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

RESEARCH PROTOCOL

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Study 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

Study Acronym: EYE-2

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1. Abstract

Background: Early Intervention in Psychosis (EIP) services improve health outcomes for young people with severe mental illness in the medium-long term, but 25% of young people disengage in the first 12 months at significant cost to their mental health, their families, society & the NHS. Our own feasibility-pilot work clarified the issues that affect engagement. This study will now refine and test the team-based motivational Early Youth Engagement (EYE) intervention to improve engagement and outcomes for young people. A process evaluation will explore implementation across setting.

Objectives: to refine a toolkit, resources and training for the EYE intervention, to evaluate its effectiveness, implementation, and cost-effectiveness and to disseminate widely.

Study design: A cluster randomised controlled trial with economic evaluation will compare the EYE intervention + standardised EIP service to standardised EIP service alone, with randomisation at service level. A qualitative study with ethnic minority service users will ensure acceptability specifically for the diverse EIP population. An implementation study, drawing on normalisation process theory (NPT), will shape the implementation toolkit and evaluate the delivery of the intervention qualitatively and quantitatively across context.

Setting: 20 EIP services in Manchester, London Norfolk, Cambridge & South of England. Sussex services will be involved in the implementation study.

Populations: 950 young people (14-35 years) with first episode psychosis (F20-29, 31; ICD-10) including ethnic minority service users; and EIP staff.

Intervention: The team-based motivational engagement (EYE) intervention, derived in consultation with service users, carers & clinicians in the original EYE study, will be delivered by EIP clinicians alongside standardised EIP services, supported by website (www.isanyoneelselikeme.org.uk), training, booklet series, schools pack, friends & family, & social group protocol.

Comparator: Standardised EIP service, provided by EIP clinicians, including NICE guidelines approved interventions.

Outcomes: Primary outcome is 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 outcomes include mental & physical health, deaths (including suicide), social & occupational function, recovery, satisfaction & service use at 6, 12, 18 & 24 months.

Economic evaluation: 12M within-trial economic evaluation of cost-effectiveness of the EYE intervention from a societal perspective, accounting for cost impacts within and beyond the mental health sector, with a secondary analysis taking a narrower NHS perspective to inform a commissioning guide.

Duration: 38 months: 9 months set-up & training, 12 months recruitment plus a further 12 months follow-up, 5 months data analysis & dissemination.

Benefits and Impact: If effective, integration of the intervention into standardised care will ensure that at least an extra 10% of young people & families with severe mental illness will maintain engagement, resulting in better physical & mental health and economic outcomes. Clinicians, managers & commissioners will benefit from a toolkit including manuals, commissioning guide, training & resources, adapted to meet the needs of the diverse EIP population, and based on an in-depth process evaluation to enable national roll out.

2. Key Words

Psychosis
Engagement
Youth
Intervention
Cluster Randomised Controlled Trial

Implementation
Ethnicity
Effectiveness
Cost-effectiveness

3. List of Abbreviations

CBTp- Cognitive Behaviour Therapy for Psychosis
EIP - Early Intervention in Psychosis
EYE – Early Youth Engagement in First Episode Psychosis
FEP- First Episode Psychosis
cRCT - Cluster Randomised Controlled Trial

4. Background

In England, 1-2% of the population [19], 7,500 new young people each year [20], develop psychosis. Psychosis has devastating consequences, with significantly poorer quality of life and high disability adjusted life year losses [21]. People with psychosis die up to 25 years earlier than the general population [22], one third from suicide, usually within the first 3-5 years [23-24]. The first 2-3 years are pivotal in determining long term trajectories [25-30]. EIP services are pro-active, person-centred mental health services offering early detection and treatment in this critical 3 year period [31-50]. The recent Access and Waiting Time Standard[11], published by NHS England, requires all Clinical Commissioning Groups (CCGs) to ensure from 2016 that at least 50% of all new emerging psychosis cases in England are engaged within 2 weeks with a NICE concordant EIP service. Yet treatment disengagement from services is high[13-15;51-57]: estimated at 30% of young people in a recent systematic review across all service types and follow-up periods[13], and 25% within the first 12 months in standalone EIP services, including in our own pilot[14-15, 7-10]. This is a significant problem. National policy, investment and service structure are focused on ensuring that young people are proactively engaged in assessment, and offered a full EIP care package to prevent them 'falling through the gaps', receiving inadequate care, poor outcomes and greater subsequent healthcare use[p27: 11], but 1 in 4 disengage. There is limited evidence for methods to promote engagement in the subsequent 3 years. Our work has begun to provide this evidence [7-10, 58]. We now understand why people disengage, and want to test the effectiveness & cost-effectiveness of a team-based motivational engagement intervention to reduce disengagement from EIP services. The large-scale process evaluation will provide knowledge and tailored resources to support health services to implement the intervention nationally.

There is a clear health need: engagement with EIP services leads to increased service user satisfaction, fewer symptoms, relapses and hospital admissions, better health, wellbeing, social and occupational function and fewer suicides[30,59-63] in the medium to long term[36-40,59]. Disengagement of young people with psychosis represents a significant cost to their health and wellbeing and impacts on families, society and the NHS.

There is an expressed need from researchers and NHS management to focus on engagement, with some researchers suggesting it is the most important outcome of EIP services [64]. The College Centre for Quality Improvement has made time to disengagement a recent EIP audit requirement [65]. This project has the capacity to generate new knowledge of how to effectively engage young people in EIP services. There is sustained interest and intent to increase access to EIP services for people of all ages who develop a first episode of psychosis. Access and Waiting Time Standards are supported by NHS England, who are committed to further access and engagement targets by 2020[11]. EIP service access is 'a clear national priority for the NHS [Kendall, 11], and local NHS services must include EIP development in their immediate and long term sustainability and transformation plans [11]. This has been supported by £40 million for staff and training, in 2015/16 alone [66-67] and £70 million by 2020 [79]. Yet disengagement from these services threatens the quality of health outcomes and nullifies this investment for 25% of young people. The financial cost of psychosis to society, including healthcare, families, unemployment and death, is estimated at £11.8 billion per year [68]. EIP services demonstrate savings of 30-50% over standard care, over periods of at least 8 years [69-70]; £5,000 per person per year based on days in hospital [58]; £7,972 net savings per person after 4 years, £6,870 in the next 4-10 years, £15 for every £1 spent on EIP services after 10 years [71]. Even with suboptimal engagement, EIP is estimated to result in £63 million of savings per year to society, £34 million of these to the NHS [72]. The potentially greater cost savings of full engagement are not yet known. A cost-effectiveness

analysis will assess whether the intervention can be delivered with cost & quality benefits. This study will also determine the service engagement needs of ethnically diverse populations, refining training and resources to ensure needs are met. We will work closely with our commissioner, manager, NHS England collaborator and co-applicants, to ensure that learning derived from this project shapes our toolkit (manuals, resources, training & commissioning guide) to aid future service delivery and help to meet and inform future NHS targets.

The process evaluation across 20 EIP services will provide in-depth knowledge of organizational factors at a macro and micro level that influence implementation and integration with standard care pathways. This will facilitate national implementation leading to real change in NHS service delivery and care outcomes. An effective engagement intervention for young people in EIP services has the potential to improve mental health, occupational and social outcomes, reduce immediate and long term financial, & other burdens on the NHS, families and friends.

Our recent RfPB grant [7-10] developed the EYE intervention, drawing on views of service users and their families of barriers & facilitators to engagement, & on literature that disengagement is linked to younger age, substance use, coping styles, family contact & knowledge of services[13, 51-52, 56]. To date, only limited evidence from our own work identifies strategies to maintain engagement from initial assessment or when a young person begins to disengage. Our Delphi consultation with clinicians & managers reached consensus on the EYE intervention & resources. Our pilot study found that service disengagement decreased from 24% prior to 14.5% post-EYE intervention. Qualitative feedback from service users, families & staff revealed improvements in personal recovery (social inclusion, hope, trust, practical goals), & engagement (communication, collaboration, family involvement). The use of anonymised data, collated & completed by research assistants in EIP teams, was feasible (100% complete for the primary outcome). A longer training, detailed manual, intervention checklist & social group protocol will enhance delivery. The study is timely; the new Access and Waiting Time Standard [11] will ensure that EIP services are the focus of sustained NHS attention, that standard EIP services are delivered according to clear guidelines, & delivery & outcomes will be measured routinely in a standard way. We now want to address this engagement evidence gap with a full trial.

5. Patient and Public Involvement

5.1 Past PPI

The PPI lead & Service User Research Forum (SURF) were consulted over several meetings to develop the research question and design for the first EYE project. They collaborated to develop the EYE intervention, training, materials, analysis and dissemination strategy. SURF's emphasis on the importance of engagement to reduce long term ill health and suicide risk informs this project. SURF and a PPI co-ordinator were consulted on the design of the current application. They proposed (i) to keep the target age range at 14-35, as EYE materials were designed for young people; (ii) consultation to finalise the social group protocol; (iii) appropriate outcome measures; and (iv) an involvement plan across the research cycle. An RDS South East PPI grant enabled us to consult new EIP service users & carers regarding appropriate recruitment strategy and incentives for participants, national roll out, and the lay summary. The PPI team have co-written the PPI section and lay summary, provided the PPI plan, and advised on PPI leadership, structure, training and costing. They will collaborate and provide consultation throughout the project.

5.2 Future PPI

The PPI plan is integral to the study design and will be led by the PPI lead from the McPin Foundation (specialists in mental health service user research). PPI activities will include (i) contribution to steering group and study meetings; (ii) reviewing ethics, recruitment and advertising materials (ii) co-facilitating qualitative interviews with ethnic minority groups to refine the intervention materials, and contributing to their adaptation; (iii) supporting training delivery at each site; (iv) supporting the delivery of the social groups at each intervention site; (v) co-facilitating the lived experience group at each site; (vi) contributing to the dissemination plan. In each site, we will recruit a senior PPI lead, 2service users and a parent of a younger person who will be involved in the local EYE training for staff and in running social groups. This will provide a local PPI group who will be trained and supervised by the PPI lead. We will ensure that under 18s are represented, and that there is a balance of age and gender across the 5 sites. Training will focus on peer research methods, ethics and bespoke training building on existing

skills & capacities. The entire PPI team will contribute to articles, VLOGS, and study newsletters. Two independent service users will serve on the steering group.

6. Methods and Design

6.1. Aims and Objectives

The main research aims are:

(i) To evaluate the effectiveness of the team-based motivational EYE intervention with respect to the primary outcome: time to disengagement, and secondary outcomes (mental and physical health, deaths (including suicide), social & occupational function, recovery, satisfaction and service use (HoNOS, Process of Recovery Questionnaire (QPR), DIALOG, service use across ethnicity, service & geography.

(ii) To determine cost-effectiveness of the intervention including cost-savings of full EIP engagement and produce a commissioning guide, with GP commissioner input.

(iii) To complete a large-scale process evaluation incorporating all clinicians involved in EYE-2 intervention delivery, assessed through questionnaire at start, mid & end of trial, and qualitatively in interviews.

Main objectives:

(i) To develop and refine an implementation toolkit (manuals, commissioning guide, implementation checklist) in the first 6 months of the project, & refine at the end of the trial for national roll out; co-developed with the Sussex EIP clinical lead, service manager, and GP commissioner, drawing on an NPT framework & knowledge obtained from the implementation study in the original Sussex site, and the process evaluation.

(ii) To refine the booklets, website & training, based on NHS England guidance on health inequalities to be 'appropriate and accessible to meet the needs of diverse [ethnic minority] communities [p9: 11]; contain current evidence; and are tailored to local service variation. This will be completed in the first 6 months of the project, & further refined at the end of the trial.

(iii) To evaluate the effectiveness of the intervention with respect to the primary (researcher collated) outcome: time to disengagement (in days from date of allocation to care coordinator to date of last contact following either refusal to engage with EIP or lack of response to EIP contact for 3 consecutive months) [15,55,80-81]; and secondary routinely collected and researcher collected outcomes (HoNOS, QPR, DIALOG, service use) derived from routine service data at 0, 6, 12, 18 and 24 months.

(iv) To develop and test a framework for implementation using (i) NPT to explore actions, context, process, structure, coherence with standard care which influence implementation, including sense-making, effort, action, commitment, participation and reflection on progress; and(ii) logic models, constructed and tailored to predict and test variation in intervention delivery in terms of roles, responsibilities, beliefs, activities, relationships, processes, structures, affective and cognitive components, at an individual, social network, team & system level. Complete a large-scale process evaluation incorporating all clinicians involved in EYE-2 intervention delivery, assessed through questionnaire at start, mid & end of trial, & qualitatively in interviews.

(v) To determine societal & NHS costs, cumulative cost savings, health outcomes and overall cost effectiveness of improved EIP engagement and produce a commissioning guide, with GP commissioner input.

(vi) To disseminate widely through the study website; peer reviewed papers; service user publications; conference presentations; VLOGS; Tweet chats; coordinated press releases; national networks; NHS England

We hypothesise that the EYE-2 intervention will: (i) reduce disengagement; (ii) improve mental & physical health outcomes; (iii) improve recovery, quality of life & satisfaction; (vi) Outcomes will be

moderated by effective implementation as measured by the process evaluation questionnaires & (v) the intervention will be cost-effective with potential societal and NHS cost-savings.

