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Building programme theory to develop more adaptable and scalable complex interventions: Realist formative process evaluation prior to full trial

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Evaluation
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Realist formative process evaluation: prioritising and elaborating theory prior to full trial of a complex intervention for prison leavers with mental health problems

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ABSTRACT *(151/150 words)*

Background

MRC guidelines recognise the need to optimise complex interventions prior to full trial through greater understanding of underlying theory and formative process evaluation. However, there are few examples. We provide a case example of a realist formative process evaluation in the feasibility and piloting phase to build the theory behind a complex intervention and develop implementation and delivery knowledge for a full trial.

Methods

Data from multiple sources (semi-structured interviews, session recordings, practitioner notes and records) were collected; monitored to inform immediate changes; and analysed using Framework analysis to inform substantive changes.

Results

The evaluation: 1) instigated immediate implementation changes; 2) built implementation and delivery knowledge for the full RCT; and 3) prioritised and elaborated programme theory about how the intervention 'works'.

Discussion & Conclusions

Realist formative process evaluation embedded in a pilot trial supports testing of feasibility and acceptability and builds critical implementation and delivery knowledge for full trial.

KEY WORDS *(up to 5)*

Realist evaluation, formative process evaluation, complex intervention development, programme theory development, feasibility and piloting

INTRODUCTION

A realist formative process evaluation was embedded in the pilot trial of the 'ENGAGER' intervention (Box 1; see (Lennox et al., 2017)) prior to the full trial (see (Kirkpatrick, 2017)). Our method of realist formative process evaluation addresses two critical objectives in complex intervention development and evaluation: the need for formative evaluation in the feasibility and piloting phase to build the theory behind the intervention prior to outcome evaluation (i.e. full trial) (Craig et al., 2013), and the need for greater attention to be paid to context during initial delivery and effective scale-up during later implementation (Moore et al., 2015). This paper provides a case example of how realist formative process evaluation develops and deepens the underlying theory behind the intervention (what works, for whom, and in what circumstances), and builds implementation and delivery knowledge for full trial.

Realist formative process evaluation of complex interventions

MRC guidance emphasises the use of evaluation to build theory, understand causal mechanisms and optimise delivery during feasibility and piloting, but do not provide exemplars of formative process evaluations (Craig et al., 2013; Moore et al., 2015). Most of the few published formative process evaluations of health interventions evaluate interventions that have been running for some time (Evans et al., 2015). A study of community-based HIV prevention in inner-city Johannesburg, informed by developing an understanding of the priorities of, and the limitations faced by, the local community is a notable exception (Scorgie et al., 2017).

To build implementation and delivery knowledge it is helpful to understand how context (individual, social, cultural, organisational) interacts with intervention components and underpinning mechanisms to bring about desired outcomes. Yet under-theorising of how

interventions depend on their social contexts is typical in public health evaluations (Hawe, 2015; Macintyre and Petticrew, 2000; Moore et al., 2015) and only limited mention of the role of context in shaping implementation and causal processes is made in the MRC complex intervention guidance (Fletcher et al., 2016).

Realist evaluation builds, tests and refines theory about how causal mechanisms, including human agency and contexts (individual- and system-level), interact to produce outcomes (intended or unintended) (Hawkins, 2014) (Pawson, 2013). The MRC guidelines for Process Evaluations acknowledge the suitability of realist evaluation approaches for process evaluations and their increasing influence, particularly in public health (Moore et al., 2015). Consideration of realist and complexity theory principles suggests that pragmatic (e.g. realist) process evaluation of pre-existing interventions *at the beginning* of the first intervention development phase of the MRC framework, in order to build the theory behind a new intervention, would improve the external and socio-ecological validity of intervention development studies and create more sustainable implementation procedures (Fletcher et al., 2016). Realist formative process evaluation has the potential to support the development of interventions in the feasibility and piloting phase that are flexible and adaptable to context, and thus more likely to succeed when scaled up and/or spread to new locations for outcome evaluation.

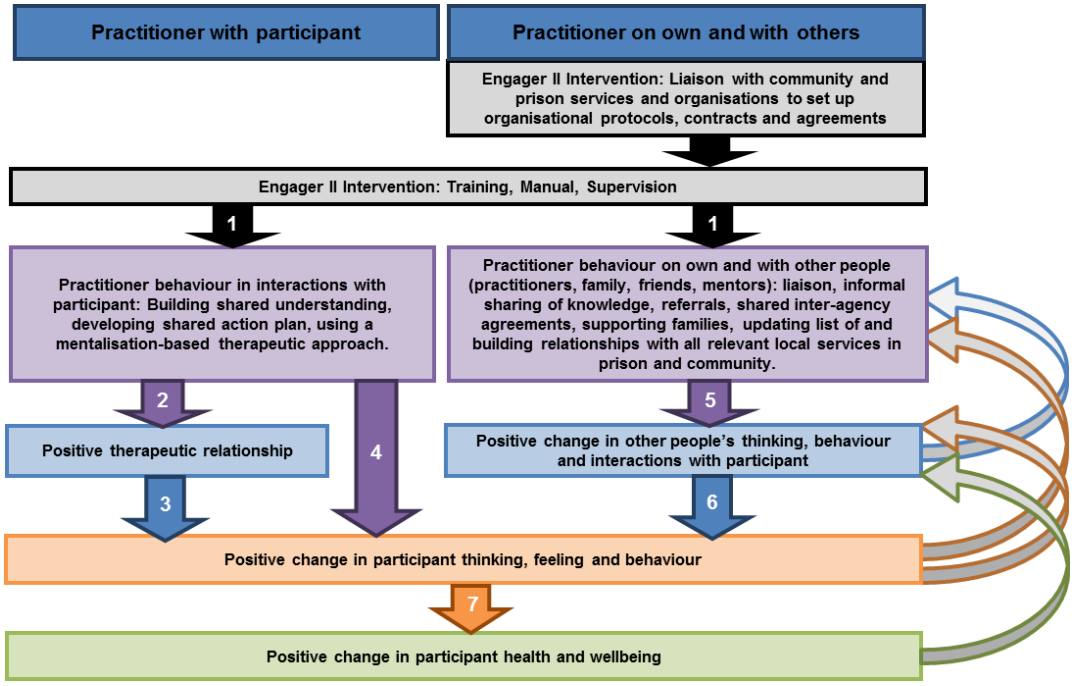
Realist theory development of the ENGAGER intervention

For ENGAGER, where a substantive intervention did not exist, we used a realist review (Pearson et al., 2015), alongside case studies, focus groups and discussion with an expert stakeholder group, including peer researchers, to produce an initial programme theory. We also incorporated extant behaviour change theory, selected according to context, which

proposed both how practitioners should work with offenders and how implementation should be achieved in the form of an implementation delivery platform (i.e. practitioner manual, training, and supervision).

The initial ENGAGER programme theory describes how change was intended to occur for whom and in what circumstances in the intervention (Diagram 1 and Box 1).

Diagram 1: The ENGAGER initial programme theory



Box 1: The ENGAGER intervention

Offenders have high rates of mental health problems (Singleton et al., 1998; Grubin et al., 1997; Brooker et al., 2002), distrust, substance misuse, homelessness and relationship difficulties and high rates of comorbidity (Georgiadis et al., 2016), but poor continuity on release from prison (Byng et al., 2012; Williamson, 2006) and minimal access to mental health care (Forrester et al., 2013; Moore et al., 2015).

