**The Early Youth Engagement (EYE-2) intervention in first episode psychosis services: a pragmatic cluster RCT and cost-effectiveness evaluation**

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**Abstract**

**Background**

Early Intervention in Psychosis (EIP) services improve outcomes for young people but approximately 30% disengage.

**Aims**

We aimed to test whether a new motivational engagement intervention would prolong engagement and whether it was cost-effective.

**Methods**

We conducted a multi-centre, single-blind, parallel-group, cluster randomized controlled trial, involving 20 EIP teams in 5 UK National Health Service sites. Teams were randomised using permuted blocks stratified by NHS Trust. Participants were all young people (14-35 years) presenting with a first episode of psychosis between May 2019 and July 2020 (N=1,027). We compared the novel Early Youth Engagement (EYE-2) intervention plus standardised EIP (sEIP) to sEIP alone. The primary outcome was time to disengagement over 12-26 months. Economic outcomes were mental health costs, societal costs, and socio-occupational outcomes over 12-months. Assessors were masked to treatment allocation for primary disengagement and cost-effectiveness outcomes. Analysis followed intention to treat principles. The trial was registered with ISRCTN 51629746

**Results**

Disengagement was low at 15.9% overall in standardised stand-alone services. The adjusted hazard ratio for EYE-2+sEIP (n=652) versus sEIP alone (n=375) was 1.07 (95% CI: 0.76-1.49; p=0.713). The health economic evaluation indicated lower mental health care costs linked to reductions in unplanned mental health care with no compromise to clinical outcomes, some evidence for lower societal costs and more days in education, training, employment, and stable accommodation in EYE-2.

**Conclusions**

We found no evidence that EYE-2 increased time to disengagement, but some evidence for cost-effectiveness. This is the largest study to date reporting positive engagement, health and cost outcomes in a total EIP population sample. Limitations included high loss to follow-up for secondary outcomes, and low completion of societal and socio-occupational data. COVID-19 impacted fidelity and implementation. Future engagement research should target engagement to those with greatest need, including inpatients and those with socio-occupational goals.

**Introduction**

Psychosis is associated with poor quality of life, high disability, premature deaths,and societal costs in excess of£11.8 billion per year in England.1-2 The first 2–3 years are pivotal for long-term trajectories.3-4 Early Intervention in Psychosis (EIP) services offer early detection and treatment,fewer symptoms and hospital admissions, better wellbeing and function and increased cost-effectiveness compared to non-specialised treatment-as-usual.5-7 NHS England require that National Institute for Health and Care Excellence (NICE) concordant EIP services are offered to all new psychosis cases within two weeks of referral.8 Service structures aim to ensure that young people are proactively engaged to prevent inadequate care and ‘falling through gaps’.8 However, systematic reviews estimate 30% disengagement from first episode psychosis services, with significant costs to individuals, families, society, and the NHS.9 Evidence for interventions targeting disengagement, crucial for improving early psychosis outcomes, is notably absent. No component of the EIP model has been demonstrated to impact engagement.10 Our Early Youth Engagement (EYE) project identified risk factors for disengagement, drawing on service-users’ and families’ views and disengagement literature. Factors comprised (i) communication style, (ii) social network engagement, (iii) risk management, (iv) staff knowledge and attitudes and (v) personal experiences. Our Delphi consultation with clinicians reached consensus on components and resources to address these factors.11 Our pilot study of the resulting team-based motivational-engagement intervention found reductions in disengagement from 24% pre- to 14.5% post-intervention.11 Qualitative data revealed impacts on service-users’ personal recovery (social inclusion, hope, trust, goals) and engagement (communication, collaboration, family involvement), reassurance for families, and pride and professionalism for staff.11 Data from minoritized ethnic and LGBTQ+ populations and preliminary implementation, led to further training and resource refinements.12 We now investigate whether this novel, theoretically-informed, team-based motivational-engagement intervention is more effective than standardised stand-alone EIP (sEIP) for the primary outcome of prolonging engagement, and secondary routine mental health, NHS, societal cost-effectiveness and socio-occupational outcomes over 12-26 months.