6.2. Overarching design and theoretical conceptual framework

The project will be formed of 6 work packages across 3 phases (i) implementation planning (ii) effectiveness and (iii) dissemination. The central trial is a parallel-group cluster randomised controlled trial (RCT), with 1:1 allocation by cluster, stratified by site, to test the effectiveness of the EYE intervention in reducing disengagement compared to standardised stand-alone EIP service.

Normalisation process theory is an explanatory theoretical model which outlines how complex interventions are introduced, understood, embedded and 'normalised' into routine clinical practice, through mechanisms that reflect the activities that people engage in, of coherence, cognitive participation, collective action and reflexive monitoring [1, 81]. This project will take Normalisation Process Theory (NPT) as a framework for implementation, and a mixed method approach to analysis to investigate the effectiveness and cost-effectiveness of a new motivational engagement intervention to improve engagement with, and outcomes from, first episode psychosis services, and to provide a toolkit for future implementation.

6.3. Implementation sub-study (work package 1)

WP1 (0-6M) will develop and refine the implementation manual, commissioning guide, training, and process evaluation tools [5]. Interviews with managers and clinicians in Sussex will investigate the original EYE project implementation, inductively using an NPT framework. A series of logic models will be constructed and tailored to predict and test variations in intervention delivery [6]. Outcomes will inform the manuals, training and process evaluation.

Site – Sussex EIP services

Participants - will be 12-16 clinicians (purposively sampled to represent all clinical disciplines, clinicians, managers and each of the 6 teams in Sussex). These numbers are based on availability of EYE trained staff.

Inclusion – Clinician or manager working within a Sussex EIP team (who took part in the original EYE study in Sussex).

Exclusion – EIP clinicians who started work in a Sussex EIP team after the completion of the original EYE project in November 2015.

Procedure
Recruitment and consent – All EIP clinicians will be provided with an information and consent sheet in advance and will then be approached by a study researcher at least 24 hours later, to screen for eligibility. All eligible clinicians will be invited to take part and 12-16 will be randomly selected from within those who provide provisional consent, sampled purposively to include all clinical disciplines, managers and all 6 Sussex teams. The selected clinicians will then provide written informed consent.

Interview process – Each clinician will be interviewed in a face-to-face individual interview with a research worker at a time and place that is convenient to them. The interview will take 30-60 minutes, and will be audio-taped for subsequent transcription, and will be led by the Implementation study topic guide.

Qualitative analysis - Transcripts of anonymised interviews will undergo Thematic Analysis [85], an established flexible approach to inductive analysis that we have used previously [86-88]. Thematic analysis aims to identify, analyse and report patterns (or themes) in qualitative data. It is a method that is independent of any epistemology or theory: it is compatible with essentialist and constructionist paradigms [85] Thematic analysis can be conducted in an inductive (bottom up, data-driven) or deductive (top-down, theory-driven) way. Given its flexibility and the aim of identifying patterns across data, this method was deemed appropriate for use in the implementation work package in the proposed

programme of research. The analytic process will entail 6 steps: 1) reading transcripts for "start codes"; 2) collapsing these into analytic categories; 3) combining categories into candidate themes; 4) examining how patterns of themes reflect transcript content (and theories where appropriate); 5) defining each theme's contribution to understanding; 6) illustrating themes with quotes. The analysis will be conducted by the post-doctoral research assistant, CI, EIP clinician and manager working together, with some input from the GP commissioner to reach a consensus on a coding frame, which will then be applied by the post-doctoral research worker to remaining transcripts. A second consensus phase will involve the same group working together to categorise and define themes.

Primary outcome – The thematic outcomes of this phase will be used to develop and refine the implementation toolkit including manual, checklist and draft logic model for use in the training and the randomised trial.

6.4. Qualitative ethnicity and minority sub-study (work package 2)

WP 2 (0-6M) will update resources (booklets, website, training pack) to ensure acceptability for ethnic and other minority populations, as well as accommodating recent evidence and site context variations. Engagement undoubtedly varies with ethnicity and diversity in EIP services [6-7], and BAME first episode psychosis service users have poorer long term mental health & service use outcomes [8]. Indeed, two key issues that affect engagement in BAME psychosis are suspiciousness of services, and coercive treatments [5],Prof Shanaya Rathod (co-I) is an expert in adapting interventions for BAME psychosis populations [9-12]. She will lead this work, with minority PPI representatives. She has developed a cultural adaptation framework, underpinned by an ethnographic approach, and co-produced with BAME service users, carers and lay members, which will be used to train research staff involved in recruitment, and clinical staff involved in intervention delivery. It has also framed the topic guide for this study. Both the researcher training and the topic guide are sensitive to the challenges in adapting interventions (e.g. stereotyping and generalisation) and the need to focus on culture as a strength. The framework emphasises the importance of the pre-engagement stage for outcomes for BAME groups and is well-suited to the current programme.

Feedback from our feasibility study highlighted that our resources should consider the role of spiritual factors as a 'treatment option' for BAME populations. Recent qualitative work in BAME EIP populations has also emphasized the importance of spirituality, religion and faith institutions [7]. WP2 will build on our own and published BAME work in EIP [7], but with a more specific focus on the BAME populations in Southampton, London & Manchester. A key aim is to ensure acceptability/accessibility of the intervention content, and to include anything in the resources and training that was missed initially in relation to spirituality, ethnicity & culture.

Sites - Manchester, London and Hampshire (Southampton) EIP services

Participants – will be 18-24 EIP service users (6-8 in each site of London, Manchester and Southampton with an additional 2-3 LGBT service users recruited from Sussex if required to represent this population) purposively sampled to reflect the main ethnic profiles of each of these urban populations. Ethnic profiles might include Black British, African, Caribbean, Asian British, Indian, Pakistani, White European and middle-Eastern.

Inclusion – EIP service users with psychosis aged 14-35 from the main regionally identified ethnic minority and other minority (e.g. LGBT) populations at each identified site.

Exclusion – EIP service users with ARMS diagnoses and/or service users who are over 35 year olds.

Procedure – Prior to commencing recruitment, the main ethnic and minority profiles of each urban site will be identified. EYE researchers will be provided with initial training in ethnic, cultural and spiritual differences, and culturally sensitive interview approaches. They will be provided with guidance on how to engage with people from different black Asian and minority ethnic populations, about respecting individuality and the risks of inadvertent stereotyping and will be provided with key information about different religious and cultural considerations.

Consideration where possible will be given to the gender of the researcher and their own ethnic background. Where possible, interviews will be conducted with researchers from ethnic minority backgrounds for greater comfort and ease of the interviewee and/or with someone with lived experience, in pairs with the researcher.

Recruitment and consent – Care co-ordinators within each EIP team will be invited to identify a convenience sample of potential service users from the designated minority populations, who would be willing to be contacted by the research team. Care co-ordinators or the EIP research assistant will first speak to the service user to elicit consent to be contacted by the research team. Interested service users will be approached by the research team, and will be provided with an information and consent sheet, a copy of the complete EYE-2 resources and website links in an electronic format, and selected sections of the resource booklet, training plan, manuals and website to provide sufficient material for discussion whilst minimizing the risk of contamination where service users are part of a service that is subsequently randomized to the standardize EIP arm. The electronic resources will be non-downloadable, and access will expire after the consultation period also to prevent contamination. A provisional interview date will be set, allowing a minimum of 2 weeks for the service user to view the materials. Approximately 24 hours before the interview date, the researcher will contact the service user to answer any questions, ensure consent and confirm the meeting. Written informed consent will be taken in person immediately prior to the interview.

Interview process – Each service user will be interviewed in a face-to-face individual interview with a research worker, (and PPI researcher where possible and acceptable/preferred by the service user) at a time and place that is convenient to them. The interview will take 45-60 minutes, and will be audio-taped for subsequent transcription. It will be guided by the Ethnicity/minority study topic guide and will explore cultural/spirituality/ethnicity issues relevant to engagement, and the EYE-2 resources.

Qualitative analysis - Interviews will be analysed thematically according to the process outlined in WP1 above. Consensus will be between the RA, PPI lead at each site and WP2 leads (SR and RdV), a subsequent cross-site meeting will reach consensus on the final theme structure and recommendations across sites.

Primary outcome - to produce adaptations to the EYE training and resources to ensure these meet the needs of the 'diverse communities' of EIP service users in relation to spirituality, ethnicity and culture, drawing also on recent published work [7]. A key aim is to ensure acceptability/accessibility of the intervention content, and to include anything in the resources and training that was missed initially in relation to spirituality, ethnicity & culture. However, a thematic framework will also be developed regarding engagement in relation to BAME EIP service users.

6.5. Pragmatic Cluster Randomised controlled trial (Work package 3)

WP3 (0-38M - 6 months set up, 3 months training, 12 Months recruitment, 12 months follow up, 5 months data cleaning, analysis and dissemination) will comprise a definitive pragmatic cluster RCT to test whether the EYE intervention [7-10] plus standardised EIP service delivered according to implementation guidance [11] is effective and cost-effective at reducing disengagement from EIP services, compared to standardised EIP service alone in a cohort of950 young people (14-35 years) with first episode psychosis (F20-F29, F31; ICD-10) [12] at 20 identified Severe Mental Health EIP service in Manchester, London, Thames Valley, Norfolk-Cambridge and Hampshire. Randomisation will be at service level, stratified by site.

EIP services will be randomly allocated between (i) the standardised EIP pathway, delivered according to published guidelines[11], provided by team clinicians and including NICE guidelines interventions, and (ii) the EYE intervention plus standardised EIP pathway.

We have selected the standardised EIP pathway as the comparison condition because it is the nationally recommended care pathway for people in England who develop a first episode of severe mental illness (psychosis). Delivery of this pathway and routine outcome measures (HoNOS; QPR; DIALOG) [76-78) are mandated by NHS England [11]. The EIP service model and suite of NICE recommended interventions are clearly defined. Training and monitoring will ensure that administration and recording of measures and intervention provision is undertaken in the EIP pathway in a robust,

standardised way across sites. Researchers that are in EIP services will make every effort to collect data that are missing and from disengagers, within 4 weeks of a time point, to ensure data are as complete as possible.

Sample Size Calculation - Time to disengagement will be analysed using frailty analysis to adjust for clustering by service. Simulation confirms that 10 clusters per arm (n=950) will achieve 90% power to detect a difference corresponding to 12 month disengagement rates of 25% (standard 12M disengagement rate from EIP service)[1-3] vs 15%, assuming time to disengagement has exponential distribution; intracluster correlation 0.05; drop-out rate 10% per year; conservative significance level 3% to correct for inflation of Type I error due to small cluster numbers; variable cluster size modelled as a uniform random variable between 35 and 60; recruitment at referral; 12 months recruitment plus 12 months followup. Simulations conducted using the SimSam package in Stata 14, see http://webspace.qmul.ac.uk/rlhooper/simsam/appl/eye2v2.html.74-75].

Researcher training - The EYE researchers will be provided with initial training in cultural differences by SR, based on her cultural adaptation framework with additional information gained from WP2. The model uses the bio-psycho-spiritual-social model of illness, taking into account the philosophical orientation of the individual, societal factors that impact on experiences, trust, technical adjustments to interventions, including the role of religion and spirituality and concepts such as body and mind, self and other, individual and collective goals [9]. Researchers will also be trained in study procedures, and data collection and intervention support roles. The Research Assistant and PPI Lead will be supervised by the designated site PI or other named lead.

Sites and services – The current EIP care pathway is variable nationally in adherence to the EIP model, with different services consisting of either standalone, hub & spoke services, or specialist workers in community teams. A 'stand-alone' service works independently from other more generic community mental health teams (CMHTs). Standalone services that adhere to the EIP model have the best outcomes, being the most clinically and cost-effective, and able to implement NICE recommended interventions [16-17]. Recent investment & targets[11, 79] mean many services are moving to this model. All services involved in the current study are standalone services, adherent to the EIP model core principles of (i) early detection (ii) assertive engagement (iii) person & recovery focus (iv) family focus (v) work with diagnostic uncertainty (vi) positive risk taking & (vii) provision of NICE recommended interventions [11] and so reflect best evidence based practice.

All services meet the following specific inclusion criteria (i) standalone EIP site with at least 2 discrete services. (ii) willingness and capacity for involvement as agreed by clinical services; (iii) identified site principal investigator with academic track record in leading RCTs in psychosis; (iv) regional EIP support; (v) individual service size of at least 35-40 new clearly defined first episode cases [19] per year aged 14-35; (vi) currently capturing NHS England mandated routine outcome data; (vii) systems (IT and staff) in place to increase routine outcome data capture; (viii) geographical spread to include urban and rural locations, ethnic minority variations, North and South of England.

Sites and service are as follows:

- London (Lambeth/SouthwarkLewisham,Croydon);
- Manchester (Bolton, Salford, Trafford, Manchester North, Manchester South/Central), ;
- Hampshire (Southampton, North Hampshire, East Hampshire, West Hampshire);
- Thames Valley (Oxford, Milton Keynes, Buckinghamshire, Berkshire)
- Norfolk-Cambridge (Norwich, Great Yarmouth, Cambridge North, Cambridge South).