The ENGAGER practitioners work with male prisoners within 12 weeks of their release date, and 3-5 months post-release. An individualised plan is built around a shared understanding of the links between his thinking, feeling, and behaviour. The ENGAGER practitioner works with a participant's personal strengths and abilities, professionals in other services, and friends and family, to mobilise available resources in prison and the community around a participant's goals.

Each of the arrows in Diagram 1 represents a group of context-mechanism-outcome configurations (e.g. Appendix 1) which we hypothesised would produce each intermediate outcome. Context is defined as social/cultural/organisational/individual characteristics required for a particular mechanism to produce a desired outcome; mechanisms as the interaction of people's reasoning with the resources that the ENGAGER practitioners offer to influence a change in behaviour or action; and outcomes as 1) a change in the thinking, emotions, or behaviour (e.g. engagement) of prison leavers, and 2) a change in the thinking, emotions, or behaviour (i.e. work-practices) of health and social care professionals working with prison leavers, that occur as a result of accessing resources provided by the ENGAGER practitioners. Feedback loops operate between the intermediate outcomes at all levels.

This initial programme theory has three important aspects. Firstly, ENGAGER practitioners are the main intervention resource (their behaviour in these dyadic relationships), which interacts with the agency of the prison leavers *and* with other health and social care professionals to produce outcomes. Secondly, based on an understanding that individual offenders' problems and contexts would be diverse, flexibility of practitioner responses to individual need was prioritised over replication of fixed intervention components. Thirdly, a concern with implementation – ensuring change happens – was built in from the start in the form of a comprehensive implementation platform.

In this paper, we provide an exemplar of realist formative process evaluation that: 1) illustrates how formative process evaluation *during the piloting and feasibility phase* not only helps identify critical and less important components of the intervention, but also ensures that barriers and facilitators to implementation and scaling up are recognised prior to the trial, and 2) shows how *realist* formative process evaluation can provide valuable knowledge about the interaction between context/s and mechanism/s and impact on desired outcome/s, thus elaborating the theory of how the intervention may work (or not) in different situations.

METHODS

Ethics

The study received NHS Ethical approval from the NRES Committee East of England (13/EE/0249) and NOMS approval (2013-187). In addition, local NHS R&D approvals were obtained from the healthcare providers in each prison establishment.

Design

The realist formative process evaluation (Diagram 2) had three phases (Table 1).

Table 1: Realist formative process evaluation phases

Phase	Action	Aim
Phase 1	Data collection and rapid feedback to ENGAGER practitioners during the	Optimise delivery and opportunities for learning

	pilot trial	
Phase 2	Initial analysis of full data set to inform substantive changes to the key components and implementation platform after the pilot trial	Prioritise key intervention functions to inform delivery planning (e.g. team structure and manual revisions)
Phase 3	In-depth analysis to elaborate core programme theory - how the intervention works, for whom, when, and in what way	Inform detailed focus and priorities of the manual and training (implementation platform) for intervention delivery in the full trial outcome evaluation

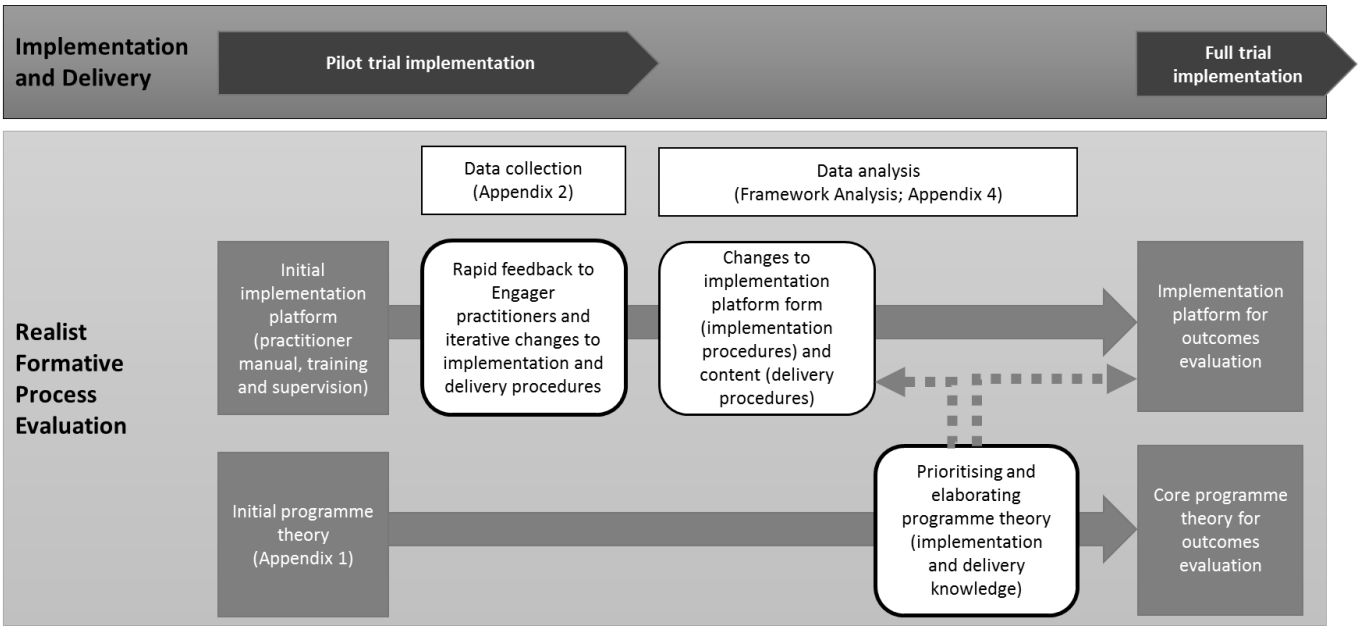


Diagram 2: Design of realist formative process evaluation showing how it moved from the initial implementation platform and initial programme theory to the implementation platform and core programme theory for the outcomes evaluation

Data collection

Face-to-face, semi-structured realist interviews (Manzano, 2016; Pawson, 1996) were digitally audio recorded and transcribed verbatim. Realist interview schedules (Appendix 3) were constructed using the context-mechanism-outcome (CMO) configurations in the initial programme theory (e.g. Appendix 4). The developing programme theory informed iterative revision of interview schedules. Interviews were conducted with:

- 4 ENGAGER practitioners (2 in South West site (SW), 2 in North West site (NW); each at three time points: early, mid, and late in intervention delivery)
- 3 ENGAGER supervisors (2 NW, 1 SW) (each at three time points: early, mid, and late in intervention delivery)
- 14 prison leavers (6 NW – 2 in prison, 4 in community; 8 SW - 3 in prison, 6 in community)
- 5 criminal justice, health and/or social care professionals (2 NW, 3 SW; 2 prison services, 3 community services)

Prison leavers were recruited using a combination of opportunity and theoretically driven purposive sampling. Opportunity sampling was used when approaching those with lower levels of engagement (e.g. returned to prison). Purposive sampling was used to recruit those with experience of the salient issues in the emerging programme theory, e.g. few contacts in prison prior to release. We purposively sampled other health and social care professionals to include professionals proving challenging to involve in ENGAGER.

ENGAGER practitioners used a pro forma to record notes about what they had done in each session with prison leavers, or on a participant's behalf, and any significant issues that had been discussed (all notes for 19 prison leavers' contacts in NW, 18 in SW). We examined scanned copies of practitioner notes to describe what components, where, and over what time were delivered.