**Method**

**Study Design**

The study was a multi-centre, single-blind, parallel-group cluster randomized-controlled-trial. Clusters were UK EIP clinical teams, allocated 1:1, stratified by site, to either EYE-2 plus sEIP or sEIP alone. Participants were followed up for between 12 and 26 months. The trial was registered prospectively (ISRCTN 51629746) and the protocol and statistical analysis plan (SAP) published prior to end of data collection following Trial Steering Committee (TSC) and DMC approval.13-14 Protocol changes are detailed in the supplement (p1).

**Cluster and Participant Eligibility**

Service inclusion criteria were: stand-alone service with at least 2 discrete teams; accepting at least 35–40 new FEP cases annually; collecting NHS England-mandated routine outcomes; selected for geographic and population variation. Service-user inclusion criteria were: consecutive referrals between mid-May 2019 to mid-July 2020; aged 14–35; meeting FEP service criteria. No consent was required for the main trial, which used deidentified, routine data. All service-users were therefore included. Written consent was obtained from clinicians, and from service-users for the societal cost-effectiveness evaluation at 12-months. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, revised in 2013. All procedures involving human subjects/patients were approved by London-Dulwich Research Ethics Committee (Reference: 18/LO/0362 IRAS: 238744).

**Randomisation and Masking**

Consenting teams were randomly assigned, online through Sealed Envelope™ to deliver either EYE-2+sEIP or sEIP alone. A randomly generated sequence of teams within-site was developed by the Brighton and Sussex Clinical Trials Unit, with permuted blocks of length 2, stratified by site. Allocation was requested by trial co-ordinators once sites achieved > 80% of care coordinators and > 70% of all staff consent for training. Research assistants (RAs), statisticians and health economists who rated or analysed primary outcomes were masked to team allocation.

**Procedures**

All teams received a half-day training in routine data collection. EYE-2 teams then received 1.5 days training from the lead researcher, Patient and Public Involvement (PPI) lead, RA, and 1–2 local service-users/carers. Booster training was delivered approximately 6-monthly, initially in-person and then on-line.

The EYE-2 intervention was distinct from standardized care in providing an engagement-focussed theoretical model, manualised training, targeted approaches and psychoeducational tools, co-produced with patients and families. The intervention was delivered over the whole period, alongside sEIP, by lead practitioners, with social groups provided by a combination of PPI leads, lead practitioners and RAs. The intervention addressed engagement through three core therapeutic processes: (i) motivational therapeutic alliance, focused on service-user treatment goals; (ii) broad systemic (social) support from families, friends and peers for treatment goals; and (iii) psychoeducation, utilizing the EYE-2 resources (booklet series, website) systematically to collaboratively promote treatment goal choices.

Teams in the comparison arm delivered a standardised ‘stand-alone’ EIP model (sEIP) only comprising early detection, assertive engagement, work with diagnostic uncertainty, positive risk-taking, person, family and recovery focus, and NICE-recommended medication, cognitive-behavioural, family, physical and vocational interventions.15

**Outcomes**

The primary outcome was time to disengagement in days, from date of allocation to lead practitioner to date of last contact following either refusal to engage or lack of response to EIP contact for 3 consecutive months. This definition and follow-up timeframes over 12-26 months are widely used in engagement research.9,16-17 For participants who remained engaged at the end of follow-up or were lost to follow-up, time to disengagement was censored. Primary outcome (engaged, disengaged, lost to follow-up) and time to event were double-rated by a masked RA and independent clinician, using a detailed protocol and case-note data. Discrepancies were treble-rated by a third rater to reach consensus.

Secondary outcomes were mandated by NHS England, and comprised (i) health and wellbeing measured by the HoNOS total, sub-scale and symptom scores,18 (ii) recovery measured by the Process of Recovery Questionnaire (QPR) total score,19 (iii) subjective quality of life and treatment satisfaction scores from the DIALOG20 collected by trained EIP clinicians or RAs at 0, 6, 12, 18 and 24 months. Only 0-12 month data were used for this investigation. Death, unplanned service use (days in hospital, emergency presentations, section 136 use), and number of NICE guidelines interventions received were recorded by RAs using case note data. Data completeness and quality was enhanced through training, manuals and monitoring. Serious Adverse Events were defined using standard criteria as resulting in death; being life threatening; requiring hospitalisation; or resulting in persistent or significant disability or incapacity. Eight criteria were prespecified for relatedness to the trial. Only events that were rated as at least possibly-serious and at least possibly-related to the trial were recorded. See protocol for further information. 13