Participants – Participants will be a consecutive sample in each service of approximately 47 (average recruitment per service) Young People (14-35 years) with first episode psychosis (F20-F29; F31 ICD-10) [12] at each of the 20 identified Severe Mental Health EIP teams in Manchester, London, Thames Valley, Norfolk-Cambridge and Hampshire. The total sample size required is 950 participants from 20 services. The RCT will include only those aged 14-35 because younger age predicts disengagement, and the EYE intervention was specifically designed to address the needs of this group.

Inclusion criteria are: (i) Consecutive referrals to the service during the study recruitment period aged 14-35; (ii) 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. . Inclusion criteria currently employed are:

Norfolk and Manchester: Experiences that would score 4 or above on the hallucinations and delusions section of the PANSS, with other items on the positive section of the scale scoring 5 or above in the context of a cluster of symptoms. The symptom must have lasted throughout the day for several days or several times a week, over a period of at least seven days duration, over the last 12 months (or if less than this then the improvement must be attributable to antipsychotic treatment).

Hampshire: A first episode of psychosis (core symptoms of hallucinations and delusions, often accompanied by 'negative symptoms' such as emotional apathy, lack of drive, poverty of speech, social withdrawal and self-neglect based on clinical judgement) presenting for the first time to mental health services and who have either not yet received any antipsychotic treatment or have been treated for less than one year within secondary mental health services.

Thames Valley: **Berkshire** - A first episode of psychosis (including bipolar with psychotic symptoms and psychotic depression).lasting for at least one week, accompanied by a decline in functioning, with symptoms emerging within the past three years, and no prior anti-psychotic treatment. In borderline cases, strong objective indicators (such as peak age; first degree relative with schizophrenia) will be taken into consideration). **Oxford**- A First-episode psychosis (based on CAARMS criteria, decline or consistently low function, frank hallucinations/delusions which meet distress/intensity/ frequency criteria for 7 days and including schizoaffective), with no prior secondary mental health service treatment for psychosis. Psychosis solely in the context of cannabis use is not an exclusion criterion**. Milton Keynes** – first episode psychosis of less than 3 years duration. **Bucks** – First episode psychosis (assessed using CAARMS and including bipolar with psychosis) defined as for Hampshire (including prolonged reaction drug use/misuse and drug withdrawal of up to 6 months, drugs as a trigger for prolonged psychosis

Cambridge: Aged 17-35 with a first episode of psychosis based on a confirmed diagnosis of Schizophrenia, Schizoaffective Disorder, Delusional Disorder, Psychosis NOS, Dual Diagnosis / Psychotic illness where psychotic illness is considered to be the primary problem, Bi-polar Affective Disorder with psychosis, Psychotic Depression (initial presentation only), following specialist clinical assessment incorporating appropriate assessments tools such as PANSS/CAARMS.

London: Aged 17.5-35 with a First Episode of Psychosis: F20-29 determined by clinical judgement, referred or treated for less than one year.

Exclusion criteria are (i) a sub-threshold 'at risk mental state', not meeting FEP criteria, (ii) referral over the age of 35, (iii) referrals where there is remaining diagnostic uncertainty about psychosis at 12 months. ; (iv) service exclusion criteria such as organic or intoxification induced psychosis and specific exclusions – In Manchester significant LD/communication impairment to prevent engagement, in-patient in out of area long-stay residential unit or receiving 24 hour residential support; in Berkshire psychosis symptoms wholly explicable as PTSD; in Milton Keynes Bipolar Disorder and in London – LD/personality disorder/substance misuse **without** clear psychosis, forensic risk considered too high, or **e**stablished psychosis(more than one year; Bucks Long DUP (over 2 years), significant mental health input and unlikely to benefit from EIP approach, Personality Disorder with 'secondary sub-threshold' psychosis, psychosis experiences in the context of another diagnostic framework. 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.

Additional site in Sussex

In addition to the main RCT study and teams, we are also delivering the intervention in all teams in Sussex, following the same protocol. All teams in Sussex will receive the training and implementation pack, and will deliver the intervention and collect outcome and process evaluation data according to the

main trial protocol. In the Sussex site, additional sub-studies will explore different aspects of implementation, and will explore mechanisms of engagement in more detail. Additional assessment tools and protocol variations will be submitted for ethical approval prior to inclusion.

Intervention - The team-based motivational engagement (EYE) intervention [7-10],is delivered by EIP clinicians, supported by training, manuals, website, 5 booklet series, schools pack, friends and family protocol, and social group protocol (adapted from WP 1 and 2) and incorporated into standardised EIP service [11].

The implementation tool kit – This is specifically, the set of hard copy resources that will be provide to each clinician as part of the training. It will comprise a single reference set of (i) the implementation manual, refined following WP1; (ii) the 5 booklets (mental health and help-seeking, EIP, for friends and family, treatment choices, getting the most out of hospital); (iii) the friends and family, social group protocol and schools pack; the EYE-2 team and individual implementation checklists and (iv) the draft commissioning guide and (v) the links to the website and training videos, which will be developed and refined following WP1 and 2. All final versions of resources will be submitted to the ethics committee, if required, prior to RCT start. The tool kit will be further refined following the outcome of the process evaluation and health economic analysis, in order to produce the final manual and commissioning guide and resources for national dissemination.

Whilst the EIP model outlines what should be done, the EYE 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. The EYE intervention is based on motivational interviewing & open social communication and the following approaches and resources:

(i) 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.

(ii) 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 protocol, booklet and service user-led social groups. Training is provided in carers' rights, and in protocols for involving friends & family. Service user led social groups, are run by and for EIP service users, undertaking social activities chosen by the group. These will be run by EIP service users themselves, who will be invited to attend either for their own social benefit or to offer social support to others. They will be set up by the local PPI lead and research assistant who will be on hand to support service users with organisation and running as required. Feedback from the first EYE study highlighted that all members attending such a group are likely to benefit, but young people are more likely to attend on the premise of helping others, than helping themselves.

(iii) 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.

(iv) 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 (see Figure 2), and promotes a hopeful, motivational, goals focussed approach, fostered also in social groups, that is of paramount importance to young people.

(v) Addressing personal barriers

Personal barriers to engagement are addressed by reaching out to service users through the discussion forum on the website, the schools pack, the 'addressing personal barriers to talking' sections in the booklets, and the social groups that are attended and co-led by young service users, All encourage young people to reach out to the service, their families, and each other.

The training

The EYE training will then be delivered by the central EYE team, local PPI lead, 2 local service users, and 1 local 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 co-ordination (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, risk taking, mental health exacerbations, treatment & admissions). Additional sessions include (ix) the implementation process - formation of local implementation plans and production of logic models to evaluate implementation & (x) the research process – ethics, consent and advertising; and training for robust data collection and recording. We will incorporate what we learn about cultural differences and strengths, and the role of spirituality in different ethnic groups with respect to engagement and treatment preferences from WP2 into the training programme. This training will be based on the cultural adaptation framework developed by Prof Rathod and co-produced with BAME service users, carers and lay members. The model uses the bio-psycho-spiritual-social model of illness, taking into account the philosophical orientation of the individual and societal factors that impact on experiences and trust, technical adjustments to the intervention approach, including the role of religion and spirituality and modification of concepts such as body and mind, self and other, individual and collective goals. Training will be 2-days for intervention sites and 1/2 a day on robust data collection training for control sites.

The Training Plan - A 3-month window is allocated to training, currently scheduled for February/March 2019. Each site comprises 3-5 services; 1-3 will be allocated to the 2 day 'intervention' training and 1-3 will be allocated to only the ½ day 'robust data collection' training. Two rounds of each training will be offered at each site, one month apart, to enable staff to attend training whilst maintaining service delivery, and to accommodate leave and absence. The ½ day training will comprise the first part of the 2-day training. All services at each site will be trained together on robust data collection, after which those allocated to the intervention arm will remain for the additional 1.5 days. Training dates and randomization of services to study arms will occur well in advance of training to enable staff to plan to attend either the full 2-days or only the ½ day. All staff will be expected to attend one training event. Any staff who are unable to attend all or part of their allocated training will be asked to attend training at an alternative site. Training will run approximately once every 2 weeks. After training at each site, there will be a preparation and consolidation phase of up to one month to allow final preparations for RCT start, assisted by the local site study team (PI, RA, PPI lead, 2 service users, 1 carer). Additional booster training will be offered if required. All sites will commence intervention delivery in March/April 2019 (months 10-11), t. Baseline and 6-monthly follow-up data will be collated, collected and entered onto the study database from all consecutive cases entering each service who meet inclusion criteria after the intervention start date. Baseline will comprise the first -4 to +6 weeks (-4/+ 6 weeks) to allow for baseline assessments in hospital prior to EIP allocation 6 weeks; follow up data will be collected at each time point -2/+4 weeks. The timetable for training is outlined in figure 2 below.

Comparator - The comparator will be the standardised EIP service [11]. The current EIP care pathway is variable nationally in adherence to the EIP model, with standalone, hub & spoke services, and specialist workers in community teams. Standalone services that adhere to the EIP model have the best outcomes [16-17]. Recent investment & targets [11] mean many services are moving to this model. All services involved in the current study are standalone services, adherent to the EIP model and so reflect best evidence based practice. The EIP model involves core principles of (i) early detection (ii) assertive engagement (iii) person & recovery focus (iv) family focus (v) work with diagnostic uncertainty *(vi)* positive risk taking & (vii) provision of NICE recommended interventions [17-18].

Contamination - We will agree with teams at each site, that once they have been randomised, if they are a team that has been randomised to receive the intervention, they will not share the EYE-2

resources with other people outside of their team. This will protect the use of EYE-2 resources during the study. We will also agree at each site that if a member of staff moves from a service that is delivering the EYE-2 study, to one that is not (or vice versa), that they will not take resources with them, and where ever possible, that they will not work directly with the study cohort participants. We will monitor this to reduce the transfer of EYE-2 resources and training between study arms.

Procedure

Randomisation
The Brighton and Sussex CTU will provide an independent randomisation service and a clinical trial database system. Randomisation, stratified by site (Manchester, London, Thames Valley, Norfolk-Cambridge, Hampshire) will be carried out early in the study using Sealed Envelope™ to enable sites to book and prioritise training.

Recruitment and consent – The EIP research assistant working as part of the EIP clinical team in each service will determine the cohort of eligible service users in that service, in discussion with lead clinicians in the clinical team and with reference to the eligibility criteria. All consecutively referred service users during a 12 month period following the start of the study, who meet criteria will form the cohort in that service. The study will be publicized widely within each service, and explicitly to all those who are eligible and defined as part of the research cohort. These participants will be provided with the leaflet and flyer, and will have the study explained to them. It will be explained that their service is part of a study that aims to improve the experience of people using the service, and that their routine data and information about their use of the service as well as other service users data will be used confidentially and anonymously in order for the EYE-2 study to see whether the new EYE-2 intervention works. They will be provided with contact information for the study team in case of questions or concerns. They will also receive the publicity materials to be produced and the pack of local support service information, both of which will be produced as recommended by our PPI group and as part of service user consultation, once the study starts. These will be submitted to the ethics committee as required prior to RCT start. It will also be explained to cohort participants, that they may also be contacted by an EIP or an EYE-2 research assistant, at some point over the subsequent 2 years. They will be told that the contact will be solely for the purpose of collecting a small amount of routine data which may be missing, and one extra questionnaire, and it will be explained to them that if they do stop using the service their information will be especially important to the study team, as it may be especially helpful in understanding whether the EYE-2 study works. It will be explained, in lay terms, that if they are contacted by a research assistant and asked to answer some questions, this will be someone working in the EIP team if they are still with the service. This person will anonymise their data into numbers. If they are no longer with the service then the EIP service will make the first contact, and will send them some basic information and they will have an opportunity to opt out of the research. For all service users who have not returned a reply slip, they will be contacted a minimum of one week later, by the EIP research assistant by telephone, or in writing. The EIP researcher will explain the study to them, with reference to the information and consent sheet, and if they are interested their details will be passed to the study research assistant. It will be explained that they don't have to take part in the study if they don't want to, but that if they do complete the questionnaires they will be remunerated for their time, effort and contribution to the study.

If the service user consents to take part they will be offered the option of completing the questionnaires by telephone or in person. If they prefer to complete the questionnaires by telephone, the consent will be noted by the researcher, in discussion with the participant. After which, the researcher will conduct the HoNOS by semi-structured interview, the QPR, the DIALOG, and at 12 months or 24 months only the Adult Service Use Schedule. They will be thanked for their time, and a postal order for £20 will be sent to them, at the address confirmed. If they prefer to complete the data in person, then written informed consent will be taken, a convenient public space will be agreed to meet to complete the measures, the same process will be followed, with the exception that £20 will be provided in cash. If at any point the participant asks to stop taking part, this will be noted and the interview will be stopped. If the participant asks not to be contacted again regarding the study, this too will be noted, and they will not be contacted again.

Cohort participants will only be contacted in three circumstances, which are (i) they remain engaged in the EIP service and their routine data for a time point are missing (in which case they will be contacted by the team RA, and asked to complete the data by telephone or in person as part of the service; (ii)

they have disengaged from the service, in which case they will be invited to complete the routine data as a standard research process following informed consent and will be reimbursed £20 for their time;
(iii) they are being asked to complete the brief Adult Service Use Questionnaire for the cost effectiveness study, and other questions at the same time, after 12 or 24 months, in which case they will be asked to complete the routine data as a standard research process following informed consent and will be reimbursed £20 for their time.