ENGAGER practitioners digitally audio-recorded 24 of their one-to-one sessions (12 NW, 12 SW; 19 prison, 5 community) with 17 prison leavers. Recordings of sessions in the community, as opposed to in prison, were particularly challenging to obtain as these sessions evolved to be more flexible and less 'formal' to meet the needs of the prison leavers (e.g. not necessarily at a table in a quiet private room). A sub-set of the recordings obtained were purposively sampled to represent different stages of the intervention delivery and sessions at particular stages of the intervention (close to prison release; close to final contact with their ENGAGER practitioner).

Data analysis

Realist evaluation is a form of interpretive case study, thus rigour in realist evaluation embraces the principles of interpretive case study in general (Stake, 1995) (Greenhalgh et al., 2009). Following these principles, care was taken to ensure immersion in the data and at the field site as far as practicable, and to define and justify the "case". This was achieved by: discussing the intervention in depth regularly with practitioners delivering it, their supervisors and the research team across both sites and listening to session recordings of intervention delivery; spending enough time at the field site to understand what is going on; collecting information meticulously and analysing it systematically; encouraging reflexivity in both researchers and research prison leavers; developing theory iteratively as emerging data were analysed; seeking disconfirming cases and alternative explanations; and exploring our interpretations with all stakeholders and participants.

As expressed by Greenhalgh and colleagues (Greenhalgh et al., 2009) (pp.396-7):

> "the realist methodology cannot be expressed simply in technical or sequential terms (first do X, like this, then move on and do Y, like this). Rather, it uses all the following approaches judiciously and in combination: Organizing and collating primary data and producing preliminary thematic summaries of these […]; Presenting, defending, and negotiating particular interpretations of actions and events both within the research team and also to the stakeholders themselves […]; Testing these interpretations by explicitly seeking disconfirming or contradictory data […]; Considering other interpretations that might account for the same findings."

During the pilot a researcher (SLB) monitored data and raised any potential problems with feasibility or fidelity of the intervention with the wider research team in regular meetings. Where appropriate, the research team provided rapid feedback to the practitioner team to redouble efforts towards fidelity or to make changes to the intervention.

During the pilot we also presented, defended, and negotiated interpretations of the evidence within the research team and in wider stakeholder groups meetings. Emergent issues from the analysis process were also explored in subsequent semi-structured interviews with the ENGAGER supervisors, practitioners, prison leavers and other health and social care professionals.

In the formal analysis after the pilot trial ended, the qualitative data were analysed using Framework analysis (Ritchie and Spenser, 1994) as we wanted to build on and adapt the deductively derived initial ENGAGER programme theory. Data were sifted, charted and sorted in accordance with this initial programme theory, which formed the structure of the framework.

Using Framework analysis within the NVivo 10 software package for data analysis (QSR International Pty Ltd, 2012) supported us in organising data according to the initial programme theory (the framework columns were CMOs or partial CMOs of interest, and rows were data) to enable our thematic analysis of evidence across all sources related to the initial programme theory; and to seek disconfirming or contradictory data.

Each stage of the Framework analysis was conducted by one researcher (SLB or AS), and reviewed by a second to raise issues (CQ or SLB), which were resolved through discussion. During this process, gaps in evidence or conflicting evidence were marked to be explored more deeply in the process evaluation of the main trial of the ENGAGER intervention.

Prior to completion of the detailed Framework analysis, pragmatic considerations and time constraints required that the analysis was fed in to the decision-making process for the intervention delivery (see discussion for serendipitous benefits of working in this way). The CMO configurations at this stage were expressed in if-then statements, or narrative summaries, of the evidence for each intervention function. The results of this stage informed a stakeholder consensus group meeting and fed in to decisions about which components of the intervention should be prioritised, amended or discarded in the main trial.

In the final stage of mapping and interpretation, one researcher (SLB) developed core CMOs from across all of the potentially important 'intervention functions'. Three researchers (CQ, RB, MP) reviewed the evidence and agreed the core mechanisms. Two researchers sense-checked the theory from the point of view of their immersion in the intervention delivery (CL, TK). An experienced qualitative researcher not immersed in the data or delivery acted as a

critical friend to facilitate reflexivity (CO). In this way intervention functions most important for delivering outcomes were prioritised, and the core programme theory underpinning each of the functions and how they worked together, was elaborated. The results of this process were used to provide further detail within the manual and inform training before and at the start of the intervention.

RESULTS

Main findings

Our findings are presented as the four intervention functions we prioritised from those in the initial programme theory as most important in delivering the desired outcomes of the ENGAGER intervention: 1) building trust and engagement, 2) using the Mentalisation-Based approach, 3) doing practical and emotional work, and 4) sharing participant's personal goals and action plans with their health and social care professionals.

For each of the prioritised intervention functions we first present illustrative findings and then the process by which the initial programme theory and related implementation platform were elaborated, emphasised, and prioritised to form a core ENGAGER programme theory and the implementation platform for the full ENGAGER RCT. For each of the four functions we show in the tables: 1) initial programme theory; 2) rapid feedback of findings during the pilot trial and immediate *formative* changes to implementation; 3) formal Framework analysis findings and *substantive* changes to the implementation and delivery after the pilot trial; and 4) elaborated, emphasised and prioritised core programme theory.

1: Trust and engagement

Illustrative findings: release day working

ENGAGER practitioner interviews during the pilot trial raised the concern that, for a range of practical reasons, including sudden early release, the length of time and number of contacts with ENGAGER in prison prior to release was far lower than intended, often as little as two weeks and 1-3 contacts. The practitioners, who were used to building trust and engagement in formal sessions, were concerned about not having sufficient time to build trust before release. However, our emerging findings highlighted that for the men receiving the intervention, anxiety about release made it difficult to do substantive therapeutic work in sessions close to release from prison. What they most valued instead was the practical and emotional support that ENGAGER practitioners provided during their release day ('release day working').
In this extract from an interview with 'Dave' soon after release, we can see the impact that being met at the gate had on his engagement:

> "[when you get out on your own] everything that you planned in [prison], oh, I'm gonna do this and I'm gonna do that, it just…it's just gone. Gone out your head. And by the time you know it, you're out of your face somewhere and you've missed all your appointments and then you [are] just recalled anyway. I don't think I would have got to any of the appointments if…if I didn't have [ENGAGER practitioner] there. I'd have jumped on the train, probably gone and got some beers, gone and got some Valium and then probably ended up in a ditch or something. [ENGAGER practitioner] just took me to every appointment. And yeah…it's best just to get it all out the way straightaway and then… You've got a list of all your follow-up appointments. […] With the ENGAGER people […] I can focus on getting all my stuff out the way so I'm not in trouble straight away already before I even start."

Similar themes came up in a number of interviews with men interviewed soon after release. It emerged that one of the most important ways in which work in prison built engagement was the setting up of release day working, which was critical for building engagement. Interviews with prison leavers emphasised that rather than pre-release meetings it was this release day working, including meeting at the gate, supporting transportation to appointments, attending appointments, and facilitating sobriety, that was most important for building their trust and engagement. However, release day working had been an add-on (as opposed to core) component of the initial intervention model, offered to men in prison as deemed appropriate and not explicitly linked to trust and engagement in the initial programme theory.

