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

Submission date
07/05/2019

Recruitment status
No longer recruiting

Registration date
10/05/2019

Overall study status
Completed

Last Edited
26/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
238744

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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

Secondary outcome measures
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 thee 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

Overall study start date
01/06/2018

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

Age group
Mixed

Lower age limit
12 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
950 participants across 20 clusters, with a minimum of 40 participants per cluster

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
England

United Kingdom

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
United Kingdom
SO30 3JB

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
The Psychosis Research Unit, Rico house, Harrop House, Bury New Road, Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital, Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House
Fulbourn Hospital
Cambridge Road
Cambridge
United Kingdom
CB21 5EF

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital, Drayton High Road

Norwich
United Kingdom
NR6 5BE

Study participating centre
Berkshire HealthCare NHS Foundation Trust
Fitzwilliam House, Skimped Hill Ln
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Central and North West London NHS Foundation Trust
350 Euston Road
Regent's Place
London
United Kingdom
NW1 3AX

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Patient and public involvement (PPI) has taken place at every stage of the project and this will continue. It is vital that young people shape the project and co-deliver the research, ensuring its relevance, usefulness and quality.

The study website will be a focal point for disseminating outputs, through newsletters, presentations, high impact peer-reviewed academic and service user publications and a tailored VLOG to service users, relatives, teams, regional and national networks. Participants will be able to provide comments and suggestions for dissemination. All national services will be invited to a results launch event, which will be recorded and added to the study website, along with other outputs.

The implementation toolkit will be formed into a series of implementation packages, tailored to different contexts, including training, manuals, checklists, website, booklets, schools pack & social involvement protocols.

The primary publications will be (i) the protocol and analysis plan (ii) the randomized controlled trial; (iii) the process evaluation; (iv) the cost-effectiveness study.

Intention to publish date
31/05/2023

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?
Protocol article		12/04/2021	14/04/2021	Yes	No
Statistical Analysis Plan		23/10/2021	26/10/2021	No	No
HRA research summary			28/06/2023	No	No
Results article		25/11/2024	26/11/2024	Yes	No