Data collection procedure – Research suggests that follow-up rates are improved by using shorter assessments, reminding service users about subsequent follow-up, updating contact details, providing reimbursement, and utilising research assistants to collect additional data [93-94]. We have incorporated all of these approaches into the current strategy. Patient reported outcomes are brief (approximately 15 minutes, 25 minutes including the Adult Service Use Schedule) and can be completed by telephone. Participants will be advised that they may be contacted and will be reimbursed £20 for their participation. The maximum follow-up rate of 8 questionnaire assessments per RA per week if no data are available routinely is achievable based on previous research in these sites (see timetable - figure 3 -below).

This study presents unique challenges as 'disengagement', has the potential to impact on missing data. A standard approach of taking individual informed consent and providing commensurate reimbursement for time, is likely to lead to disproportionate data loss in those who are likely to disengage, who are also the least likely to consent. Our data collection strategy builds on learning from the original EYE study and advice from our PPI group including those who disengage.

There are 3 main methods of data collection in this study that have been specifically designed to maximise data completeness. First, primary outcome data are recorded routinely by the service, but collated by the research assistant working within the EIP service and transferred anonymously to the research team (disengagement and service use data). Second, there are data that are routinely collected by EIP clinicians but collated by the researchers (HoNOS; QPR; DIALOG, NICE interventions use); and transferred anonymously to the study team. These researchers in their role with the team will also collect additional missing routine data. Finally, where routine data are missing at 12 months, for cost-effectiveness data at 12 or 24 months (AD-SUS), and for routine data from those who disengage we will undertake a standard informed consent process prior to data collection as described above. An additional option will be provided (in light of COVID-19) for the HoNOS to be collected at any time point by telephone interview as might occur anyway with missing data.

Engagement and service use data will be captured continuously. Secondary data will be collected at 0, 6, 12, 18 and 24 months according to NHS mandate. The study will include a 12 month recruitment period and an additional maximum 12 month follow-up period. Those who enter the study at the start of the cohort will be followed up for 24 Months, whilst those who enter at the end of the cohort will be followed up to 12 month outcome.

Table 1: Table to demonstrate how different measures will be collected in the EYE-2 study

	ROUTINELY RECORDED BY SERVICE, COLLATED BY RAS IN TEAMS	*ROUTINELY COLLECTED BY CLINICIANS, COLLATED BY RAS IN TEAMS*	*COLLECTED BY RAS IN TEAMS FOR AD-SUS, DISENGAGERS AND MISSING DATA*
DISENGAGEMENT	✓		
SERVICE USE	✓		
HONOS		✓	✓
QPR		✓	✓
DIALOG		✓	✓
NICE INTERVENTION USE		✓	✓
ADULT SERVICE USE SCHEDULE			✓
PROCESS EVALUATION QUESTIONNAIRES			✓
QUALITATIVE INTERVIEWS AND FOCUS GROUPS			✓

Blinding and reliability – Each study site will employ 2 research assistants, the first will be employed as part of the EIP clinical teams, and will be involved in study setup, co-ordinating and monitoring the intervention delivery, collating data and collecting baseline and other routine missing data. They will provide initial coding of the primary time to disengagement outcome. Data which are routinely collected by clinicians and the EIP RA will not be collected blind to study arm.

The second research assistant will be blind to study arm, and will double code primary outcome data. Any discrepancies identified on entering into the eCRF will be double checked by the EIP clinical RA, with reference to patient notes. The second RA will also collect routine data that are missing at 12 months, cost-effectiveness data and 12 or 24 months, and data from disengagers, blind to study arm and following a fully informed consent process. Primary outcome data and secondary researcher collected data will therefore be collected blind to study arm.

We will record when data have been collected blind and unblinded for subsequent inspection. All outcome data will be analysed blind to study arm.

Outcome Measures - will evaluate the impact of improving engagement on mental/physical health, social/occupational function, deaths (including suicide), recovery and service satisfaction, derived from NHS England mandated routinely collected service data [11], and collected by researchers for those who disengage at 0, 6, 12, 18 & 24M. This means that for those who enter at the start of the recruitment phase, data will be collected also at 18 & 24 months; for those who enter the cohort at the end of the recruitment phase, data will be collected to 12 months. Staff training will maximise reliability and fidelity for the intervention and for routine data collection.

Primary Outcome measure - Disengagement

The primary outcome is time to disengagement (in days, from date of allocation to care coordinator to date of last contact following either refusal to engage with an EIP team or lack of response to EIP contact for 3 consecutive months). For participants who remain engaged until the end of the study follow-up period, time to disengagement is treated as censored (unknown) beyond this point. This definition is widely used in engagement research [15, 55, 80-81]. People who engage intermittently every few weeks or via text or phone would still be engaged. Service users who move to a service not in the study, or in the opposite study arm, or move out of the UK and cannot be referred to a mental health service will no longer be receiving the intervention are deemed lost to follow up. This occurred in less than 10% of cases in the pilot study, which included transient asylum seeker and student populations.

Secondary outcome measures

1. **Service use and deaths**

Service use data, as advised by our GP commissioner will include (i) number of days spent in hospital; (ii) number of A&E presentations; (iii) number of instances of section 136 use. Deaths (including from suicide will also be recorded). The primary endpoint will be at 12 months.

2. **Health of the Nation Outcome Scale [HoNOS; 76]**

The HoNOS is the most widely employed routine clinical outcome measure in UK mental health services. It is a 12-item clinician-rated scale, which covers a wide range of health and social outcomes including mental health symptoms (psychosis, depression, other), physical health, self-harm, substance use, cognition, function (occupational and daily), relationships and housing. Each item is rated from 0 (no problem) to 4 (very severe), for the preceding 2 week. The HoNOS is used to 'cluster' mental health service users according to clinical need. These clusters map onto NHS commissioning tariffs and can be used to determine cost-savings. It is reliable (ICC= .77) and valid (r=.84 with BPRS).

3. Process of Recovery Questionnaire [QPR; 77]

The Process of Recovery Questionnaire is a 15 item measure, developed by psychosis service users to capture recovery. Items include social inclusion, assertiveness, motivation, positive relationships, purpose, empowerment, self-esteem, self-efficacy, meaningful activity, understanding, acceptance, enjoyment and positive risk-taking, each rated on a 5 point scale from strongly disagree to strongly agree. It is reliable (r= .77-.87) and valid [r= .39-.83 with Quality of Life and General Health]

4. DIALOG [78]

The DIALOG assesses patient reported satisfaction with 11 aspects of subjective quality of life including health (mental and physical), function (work, leisure), social (friendships/family relationships), accommodation, personal safety; and treatment (practical and mental health support, medication) all rated on a 7-point scale from Totally Dissatisfied to Totally Satisfied. It is reliable (Cronbach's alpha = .57-71) and valid (r = 0.95 with Manchester Assessment of Quality of Life (MANSA)).

5. NICE-recommended Intervention Use [11]

Use of NICE-recommended interventions, are recorded on electronic care record systems as SNOMED-CT (Systematized Nomenclature of Medicine Clinical Terms) Terms, a set of comprehensive scientifically validated terms used internationally, and designated for NHS use [11]. Relevant codes for EIP are CBT for psychosis, Family Interventions for Psychosis, Antipsychotic medication & monitoring, Physical Health interventions & monitoring, Supported employment & vocational/educational rehabilitation; care & treatment planning, substance use assessment & intervention [11].

6. Adult Service Use Schedule [90-91]

The AD-SUS is a structured questionnaire designed to elicit self-report contact with services and employment outcomes across a wider spectrum of services including primary care, social services, police and criminal justice contacts, education and training services and occupational outcomes. It has been used widely in various forms in a number of economic evaluations of child/adolescent and adult mental health services. We will pilot this measure during the first 6 months of the study in 35 young people who have received 12 months service provision to evaluate acceptability and data quality.

Outcome measures 3-6 comprise the Mental Health Services Dataset (MHSDS) for EIP services [11].

RCT analysis plan- Following CONSORT principles, we will report all participant flow and analyses will be conducted on an intention-to-treat (ITT) basis. Time to disengagement will be compared between trial arms using Cox regression with a gamma-distributed shared frailty to allow for the clustering by service. If this analysis fails to converge we will employ fully parametric time-to-event regression analysis with shared frailty. Analyses will be conducted using Stata v14 or above (Stata Corporation, College Station TX USA). With a relatively small number of clusters per arm there is a risk that the Type I error rate will be inflated – we will use a permutation test or similar approach in order to obtain a true significance level. Time to disengagement or the time beyond which observations are censored (due to drop-out or end of data collection) will be known for all participants. Secondary, quantitative outcome measures will be analysed using mixed regression analysis of all non-missing data (valid if outcomes are "missing at random"), with a random effect for service and a Kenward-Roger small-sample correction. We will investigate the sensitivity of our conclusions to the missing at random (MAR) assumption by imputing outcome data under departures from this assumption. Secondary analyses will be conducted to investigate whether the intervention effect is mediated by adherence and context effects, as measured in the process evaluation.

Randomisation stratified by site aims to address regional variation in service level factors. Statistical analyses will allow for variation (clustering) between services. We will adjust for measured service-level factors (e.g. variation in NICE interventions, deprivation) & individual-level factors (e.g. ethnicity, gender, duration of untreated psychosis) which could be important in predicting outcome [3]: these will be finalised in the statistical analysis plan prior to locking the database and unblinding. Secondary analyses will be conducted to investigate whether the intervention effect is mediated by adherence and context. A full analysis plan will be written prior to final analysis

6.6. Process Evaluation (Work Package 4 (WP4))

WP4 (3-36M) a large-scale process evaluation will investigate what is delivered, how it is delivered and fidelity to the intervention inductively using an NPT framework [1,82-84]; and prospectively using logic models [6], (derived from WP1) in a 2 year longitudinal study; and qualitatively in interviews with purposively sampled clinicians and managers from each service.

Participants – Participants for the questionnaire study will be all clinicians involved in the delivery of EYE-2 and EIP arms of the study. Participants for the qualitative study will be 33-40 EIP staff purposively sampled to include 2 clinicians and 1 manager in each of the 10 services that are delivering the EYE-2 intervention, to understand barriers and facilitators to EYE-2 intervention delivery, and 1 additional clinician/manager in each of the 10 standard EIP teams.

Inclusion criteria – EIP clinicians delivering EYE-2 and/or EIP services as part of the RCT.

Exclusion criteria – None.

Recruitment and consent – All EIP clinicians will be provided with an information and consent sheet in advance (during the training phase). Clinicians will then be approached by a study researcher at least 24 hours later, (during day 2 of the training or subsequently) regarding completion of the questionnaires and involvement in individual interviews. All eligible clinicians will be invited to take part and will then provide written informed consent. A sub-group of 33-40 will be randomly selected from within those who provide consent, sampled purposively to include all clinicians and managers across all 10 EYE-2 teams, with a further 10 participants from EIP teams to take part in an individual interview.

Questionnaires - Process evaluation questionnaire data will be collected from all consenting clinicians at 3 time points (start, mid, end) during intervention delivery. The questionnaires will take 20-30 minutes and can be completed on the telephone, by email or in person, at an NHS base or somewhere else local to the clinician. All clinicians and managers in each intervention service will be invited to complete the process evaluation questionnaires. In the EYE-2 arm, clinicians will complete a single questionnaire (Clinician questionnaire- EYE-2 - version 2 071019) comprising (i) the EYE-2 checklist, in relation to their own/team intervention practice; (ii) the NOMAD tool which will explore attitudes and behaviour towards the intervention informed by Normalisation Process Theory and logic models; (iii) the working alliance inventory and (iv) subscales of the spontaneous self-affirmation measure. In the EIP arm, fidelity to the EIP model will be examined using (i) the RCPsych EIP self-assessment tool [92]; other national and local service level data and; (ii) and an adapted clinician questionnaire (Clinician questionnaire –EIP – Version 2 071019) to explore variations in adherence to the EIP model, employment of EYE principles, and inadvertent access to EYE intervention resources, or relevant training (motivational interviewing, open dialogue, EIP or engagement). Research assistants will also complete a second section of the EYE-2 –EIP checklist (RA Questionnaire v1 EYE-2 071019 hat relates to broad service profiles and practices. Items included in the RA questionnaire reflect issues identified by clinicians in WP1 or training in WP3, to influence whether the EYE-2 approach and EIP are delivered. The questionnaire will be completed with reference to team policies and in consultation with the team leader, and will be conducted in all teams in both arms of the study, immediately post- identification phase. Baseline and mid-trial fidelity assessments will be summarized and fed back to services to boost fidelity.

Interview process – . A random sub-sample of at least 2 clinicians and 1 manager at each of the 10 intervention service (n=33-40) will also complete a brief semi-structured interview to explore barriers and facilitators to intervention delivery including context and turbulence at 3 time points, with at least 10 participants completing each time point of beginning (10+), middle (10+) and end (10+) of the

intervention. Each clinician will be interviewed in a face-to-face, telephone, or Microsoft Teams/Zoom individual interview with a research worker at a time and place that is convenient to them. The interview will take 20-30 minutes, and will be audio-taped for subsequent transcription. Interviews being conducted over Microsoft Teams or Zoom will be audio-recorded (without video) directly, using the recording function in the software, rather than using a separate recording device. It will be guided by the Process evaluation topic guide, and will use a range of visual aids, developed during WP1 to prompt discussion. The process evaluation topic guide will be informed by normalisation process theory and the logic model for EYE-2 as developed in WP1.