Illustrative if-then statements

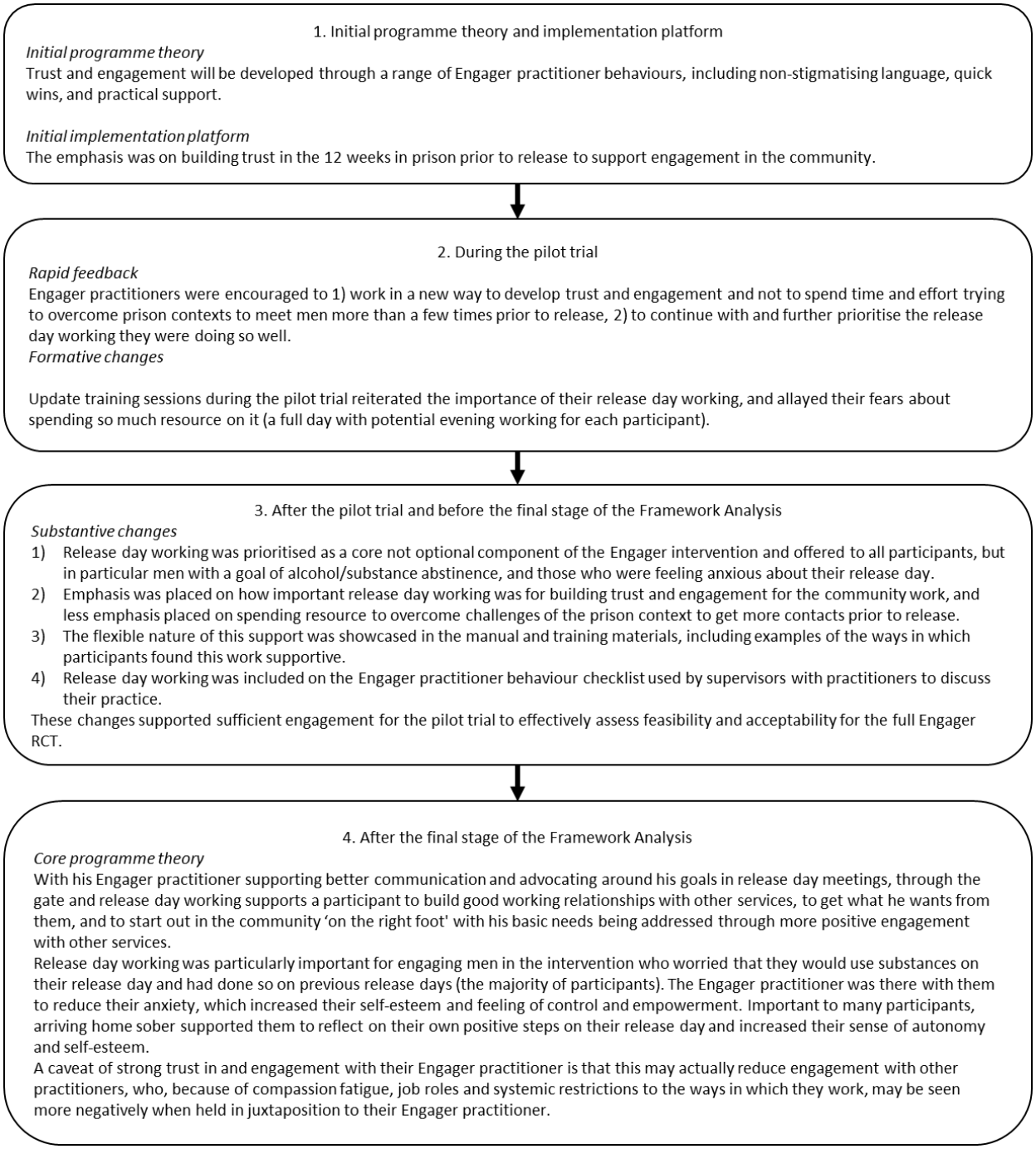
'IF a participant would usually go straight out from prison and use or drink and get stuck in same rut AND he is met at the prison gate by his practitioner (whom he knows from their prison meetings) and that practitioner goes with him to all of his release day appointments at services, advocates for him and supports communication with other services, THEN the participant has less time and less inclination to use substances and/or alcohol on his release day, is more likely to get home without using or drinking and to feel proud of himself for his release day abstinence AND THEN he will feel increased trust in his ENGAGER practitioner and will want to engage with them in the community.'

Knowledge mobilisation: trust and engagement

These findings 1) prioritised release day working as a key driver for trust and engagement, and 2) informed formative and substantive changes to programme theory and implementation platform (Table 2), including that release day working became a core, rather than optional,

intervention component; and emphasising the importance of release day working in the manual, supervision and training for ENGAGER practitioners.

Table 2: rapid feedback, formative changes, and substantive changes to the implementation platform and programme theory for the prioritised intervention function ‘trust and engagement’



2: Supporting positive relationships using a Mentalisation-Based (MB) approach

Illustrative findings: MB approach

Early on in the pilot trial delivery, interviews with all ENGAGER practitioners highlighted that there was a lack of understanding and considerable uncertainty about what a

Mentalisation-Based (MB) approach was and how to use it. Fidelity analysis of audio recordings of sessions between ENGAGER practitioners and prison leavers supported this, highlighting consistent practitioner behaviour not in line with the MB approach. Some ENGAGER practitioners reported reverting back to their usual way of working due to not understanding how to use this new approach.

In response to the addition of further supervision and support from an expert in using a MB approach with people in prisons (Table 3), interviews and recordings of intervention sessions showed a substantial improvement in practitioner use, acceptance, and understanding of the MB approach. Some practitioners later reported how helpful and engaging they found the MB approach, so much so that they had begun using it in other areas of their work. ENGAGER practitioners reported that once they understood and used the MB approach it supported the development of the shared understanding and shared action plan (core resources used in the intervention delivery). The MB approach supported ENGAGER practitioners to enable prison leavers to see different perspectives regarding things that have gone wrong for them. For example, one ENGAGER practitioner described a participant who hated his probation worker because he believed that she wanted him to fail. Using the MB approach, the ENGAGER practitioner supported him to see the probation officer's behaviour from a different perspective. The ensuing change in the participant's behaviour in meetings with the probation officer resulted in the probation worker feeling more understanding of the participant's goals. ENGAGER practitioners reported that the MB approach supported prison leavers to feel less distressed, to have better relationships, to be calmer and thus more able to focus on the shared work with the ENGAGER practitioner in their sessions, to engage with the ENGAGER practitioner, and to work more productively with other practitioners (during and after the ENGAGER intervention).

