



Engager – methodological issues for a 'realist' trial of a complex intervention for complex needs

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Outline

**Flexible complex intervention for heterogeneous
complex needs**

- **1. Getting the intervention into practice**
- **2. Selecting outcomes**
- **3. Understanding how the intervention works
(or not)**

Discussion

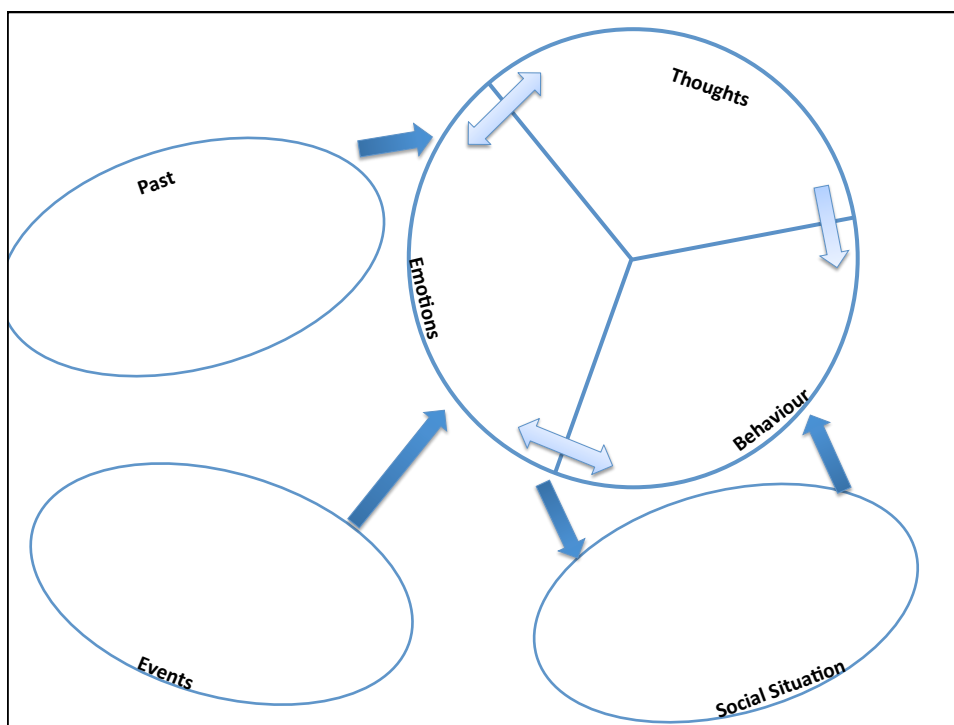
Participant characteristics

- Prison leavers
- Varied and many social problems – relationships, housing, employment
- Often distrust, impulsivity, previous trauma/ attachment issues
- Some less distressed while in prison, so.....
- with or likely to have common mental health problems (anxiety/depression/PTSD)
- Likely to have substance misuse, thoughts of self harm, traits found in so called 'personality disorder'

