

Development and evaluation of a collaborative care intervention for male prison leavers with mental health problems: the Engager research programme

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language that may offend some readers.

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Scientific summary

The Engager research programme

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Scientific summary

Background

As of February 2020, there were over 83,000 people incarcerated in England and Wales, the majority (95%) of whom were male. A large proportion of these people have past trauma and have mental health problems with symptoms that meet the criteria for diagnoses such as depression, anxiety, post-traumatic stress disorder, substance misuse and personality disorder. Comorbidity is the norm, and individuals can often also have a range of social issues, such as homelessness, unemployment and broken relationships. This complex and variable mix is often described as 'complex needs', although it is also recognised that individuals have a range of strengths.

Prison mental health services for those with severe mental illness has improved. In contrast, identification of common mental health problems (e.g. depression, anxiety) is haphazard and few prison leavers access community services. Worldwide, no systems of care have been developed and evaluated for engaging people with common mental health problems while in prison, including providing mental health and practical support and working with them to link with community services after release.

Aims and objectives

The aim of the Engager research programme was to develop and evaluate a complex intervention (i.e. Engager) that was designed to support individual males with common mental health problems and other complex needs before and after release from prison. To achieve this, we completed a research programme from 2013 to 2020.

Phase 1

- We developed a person-centred intervention based on evidence from a range of sources and tested it in practice (workstream 1).
- We developed trial science methodology to evaluate the intervention (workstream 2).
- We used health economics modelling to inform willingness to pay for benefits (workstream 4).

Phase 2

- We carried out a randomised controlled trial (RCT) comparing Engager plus usual care with usual care only (workstream 3).
- We carried out a health economic analysis (workstream 4).
- We used a mixed-methods process evaluation approach to examine fidelity, implementation challenges and opportunities, and potential refinements to theory (workstream 3).

Our public and patient partners contributed extensively across both phases individually and as a Peer Researcher Group. Overall, the programme took a realist-informed approach to theory-building and evaluation. The exploratory trial that was proposed initially was replaced with a fully powered RCT and the outcome measurement was extended to 12 months.

Developing a theoretical model of the intervention (phase 1, workstream 1)

The aim was to develop the Engager intervention. Realist-informed methods were used to establish the mechanisms that might lead to positive outcomes. The intervention was viewed as a two-step behaviour change model, that is, how the system and research team supported practitioners and then how practitioners supported offenders. Findings were integrated in two processes of synthesis before and after the pilot work, which included a formative evaluation to shape and provide further detail to the intervention.

Methods

- A realist review aimed to specify how an integrated person-centred system to improve the mental health of offenders with common mental health problems might work. It followed a three-stage process: (1) an iterative database search, (2) consolidation and (3) development of a conceptual platform.
- Four organisational case studies aimed to gain learning from a range of promising services, using documents (e.g. service standard operating procedures), field notes and semistructured interviews.
- Focus groups explored the views of subgroups of the target population whose experiences were not adequately captured elsewhere.
- A formative process evaluation involved testing the prototype Engager theory in practice in incorporated semistructured realist interviews (with individuals receiving the intervention, as well as with Engager practitioners and supervisors and other professionals), practitioner pro formas and health-care records.

Results

At the heart of the intervention theory sit the core interactions between Engager practitioners and intervention participants, within which lie mechanisms that are proposed to affect offenders' thinking, emotion and behaviours. Around those are supporting mechanisms for change that require optimising practitioner performance and support from multiple local services.

Key themes for success included the following aspects of intervention theory:

- Multiple ways to build trust and engagement (e.g. feeling cared for and practical 'quick wins').
- Therapeutic approaches for emotional needs (e.g. mentalisation-based approach selected as the main therapeutic modality).
- Addressing practical challenges of the immediate post-release period (e.g. homelessness).
- The importance and variety of relationships with family and friends.
- Value of peers for some, but not all.
- Specific mechanisms to generate collaboration with other services (e.g. actively engaging other practitioners in developing the written 'shared plan' and preparations for endings needing to start early).

Delivery of the intervention is mainly achieved through Engager practitioners working flexibly, with a caseload of about 10–12 individuals, in prison during the 4–16 weeks before release, on the day of their release and for 3–5 months post release. The practitioner is part of a team and is supported by a supervisor. Initial work is to develop trust and a 'shared understanding'; this is followed by developing a person-centred plan and providing emotional and practical support. Attention is paid to planning for endings and ongoing care.