Illustrative if-then statements: MB approach

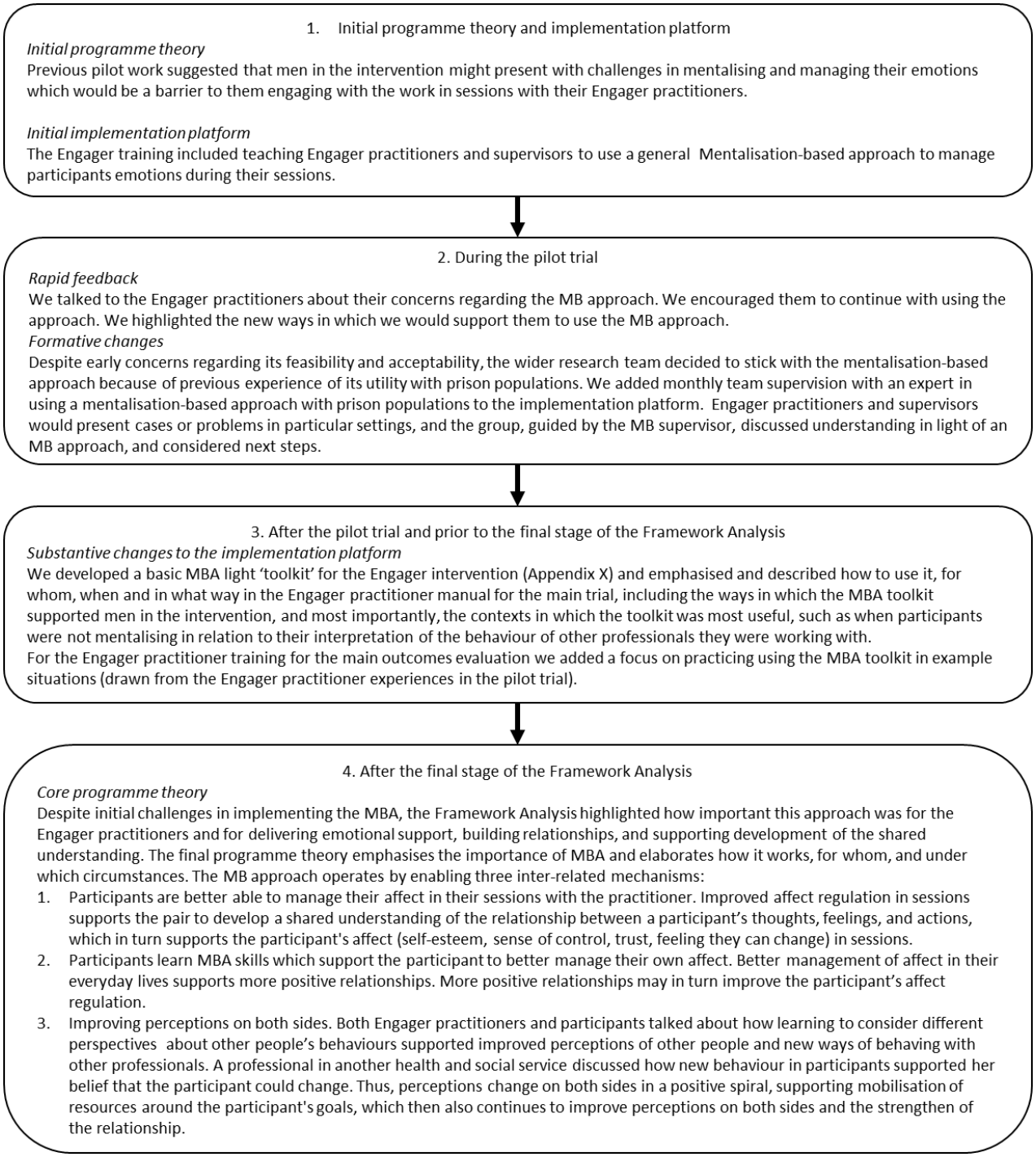
[PT2b] IF a participant usually bottles up their feelings and tells no one and then 'explodes' in a way that has a negative impact on them or on people around them, THEN the ENGAGER Practitioner using the MB approach toolkit with them will help them to manage their emotions in sessions with the ENGAGER Practitioner and in their everyday life, AND THEN the participant's emotions are less likely to build up and 'explode' in ways that harm themselves or others.

[PT2c] IF the ENGAGER Practitioner uses the MB approach toolkit with a participant in their sessions, THEN the participant will be supported to regulate his affect in sessions (i.e. not to become too overwhelmed by emotions in sessions - over-arousal) AND THEN the participant and the ENGAGER Practitioner can reflect on and build a Shared Understanding of the links between thinking, feeling, and behaviour that are related to recurring 'crises' in the participant's life.

Knowledge mobilisation: MB approach

These findings 1) prioritised the MB approach function in the intervention model, and 2) informed formative and substantive changes to programme theory and implementation platform (Table 3), including detailed elaboration of how to use the MB approach, for whom, when and in what way.

Table 3: rapid feedback, formative changes, and substantive changes to the implementation platform and programme theory for the prioritised intervention function ‘MB approach’



3: Emotional support

Illustrative findings: emotional and practical support

Our interviews highlighted early concerns of ENGAGER practitioners that they were unable to provide 'emotional support' and that they were spending a lot of time instead on practical support. However, we observed in interviews with both ENGAGER practitioners and prison

leavers that practical support was in fact a critical way in which the ENGAGER practitioners were delivering emotional support. Men in the intervention described how the practitioner supporting them in getting their benefits, in finding accommodation, or getting to appointments with other professionals such as probation, showed that the ENGAGER practitioner cared about them and was willing to go the extra mile for them.

The feedback from practitioners and prison leavers in the pilot trial highlighted the importance of both 1) 'practical support' and 2) 'working with crises' in delivering emotional support. Practical support was prevalent in the pilot trial delivery of the intervention but was not theorised in terms of how it provided emotional support. Prison leavers described how everyday practical support from the ENGAGER practitioner built their trust, self-esteem, and feeling of being cared for, which supported their engagement with their ENGAGER Practitioner. ENGAGER practitioners discussed how anxiety about imminent release made prison leavers less able to focus on longer-term or more abstract conversations, such as the links between thinking, feeling, and behaviour, but more able to focus on short-term practical issues to do with their release and return to the community.

Some other services described the everyday 'crises' that this population present with as a barrier to getting to the 'real work'. ENGAGER practitioner interviews showed how these crises provide an opportunity for rich, engaging, and person-centred emotional support. Using the MB approach of 'micro-slicing' in detail what happens when things go wrong in their everyday lives in the community helps to identify and address recurring problems in the participant's life. For example, supporting him to understand what happens just before he 'sees red' and acts aggressively.

Illustrative if-then statements: emotional and practical support

Illustrative findings

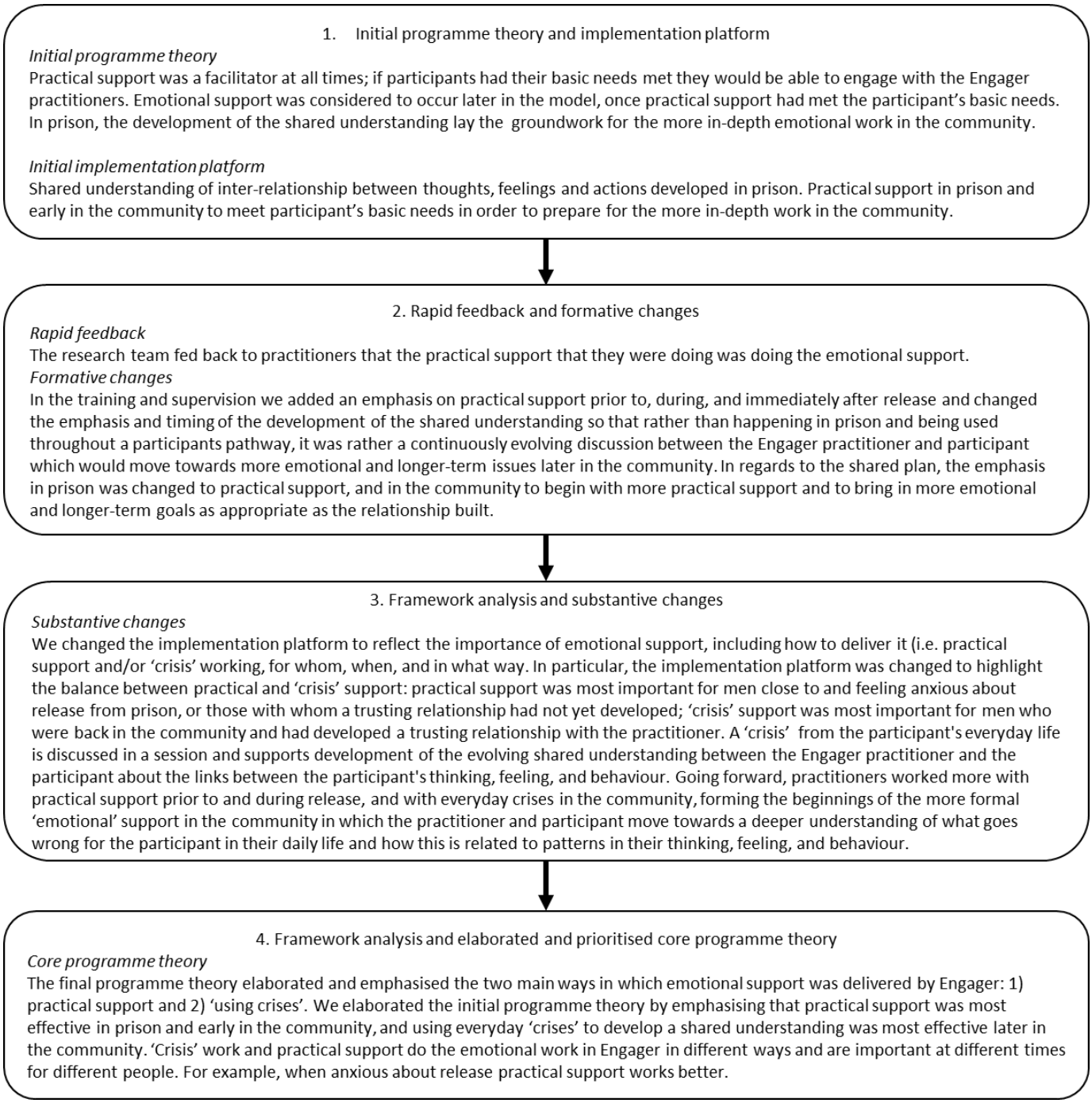
[PT1c] IF an ENGAGER Practitioner uses practical support around a participant's personal goals (i.e. in supporting actions in his Shared Action Plan), THEN the participant will feel that someone genuinely cares about him and wants to help him AND will increasingly trust his ENGAGER Practitioner.