Need for a person not 'disorder' focussed intervention

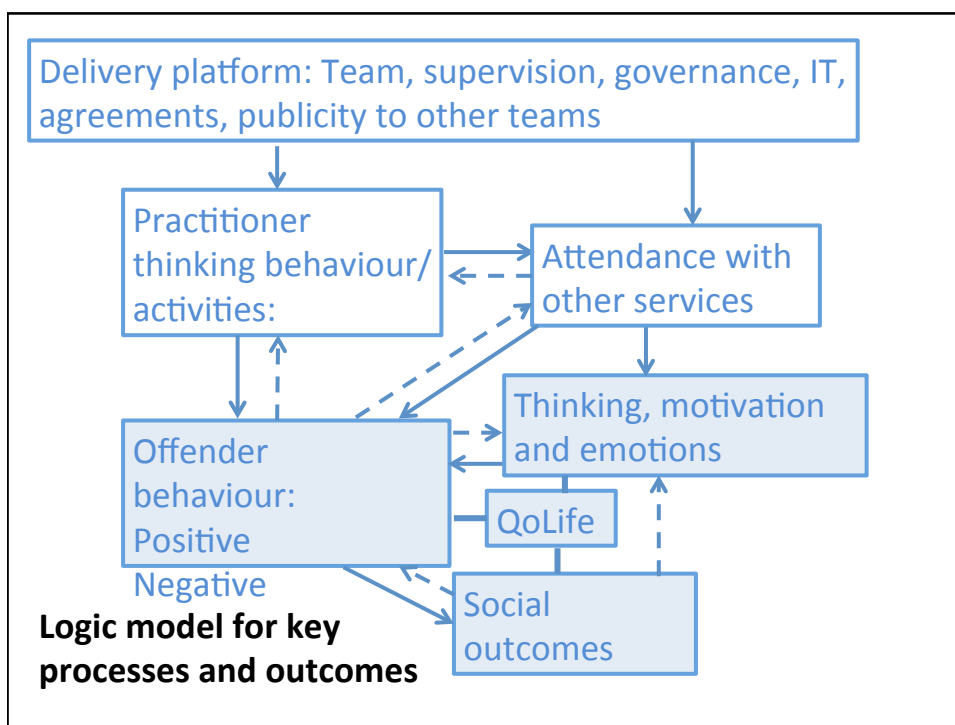
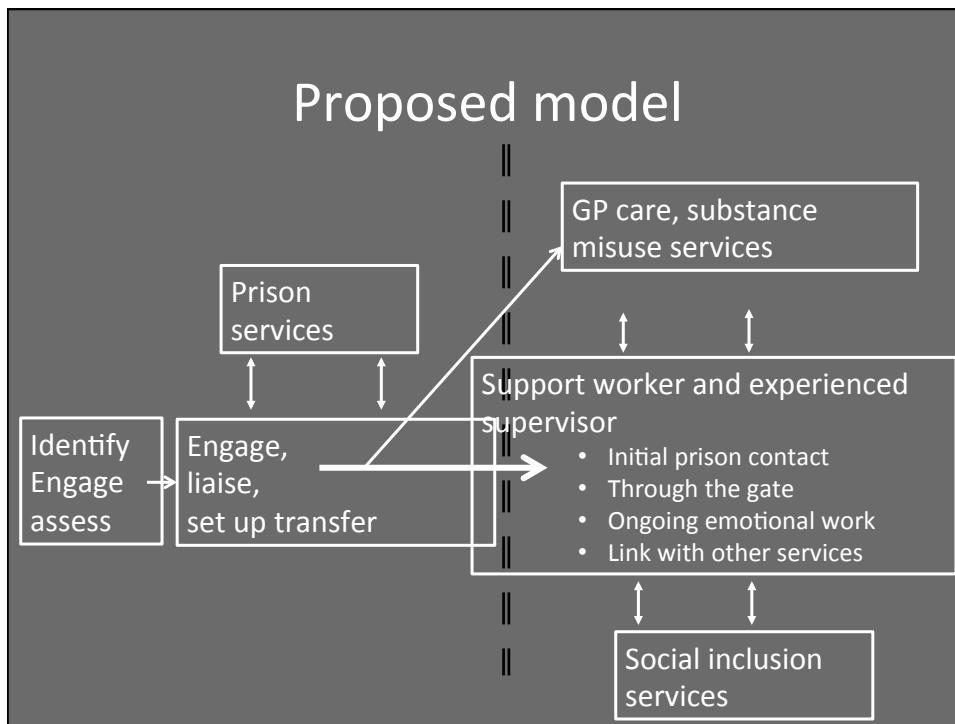
Intervention characteristics

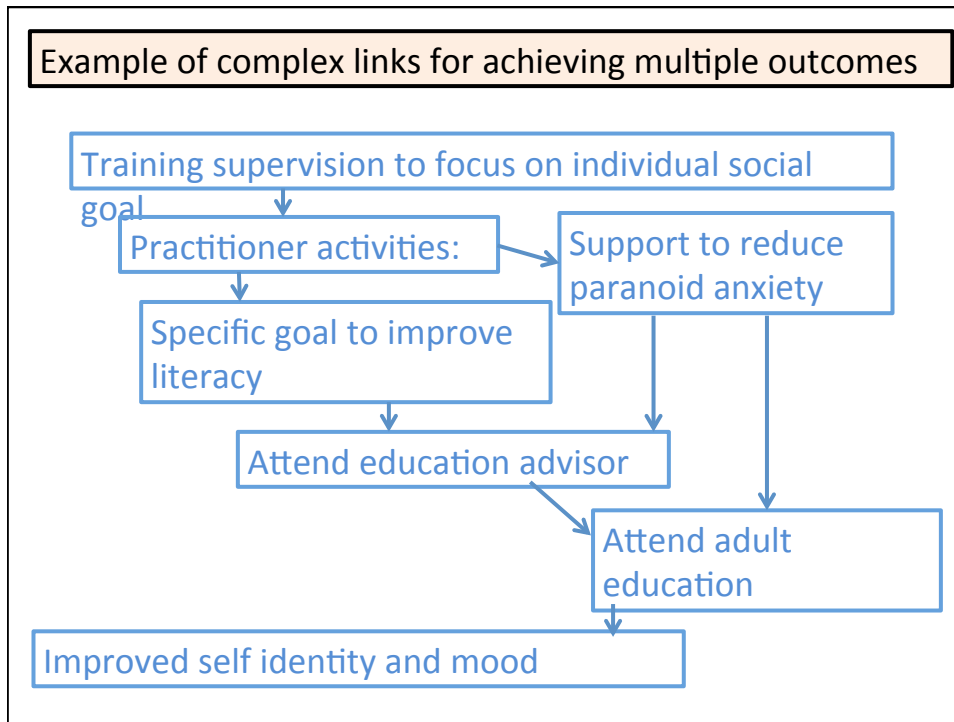
- Engage and build trust before and after release
- 2 Practitioners and team leader/supervisor at each prison
- Work for 3-5 months after release
- Shared understanding – thoughts, emotions and behaviour at heart of intervention
- 'Manualised flexibility' according to need
- Shared plan – resources 'mobilised' from personal strengths, practitioner skills, local opportunities, statutory services