The economic evaluation investigated the incremental cost of mental health service contacts associated with EYE-2 compared to sEIP, measured using case note data which was available for all patients. A probabilistic incremental cost-effectiveness analysis (CEA) was carried out from a mental health service perspective using HoNOS scores to measure patient outcome. The CEA included intervention costs associated with EYE-2 delivery. Secondary economic analysis investigated differences in mental health plus wider care system costs (societal costs); and socio-occupational outcomes (days in stable accommodation, employment, education and training), collected retrospectively at 12-months by RAs masked to group allocation, from all consenting participants, using the Adult Service Use Schedule and costs, in British Pound, derived from 21/22 national reference costs according to the Health Economic Analysis Plan. No discounting was needed as all the analyses happened within 12 months.

For the trial process evaluation, all lead practitioners were invited to complete a bespoke questionnaire to determine fidelity to the EYE-2 model at early-, mid- and late-intervention. A composite mean fidelity score was calculated for each clinician and team by averaging clinicians’ scores for use of booklets, website and social groups. Scores ranged from 0 (not used) to 4 (used with 76-100% service-users). Average lead practitioner caseload was obtained from the national EIP triangulation tool.21

**Statistical Analysis**

The study was powered to detect a difference corresponding to 12-month disengagement rates of 25% versus 15% with 90% power, and 5% significance level. The 25% rate was based on 30% disengagement rates of first episode psychosis patients from all service types, and 24-25% disengagement from standalone EIP services, including our pilot study 9,11,13-14. The 10% reduction derived from our pilot data.11, 13-14 Simulations confirmed that 10 teams per arm with 950 participants in total across 20 teams would be sufficient. See the published protocol and SAP for assumptions and simulations.13-14

Analyses were performed in Stata 17.1 or later. Baseline characteristics were summarized overall and by arm. Intention to treat principles were followed, and estimates, 95% confidence intervals and p-values reported for comparisons between arms. Time to disengagement was known or censored for all participants and modelled with treatment allocation, site, age at allocation to lead practitioner and HoNOS substance misuse score at baseline as fixed effects. The SAP specified Cox regression with a gamma-distributed shared frailty to allow for team clustering and a permutation test to obtain a true p-value.22 However, clustering was negligible, so a multivariable Cox regression without clustering or permutation test was used. The proportional hazards assumption was assessed using Schoenfeld residuals.

In this real-world trial, secondary routine data were mostly collected outside pre-specified windows of -2 to +4 weeks due to clinical service pressures. Data were swapped to the nearest interim (pseudo) time point (3 or 9 months), except HoNOS which was collected at baseline, and included as a covariate. For QPR and DIALOG, data could be collected after true baseline and reassigned to the closest empty time point, so baseline score was included in the outcome variable, and true baseline was assumed equal between groups. An interaction between treatment allocation and time was included, but no treatment allocation main effect, which would compare outcomes at baseline. HoNOS, QPR and DIALOG were analyzed using mixed effects linear regression analysis of all non-missing data, with site and age at allocation to lead practitioner as fixed and individual as random effects. Treatment effect was estimated at each time-point. The HoNOS analysis adjusted for HoNOS score at baseline. Analyses of QPR and DIALOG included baseline as an additional time-point, due to data collection after true baseline, but constrained the treatment effect at baseline to zero. Robust standard errors were estimated as assumptions of normality of residuals were not appropriate. Unobserved participant data was assumed missing at random and sensitivity analysis examined the effect of missing data by imputing 12-month outcomes.23-26 Individual missing question items were replaced for QPR and the DIALOG QoL domain with the relevant average score for a participant if more than 80% of items were completed by that participant. Missing values were not replaced for DIALOG TS as this comprised only 3 questions. Sensitivity analyses for HoNOS, QPR and DIALOG explored the impact of (i) data collected within planned time frames only, (ii) HoNOS data collected by lead practitioner only and (iii) baseline data collected before versus after the first UK COVID-19 lockdown (23/3/20), with pooled estimates from each pair of models using a fixed-effects meta-analysis.