[PT1f] IF an ENGAGER Practitioner provides practical support and uses everyday crises to explore links with the participant, THEN the work shared between the ENGAGER Practitioner and the participant will provide emotional support in a way that the participant finds helpful, that focuses on his personal experiences and goals, and that he is able to engage with.

Knowledge mobilisation: emotional support

We 1) elaborated and emphasised these two forms of delivering emotional support in the core programme theory, and 2) made substantive changes to the implementation platform, including detailed examples and description of how ENGAGER delivers emotional support, when to use these two forms of delivering emotional support (practical in prison and crisis-based in the community), for whom (e.g. tailor type of support to anxiety levels), and in what way (Table 4).

Table 4: rapid feedback, formative changes, and substantive changes to the implementation platform and programme theory for the prioritised intervention function ‘MB approach’



4: Supporting working with others and the shared understanding and plan

Illustrative findings: working with others

Early in the intervention delivery it become clear that ENGAGER practitioners were often not developing shared understandings with men in prison, and they discussed in interviews

how the prison leavers were distracted and anxious the closer to release they were. In the community, once their immediate needs and concerns were addressed, prison leavers were able to focus more on discussions of more abstract concepts like feelings and long-term goals. Further findings confirmed the increased feasibility and acceptability of changing the time for developing the shared action plan and shared understanding. ENGAGER practitioners discussed many barriers and facilitators to developing good working relationships with other practitioners; one main facilitator was the Shared Action Plan. The plan was considered to be particularly important in overcoming other professionals' perception that the ENGAGER practitioners were encroaching into their professional space and responsibilities ('stepping on their toes'). It could facilitate discussions about how the ENGAGER practitioners' role complemented and supported that of other key professionals. However, the findings showed that the plan could be counter-productive to mobilising the resources of other practitioners if it contained steps towards a participant's goals that were impossible to provide within the entrenched constraints of the health and social care system.

Illustrative if-then statements: working with others

[PT13d] IF an ENGAGER Practitioner supports a participant to attend appointments with other services that the participant finds it hard to communicate with or has negative perceptions about, THEN engagement with these services will increase, AND the participant will get more out of meetings with these other services.

[PT13e] IF an ENGAGER Practitioner supports communication between a practitioner from another service and the ENGAGER participant, THEN the participant will feel less frustrated in meetings with other practitioner, AND THEN the other practitioner will begin to see the participant more positively and be more willing to mobilise their resources for them.

[PT17a] IF the Shared Action Plan is used to communicate participants' goals with relevant other services, THEN other practitioners can understand how their work and ENGAGER's work is complementary, can feel less defensive of ENGAGER also working with their prison leavers, can see how ENGAGER fills a meaningful gap in current service delivery (particularly this is seen by other practitioners in the through the gate working ENGAGER can do that they often cannot do), AND THEN supports other services to mobilise their resources around a participant's goals.

[PT17d] IF other practitioners have negative perceptions of the participant, or of offenders in general, that affect their engagement with them, THEN the Shared Action Plan is a way to bypass or address negative perceptions by centering discussion around the participant's goals in a non-threatening way, AND THEN resources can be mobilised around a participant's goals that would not have been available otherwise.

Knowledge mobilisation: working with others

These findings 1) elaborated the ways in which the shared understanding and shared plan co-evolved and developed over time, and 2) informed formative and substantive changes to the implementation platform. For example, the shared plan could be used to engage other practitioners; both those who seem defensive of their roles by showing them how ENGAGER complements and supports their role, and also those who have 'compassion fatigue' for prison leavers by showing them the progress the participant has made to achieve their goals (Table 5).

Table 5: rapid feedback, formative changes, and substantive changes to the implementation platform and programme theory for the prioritised intervention function 'supporting working with others'

1. Initial programme theory and implementation platform

Initial programme theory

Engager practitioners supporting participants to work with other people was a core part of the initial programme theory.

Initial implementation platform

The main resources to deliver this were the Shared Understanding and the Shared Action Plan. The shared action plan was the vehicle to support shared working between practitioners and to communicate the participant's goals and desired steps to achieve them. The shared understanding was to be built at the beginning of the work with a participant in prison, and used to shape the work with the participant throughout the intervention.

2. During the pilot trial

Rapid feedback

We fed back to the Engager practitioners that the shared understanding was now an evolving resource and not something that must be developed in the few prison sessions.

Formative changes

The shared understanding was re-articulated to feed in to the shared action plan. We updated training sessions and ongoing supervision so that rather then trying to get participants to discuss their thoughts, feelings and actions and build a shared understanding in prison, to leave this work until later in the community, when participants would be more able to engage with this. We changed the shared action plan such that it was developed over time, in prison focusing on short-term practical goals around release, and building up later in the community to include longer-term more abstract and emotional goals.

3. After the pilot trial and prior to the final stage of the Framework Analysis

Substantive changes

We refined the implementation platform to highlight how to tailor the shared understanding and shared action plan and for whom (e.g. socially anxious or with past negative experience of other professionals), and under what circumstances (e.g. where the Engager practitioner became aware of an issue in a relationship between a participant and a particular professional). The manual was changed to include a template for a shared action plan that emphasised incorporating changes to the shared understanding after each session, a participant's evolving goals and next steps toward them, which other professionals should be involved in each step, and how the plan worked with these other professionals' own plans. It was designed to support co-evolution of the shared understanding and shared action plan and to facilitate showing other professionals how Engager could support and complement their own role and avoid the impression of Engager 'stepping on other professionals' toes'. The manual highlights the importance of sharing this action plan in particular with professionals who have existing negative impressions of a participant from previously working with him, or who do not seem open to engaging with the Engager practitioner. The revised manual encourages practitioners to have conversations with other professionals to identify and troubleshoot any potential barriers to steps in the action plan.