An intervention delivery platform (IDP) was developed as a means of supporting practitioners to deliver the intervention as intended and this formed part of the overall Engager theory. Prior to the feasibility pilot study, the IDP incorporated training, a manual and supervision. Organisational agreements (information-sharing, risk management, etc.) were incorporated during feasibility work. A rapid realist review identified the importance of catering for different learning styles and of describing the intervention in ways that aligned with existing services. The review also suggested that supervision should be delivered in a way that was theoretically consistent with the intervention. The IDP was strengthened by adding top-up training, additional supervision for mentalisation and combining the role of Engager team leader and supervisor to create coherence and promote decisions in the local setting.

Development of trial methodology (phase 1, workstreams 2 and 4)

Methods

The Engager programme aimed to establish a theoretically sound and feasible trial methodology through the following substudies:

- Development of a set of outcomes, which involved a single-round Delphi survey, a focused review to identify measures, testing measures in the target population to assess acceptability and the psychometric viability, and a consensus panel meeting to agree measures for the RCT.
- A pilot trial to test the feasibility of recruitment, randomisation and follow-up, alongside the intervention formative evaluation.
- Development of measurement of process for usual care and the Engager intervention.
- A scoping study for economic modelling.

Results

In the single-round Delphi exercise, the most important areas were mental health symptoms, substance misuse and social inclusion. At the consensus meeting, the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) was selected as the preferred mental health measure. The CORE-OM and Camberwell Assessment of Need – Forensic Version received equal votes to be the primary outcome measure. We opted for the CORE-OM because of its psychometric properties.

In the pilot trial, 60 eligible male participants were randomised at a ratio of 2 : 1 to receive either Engager plus usual care or usual care only. We achieved follow-up rates of 73% at 1 month and 47% at 3 months post release. Researchers became aware of trial arm allocation of most participants; otherwise, the trial procedures were acceptable and feasible. To capture care provided by the Engager practitioners, we developed timesheets and a series of ‘if-then’ statements that captured the extent to which components were delivered and the consequence.

In the economic evaluation scoping work, we developed a discrete event simulation model and demonstrated the major challenges of obtaining adequate data to generate plausible cost and cost-effectiveness. We concluded that a cross-sectoral estimated value of perfect information analysis was not viable.

Randomised controlled trial and health economics analysis (phase 2, workstreams 3 and 4)

Methods

The trial was performed in three prison settings (south-west of England, $n = 2$; north-west of England, $n = 1$) and 280 participants were recruited and randomised (in a 1 : 1 allocation) to either Engager intervention plus usual care ($n = 140$) or usual care only ($n = 140$). The Engager practitioners provided mentalisation alongside psychological and practical support, with supervision starting in the prison, including day-of-release work, and continuing for 3–5 months post release.

All participants were assessed at six time points, that is at baseline (i.e. before randomisation), during the week before release from prison and at 1, 3, 6 and 12 months post release from prison. The primary outcome was psychological well-being measured by the CORE-OM. We evaluated the mean incremental cost per quality-adjusted life-year (QALY) gained with the Engager intervention compared with current practice.

Results

At baseline, there was some imbalance between the groups, with the Engager group having a higher proportion of participants in unstable accommodation, unemployed and with poorer physical health,

whereas a higher proportion of participants in the usual-care group had experienced relational trauma. At 6 months, 184 (66%) participants were followed up.

There were no significant differences in mean CORE-OM scores between the groups at 6 months {Engager group mean 12.6 [standard deviation (SD) 6.9], $n = 92$; usual-care group mean 11.9 (SD 7.7), $n = 90$; between-group difference 1.1 (95% confidence interval -1.1 to 3.2); p -value 0.325}. There were a small number of statistically significant differences between the two groups on the secondary outcomes for a variety of sensitivity analyses.

For the primary economic evaluation, the mean cost difference was £2133 and the mean QALY difference was -0.017 and, therefore, the Engager intervention is less effective and more costly than usual care. There is a 0% probability that the intervention is cost-effective at the £20,000–30,000 willingness-to-pay threshold for a QALY gained (i.e. the standard willingness-to-pay threshold for recommending treatments for the NHS).

Parallel process evaluation (phase 2, workstream 3)

The mixed-methods process evaluation aimed to examine the extent to which the intervention was delivered, how the core components and mechanisms of the intervention produced the intended outcomes and what could be improved. The mixed-method process evaluation was also used to facilitate interpretation of the RCT.