Subgroup analyses were conducted for the primary outcome using interaction terms for treatment allocation with factors hypothesized to influence implementation [average lead practitioner caseload] or engagement [substance misuse, symptom severity, ethnicity, educational attainment, socioeconomic deprivation, gender]; and for secondary outcomes with factors affecting implementation.

Multivariable Poisson regression (for nights in hospital) and logistic regression (due to low A&E visits) were fitted respectively with robust standard errors. Section 136 was not modelled due to its rarity. We report the estimated incidence rate ratio for the treatment effect and its 95% CI and include fixed effects for site, treatment allocation, baseline HoNOS score and age.

For the economic evaluation, generalised linear models were fitted, and cost differences identified using a trial allocation dummy variable. Covariate adjustments included site fixed effects and baseline HoNOS scores. Sampling error was accounted for using probabilistic analysis implemented through boot-strap re-sampling and repeated estimation of cost and outcome models on each bootstrap sample replication. The distribution of jointly estimated incremental cost and outcomes were used for the cost-effectiveness analysis. Mean values were used as ‘best-estimates’ of cost and outcome differences. Probabilities derived from the bootstrap distribution of estimates were used to assess uncertainty around mean estimates. Missing case-note and self-report data were assumed missing-at-random and imputed through multiple imputation methods (see supplement p1).

**Results**

Eleven teams were randomised to deliver EYE-2+sEIP, and nine to deliver sEIP alone; 3,816 patients were referred during the identification period from 13th May 2019, and 1,027 (652 EYE-2; 375 sEIP) met eligibility criteria (see figure 1). Forty percent (1,525 patients) were assessed as not FEP. However, this proportion varied widely by team (16.6%-66.1%), with acceptance rates by team ranging from 9.5-42.5%. Twenty-one percent of patients in each arm were lost to follow-up, mostly due to migration to another mental health service (11%), or mutually agreed discharge (almost 5%).

[Insert Figure 1 here]

Mean age was 25 years, with more men than women, and white British compared to other ethnicities. Most patients were educated to age 18. Participant characteristics were relatively well balanced between trial arms (see Table 1). Deprivation level and non-white ethnicity were slightly greater and educational attainment slightly lower in EYE2+sEIP vs sEIP.

[Insert Table 1 here]

Of the 272 staff in EYE-2 teams and 190 staff in sEIP teams, 204 (75%) and 132 (70%) attended training, including 116 (85%) and 71 (82%) lead practitioners (supplement p1).

Disengagement ratings were 85% concordant between the first- and second-masked rater, with remaining cases agreed through consensus. Median time to disengagement was 258 days. Disengagement was lower than expected at 16% in EYE-2+sEIP and 15.7% in sEIP (see figure 2; supplement p2). The Multivariable Cox regression was fitted to 1,005 participants, adjusting for site, age, and baseline substance use. Twenty-two participants were excluded due to missing baseline substance use. The adjusted Hazard ratio for EYE-2+sEIP to sEIP alone was 1.07 [95% CI 0.76-1.49; p=0.71]. The point estimate indicated a marginally higher observed risk of earlier disengagement in EYE-2+sEIP. The confidence interval ruled out a reduction of more than 24% in the risk of earlier disengagement in the intervention arm. Sensitivity analyses (supplement p3) were consistent with the primary analysis, and subgroup analyses revealed no interactions with any factor predicted to affect engagement.

[Insert figure 2 here]

HoNOS, QPR and DIALOG data collected within and outside data collection windows and a visual summary example of data reallocation are presented in the supplement (p 4-5). Secondary 12-month data was either collected or unavailable due to loss to follow-up for 79.2% of HoNOS, 49.4% of DIALOG and 50.6% of QPR data (supplement p6). HoNOS, QPR and DIALOG descriptive data, adjusted coefficients (mean difference in score by arm) over time and as derived from models are presented in the supplement (p7-12). Linear mixed-effects regression models were fitted for HoNOS, Recovery (QPR), Quality of Life (DIALOG QoL) and Treatment Satisfaction (DIALOG TS). The adjusted coefficients did not favour either arm for any score or timepoint (p>0.10 for all outcomes; supplement p13-14). HoNOS and DIALOG TS generally improved from baseline to 6 months, whilst recovery (QPR) and DIALOG QoL improved across all time points in both arms (supplement p15). Conclusions were not robust to departures from the missing-at-random assumption (supplement p16-19).