Quantitative analysis - The process evaluation will follow a mixed-methods analysis approach. Questionnaire data [5] will be used to produce scores for implementation which will be analysed using mixed regression analysis of all non-missing data (valid if outcomes are "missing at random"), with a random effect for service and a Kenward-Roger small-sample correction to explore changes in scores over time, for implementation of the EYE-2 intervention through core mechanisms of coherence, cognitive participation, collective action and reflexive monitoring. Secondary analyses will be conducted to investigate whether the intervention effect is mediated by adherence and context. Outcomes across site will be investigated in relation to turbulence (macrolevel stressors, complexity and changes within the NHS) over time.

Qualitative analysis - Qualitative interview data will explore implementation, barriers, facilitators, contextual effects and turbulence in the service (macrostressors, complexity, change) over time. Interviews will be analysed inductively using the thematic approach described in WP1 above. Resulting codes will be applied to the constructs of NPT to describe change in practice, and contributing factors including barriers and enablers.

Primary outcome - The primary outcome will be the variation in delivery across sites as measured by the EYE-2 checklist (and NOMAD tool).

Secondary outcomes - Themes derived from the qualitative sub-study will contribute factors that influence delivery, including context and turbulence.

The results will inform a final iteration of the toolkit for future national roll out

6.7. Cost-effectiveness Analysis (Work Package (WP5))

WP5- (0-38M) will be a 12M economic evaluation of the cost-effectiveness of the EYE intervention undertaken primarily from a societal perspective, accounting for cost impacts within and beyond the mental health sector, with a secondary cost-effectiveness analysis taking a narrower NHS perspective. To support the economic evaluation, a common NHS England mandated dataset will be used to measure patient outcomes (HoNOS scores) and resource use pertaining to contact with EIP & other interventions developed for this patient group, psychiatric in-patient admissions, service use relating to s136, and A&E contacts. The Adult Service Use Schedule (AD-SUS) will be administered at 12 months, and will measure, through participant self-report, wider service use over follow-up (e.g. primary care, social services, education and training, police and criminal justice services) and employment-related outcomes.

Piloting - We will pilot this measure during the first 6 months of the study in WP5, in Sussex, in 10 young people who have received 12 months service provision. This will evaluate acceptability and data quality regarding self-report at 12 months, as well as testing the quality of other available data obtained from clinic notes, routine measures, demographics and care co-ordinator report. We will then pilot the tool in 5 service users in each of the 5 sites (25 additional service users in total), in order to finalise the process for collecting this measure at each site. This will form part of the preparatory work at each site to ensure robust data collection. We have added a small additional cost (£20 per participant) for pilot participant's time.

Participants, Inclusion and exclusion criteria – as for WP3. Pilot participants will be current EIP service users in the stated sites with at least 12 months EIP contact.

Recruitment, consent – as outlined in WP3. In addition, since participants may have fewer face-

to-face contacts with their clinical teams and research assistants during COVID-19-related lockdown restrictions, an additional way of contacting participants is also being used in this period. For participants who could not be contacted, the clinical research assistant will contact the primary named carer in order to schedule a meeting or call with the participant and invite them to participate. Care will be taken to ensure to only contact the carer if based on patient records and clinical information a) they are currently involved in providing care for the individual and b) there is no indication that a participant would not wish to involve them in their care.
If following this approach participant is still not available, in order to optimise data collection for the estimation of economic and societal costs (WP5), the primary carer contacted by the research assistant will be recruited as an informant for the Adult Service Use Schedule revised for carers. Consent will be recorded via the previously approved Parent Information Sheet (v2).

Procedure – as outlined in WP3.

Data collection – as outlined in WP3.

Primary outcome – Societal impact as measured by the Adult-Service Use Schedule collected at 12 months. The Adult Service Use Schedule (AD-SUS), which includes structured questions to elicit self-report contact with services and employment outcomes. It has been used widely in various forms in a number of economic evaluations of mental health services.

Secondary outcomes – NHS impact as measured by HoNOS tariff and cluster outcome, and NHS service use. A key aim of the research is to support the development of a commissioning tool for early intervention services.

Analysis

The economic evaluation will be composed of

1. A primary cost-effectiveness analysis conducted from a broad societal perspective including primary care, social services, police and criminal justice contacts, education and training services and occupational outcomes. This will examine patient outcomes (measured using HoNOS scores) alongside the incremental societal costs arising from the intervention over the 12 month trial follow-up period. This will include an assessment of the costs of investing in staff training in intervention methods, the cost of increased engagement with EIP and other NICE recommended interventions, cumulative savings from reduced inpatient admissions and A&E contacts and the intervention impact on the cost of wider service contacts and outcomes (e.g. primary care, education and training, police and criminal justice systems, employment). . The cost-effectiveness analysis will subsequently combine evidence on the cost implications of the EYE intervention with health outcomes data (HoNOS scores; see section 5.4.i) to evaluate whether EYE was cost saving (from a societal perspective) and equivalent or superior (to usual care) in terms of patient outcomes, or whether improved patient outcomes were achieved at greater overall cost over the follow-up period of the trial.

2. A secondary analysis of cost-effectiveness that takes a narrower NHS (commissioner and provider) perspective by combining health outcomes data with an examination of intervention impacts purely within mental health and other NHS services (e.g. psychiatric inpatient admissions and A&E attendance). We will also use HoNOS data to determine the mental health cluster (and therefore tariff) to which a service user would be allocated based on assessment of need at 12 months (e.g. a “step up” or “step down” service need). This will serve as a means to approximate the impact of the intervention on potential future resource use based on payments tariffs linked to cluster.
Service use measured through administrative and self-report data (via the AD-SUS) will be combined and costed using appropriate unit cost evidence either newly developed where necessary (if gaps in unit cost evidence exist) or from existing sources (e.g. Unit costs of Health and Social care, PSSRU; NHS Reference Costs). Employment outcomes (including absenteeism or employment gained or lost) will be valued using the “human capital” approach (using occupational pay rates to value time spent in or out of paid or unpaid work). Estimated societal costs per trial participant will be examined in total and by service sector so that further insight into the distributional burden of costs by sector for this patient group can be gained.

The cost-effectiveness analysis itself will use statistical bootstrapping methods to generate a distribution

of mean total societal costs and HoNOS scores for the intervention and control arms. For comparability any baseline differences between intervention and control cluster participants in clinical scores or social and demographic characteristics that might be expected to be predictive of costs and outcomes over follow-up will be statistically adjusted. The bootstrapped distribution will be used to evaluate the probability that the EYE intervention is either dominant in cost-effectiveness terms (i.e. better/equivalent patient outcomes compared to usual care achieved for a lower overall societal or whether EYE improves outcomes at greater overall cost compared to usual care. Where there is a trade-off identified between cost and outcome, the analysis will evaluate the incremental cost per additional unit of health outcome gained. This analysis will be repeated for the secondary cost-effectiveness analysis taking a narrower NHS perspective. The health economics analysis will also unpack any key NHS cost impacts linked to the EYE intervention, including its effect on A&E attendance and psychiatric inpatient admissions and associated costs. The impact of uncertainty around key assumptions on cost-effectiveness conclusions will be handled through sensitivity analysis. We will work closely with our commissioning partner in the project to integrate the findings from the economic evaluation into a commissioning toolkit. If there is significant missing data we will explore whether the process of missing-ness satisfies assumptions required to use multiple imputation methods to handle loss of information. Whilst there may be differential missing data between study arms, this data is most likely to be Missing At Random. We can expand our analysis strategy to investigate sensitivity to the MAR assumptions.

6.8. Trial Stop-Go Criteria

Based on recent recommendations [92], success criteria are presented that represent the research ambition, and stop criteria are presented that focus on trial recruitment and protocol adherence. Any performance that falls between these criteria, will be discussed with the Trial Steering Committee and funding body as appropriate to allow opportunities to remedy early problems.
Success (go) criteria

1. End of month 9 – Number of services randomised - 20 services should have been randomised
2. End of month 16 – Number of participants identified - 440 participants (50% of cohort) should have been identified
3. End of month 16 – Fidelity data – Initial fidelity data should be available at all sites

The following sequential decision gates and stop criteria are proposed. The trial will be considered infeasible if any of the following conditions apply:

1. End of month 12 – Number of services randomised - < 17 (80% of services) services have been randomised
2. End of month 19 – Number of participants identified - < 340 (40% of cohort) participants have been identified
3. End of month 19 – Fidelity data – Initial fidelity data is available for fewer than 3 sites

7. Safety Reporting

International Conference for Harmonisation/Good Clinical Practice (ICH/GCP) requires that both investigators and Sponsor to follow specific procedures when notifying and reporting adverse events/reactions in research studies. These procedures are described in this section of the protocol.

Table 1: Definitions for adverse events and reactions applicable in EYE-2 project

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient treated on a study protocol, which does not necessarily have a causal relationship with a study intervention. An AE can therefore be any unfavourable and unintended sign, symptom or disease temporally associated with the use of a study intervention, whether or not related to that study treatment.

Adverse Reaction (AR)	All untoward and unintended responses related to a study intervention. A causal relationship between a study intervention and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out as there is evidence or arguments to suggest a causal relationship.
Unexpected Adverse Reaction (UAR)	An adverse reaction, the nature or severity of which is not consistent with the information about the trial intervention.

Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR) or Suspected Unexpected Serious Adverse Reaction (SUSAR)	Respectively any adverse event, adverse reaction or unexpected adverse reaction that: • results in death • is life-threatening* (only including self-harm or suicide ideation or suicide attempt requiring hospitalization or serious threat or act of harm to others); • requires inpatient hospitalisation or prolongation of existing hospitalisation** (in the case of psychosis or suicide ideation grade 4 or suicide attempt grade 4 or 5 as according to CTCAE v.5.0; November 27, 2017 (see table below) or serious threat or act of harm to others requiring hospitalisation); • results in persistent or significant disability or incapacity (based on clinician's judgement) • consists of a congenital anomaly or birth defect

Life-threatening (*), in the definition of 'serious', refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

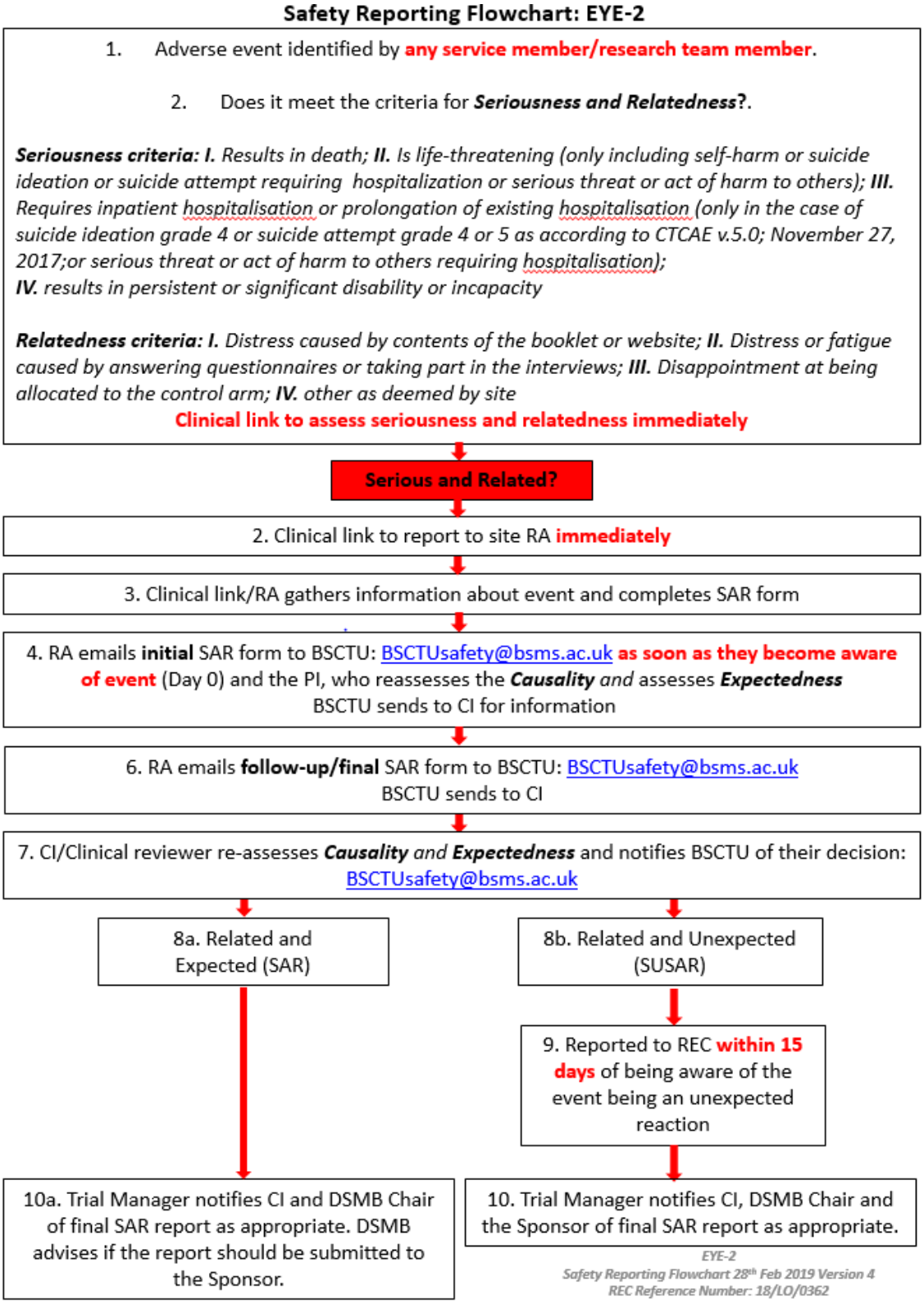
Hospitalisation (**) is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition (excluding psychosis) including elective procedures that have not worsened do not constitute an SAE.