Methods

The following analyses were carried out:

- A fidelity analysis that quantified the extent of the intervention delivery.
- A thematic analysis that surfaced the wider issues that may have supported or inhibited the delivery of the intervention.
- An analysis of the extent to which individuals and practitioners experienced the intervention components as having been delivered and as having a positive impact, using the 'if-then' checklist.
- A realist-informed in-depth case study analysis that explored:
 - how the quality of delivery of various components of the intervention related to individual responses
 - how key outcomes were or were not generated through practitioner activity.

Results

Less than half ($n = 62$, 48%) of the participants received the minimum dose considered necessary to have an impact and just over one-third ($n = 48$, 36%) of the participants received any release day contact. The volatile prison environment, as well as practitioner focus on release day work and community provision, limited delivery of pre-release components.

Records showed that practical work was delivered more consistently than psychological components. Practitioners confirmed this and individual reports from the 'if-then' questionnaires showed that individuals mostly felt cared-for by practitioners, but far less commonly felt supported to understand their emotions.

The realist-informed in-depth case studies showed how variations in delivery were associated with differing engagement and responses. We identified five typologies of states that participants might be in or move through, and 'crises but coping' state was the most positive (i.e. the individual engages with the intervention and makes positive incremental changes over time despite setbacks). The positive but idiosyncratic outcomes achieved by these individuals did not correlate with the standard trial measures.

The other states were less positive. In the 'resigned acceptance' state, the participant initially engaged superficially, but issues and challenges continued and the participant became resigned that their circumstances would not change. In the 'crises and in chaos' state, participants initially engaged well with the intervention, but development of a psychosocial shared understanding was limited and, when confronted by challenges, the participant became overwhelmed and disengaged. In the 'wilful withdrawal' state, the participant declined support early on and trust was never established. 'Honeymooners' were motivated to make changes, but believed that they could manage without support and therapeutic work was shallow.

Analysis as to how key intermediate outcomes, such as emotional and psychological competencies (e.g. emotion regulation, coping strategies) and social skills and capital (e.g. behaviours, building positive relationships), were and were not achieved showed that use of mentalisation approaches and supporting a shared understanding, and not just practical support and empathy, were critical. Formal and flexible supervision appears important for achieving this.

Discussion

Strengths and limitations

The iterative realist-informed peer researcher-supported method of intervention development provides an exemplar for person-centred complex interventions. Engager programme theory distinguished the theory of what practitioners should deliver from the support provided to achieve delivery.

Trial science work was also extensive and the delivery of the full trial was a significant logistical achievement. The trial recruited to target. Sixty-six per cent follow-up is arguably impressive for the population, but it is still considered a weakness, as it is less than the 70–80% considered necessary in mental health trials. The small number of statistically significant changes are most likely due to multiple testing.

The parallel process evaluation was especially important, given the neutral trial finding that showed difficulties in implementation but positive outcomes for some people who engaged. There are concerns that the often idiosyncratic steps towards rehabilitation made by people engaging well, but with lifelong experiences of adversity, may not have been measurable with standard trial measures.

Conclusions

The outcomes measured in the trial showed no differences between arms. Although it is possible that the intervention theory has no merit, we found evidence of three contributors to the neutral results: (1) suboptimal implementation, (2) weak theory in a few areas of the intervention and, potentially most importantly, (3) problems in using standard trial outcome measures to detect small unpredictable steps in recovery.

There are potential implications for practice. The Engager programme demonstrated the potential for applying mentalisation flexibly to a population with complex needs outside the traditional hour-long therapy sessions. There was evidence that effective team-based formal and informal supervision helped practitioners in the challenging work of using a mentalisation-based approach, including formulation for individuals who were engaged and decision-making about when not to pursue work that was futile. We showed that some practitioners working in support worker roles outside mental health systems were able to use formulation-type approaches.

The Engager programme demonstrated, in contrast to other evaluations, that it is possible to carry out practical 'through the gate' work. Working practices included reliably meeting individuals, safely using a car for transport, protocols for leaving individuals who may still be without accommodation and supporting attendance at meetings.

Supporting professionally unqualified practitioners and embedding mental care into existing non-health teams (e.g. substance misuse and housing) is a potential alternative and less costly strategy, compared with the stand-alone Engager team tested in the trial, for putting Engager principles into practice, and this aligns with national policies.

Trial registration

This trial is registered as ISRCTN11707331.

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