Sensitivity analyses for HoNOS, QPR and DIALOG suggested that findings were not impacted by the COVID-19 pandemic, or variations in timing or method of data collection. However, QPR and DIALOG COVID-19 sensitivity analyses excluded participants without baseline measures, so involved smaller samples than the main analyses, and dichotomising participants with baseline assessment either side of the first lockdown date is a blunt approach to assess COVID-19 impacts when 12-16 months of the EYE-2 intervention occurred during COVID-19. Sub-group analyses revealed weak evidence that EYE-2+sEIP performed slightly less well than sEIP alone in improving recovery in teams with low average caseloads, with no other caseload effects on secondary outcomes. The difference in QPR score between arms in the low average caseload group compared to high was -3.53 (-7.00- -0.55, p= 0.046), was small and opposite of anticipated effects for both EYE-2 and lower caseload which should aid clinicians to promote recovery, so this may be a chance observation. Visual summaries of primary and secondary analyses are included in the supplement (p20-21)

In terms of service use, 42% of the sample had at least one hospital admission, 20% had at least one A&E visit, and 4% had a section 136 use. Proportions were similar across arms, although median nights in hospital for people who were admitted was lower in EYE-2 (26 nights) compared to sEIP (33 nights) (supplement p22). Models were fitted to 866 participants, adjusting for site, age and substance use: 161 participants were excluded due to missing nights in hospital and A&E outcome (n=139), substance use at baseline (n=17) or both (n=5). The Robust Poisson regression model for number of nights in hospital revealed a slightly lower Incidence Rate Ratio (IRR) in EYE-2+sEIP, but insufficient evidence of a difference between arms [adjusted IRR for EYE-2+sEIP vs sEIP: 0.83 (95% CI 0.61-1.13, p=0.23)]. The logistic regression model for A&E visits (N=174 with ≥1 visit vs 709 with no A&E visit) showed the odds for at least one A&E visit were slightly lower in EYE-2, but there was insufficient evidence of a difference between arms [adjusted OR for EYE-2+sEIP vs sEIP: 0.81 (95% CI 0.57-1.17, p=0.26). Four patients (0.4%) died over 12 months: 3 (0.8%) in the sEIP arm (2 by suicide) and 1 (by suicide) (0.2%) in the EYE-2 arm, and 1 person died by suicide in the EYE-2 arm after 12 months. The median number of NICE-recommended interventions received per participant was 5 in each arm (supplement p23). Medication, physical health assessments, care planning, vocational and family support were most common, followed by CBT. The low proportions of patients in receipt of some interventions may have reflected delivery during COVID-19 and in the first 12 months of service use.

For the economic evaluation, descriptive cost data, adjusted differences in mental health service costs are presented in the supplement (p24-26). Mean costs were estimated to be £1,280 lower for unplanned mental health service contacts (95% CI -£4,126-£1,566) and £25 lower for planned contacts (95% CI -£173 to £122) for EYE-2 participants. The average total cost of all contacts (planned and unplanned) was £788 lower in the EYE-2 arm (95% CI -£3,571-£1,994). The probability that these costs were higher in the EYE-2 arm was 28.8%. For the cost-effectiveness analysis, adjusted differences in HoNOS scores were “inverted” so that positive differences indicated better mental health state for intervention participants. The mean values for cost (-£788) and outcome (0.13 on HoNOS) differences point to EYE-2 “dominating” usual care (lower cost, superior outcome) (supplement p27). Uncertainty in this finding is shown with 43.4% probability of EYE-2 dominance; 14.1% probability of usual care dominance; 27.8% probability of lower total cost but lower clinical outcome with EYE-2; and 14.7% probability of higher clinical outcomes but higher cost with EYE-2. Societal and socio-occupational data were collected from 232 consenting participants: 456 did not consent, and 339 were lost to follow-up/not approached. Consent rates were proportionate to the sample size in each arm. The sub-sample interviewed had a similar mean age(25.4 years), and baseline HoNOS score(5.6) but higher white ethnicity(59.7%) and fewer males(59.5%) compared to the whole sample. The expected total societal cost per participant was £526 lower for EYE-2 with a 43% probability of this outcome (supplement p28). The EYE-2 intervention was associated with on average 5.73 more days in stable independent accommodation, 7.56 more days in employment and 30 more days in education and training, with probabilities ranging from 77-99% (see Table 2).

