



Extended Research Article

Team-based motivational engagement intervention in young people with first-episode psychosis: the EYE-2 cluster RCT with economic and process evaluation

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Scientific summary

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Scientific summary

Background

Psychosis is a potentially devastating condition affecting 1–2% of the population, impacting mental health, quality of life and life expectancy. Early Intervention in Psychosis (EIP) services are pro-active, person-centred mental health services offering early detection and treatment in the critical first 3 years of illness. These services improve outcomes for young people, but 25% are reported to disengage within the first 12 months, at potentially substantial cost to their health and well-being. Our pilot work shed light on the barriers and facilitators to engagement in first-episode psychosis [FEP; Early Youth Engagement (EYE) study] and informed the development of a team-based, motivational engagement intervention (EYE-2) to improve engagement in EIP services.

Objectives

The main objectives for the EYE-2 study were:

1. To develop and refine an implementation toolkit (resources and training) for national roll-out; drawing on a normalisation process theory (NPT) framework and knowledge obtained from an implementation study in the original Sussex site.
2. To adapt the booklets, website and training to the needs of the diverse population of EIP service users; and to ensure they were up to date and tailored to local service variation, incorporating information from the ethnicity and lesbian, gay, bisexual, transgender and queer or questioning (LGBTQ) minority study.
3. To evaluate the effectiveness of the EYE-2 intervention with respect to the primary outcome: time to disengagement (in days from date of allocation to care co-ordinator to date of last contact following either refusal to engage with EIP or lack of response to EIP contact for 3 consecutive months); and secondary outcomes [Health of the Nation Outcome Scales (HoNOS), questionnaire on the process of recovery (QPR), DIALOG, service use] derived from routine service data at 0, 6, 12, 18 and 24 months post entry into the study, defined as date of allocation to an EIP care co-ordinator
4. To quantify the impact of the EYE-2 intervention on NHS mental health care, wider societal care system costs, clinical and social outcomes over a 12-month period; to evaluate the cost-effectiveness of the intervention; and to investigate the potential resource implications of the intervention for NHS mental health commissioners.
5. To develop and test a framework for implementation through a large-scale process evaluation using (1) NPT and (2) logic models, and incorporating all clinicians involved in EYE-2 intervention delivery.
6. To disseminate widely through the study website, peer-reviewed papers, service user publications and conference presentations.

Methods

Patient and public involvement (PPI) was integral throughout the project and used a multilevel team approach led by the McPin Foundation, with a PPI lead and a Lived Experience Advisory Panel at each site. The PPI team collaborated and led on aspects of design, training, delivery, evaluation and dissemination.

To address objective 1, we conducted 15 interviews with clinicians in Sussex, from all teams and disciplines involved in delivery of the original EYE intervention, using a topic guide informed by NPT to explore intervention processes, implementation processes and contextual barriers and facilitators. Data were analysed thematically, mapped onto NPT processes and used to refine the toolkit and develop the logic models.

To address objective 2, we interviewed 21 young FEP service users purposively sampled to reflect the main ethnic and LGBTQ profiles, and variations in spirituality, in 3 inner-city sites: London ($n = 8$), Southampton ($n = 7$), Manchester

($n = 6$). The topic guide was co-produced with PPI and informed by the Cultural Adaptation Framework (CAF). Participants had access to the original EYE booklets and website link for 2 weeks prior to interview. Data were analysed thematically, mapped onto the four domains of the CAF and used to adapt the training and resources.

To address objective 3, we conducted a parallel-group pragmatic randomised controlled trial: 20 EIP teams (clusters) were randomised, stratified by site (London, Manchester, Thames Valley, East Anglia and Hampshire), to deliver either the EYE-2 intervention plus the standardised EIP (sEIP) service (11 teams), or sEIP alone (9 teams). The primary outcome was time to disengagement. Ratings of disengagement were based on deidentified case note data, and double-rated, blind to team and study arm by a trained RA and clinician. Secondary mental health (HoNOS), recovery (QPR), quality of life (DIALOG), death and service outcomes were evaluated using routinely collected NHS-England-mandated outcomes and case note data.

A pre-study power calculation confirmed that 90% power to detect a difference in disengagement at 12 months from 25% to 15%, would be achieved with 20 teams and 950 participants identified over a 12-month period, with an additional 12-month follow-up, allowing for 10% loss to follow-up per year. In the event, a total of 1027 participants identified over 14 months (with an additional 12-month follow-up) took part in the trial. The sample comprised *all* new FEP service users aged 14–35 who were allocated to a care co-ordinator during the identification period.