Taken from 'Common Terminology Criteria for Adverse Events (CTCAE), V.5.0, November 27, 2017;)

Psychiatric disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Mania	Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)	Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)	Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalization not indicated; new onset	Life-threatening consequences, threats of harm to self or others; hospitalization indicated	Death
Definition: A disorder characterized by excitement of psychotic proportions manifested by mental and physical hyperactivity, disorganization of behavior and elevation of mood. **Navigational Note:** -					
Personality change	Mild personality change	Moderate personality change	Severe personality change; hospitalization not indicated	Life-threatening consequences, threats of harm to self or others; hospitalization indicated	-
Definition: A disorder characterized by a conspicuous change in a person's behavior and thinking. **Navigational Note:** -					
Psychosis	Mild psychotic symptoms	Moderate psychotic symptoms (e.g., disorganized speech; impaired reality testing)	Severe psychotic symptoms (e.g., paranoid, extreme disorganization); hospitalization not indicated; new onset	Life-threatening consequences, threats of harm to self or others; hospitalization indicated	Death
Definition: A disorder characterized by personality change, impaired functioning, and loss of touch with reality. It may be a manifestation of schizophrenia, bipolar disorder or brain tumor. **Navigational Note:** -					
Restlessness	Mild symptoms; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by an inability to rest, relax or be still. **Navigational Note:** -					
Suicidal ideation	Increased thoughts of death but no wish to kill oneself	Suicidal ideation with no specific plan or intent	Specific plan to commit suicide without serious intent to die which may not require hospitalization	Specific plan to commit suicide with serious intent to die which requires hospitalization	-
Definition: A disorder characterized by thoughts of taking one's own life. **Navigational Note:** -					
Suicide attempt	-	-	Suicide attempt or gesture without intent to die	Suicide attempt with intent to die which requires hospitalization	Death
Definition: A disorder characterized by self-inflicted harm in an attempt to end one's own life. **Navigational Note:** -					

Where the Serious Adverse Event (SAE) is not life threatening or a hospitalisation, clinical judgement should be exercised in deciding whether an Adverse Event (AE)/Adverse Reaction (AR) is serious. For example Important AE/ARs, that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above (at grade 3), may also be considered serious, based on clinical judgement.

NB., in those whose First Episode Psychosis (FEP) status is delayed, (i.e. they have a period of extended assessment) we will gather data on and report retrospectively on SAEs that are raised from the point of entry into the service.



Event Assessment

(a) Seriousness

When an AE occurs, local clinical link first assesses whether the event is serious using the definition given in Table 1 [events categorised as grade 4 or 5; grade 3 if considered serious based on clinical judgement of the local investigator].

(b) Causality

For any AE classified as Serious, the clinical link person or team clinician will also assess the causality in relation to the trial intervention using the definitions in Table 2. There are 5 categories of causality: unrelated, unlikely, possible, probable and definitely related. If the causality assessment is unrelated or unlikely to be related the event is classified as an SAE. If the causality is assessed as either possible, probable or definitely related then the event is classified as a SAR.

Table 2. Definitions of causality for adverse events

Relationship	Description	Event Type
Unrelated	There is no evidence of any causal relationship	SAE
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention). There is another reasonable explanation for the event (e.g. the patient's clinical condition, other concomitant treatment).	SAE
Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after the trial intervention, and there is some possible link to the trial). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant treatments).	SAR
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	SAR
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	SAR

For example, related events may be as follows:

I. Distress caused by contents of the booklet or website;

II. Distress caused by answering questionnaires or taking part in the interviews;

III. Disappointment at being allocated to the control arm;

IV. Distress related to the involvement with or breach of confidentiality related to involvement of a non-standard member of the social network such as friend or other non-family member

V. Distress triggered by attendance at an EYE-2 social group

VI. Distress caused by concern about data security in the trial (routine data/posts on the forum)

VII. Distress caused by a response to a post on the forum or other forum content

VIII. other as deemed by the site.

(c) Expectedness

The expectedness of the SAE will also be assessed by the local delegated investigator (named PI) and the CI. The definition of an unexpected adverse reaction (UAR) is given in Table 1 (An adverse reaction, the nature or severity of which is not consistent with the information about the trial intervention). If an SAE is assessed as being possibly, probably or definitely related, and unexpected it becomes a SUSAR and must be reported to the BSCTU immediately (bsctu@bsms.ac.uk).

(d) Recording and Reporting of Adverse Events/Adverse Reactions for this Trial

This trial is unusual in that it is a pragmatic cluster trial which includes the entire cohort of 20 Early Intervention in Psychosis services in England for one year, followed up for a further year. It is therefore expected that there will be a very large number of SAE's due to the natural fluctuation in severity of psychosis experiences in this population, and the intervention itself is a comparatively low risk social, motivational and psychoeducation intervention. For this reason, it was decided to take a pragmatic approach to reporting of adverse events, this has been discussed with the trial management team, and DMEC, and follows the approach used in a previous cluster RCT [95]. Clinicians and clinical link persons in each team will raise to the research team any serious adverse event that is deemed to be possibly, probably or definitely related to the trial, for further action.

Table 3 Summary of Recording/Reporting requirements:

Type of Event	Action Required
Adverse Event (AE)	none
Serious Adverse Event (SAE)	none
Unexpected Adverse Event (UAE)	none
Adverse Reaction (AR)	none
Serious Adverse Reaction (SAR)	Using the SAR reporting form Report within 24 hours of being made aware to BSCTUsafety@bsms.ac.uk and to the site PI
Suspected Unexpected Serious Adverse Reaction (SUSAR)	Using the SAR reporting form Report within 24 hours of being made aware to BSCTUsafety@bsms.ac.uk and to the site PI

Notification Procedure for SARs and SUSARs:

1. The initial SAR form must be completed by the local link person/RA (as named on the signature list and delegation of responsibilities log who is responsible for the patient's care).

2. Send the initial SAR form with as much information as possible by email to BSCTUsafety@bsms.ac.uk and the PI as soon as site becomes aware of it. The PI reassess the causality and assess the expectedness. The initial report shall be followed by detailed, follow up reports as appropriate.

3. Follow-up: Patients must be followed-up until clinical recovery is complete, or until the event has resolved. Follow-up should continue after completion of protocol treatment if necessary. Follow-up information must be reported on the follow-up/final SAR report. In the absence of the PI, the form should be completed and signed by another trained member of the site trial team who is named on the delegation log (as designated by local PI) The PI should subsequently check the SAR form, make changes as appropriate, sign and then send to the Brighton & Sussex CTU as soon as possible. The patient must be identified by trial number. The patient's name should not be used on any correspondence. This final SAR report is then graded SAR or SUSAR on the basis of expectedness judged by the PI and CI.

4. The BSCTU will notify the research ethics committee of SUSARs as per the conditions of the favourable opinion and according to CTUSOP018 within 15 calendar days of the BSCTU first being notified of the event.

8. Data Management & Analysis

8.1 Summary of the Types of Data

1. WP1 will generate qualitative data from 12-16 individual interviews; they will be audio-recorded and transcribed into Mp3 files and word documents, respectively
2. WP2 will generate qualitative data from 18-24 individual interviews; they will be audio-recorded and transcribed into Mp3 files and word documents, respectively
3. WP3 data will be routinely recorded, routinely collected and researcher collected routine outcome measures included primary time to disengagement outcome data, descriptive data on service use, and NICE guidelines interventions use and clinician and service user questionnaire data on 950 participants administered on paper in person or by telephone. Anonymised data will be entered onto the MACRO database using the eCRF, at 3-5 time points (0, 6, 12, 18 and 24 months).
4. WP4 data will be questionnaire and checklist data collected from all clinicians involved in the study at beginning (11+), middle (11+) and end (11+) of intervention, and qualitative data collected in person or by telephone in 33-40 individual interviews with clinicians in well, intermediate and least well performing services.
5. WP5 data will be questionnaire data collected in person or by telephone at 12 months.

8.2 Research Variables Form (RVF)

Not applicable at this stage. Research variables will be generated during the course of the study.

8.3 Dummy results tables

Not applicable at this stage

8.4 Data collection, entering, coding and checking process

Data collection, coding and checking procedures are outlined in the relevant procedures in section 6 above. The CTU will develop an electronic Case Report Form (eCRF), using Elsevier MACRO. The system is Good Clinical Practice (GCP) and 21 CFR Part 11 compliant with a full audit trail and database lock functionality. Staff at each site will be trained to ensure that data are captured reliably using a standard eCRF proforma according to the processes defined above. Proforma data will be recorded anonymously using a distinct code to represent each service user, monitored for completeness, collated and entered consistently in anonymised form by the clinical EIP RA in each service on the MACRO database for the research team who will be blind to study arm. The second RA who will also be blind to study arm will enter data that is collected following informed consent. The CTU will monitor for data completeness and will alert RAs to any data that are missing The linkage between personal and routine data and the individual participants will be stored separately and securely in a password protected file.

8.5 Missing data policy

Approaches to missing data are outlined in the relevant analysis sections above.

8.6 Potential bias

Guidelines for identifying, avoiding and reflecting on potential bias will be followed for the analysis of the qualitative data. The quantitative data will be checked using methods outlined in section 6 above on blindness and reliability.

8.7 Data custodian and data ownership.

Name of data custodian: Dr Kathryn Greenwood.

Name of data owner: Sussex Partnership NHS Foundation Trust.

8.8 Data quality and Standards

The Clinical Trial Unit data manager and trial manager will be responsible for data quality standards, supported by close liaison with the site PIs and Research Assistants at each site. The project team has significant experience of conducting research with people experiencing psychosis.

Project management, trial steering committee and DMEC committee are outlined in the relevant project management sections below.

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8.9 Data security

Confidentiality will be ensured by following Sussex Partnership NHS Foundation Trust (SPT) and all regional NHS Trust guidelines regarding storage of research data.

a) Physical and electronic data security

Wherever possible, all personal and research data will be entered and stored only in electronic format. Where it is necessary to store personal or research data in hard copies, for example where there is no access to a laptop or where staff complete paper versions of a questionnaire, data will be stored at the designated NHS trust base in a locked filing cabinet.

Electronic copies of personal and study data will be stored on secure shared drives at each NHS site. All data will password-protected using a password known only to the study team. No personal or study data will be downloaded or stored on individual employee drives or desktops. Data will be entered onto the MACRO eCRF which is the electronic data management system and is Good Clinical Practice (GCP) and 21 CFR Part 11 compliant.

b) Confidentiality of personal data

The project team will adhere to the good practice and standards principles which are set out in the Sussex Partnership Policy for Data Protection, Security and Confidentiality 2013. This policy reflects the recommendations from current legislation, including The Caldicott Report (1997), the British Standard (ISO IEC 27002) for Information Security, the Data Protection Act, 1998 and the Sussex Partnership Foundation Trust Research Policy 2012. All research will be carried out under the above standards and will be reviewed by an NHS Ethics Committee and given approval by the R&D Department under the NHS Research Governance Framework 2005. These principles relate to the need to protect personal data and guard against any unauthorised use, inform patients (and professionals) of its use, and allow patients choice regarding how their personal data is disclosed or used. All members of the study team will be made aware of this code of conduct and their responsibilities in accordance with this.

Participant personal data for all work packages will be stored in a secure password-protected file at each study site. The drive will only be accessible to the research assistants who are employed and working as part of the EIP and Research teams. In both hard and electronic versions, personal and study data will be kept completely separate. Study data will be identified using a participant identification number (ID). This ID will be linked to the participant's name in a linked file. This file will be password protected, with password known only to the study team.

c) Long-term data storage arrangements

Research data will be stored for 10 year duration in line with SPT policy, and will be archived at each site, and centrally for all centrally collated electronic data.

Audio recordings will be uploaded to the secure shared drive at each site, and stored in an anonymised and encrypted form. The audio-recording will then be deleted from the portable device within 24 hours of recording. After the 10 year period, research data will be shredded, deleted or destroyed using confidential data destruction measures in place for each organisation.

8.10 Data sharing

Data will not be shared with anyone outside of the project team and organisations hosting the research.