[Insert Table 2 here]

High fidelity to the EYE-2 intervention was expected with clinicians using resources with at least 75% of their service-users: represented by a score of 3 or above. However, median scores of 2-2.3 out of 4 revealed moderate fidelity with clinicians using EYE-2 resources with approximately half their EYE-2 service-users. Only 64% (7/11) of teams reported scores of 3 or more, and fidelity decreased from early- to late-intervention in most (83%) teams, linked to challenges during COVID-19 (supplement p29).

No serious adverse events were recorded that were at least possibly related to the trial.

**Discussion**

We found no evidence for superiority of EYE-2+sEIP over sEIP for time to disengagement over 12-26 months or secondary mental health outcomes: 15.9% of service-users disengaged across arms. The economic evaluation indicated lower mental health care costs linked to shorter admissions, slightly lower societal costs, and more days in education, training, employment, and stable accommodation with EYE-2. The impacts on unplanned crisis care and socio-occupational outcomes are consistent with the EYE-2 focus on engagement in crises and to support goals. Societal and socio-occupational outcomes must be viewed cautiously as only 22% consented to provide data.

The lack of intervention effects on outcomes may have resulted from low overall disengagement rates, consistent with our own recent meta-analysis,27 and possibly resulting from high quality stand-alone service delivery, improved NHS England standards,8 and increased stringency in EIP acceptance criteria. Implementation was also substantially impacted by COVID-19. Social engagement stopped entirely before restarting in a limited online format, goal-focused therapeutic alliance was impacted by restrictions on social-occupational activities, online consultations and personal protective equipment, and psychoeducation was hampered by inability to access resources, although partially ameliorated by EYE-2 website use (supplement p30). Only those seen face-to-face in crisis, and those who engaged effectively on-line potentially received the intervention as planned.

This is the largest study to date to investigate disengagement from EIP services, the only evaluation of an intervention to reduce disengagement and the largest longitudinal cohort of EIP service-users in over a decade. The whole population cohort comprised all new FEP patients from 20 EIP teams across 5 representative NHS sites (9 trusts) in England (supplement p31); comprising approximately 10% of new FEP patients in England in this period. The sample is similar in size and demographics to the national EDEN sample, but comprises a whole population, and a higher representation of minority ethnic populations (48.2% vs 27%).28 We revealed improvements in mental health, wellbeing, social function and treatment satisfaction in the first 6 months and continuous improvement, consistent with recovery models, in recovery and subjective quality of life, over 12 months, across both EYE-2 and sEIP teams. Hence, stand-alone EIP services achieve positive outcomes and low disengagement, but may be more cost-effective with better societal and socio-occupational outcomes, with an added engagement approach.

EIP team acceptance rates were very low (9.5%) in some services due to stringent exclusion of specific diagnoses and early non-engagers, 40% of patients did not meet service inclusion criteria, 40% had an inpatient admission at or within 12-months of acceptance, and 5% were discharged by mutual agreement. These figures are concerning as service-users with initial non-engagement, other diagnostic comorbidities and early discharge may present later with greater severity or inpatient admissions.29 Just over 12% migrated across (10.9%) or out of the country (1.8%), many returning home after onset, raising the possibility that migration, and isolation from supportive social networks contribute to psychosis onset in young people, even within the UK.30 We should consider how to best support young people who do not engage from the outset, are isolated, present with psychosis in the context of mood disorders or request early discharge.