4. After the final stage of the Framework Analysis

Core programme theory

The shared understanding and shared action plan co-evolve. The shared understanding develops over time and feeds in to the shared action plan. The shared action plan (informed by the shared understanding) evolves from practical short-term goals towards more abstract long-term goals in the community.

The shared action plan supports Engager practitioners to help other professionals to relate to and communicate about the participants' goals with the Engager practitioner, including by sharing plans between services in a non-threatening and collaborative way. It supports other practitioners to see how Engager complements and fills in gaps of their service delivery, rather than stepping on their toes and making them feel defensive. Perhaps most importantly for overcoming the barrier of compassion fatigue, it supports other practitioners, who may have worked with the same man repeatedly on release from prison before, to have renewed hope that he can do something different this time with his Engager practitioner supporting him.

5. Inter-relationships between the four prioritised functions of the ENGAGER intervention

We found important and unanticipated inter-relationships between the intervention functions: MB approach, delivery of emotional support and the shared understanding, all of which were underpinned by building trust and engagement. The RFPE supported us to capture and understand these interactions in the core programme theory, by illustrating the operation of the CMO configurations *across* the intervention functions, and thus to articulate them in the implementation platform.

In practice, in delivering the intervention, ENGAGER practitioners merged the intervention functions in the initial programme theory to produce something greater than the parts, and it worked in inter-related, unexpected and important ways. In the initial programme theory: the MB approach intended to support ENGAGER practitioners to engage prison leavers by helping practitioners to manage and respond to prison leavers' emotions during sessions; the shared understanding of the links between thinking, feeling and acting was to be developed in prison and used to guide future sessions; emotional support was delivered through one-to-one working in empathic and person-centred ways. These three functions had not been conceptualised in terms of how they facilitated and enhanced each other, as identified from the analysis.

ENGAGER practitioners in the act of delivering these intervention functions used the MB approach to deliver emotional support in discussing and caring about 'crises', and in turn, the understanding over time of these everyday crises formed the basis of the shared understanding and thus the shared action plan. Through linking these functions together using a realist approach, highlighting the nested CMO configurations involved in ENGAGER, the 'what to do when, for whom and in what way' details emerged across these intervention functions. With the evolution of the shared understanding in response to prison leavers'

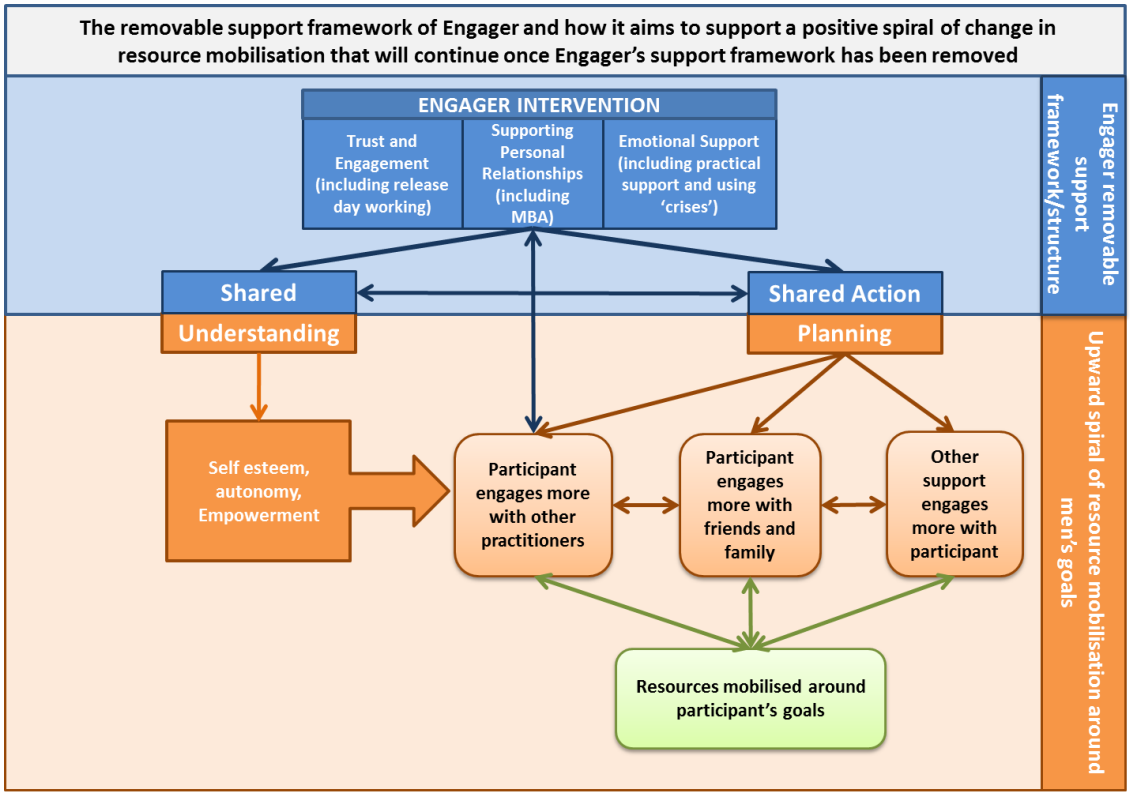
changing ability to focus on non-practical issues over time, the shared plan evolved from short-term practical goals (like finding somewhere to live) towards more abstract longer-term goals (like building stronger relationships). Through the opportunities presented by returning to the community and re-engaging in problematic patterns of thinking, feeling, and behaving, the ENGAGER practitioners could use the MB toolkit to support prison leavers to build engagement, understanding, and progress towards goals, which in turn supports the engagement of other practitioners' resources around the prison leavers' goals.

The MB approach appeared to be most useful for this population in the community sessions. This resource interacted with the reasoning of the prison leavers and practitioners to produce a shared understanding of the links between the prison leavers' thoughts, feelings, and behaviours. During sessions, prison leavers presented challenging situations from their lives back in the community. Practitioners using the MB approach slowed down the telling, and supported links to be made between what the participant was thinking and feeling before a problem behaviour (such as aggression or substance use). This approach has a number of outcomes: it made prison leavers feel listened to and so they shared more from their everyday lives; it made prison leavers feel cared for and so their engagement increased; it helped the practitioner and participant to get a clearer idea through concrete day-to-day examples of what it is in these 'crises' that goes wrong for the participant, and so to reflect and consider different ways of managing challenging thoughts, feelings, and behaviours.

The prioritised functions of the ENGAGER intervention interact to mobilise the resources of health and social care professionals around the goals of men nearing and after release from prison who have common mental health problems (Diagram 3). In this diagram, prioritised functions 1-3 are in the top row; Prioritised function 4 is represented by 'shared

understanding' and 'shared action plan', to illustrate the evolving relationship between them and the interactions with and between other elements).

Diagram 3: How ENGAGER mobilises resources around a prison leaver's goals during and after the intervention



DISCUSSION

The realist formative process evaluation provided an analysis which demonstrated how the ENGAGER intervention mobilises the resources of health and social care professionals around prison leavers' goals. It clarified that the core intervention functions that the ENGAGER practitioners used to achieve this mobilisation were: 1) working with prison leavers in prison and in the community in person-centred, flexible ways to build trust and engagement, including release day working, 2) supporting more positive relationships

between prison leavers and health and social care professionals, including using a Mentalisation-Based toolkit to improve perceptions on both sides, 3) delivering the 'emotional work' through practical support and working with everyday crises to support understanding of the links between a participant's thinking, feeling, and behaving, and 4) sharing a participant's personal goals and plans with their other health and social care professionals. These findings were derived in a staged way, feeding both directly back into the pilot and in to the theory and intervention for the subsequent main trial. This discussion provides reflection on our learning about this new methodological approach.