To address objective 4, case note data were screened by research assistants (RAs) to record all mental health service use over a 12-month period following allocation to care co-ordinator. Interview data on wider (societal) service use and social outcomes were collected retrospectively at 12 months, by RAs blind to study arm, from all consenting participants, using an adapted adult service use schedule. Costs were derived from national reference costs and tariffs. Intervention costs were calculated for training delivery, website and resource production and printing. The mental health clustering tool was used to derive likely future cluster in terms of low, moderate or high cost, and a cost-effectiveness analysis determined whether the EYE-2 intervention was dominant in terms of cost and/or outcome.

To address objective 5, a mixed-methods longitudinal process evaluation was conducted with all clinicians involved in delivering the EIP or the EYE-2 intervention, informed by the logic models and NPT and comprising the training evaluation ($n = 197$ for EYE-2 training and $n = 282$ for data collection training), a qualitative study of routine service delivery with 1 clinician in each EIP team ($n = 20$), a longitudinal qualitative study of experiences of EYE-2 delivery with 32 clinicians interviewed early ($n = 11$), mid ($n = 10$) and late ($n = 11$) intervention and a longitudinal quantitative study at the same 3 time points incorporating standardised and bespoke questionnaires ($n = 70$; $n = 81$; $n = 68$).

Results

The PPI team co-delivered the EYE-2 training, refined and delivered the intervention social groups and co-developed the evaluation tools. The implementation study revealed 13 themes relating to lasting impressions of the EYE intervention, implementation processes and barriers. Organisational support was deemed important; and resources, patient and staff characteristics, such as patient literacy, staff caseload and the need for memory prompts and booster training could impact implementation. Adaptations to the resources and toolkit were proposed and incorporated. The process-oriented logic model identified three core and interacting mechanisms of change: (1) the use of the social network as systemic support to identify and achieve goals; (2) an enhanced therapeutic alliance and motivation to achieve goals; and (3) the use of the resources as a psychoeducational tool to facilitate goals and treatment choices. It was anticipated that use of these approaches would improve engagement and outcomes.

The ethnic and LGBTQ diversity study identified seven cultural factors with the potential to impact on engagement. In terms of philosophical orientation, there was a need to consider differing cognitions and beliefs between staff, service users, family members and spiritual leads; to consider the multiple intersecting facets of culture, and the role of faith-based support. Language was a barrier to engagement, especially for families, and use of interpreters raised confidentiality concerns. Practically, service users described stigma and discrimination relating to mental ill-health, LGBTQ and ethnic minority status. For some families, mental illness was a taboo topic, and some LGBTQ service users described their sexuality as invisible in services. Adaptations were made to the resources and training. Booklets

were translated into 12 languages. There was hope that the resources could open up topics for discussion. In terms of technical adjustments, it was critical for those from diverse backgrounds to increase trust in the therapeutic alliance, and in terms of theoretical modification, the adaptation of therapeutic approaches to individual differences was crucial.

The trial revealed that baseline characteristics were well-balanced across the intervention ($n = 652$), and sEIP ($n = 375$) arms: 21% of participants were lost to follow-up, and of these 60% moved out of area, or abroad. Data from participants lost to follow-up were censored, so primary outcome data were available for the entire sample. Disengagement rates were very similar across the intervention and sEIP arms (16% vs. 15.7%). Multivariable Cox regression on 1005 participants, adjusting for site, age and substance use at baseline, estimated an adjusted hazard ratio (95% CI) for EYE-2 + sEIP to sEIP alone of 1.07. This indicates the observed hazard of disengagement was slightly higher in the EYE-2 + sEIP arm though, within limits of 95% confidence we estimated the hazard ratio to be between 0.76 and 1.49, hence ruling out a reduction of more than 24% in the risk of disengagement in the intervention arm ($p = 0.713$). There were no differences between arms for any of the secondary outcome measures. Service users in both arms improved similarly in mental health, recovery and quality-of-life outcomes, and there were no differences in nights in hospital, accident and emergency visits, or Section 136 use. Although for those who did have an admission, median nights in hospital were marginally fewer for the intervention arm (27 vs. 33 nights). There were four deaths up to 12 months: one in EYE-2 and three in sEIP. The median number of National Institute for Health and Care Excellence guidelines received was five in each arm. Sensitivity and subgroup analyses suggested no effects of COVID-19 (based on baseline collected pre vs. post lockdown), substance use, symptom severity, ethnicity, or educational level on outcomes.