**Limitations**

Whilst the real-world pragmatic trial design is a strength for generalizability, missing routine secondary data, and modest implementation, impacted by COVID-19, are limitations. Secondary data completion was nevertheless higher due to the whole population sample than the previous largest cohort where only 49% of service users consented to provide data.28

**Summary**

This is the largest real-world whole-population investigation of disengagement, effectiveness and cost-effectiveness in EIP services and the first to evaluate a disengagement-focussed intervention. The EYE-2 intervention is a low-cost therapeutic model with psychoeducational resources, co-produced with patients, carers and clinicians that is safe, well-liked and easy-to-use to engage new patients. We found no evidence that the EYE-2 intervention is superior to stand-alone sEIP services in improving time to disengagement or secondary mental health outcomes, but disengagement was low overall. The EYE-2 intervention added to sEIP services may be more cost-effective with better societal and socio-occupational outcomes, but the latter outcomes should be viewed cautiously due to low sample sizes. Study outcomes may be specific to standalone services adhering to an EIP model. New services internationally and those looking to reconfigure should consider carefully, the potential impact of non-standard EIP models on disengagement, health, societal and cost outcomes. Future research should investigate core components that maximize engagement across EIP models, and in target populations at greatest risk for disengagement, presenting in crisis and with socio-occupational goals.

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[Implementing the Early Intervention in Psychosis Access and Waiting Time Standard: Guidance (nice.org.uk)](https://www.nice.org.uk/guidance/qs80/resources/implementing-the-early-intervention-in-psychosis-access-and-waiting-time-standard-guidance-2487749725)

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**Declaration of Interests**

KG has received NIHR funding for previous research, and has received funding from the University of Sussex, Sussex Partnership Foundation Trust and South-East Network for Social Sciences (SeNSS) for work linked to this project. She has received funding for a conference presentation from Boehringer Ingelheim. RJ is a GP and was local CCG Clinical lead until June 2021. SR has received consultancy fees and honoraria from various industry providers, does medicolegal work and sits on an industry advisory Board. PP has received NIHR funding, industry funding, book loyalties and honoraria from universities for lectures and presentations. PF has received previous NIHR research funding and is clinical advisor to the National Clinical Audit of Psychosis. He has sat on HTA Prioritisation and funding panels. PG has received funding from NIHR and Wellcome and is a member of an expert international advisory committee. DF has received previous NIHR research funding. TM has received previous NIHR research funding. EP has received funding from the Medical Research Council and NIHR. LJ has received funding from NIHR for research, received book royalties and payment for workshops. SB has received previous NIHR funding. CM has received financial reimbursement for travel to present on NPT. KG, SC, SN, LJ, MP, JP and AO’D either currently or previously worked in Early Intervention in Psychosis services, and BL and PF have been regional EIP leads. No interests declared for HL, JH, RT, IA,NY, RdV, GB, RW, AH, CJ, RH, JG.

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**Contributions**

KG led the design and coordination of the study, contributed to data analysis and interpretation and wrote the report. CJ contributed to the design of the study, conducted the analysis and drafted the initial results. NY contributed to the design of the study, conducted the health economic analysis and contributed to drafting of the results. AH contributed to the design of the study, co-developed and oversaw the health economic analysis, and drafted the initial results. CM contributed to the design of the study and co-led the process evaluation with KG. SB contributed to the design of the study, co-developed and oversaw the analysis. RH contributed to the design of the study, conducted power calculations and oversaw the statistical analysis plan. SR, PP, BL, LJ, PF, JH, MP and EP contributed to the design and were responsible for site management and supervision. HL contributed to the design of the study and supported site management and supervision. SN and JP were responsible for site management and supervision. RdV contributed to the design.TM led on all aspects of Patient and Public Involvement (PPI). GB, JG and RW were the trial managers, and oversaw all aspects of supervision and delivery.IA was the trial manager with oversight of data and site management.RT contributed to the design of the study and led on all aspects of PPI. DF and PG contributed to the design of the study, and the interpretation of the results. AO’D and SC contributed to the design of the study, and study set-up. RJ advised on health economic analysis. All authors had full access to all the data in the study, reviewed the paper for important scientific content and had final responsibility for the decision to submit the manuscript for publication.

**Transparency Declaration**

The lead author and manuscript guarantor (KG) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

**Data availability**

Fully anonymized data will be available from KG upon reasonable request, subject to submission and approval of a research proposal and review and contract with Sussex Partnership NHS Foundation Trust, following the publication of all results from this study. Due to the personal nature of case note data pertaining to engagement or disengagement, this data will only be made available in a suitable abbreviated form to ensure anonymity.

**Analytic Code Availability**

Analytic code will be available from CJ, SB, RH, AH upon reasonable request.

**Research Material Availability**- Trial materials can be obtained from KG on reasonable request. Intervention resources are also available at www.likemind.nhs.uk

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