8.11 Data confidentiality and transfer

Data will be stored confidentially and securely. Anonymised outcome data will be stored separately from personal information. All data will be stored in password protected format and any data that is transferred will be done securely and using encrypted zip files in for example, CSV, STATA, SAS or SAS format

9. Dissemination and Projected outputs

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. These will be made available to clinicians, managers and services to support delivery in the NHS. A broader package of learning, relating to implementation in youth & mental health services, will be made available for other youth and psychosis services (NHS and non-statutory). The commissioning guide, developed with our GP commissioner, will be provided for commissioning purposes. Our collaboration with NHS England EIP lead (JN) will allow us to adapt approaches and materials during the study, and release these to support and guide future NHS England targets. We will present our findings to the public, participants, services and academic audiences through the Sussex Psychosis Research Interest Group, and other site specific and local feedback events, national & international conferences. We will draw on our national collaborations, and regional links, so that if effective, we can readily disseminate the outcomes of this study, and guidance for implementation to all EIP teams in England, alongside the manuals, and commissioner guidance. A series of Tweet chats involving national and international colleagues, offered to services throughout the UK will support further implementation planning. Researchers, clinicians & services will thus be kept informed and able to use new information regarding (i) the effectiveness & cost-effectiveness of the intervention; (ii) the engagement needs of ethnic minority EIP populations;(iii) variations in implementation & outcomes based on NHS service context, turbulence, macro & micro stressors. Service users & families will thus, in a timely manner, receive engagement focussed services, supported by 'myth-busting' resources that address their personal goals & needs.

EIP services throughout the UK will be supported to implement the EYE intervention. The results of the study, if effective & cost-effective, will be widely disseminated through our network of regional and national channels, to clinicians, services, trusts & CCGs, supported by NHS England. We will offer a set of training & implementation packages tailored to different contexts and services, including manuals, resources & commissioner guides. The normalisation process theory framework will enable us to lay out specific changes that will be required in terms of roles & responsibilities, beliefs, behaviours, relationships, processes & structures to deliver the EYE approach at an individual, social network, service & NHS trust level. This will enable a real and meaningful change in how individuals work and services are delivered, based on core EYE intervention principles.

10. Plan of Investigation and timetable

The project will take 38 months in 6 stages (with an additional preparatory stage prior to start). It will be monitored with 21 key milestones to ensure the project is on track and to support the production of key outputs, as shown also in the Gantt chart.

Stage 0 Preparatory phase - 5 months before start; Detailed Trial Protocol drafted; Ethics and all R&D approvals granted; initiation of staff recruitment; preparation for stage 1 participant recruitment.

Stage 1 Months 0-6 Final set-up; qualitative analysis, finalising materials, building database. Initial round of staff recruitment complete. Recruitment, conduct & analysis of implementation and ethnic minority focus groups complete (WP 1 & 2); manuals, training package and process evaluation tools complete; booklets, website and resources complete.

Milestone 1 end of month 3: Recruit & run Sussex clinician & manager focus groups
Milestone 2 end of month 5: Analyse implementation focus group data
Milestone 3 end of month 6: finalise manuals, training and process evaluation tools
Milestone 4 end of month 4: Recruit and run ethnicity focus groups in Manchester/London/ Hampshire
Milestone 5 end of month 5: Analyse ethnicity focus group data
Milestone 6 end of month 6: Finalise booklets, website and resources

Stage 2 Months 7-9 Training and site set-up including, pilot testing of data collection, extraction and monitoring processes; database built; protocol submission for publication by end of month 9.

Milestone 7 end of month 9: pilot & confirm data collection, extraction & monitoring process at each site
Milestone 8 end of month 9: complete site training - Hampshire, Thames Valley, Norwich-Cambridge. Manchester, London

Stage 3 Months 10-21 Baseline recruitment; 50% of cohort identified at month 16 and 100% at month 22; Intervention delivery and monitoring for fidelity; Baseline and initial 6M and 12M data collected for WP 3 &5; Data completeness and attrition rates monitored with checks at months 16 and 22; First round of process evaluation questionnaire data collected; initial qualitative process evaluation data (WP4).

Milestone 9 end of month 15: 50% of cohort identified and 50% baseline data complete
Milestone 10 end of month 16: data completeness and attrition monitored
Milestone 11 end of month 21: 100% of each cohort identified, 100% baseline and 50% 6M data complete, 12M data started
Milestone 12 end of month 22: data completeness and attrition monitored
Milestone 13 end of month 22 First round process evaluation questionnaires & qualitative data complete

Stage 4 Months 22-33 Follow-up data collection; Follow-up data collected for 12-24M for WP 3 & 5; second round of process evaluation questionnaire data collected; final qualitative process evaluation data collected (WP4).

Milestone 14 end of month 27 all 6M data complete and 50% of 12M data complete, 18M data started
Milestone 15 end of month 34: all 12 M data complete and 50% of 18M data complete
Milestone 16 end of month 34 final round process evaluation questionnaire & qualitative data complete
Stage 5 Months 34-35 Database completion and checking; All follow-up data collected. All data entered, checked, cleaned and database locked ready for analysis by month 35.

Milestone 17 end of month 35: all available remaining 18 and 24M data complete
Milestone 18 end of month 35: all data checked, cleaned and database locked

Stage 6 Months 36-38 Final analysis and writing up stage; Data analysis by end month 37, final report and effectiveness paper drafted month 38; initial dissemination.

Milestone 19 end of month 37: analysis complete
Milestone 20 end of month 38 final report and efficacy paper drafted
Milestone 21 end of month 38: national launch event

11. Project Management

Sussex Partnership NHS Foundation Trust will be the sponsor. At each site, research assistants, service user researcher, service users & carer will form a mini-team, supervised locally by the site lead, and centrally by the CI & CTU. Work packages & PPI activity will be led by relevant co-applicants and the CI (see section 5.1.i). Monthly project management meetings chaired by the CI and involving all co-applicants will manage day–to-day project management, ensure good communication between sites, receive monthly site reports on data collection, intervention delivery & progress, and address problems. The trial steering committee (TSC) will comprise independent chair, clinical implementation academic,

statistician, health economist, 2 PPI members plus CTU lead & CI. It will meet 6-monthly or more often if required to provide overall trial supervision and independent advice, including review of project reports, protocols, amendments & adherence to protocol. An independent DMEC committee, clinical academic and statistician will meet 6-monthly or more often if required prior to TSC & will review trial data & serious adverse reactions, consider if interim analyses are warranted and if for ethical or safety reasons the trial should end early.

The CTU will oversee study conduct & ensure adherence to Standard Operating Procedures (SOPs) & protocol. The trial manager will work with the study team to ensure the study is managed in accordance with all regulations & governance frameworks. They monitor recruitment & study conduct based on a risk adaptive approach using CTU SOPs, and provide reports to the study team & oversight committees. The trial manager together with the CI will train staff in study requirements. The data entry will be quality controlled by the system as it is being entered (flagging up errors in real time). The data manager will monitor data collection & management in accordance with protocol, including design of data collection tools, undertaking data validation checks, writing the data management plan. They will work with sites to ensure all data entry is accurate and entered in a timely manner. They will provide data & information for oversight committees & undertake data cleaning prior to statistical analyses. All data will be archived in the Trial Master File and retained securely for a minimum of five years following completion and closure of the trial.

12. Ethical Considerations

This project raises a number of complex ethical issues, and as a result, we have consulted closely with several groups of Early Intervention in Psychosis (EIP) service users, including service users from ethnic minority populations. We have also consulted with the chair of the ethics committee, prior to submitting the grant application for this study, and have run a previous Early Youth Engagement study which developed the intervention approach, and undertook feasibility and pilot testing. Finally, we have checked the Confidentiality Advisory Group precedent set categories, to confirm that it is acceptable when accessing data on site to extract anonymised data, to fund a member of the EIP team to undertake this role, and that this approach does not require additional CAG approval. The previous study had significant patient and public involvement throughout design, delivery and dissemination, and lived experience researchers were co-applicants.

The intervention approach, has itself been developed by asking young EIP service users, their families, and other young people not using services, including those who have disengaged despite therapeutic need, for example in homeless hostels, what would make them more or less likely to engage. We presented what we learnt in themes to clinicians, and asked them to rate the feasibility and importance of a larger set of intervention approaches. We selected the EYE intervention approaches that were rated as both important and feasible to deliver, and finalised the EYE intervention. We then tested the feasibility of delivering the intervention, identifying and following up a cohort and collating their routine engagement outcome data in a small pre-post cohort study with process evaluation and qualitative sub-study. The feasibility study demonstrated that it was feasible to extract and collate routine engagement outcome data. Research assistants who were employed as part of the EIP teams, collated this data as anonymous service level engagement outcome data, and transferred it in anonymised format to the research team. Our pilot cohort study suggested that using the EYE intervention might reduce disengagement by 10%, and our qualitative study of experiences with the intervention suggested that service users felt more hope, trust and collaboration, and less isolation as a result of the EYE approach.

The primary aim of the new EYE-2 study is to test the effectiveness (Work Package (WP) 3) and cost-effectiveness (WP5) of the intervention that aims to improve the engagement of young people in EIP services. This is important because approximately 25% of young people disengage from EIP services in the first year, with potential negative impacts on their longer term mental health. A process evaluation (WP5) will explore delivery across context and turbulence in the NHS. Prior to starting the cluster RCT, we plan to refine the resources used as part of the intervention, based on feedback obtained from the study of implementation in the Sussex services that were part of the original EYE study (WP1), and from feedback obtained from the ethnicity and diversity study (WP2).

Ethical Issues

The main ethical issues relating to this project are in (i) the significant challenge and methods for collecting data to ensure that this is both accurate, reliable and valid to explore the issue of disengagement and its impact on mental health outcomes, and is also ethical and safe; (ii) the safe and ethical conduct of the service user led social groups in EIP services.

General data collection methods:
Below we outline the ethical issues in our data collection methods and the processes that we have employed in order to address these issues. As part of these approaches we will be consulting with our study PPI group, who will work with us to develop (i) publicity/advertising materials for the intervention (e.g. mugs and pens); (ii) the resource pack of localized non-statutory and voluntary youth support services; (iii) the adapted Adult Service Use Schedule and; (iv) the semi-structured interview that will be used to enable the completion of the HoNOS scale for people who are not engaged in services and for any other time point as necessary (following COVID-19). The semi-structured interview will be submitted for ethical review as a substantial amendment prior to use.

(i) data collection methods.

A significant challenge in this study, is how to collect reliable, valid data in an ethical and safe manner bearing in mind that it is vital to the meaningfulness of the study to obtain this data from people who are ambivalent, minimally engaged or disengaged from services. This group of people who are ambivalent and least likely to be engaged are also least likely to be available and open to consent to take part in research.

All teams and clinicians will be trained in robust reliable routine data collection, and in describing the study to service users. They will also be trained in delivering the intervention.

We have then developed a number of approaches to support data collection, following from our previous study and in consultation with our PPI group.

First, we will advertise the study widely in all teams that are involved in the project. All service users who are part of the cohort will be provided with the poster, leaflet, and advertising materials (e.g. pens and mugs designed in consultation with our PPI group) and will have the study explained to them by their clinical team.

We plan to utilize anonymized routinely collected and recorded outcome data wherever possible. Engagement and service use is recorded in notes. The HoNOS is a clinician rated measure that is routinely collected and used for tariff clusters. The QPR and DIALOG are patient reported outcome measures that are mandated for routine collection by NHS England. This routine data will be collated and anonymized, along with basic demographic information by Research Assistants who will be employed as part of the clinical EIP teams. These RA's will be based and supervised within the teams. These RAs will work closely with the teams to ensure that this data is reliably collected and recorded, and entered into anonymised electronic clinical record forms (eCRF) for data entry purposes. Where data is missing due to limits in care co-ordinator time and capacity, the RAs in teams will also collect missing data wherever possible, either in person or by telephone dependent on the preference of the service user. This data will be treated as service level descriptive cohort data and will not contain personalized information. Individual informed consent will not be sought for the use of this data, due to the significant problems of data integrity from minimally engaged service users and in light of the routine anonymized format.

Where service users have disengaged from the service at a particular time point, and for the Adult Service Use Schedule data at 12 or 24 months, the RA from within the EIP team will send a letter to the service user, reminding them about the involvement of the service with the EYE project, including useful EYE project materials (e.g. mugs/pens), and for people who have disengaged, a pack of information about local support services information in case they have need of support and do not wish to recontact the EIP team. The study information sheet and consent form will also be included. The letter will advise service users that they will be contacted shortly, by someone from the EYE team. They will be advised that this will be to answer some routine questions that the EYE study is using, about their health, wellbeing and satisfaction with NHS services, that this will take 20-30 minutes, and can be completed by phone, or in person if they prefer and that they will be reimbursed £20 for their time. They will be told

that if they do not wish to take part, they can either return the reply slip in the next week, or tell the researcher when they are contacted. They will be provided with a stamped addressed envelope with a reply slip which they can return if they do not want to be contacted.

For all service users who have not returned a reply slip, they will be contacted a minimum of one week later, by the EIP research assistant by telephone, or in writing. The EIP researcher will explain the study to them, with reference to the information and consent sheet, and if they are interested their details will be passed to the study research assistant. If the service user consents to take part they will be offered a telephone interview to complete the questionnaire (or a face to face meeting at a point that this becomes possible again following the reduction in covid-19 restrictions). If they complete the questionnaires by telephone, the consent will be noted by the researcher, in discussion with the participant. After which, the researcher will conduct the HoNOS by semi-structured interview, the QPR, the DIALOG, and at 12 months or 24 months only the Adult Service Use Schedule. They will be thanked for their time, and a postal order for £20 will be sent to them, at the address confirmed. If they prefer to complete the data in person, then written informed consent will be taken, a convenient public space will be agreed to meet to complete the measures, the same process will be followed, with the exception that £20 will be provided in cash. If at any point the participant asks to stop taking part, this will be noted and the interview will be stopped. If the participant asks not to be contacted again regarding the study, this too will be noted, and they will not be contacted again.