An exemplar of realist formative process evaluation

Using the ENGAGER intervention as an exemplar, we have detailed how a realist formative process evaluation has the potential to prioritise (or drop) components of the intervention and to elaborate and emphasise key functions with an initial programme theory. Use of realist methods and CMOs supported a clear articulation of what works about an intervention, whom it works for, under which circumstances and in what way, to build detailed implementation and delivery knowledge and procedures for full outcome evaluation. Our exemplar contributes to an emerging body of scholarship focussing both on formative evaluations prior to trials and on the use of realist methods in complex intervention development. We have also demonstrated how realist formative process evaluation can be used at the feasibility stage where there are no comparable pre-existing interventions to evaluate (see (Fletcher et al., 2016; Moore et al., 2015)).

The method provided rich implementation and delivery knowledge for the main trial: the analysis fed in to both the *form* of the implementation platform (e.g. increasing the frequency and changing the style of MBA supervision) and to its *content* (e.g. providing detailed

information in the manual about what practitioners should do, for whom, when, and in what way).

Our findings demonstrate the utility of realist formative process evaluation in theory development, from initial programme theory to elaborated, emphasised, and prioritised core programme theory. They show this through four examples, which illustrate how this developing theory informed refinement of the implementation platform's form and content at two stages: pragmatic rapid changes during the pilot trial based on emerging findings, and evidence-based substantive changes after the pilot trial based on formal analysis of findings.

Supporting successful implementation and delivery in an outcome evaluation

Realist formative process evaluation increased the likelihood of 1) successful implementation in the pilot trial and the outcome evaluation, 2) delivery of an intervention in the outcome evaluation that brings about the intended change, and thus 3) the increased likelihood of evidencing an impact in the outcomes evaluation. A clearly articulated underlying realist programme theory also provides a clear theory for testing in the main trial process evaluation.

Prioritising resources used in the intervention

Realist formative process evaluation builds understanding about what works, for whom and in what circumstances, and informed prioritisation of resources in implementation and delivery. Using the example of release day working in the results section: early in the evaluation it was clear that meeting men multiple times in the prison setting to build trust and the shared understanding was often not feasible. At the same time, interviews with prison leavers revealed that release day working was considerably more important to them than prison contacts. This finding was fed back to practitioners with advice to prioritise release

day work (despite it taking a full day) over multiple contacts in prison. Focusing limited resource on what is more likely to work is critical for the success of complex interventions.

Levels of analysis, abstraction and outputs

As with any project, different levels of abstraction in the findings were required for different project outputs and stakeholders. In the realist formative process evaluation there were broadly three levels of abstraction at which the findings informed the intervention: 1) emergent findings at the level of the data (i.e. no analysis performed) informed rapid changes to form and content during the pilot trial; 2) findings at the penultimate stage of the Framework analysis in the form of if-then descriptions of groups of data within each column of the framework (i.e. related to one CMO from behind one intervention function) directed changes to overall configuration of components and detailed aspects of the intervention; 3) final Framework analysis findings in the form of 'core programme theories' that 'emerged' through iterative analysis from across all initial intervention functions in the framework. This third and highest level of abstraction added both simplicity – by emphasising key overarching functions – and further elaboration of these core theories.

The benefits of designing an evaluation in this way were somewhat serendipitous. The rapid and iterative changes introduced in response to emerging findings during the pilot that needed addressing had not been planned but maximized the potential for creating an optimum model prior to the trial. They share similarities with other quality improvement approaches such as the use of Plan-Do-Study-Act cycles in Quality Improvement (see (Taylor et al., 2013)) and with action research (e.g. (Waterman et al., 2001)).

After the pilot trial, during the formal Framework analysis, time pressures required the analysis feed into the intervention delivery planning prior to the final stage of analysis. At this stage of analysis the findings were in the form of groups of if-then statements that describe the data within each column of the framework (i.e. related to one CMO configuration in the initial programme theory). These if-then statements, although abstracted from the data, still contained fine-grained contextualised information that at the next level of abstraction (the final stage of Framework analysis) was necessarily lost. The detailed level of the contextual information informed in detail what the practitioners needed to do for different types of participant, under which circumstances, and in what way. This was invaluable for writing manual content that focused on how practitioners could tailor the intervention to each individual and their unique contexts in prison and the community.

The final stage of the Framework analysis involved emerging core programme theories from across all groups of if-then statements. This stage resulted in elaborated, prioritised and abstract theory that was suitable for articulating the more generalised intervention model and core programme theory for the full outcome evaluation. It was particularly important during training to be able to emphasise key intervention functions.

Limitations

A challenge for using realist evaluation alongside a pilot trial to inform intervention development was managing the level of context. For pragmatic reasons we focused mostly on the individual-level contexts at play in the dyadic relationships that are the vehicle for change in the ENGAGER intervention. This focus supported the formative development of the ENGAGER practitioner manual, supervision, and training to support practitioners to deliver the intervention in a way that was responsive to prison leavers' needs in light of their

individual-level contexts. However, some detail of wider context was lost during this process, and this is reflected in the final ENGAGER theory presented, where contexts are mostly individual- rather than higher-level (e.g. organisational or cultural).

The ENGAGER intervention is a complex intervention operating in a complex system, and pinning down core mechanisms and the contexts on which they are contingent to produce particular outcomes (CMOs) is challenging. There are many inter-related mechanisms operating at many levels across the different prison and community contexts, and it was sometimes difficult to maintain the analytical gaze on the intended mechanisms as described in the initial programme theory. Using the analytical tool of discrete CMOs within a Framework analysis approach puts to one side much (but certainly not all) of the complexity, inter-relatedness, and contextual richness, but this was necessary to end up with useable conclusions from the evaluation to inform intervention development for the full RCT.

Another challenge was prioritising which aspects of the initial programme theory to evaluate and bounding the extent of the evaluation. The initial programme theory was large and complex, with many inter-related parts. Choosing which were likely to be important and thus which to focus evaluation resource on proved challenging at first. Working in multi-disciplinary teams with depth and breadth of expertise and experience can result in a broad range of ideas of what is likely to 'work' in the intervention to be piloted.

Conclusion and recommendations

A formative realist process evaluation embedded in a pilot trial during the feasibility phase of intervention development and evaluation provided rich contextualised implementation and delivery knowledge and procedures for full outcomes evaluation. We offer the ENGAGER

realist formative process evaluation as an exemplar of how formative process evaluations in the feasibility phase can provide valuable knowledge about implementation and translation (especially scale-up for a full trial) and support sustainable implementation procedures for the outcome evaluation. It also demonstrates how a realist approach can provide rich contextualised information that informs both form and content of the implementation platform (i.e. practitioner manual, training and supervision to support delivery) in terms of what it is that works about an intervention, who does it work for, in what circumstances, and in what way.

We recommend that the MRC intervention development and evaluation guidelines include case studies of this form of realist formative process evaluation during the feasibility phase for developing and evaluating novel interventions in which there are no comparable pre-existing interventions to evaluate.

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The authors confirm that they have no conflict of interest.

Appendices

Appendix 1: Example realist matrix of programme theories behind the arrows of the map (1a)

Appendix 2: Data collection grid example

Appendix 3: Realist interview schedule example

Appendix 4: Data analysis framework example

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