementation, effectiveness & cost effectiveness of a team-based motivational engagement intervention to improve engagement

### **Acronym**

EYE-2

### **Study objectives**

The primary hypothesis is that the EYE-2 intervention delivered within the standard Early Intervention in Psychosis (EIP) service will improve engagement compared to the standard EIP service alone in people with first episode psychosis attending EIP services.

Secondary hypotheses are that the EYE-2 intervention will also (ii) improve mental health outcomes; (iii) improve recovery, quality of life & satisfaction; (iv) Outcomes will be moderated by implementation as measured by the process evaluation questionnaires & (v) the intervention will be cost-effective with potential societal and NHS cost-savings.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 10/05/2018, London - Dulwich Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, Tel: +44 (0)20 7972 2561; Email: nrescommittee.london-dulwich@nhs.net), ref: 18/LO/0362/AM01

## **Study design**

Multi-site cluster randomized controlled trial with single-blind rating of primary outcome, comparing the EYE-2 intervention + standardised Early Intervention in Psychosis (EIP) service to standardised EIP service alone. Randomisation is at team level, stratified by site (Manchester, London, Thames Valley, Norfolk-Cambridge, Hampshire) using Sealed Envelope.

A process evaluation will investigate what is delivered, how it is delivered and fidelity to the intervention deductively using a Normalisation Process Theory framework, prospectively using logic models in a 2-year longitudinal study; and qualitatively in interviews with purposively sampled clinicians and managers from each service.

A cost-effectiveness analysis will be conducted from a broad societal perspective with secondary analysis of cost-effectiveness from an NHS (commissioner and provider) perspective.

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Young People (14-35 years) with first-episode psychosis (F20-F29; F31 ICD-10) as determined by each local service according to their own established criteria

## **Interventions**

The team-based motivational engagement (EYE-2) intervention, is delivered by EIP clinicians, supported by training, an intervention manual, website, 5 booklet series, friends and family involvement, and social group protocols and is incorporated into standard Early Intervention in Psychosis teams.

The comparison is standard EIP teams. All participating teams meet the following specific inclusion criteria: (i) standalone EIP service with at least 2 discrete teams; (ii) willingness and capacity for involvement as agreed by clinical services; (iii) individual team size of at least 40 new clearly defined first episode cases per year aged 14-35; (iv) currently capturing NHS England mandated routine outcome data; (v) geographical spread to include urban and rural locations, ethnic minority variations, North and South of England.

The implementation tool kit is a set of hard copy resources that will be provided to each clinician as part of the training. It will comprise a single reference set of (i) the implementation manual; (ii) the 5 booklets (mental health and help-seeking, EIP, for friends and family, treatment choices, getting the most out of hospital); (iii) the EYE-2 team and individual implementation checklists and (iv) the links to the website and training videos.

Whilst the EIP model outlines what should be done, the EYE-2 intervention is complementary to this pathway, providing detail regarding how staff and service should operate, and the tools, resources and breadth of social network with which they should work to promote better engagement.

The EYE-2 intervention is framed around a novel therapeutic engagement model derived from a previous study (The EYE project) and a subsequent implementation study. It is based on motivational interviewing & open social communication, and includes the following approaches and resources:

1. Communication: transparent, open & honest communication

All staff are trained by the EYE team in open communication approaches, supported by the website & myth-busting booklet series, which address young people's real concerns in a direct, honest manner.

2. Social Involvement: support for the whole social network

Staff and service users are encouraged to draw on a wide social network of friends, family and peers, supported by the friends and family booklet and service user-led social groups run by the Patient and Public Involvement lead, and research assistant. Training is provided in carers' rights, and in processes for involving friends & family.

3. Mental Health Service: collaboration & choice regarding difficult treatment issues

Collaboration and choice is supported by the staff training, and service user led training videos regarding difficult treatment issues, risk and hospital admission. It is supported by the 'challenges you may face' section on treatment in the Family and Friends booklet and by the 'Treatment choices booklet', a comprehensive, highly valued, user-friendly, honest review of treatment options, co-produced with service users, carers, and all clinical disciplines.

4. Mental Health Staff: hopeful support for meaningful goals & needs

The staff training, based on motivational interviewing & open social communication, is supported by service user led training videos, and promotes a hopeful, motivational, goals-focussed approach.

5. Addressing personal barriers

Personal barriers to engagement are addressed by reaching out to service users through the discussion forum on the website, the 'addressing personal barriers to talking' sections in the booklets, and the social groups that are attended and co-led by service users.