(ii) Contacting EIP service users to complete questionnaires, including those who are not currently in contact with the service.

There are a number of ethical issues associated with contacting service users to complete questionnaire measures.

First, service users who are minimally engaged or disengaged from the service may be surprised, suspicious or unhappy about being contacted. To alleviate this risk, we will publicise the study actively in all teams and to all service users. We will send a pack of useful information to all service users, including information to advise them before the EYE team contacts them. We will provide them with an easy stamped-addressed-envelope reply so that they can opt out if they don't want to be contacted.

Second, service users may be unwell or at risk, when they are contacted. This presents potential ethical issues and risks for both the service user and the researcher. For the service user, it will be important for researchers to explain, in writing, in telephone contact, and in person if there is a face to face contact that if there is any risk identified to the young person or anyone else during the course of completing the questionnaires, that confidentiality will be broken and that the person's team, GP, or emergency services will be contacted. The researcher will be trained to deal with this eventuality by the research team. If it is necessary to breach confidentiality, the researcher will attempt to keep the service user on the phone, or in the meeting, whilst services are contacted and a safety plan is identified in collaboration with the service user. If the young person presents as unwell but not imminently at risk, the researcher will discuss with the service user, option for help-seeking and support including a representation to EIP but also help-seeking to other non-statutory services if they prefer. They will be directed to the resource pack of local services, which will be resent if this has been lost or misplaced, and help-seeking will be facilitated by the researcher if the service user prefers. For the researcher, if the young person prefers to meet in person, it will be important to ensure that this is in a public space, such as an NHS setting, GP surgery, or other public or community location, as for people who have disengaged from services their current risk may not be known. The approach to confidentiality and risk will be as identified above, but in addition, consent will be obtained verbally to check the most recent service user notes. This will allow the researcher to prepare for the interview including, checking for any known previous risks, and adjusting the meeting plans accordingly, for example meeting as a pair of researchers or in a more secure NHS setting if previous risks are identified.

(iii) The use of telephone interviews

We have included telephone interviews as an option to collect data from service users who may have disengaged from services. This is because those who are ambivalent about engaging with services, may be reluctant to meet in person, but may instead be willing to take part in a brief telephone discussion. We have used telephone interviews in previous studies with young service users with psychosis. Additional measures are put in place to ensure that telephone interviews are conducted safely and in such a way as to minimize distress. Initial telephone contact will be conducted during

normal working hours to ensure that services are routinely available in the case of any risk or distress expressed by the service user, and the researcher will have local support and emergency contacts available to them in case of any risk issues or distress. The questionnaires are routinely used in services for people with psychosis, but the researcher will allow sufficient time, to discuss any distress caused or concerns raised by the service user. In addition, as outlined below, the semi-structured interview to elicit answers to the questions will be written with service users, who will also train the researchers to ensure that discussions are conducted sensitively.

(iv) Distress or fatigue caused by answering questionnaires or taking part in interviews

The questionnaires to be used as part of the research are those which are routinely collected by the services. They are largely positively framed and focused on recovery and satisfaction. The two patient reported outcome measures QPR and DIALOG are both either designed by service users themselves, or were produced with significant service user involvement. The HoNOS measure is rated by the clinician/researcher on the basis of their knowledge gained from discussions with the service user, and does include sensitive issues such as self-harm, substance use, mental health, relationship, living arrangements and occupation. Similarly the Adult Service Use Schedule asks about contacts with a range of services including health, mental health, social, emergency and criminal justice services. These are both routinely used in research and/or clinically with young people with psychosis, and the semi-structured interview will be written with our PPI service users to minimize the risk of any distress. Researchers will be advised that they should discuss the resource pack with service users prior to commencing the questionnaires, to make sure that service users are reminded in advance of the support that is available to them, in case of any distress. This will then be discussed further if any distress is expressed and the researcher will be trained to continue a conversation until possible supports and routes to access have been identified. If the service user discontinues the call which may happen if they have already disengaged from services, and there is no immediate risk identified, then the researcher will send a letter and leaflet outlining the most appropriate form of support. It is also possible that service users may feel fatigued by completing the questionnaires, and this may be further exacerbated if they also travel to meet the researcher. The number and length of questionnaires has been kept to a minimum to reduce fatigue and in addition, service users will be told that they can take a break whenever they need to during the questionnaires, and can stop at any time.

It is possible also that the individual interviews about adapting services and resources for ethnic minorities may also discuss sensitive topics that could be distressing, particularly about the extent to which service users ethnic, cultural and spiritual needs are recognized and supported in the NHS. The service users who take part in these interviews will be current service users. In the event of any distress, they will be supported by the researchers who will be trained in cultural awareness, and in supporting EIP service users who are distressed. We will identify local BAME support groups where available, as well as encouraging service users to raise any prolonged or significant distress with their clinician. Breaks will be offered as appropriate if service users become distressed or fatigued by the interviews, and the service users will be advised that they can stop at any time.

(v) Rate of reimbursement for time

We have consulted with multiple patient and public involvement groups of EIP service users about the appropriate rate of reimbursement for service users for completion of the questionnaires and interviews. This is because in our original EYE project, we did include PPI members who were minimally engaged with services and these PPI members told us that the best way to ensure representation and outcomes from service users who are minimally engaged, or who disengage is to reimburse them for their time. At the same time, we are aware of the ethical issues in providing a level of reimbursement that is too high such that it could be viewed as coercive to service users to take part in research. We have therefore consulted with our PPI groups about the level of reimbursement that would be valued by people who are minimally engaged, or disengaged from services, without this being too high. We have been advised that in light of the time commitment (20-30 minutes for questionnaires or up to an hour for interviews) that £20 would be an appropriate level of reimbursement, and we will offer this for each set of data that is collected following informed consent.

(vi) Social Groups

One part of the EYE-2 intervention involves service users within EIP services setting up and running their own social groups. Various roles for peer workers were explored as part of the original EYE study, and this model was the most popular and the most successful. According to this model, service users can attend the group both in order to facilitate their own social recovery, but also in order to help others, and at the same time, everyone gains more confidence by attending the group. However, this raises both organizational and ethical issues, as service users will be meeting each socially without clinician facilitation.

The groups will be set up organizationally by a local Patient and Public Involvement (PPI) lead in each team, 2 service users and a carer, and by the RA who is working as part of the EIP team. Each of these local teams will work together with service users to develop the basic outline and ground rules for the groups, and will work with staff to identify and encourage service users to join the groups. The groups will have a social focus but will be flexible to the interests of the group. The main ethical issues are that service users, including PPI members, who attend the group will socialize with other service users, some of whom may be less well than themselves. This may result in service users discussing sensitive, or triggering issues such as suicidal thoughts or self-harm. The PPI lead at each site will be highly experienced in facilitating service user groups, and will be available to support the group each week, along with the RA, although they may not directly lead the group. Both will be experienced in managing groups where some people may be less well, and will be able to respond appropriately if any risks are raised. The process of producing a set of 'ground rules' at each site will involve explicit discussion of how social group members will behave respectfully with each other (and what is considered to be respectful and disrespectful behavior, which may be different in certain cultural contexts), how they may discuss sensitive issues (again different issues may be considered sensitive in some cultural contexts), and how the group will work together to make decisions about what they do and how to resolve conflicts. There will also be an agreement with the group about how staff will be available to support members expressing distress. By working together as a team with other service users, if someone is unwell or expressing risk or distress, an experienced member of the team can speak with them individually outside of the group and can take the appropriate course of action, whilst other team members will be available to talk with the rest of the group about any impacts, and about how the group might support the person in the future. If the social group meets or travels off the NHS site, then at least 2 members of the group will act in a facilitating role, will have access to emergency contacts and strategies and will call in when the group ends. We have piloted these approaches in the original EYE study. The social and PPI groups, will be supported by the overarching PPI lead (RT) who is a senior researcher and PPI lead in the McPin Foundation. She is experienced in managing and supporting teams of researchers with lived experience of mental health difficulties, and knowledgeable in the principles and logistics of peer support and in supporting service user groups of this kind. She and founding members of McPin have a wealth of knowledge regarding how to run these groups effectively.

(vii) Informed consent for 14-15 year olds.

In order to represent all young people using EIP services, we would like to recruit also 14-15 year olds to the ethnicity and minority study, the cost-effectiveness study and to the effectiveness study where data is missing or the young person has disengaged. We are aware that this raises additional issues in relation to informed consent. For the ethnicity study, the young person will first be approached by someone within the EIP team. If they are interested, both they and the parent or responsible adult whose name is provided by their local service will be contacted. In the situation, where the young person is invited because they are part of the LGBT population, care will be taken to ensure that the family is aware of this, before the young person is invited. If there is any doubt over the families knowledge and this poses any risks to the young person themselves, they will not be invited to take part. For the cost-effectiveness, and for the effectiveness study where the young person has disengaged or their data is missing, the first contact will be through the care team who will provide the resource pack, advertising materials, introductory letter and information and consent sheet. Again, a parent/responsible adult version of the letter, along with the information and consent sheet will be sent. We will then follow the same approach described above, except that we will also obtain consent from parents, prior to collecting any data. This may be verbal consent by telephone, written consent by email or by post, or in person consent in the ethnicity study or in the effectiveness, cost-effectiveness study if the young person chooses to complete the questionnaires in a face-to-face meeting.

In all circumstances we will explain the nature of the project and what would be involved. We will allow extra time for describing the project and answering questions both from parents and from young people, and will allow extra time for young people and their parents to think about and discuss this prior to consent. We will aim to proceed with consent from both the young person and their parent. We have separate parental information and consent forms and forms for 14-15 year olds with simpler language.

(viii) Exclusion of older EIP service users from the EYE-2 intervention.

Since the initial study was conducted, EIP services have changed their age criteria, and now work with people aged 14-65, rather than the younger 14-35 year old population. The EYE-2 intervention and resources, however, were specifically developed to address a particular problem with disengagement in the younger 14-35 year old population.

Both our PPI group and the funding body agreed that the study should continue to focus explicitly on the younger age group, and the research study will not include service users over the age of 35. However, the intervention is a 'service level' intervention, and we do not want to exclude any older service users from having access to EYE-2 resources. Clinicians will therefore be free to make use of any resources and knowledge gained from training in their work with those who are over 35. Similarly, although the social groups are specifically designed for younger service users, older service users will not be excluded from the groups if they want to attend.

(ix) Disappointment at being allocated to the control arm of the study

It is possible that both service users and clinicians will be disappointed at not being allocated to the EYE-2 intervention arm. We will make clear, that at this stage we do not know for sure if the intervention is helpful, but that either way, we will make all of the resources and training available to those in the control arm at the end of the intervention. We will also advise clinicians and services that even if they are allocated to the control arm, they will still get a 1/2 day training in robust EIP NHS England data collection, and will receive a continuous professional development (CPD) certificate on completion, support from a specially trained EIP research assistant to help collect this data, and access to EYE-2 advertising materials (e.g. mugs and pens).

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14. GANTT charts and timetables

Figure 1 - Project GANTT chart (organised in months)

Activity	1-2M	3-4M	5-6M	7-8M	9-10M	11-12M	13-14M	15-16M	17-18M	19-20M	21-22M	23-24M	25-26M	27-28M	29-30M	31-32M	33-34M	35-36M	37-38M
WP1 recruit & run Sussex clinician/manager focus groups																			
WP1 Analyse focus group data																			
WP1 Finalise manuals, training and process evaluation tools																			
WP2 recruit/run ethnicity focus groups Manchester/London/Hampshire																			
WP2 analyse focus group data																			
WP2 finalise booklets, website and resources																			
WP3 pilot data collection, extraction, monitoring process																			
WP3 Training across sites (Hampshire, Thames Valley, Manchester, London)																			
WP3/5 Cohorts determined, baseline and on-going data collected (10-21M)																			
WP3/5 12-24M follow-up data collected (22-33M)																			
WP4 Process evaluation questionnaire data collected (x3) and qualitative interviews																			
Data cleaning and analysis																			
WP6 Dissemination and write-up of project report																			

15. Figure 2: Training Plan for sites

Date Site	26/11	3/12	10/12	17/12	24/12	31/1	7/1	14/1	21/1	28/1	4/2	11/2	18/2	22/2	4/3
Norfolk-Cambridge	T1				Christmas			T2			I				
Hampshire		T1							T2			I			
Thames Valley		T1								T2			I		
Manchester			T1								T2			I	
London			T1									T2			I

NB: T1 = first training round, T2 = second training round, I = intervention start.

Figure 3 – Assessment planning for sites

	M1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	47
Base	16	16	16	16	16	16	16	16	16	16	16	16															
6M							16	16	16	16	16	16	16	16	16	16	16	16									
12M													**16**	**16**	**16**	**16**	**16**	**16**	**16**	**16**	**16**	**16**	**16**	**16**			
18M																			16	16	16	16	16	16	16	16	16
24M																									16	16	16

NB. The absolute maximum number of assessments by a Research assistant is 32 per month, and for the most part, this will be 16, which is between 4-8 x15 minute telephone interviews per week as a maximum.