Possible explanations for the lack of differences between arms included: lower than expected rates of disengagement due to insufficient follow-up times; stringent disengagement definitions; stringent caseload acceptance criteria; improved quality services due to Access and Waiting Time Standards (AWTS) and data collection training, such that there was limited room for further improvement on the primary outcome, and issues with fidelity to the intervention which was impacted by COVID-19. For secondary outcomes, differential missing data for those who disengaged meant there was limited opportunity to capture an effect of the intervention after someone had disengaged, and the choice of secondary outcome measures, while presenting the best opportunity to collect data on people who were disengaging, may not have captured the most critical effects.

Health economic case note data were available for up to 945 (92%) of the sample and revealed a lower mean cost of mental healthcare utilisation, after accounting for intervention costs, in the intervention arm of $-\pounds 788$ (95% CI $-\pounds 3571$ to $\pounds 1994$) with a probability of 28.8% that the total mental health system costs would be higher for intervention. This reflected lower costs for unplanned admissions, crisis and Mental Health Act assessments. The cost-effectiveness analysis indicated a 43.4% probability that the EYE-2 intervention was dominant in overall cost reductions in the context of marginally better mental health states, compared to sEIP. Mean total societal cost was lower in the intervention arm $-\pounds 526$ per participant ($-\pounds 7031$ to $\pounds 5980$) with a probability of 43% that this would be higher in the intervention arm. Only 22% of the eligible sample consented to and completed the societal cost interview which indicated that the EYE-2 intervention was associated with 5.73 more days spent in stable, independent living (95% CI -1.79 to 13.25) with the probability of a positive outcome for the intervention of 98%; 7.56 more days spent in paid or unpaid employment (95% CI -35.64 to 50.76) with the probability of a positive outcome for the intervention of 77%; and 30 more days spent in education and training (95% CI 1.52 to 53.68) with the probability of a positive outcome for the intervention of 99%. Although these findings are consistent with key aims of the EYE-2 intervention and components of the manuals, training programme and resources had some margin for error when considering Cis and the analysis of wider care system costs and social outcomes must be viewed with particular caution as only 22% of the eligible study sample provided data.

The process evaluation revealed widespread disruption due to COVID-19 and impacts of AWTS on caseload such that only schizophrenia-spectrum cases were likely to be accepted. Implementation processes were highly heterogeneous and fluctuated over time, with both facilitators and barriers in operation and a constant pressure to adapt to the changing context. Two of the three mechanisms of change (systemic support and therapeutic alliance) were disrupted by COVID, and there was no effect of the intervention on therapeutic alliance. The most likely active mechanism for

change was via psychoeducational processes, as the EYE-2 resources were very well-received, used in structured ways, positively appraised and associated with stronger therapeutic alliance.

Limitations

Limitations include the high loss to follow-up, especially for secondary outcomes in those who disengaged, the smaller subsamples of clinician in the process evaluation and service users in the societal cost evaluation, the non-standard secondary data collection processes for HoNOS and the delivery of the engagement intervention during a global pandemic which impacted on implementation and outcomes.

Conclusion

In the primary analysis of clinical effectiveness, 95% confidence limits ruled out a reduction of any more than 24% in the risk of disengagement using the EYE-2 intervention. COVID-19 had a substantial impact on implementation of the EYE-2 intervention and fidelity to intervention delivery was low across multiple teams and time points. Access and Waiting Time Standards had a substantial impact on the quality of standard EIP service delivery during the trial, which likely impacted results. In a cost-effectiveness analysis, estimates fell in the direction of dominance of the EYE-2 intervention (reduced costs, better mental health states and social outcomes). The intervention was most likely delivered as a standardised psychoeducational tool. Clinically, this project is valuable, comprising the largest study to date, looking at engagement, mental health and EIP outcomes in a total population sample. Qualitative feedback suggests that the booklets, website and psychoeducation approach were highly valued by clinicians, service users and families, and together the resources and model for lead practitioners might support and standardise best practice in EIP. Future research should consider targeted engagement programmes focused on inpatient staff and FEP service users where there is substantial need, and psychoeducational and supported self-management programmes aimed at those wishing to enhance their social and vocational outcomes. More research is required regarding engagement with EIP services in the UK and on the impact of youth migration within the UK on their social isolation and mental health outcomes.

Study registration

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