### The training

The EYE training is delivered by the central EYE team, local PPI lead, local service users, and carer at each site to provide local service connections, supported practically by the site research assistant. Core sessions include: (i) Introduction to the EYE intervention and resources; (ii) value of hopeful care coordination; (iii) goal-focussed care-planning; (iv) service user-led introduction to honest open communication; (v) carers rights & family and friends protocol; (vi) peer workers & social groups; (vii) motivational interviewing for goal focussed engagement; (viii) applying open communication approaches in the context of risk. Additional sessions include: (ix) the implementation process - formation of local implementation plans and (x) the research process – ethics, consent and advertising; and training for robust data collection and recording. Training is 2 days for intervention teams and 1/2 a day on robust data collection training for control teams.

The primary outcome is time to disengagement. Secondary outcomes are mental health, social & occupational function, recovery and satisfaction at 6, 12, 18 and 24 months.

A process evaluation will explore intervention delivery, and an economic evaluation will explore cost-effectiveness.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Time to disengagement: time in days from date of allocation to care coordinator to date of last contact following refusal to engage with EIP service, or lack of response to EIP contact for a consecutive 3-month period

## **Key secondary outcome(s)**

Secondary outcomes include mental health, social & occupational function, recovery and satisfaction:

1. Mental health, social and occupational function is measured with the Health of the Nation Outcome Scale (HoNOS) clinician-rated at baseline, 6, 12 (18 and 24 months or until end of study if this is sooner)
2. Recovery is measured by the Questionnaire on the Process of Recovery (QPR) patient-rated at baseline, 6, 12 (18 and 24 months or until end of study if this is sooner)
3. Satisfaction measured by the DIALOG questionnaire at baseline, 6, 12 (18 and 24 months or until end of study if this is sooner)

Process evaluation questionnaire data will be collected from all consenting clinicians at three timepoints:

1. An Adapted NOMAD questionnaire will measure attitudes and approaches towards implementation at start, mid and end of the intervention
2. Fidelity will be measured using a bespoke EYE-2 fidelity checklist at start, mid and end of intervention delivery

Implementation will also be evaluated qualitatively using a brief semi-structured interview to explore barriers and facilitators to intervention delivery, including context and turbulence, across three timepoints at start, mid and end of the intervention.

Finally, the cost-effectiveness analysis will utilise the:

1. Societal costs measured with the Adult Service Use Schedule collected at 12 months
2. NHS costs measured by case-note data on service use for the period from baseline to 12 months, and by the HoNOS questionnaire data at baseline and 12 months

## **Completion date**

31/01/2022

## **Eligibility**

### **Key inclusion criteria**

1. Consecutive referrals to the EIP service during the study recruitment period aged 14-35 years
2. Meeting criteria for a first episode of psychosis (FEP) as determined by each local service according to their own established criteria. The inclusion criteria used to make these decisions will be recorded for each service, and made available for subsequent inspection

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

12 years

**Upper age limit**

35 years

**Sex**

All

**Total final enrolment**

1059

**Key exclusion criteria**

1. A sub-threshold 'at risk mental state', not meeting first episode of psychosis criteria
2. Referral over the age of 35
3. Referrals where there is remaining diagnostic uncertainty about psychosis at 12 months
4. Participants will be withdrawn from the study if (i) they move to a mental health service outside the study or (ii) they move to a service that is in a different arm of the EYE project

**Date of first enrolment**

13/05/2019

**Date of final enrolment**

07/07/2020

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**South London and Maudsley NHS Foundation Trust**

Bethlem Royal Hospital

Monks Orchard Road

Beckenham

London

United Kingdom

BR3 3BX

**Study participating centre**

**Southern Health NHS Foundation Trust**

Research & Development, Tom Rudd Unit, Moorgreen Hospital  
Southampton  
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SO30 3JB

**Study participating centre**

**Greater Manchester Mental Health NHS Foundation Trust**

The Psychosis Research Unit, Rico house, Harrop House, Bury New Road, Prestwich  
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**Study participating centre**

**Oxford Health NHS Foundation Trust**

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**Study participating centre**

**Cambridgeshire and Peterborough NHS Foundation Trust**

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**Study participating centre**

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**Study participating centre**  
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## Sponsor information

**Organisation**  
Sussex Partnership NHS Foundation Trust

**ROR**  
<https://ror.org/05fmrjg27>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Health Services and Delivery Research Programme

**Alternative Name(s)**  
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

**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?
<a href="#">Results article</a>		25/11/2024	26/11/2024	Yes	No
<a href="#">Results article</a>		01/09/2025	15/09/2025	Yes	No
<a href="#">Protocol article</a>		12/04/2021	14/04/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Statistical Analysis Plan</a>		23/10/2021	26/10/2021	No	No