Potential underlying mechanisms:

- Engagement/connection/therapeutic relationship will enhance trust
- Developing a 'shared understanding' linking mind, behaviour and social situation – is therapeutic, engaging and can drive care
- Making idiographic outcomes/goals the focus of care (not just needs as known for the care group) will ensure motivation
- Mobilising the individual's strengths, creativity will contribute to generating wellbeing
- Family, community and other services – often just seen as context - have causal power which needs harnessing to generate outcomes that matter





Traditional Psychology Intervention Research vs Engager

Traditional psychology interventions

- Specific techniques targeted at specific thinking patterns and emotions
- Specific techniques targeted at 'disorders'

Engager – exemplar of pragmatic

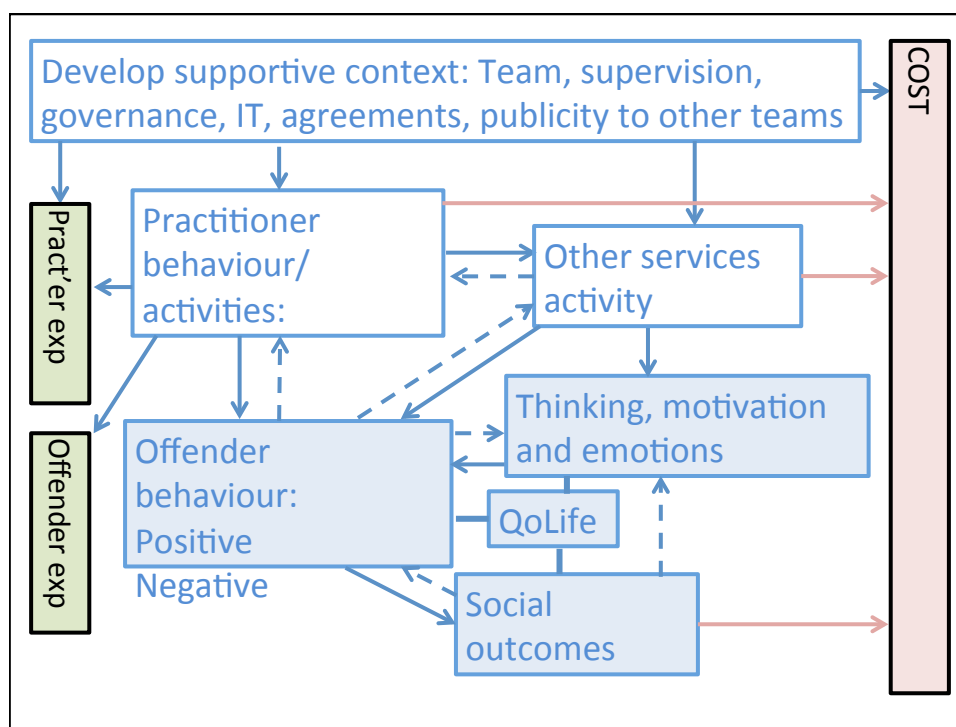
- General and specific techniques vs a group at a particular point in the system
- Explicitly mobilising and so needing to measure 'contextual' resource

Engager – Trial outline

Recruitment – screen all leaving to local area
Randomise individually in prison
Intervention up to 3 months in prison and 3-5
Highly personalised follow up procedures
(70%)
Follow up 5-8 months post release
280 individuals

Engager –Full trial issues

1. Selecting outcomes
2. Getting the intervention into practice
3. Understanding how the intervention works
(or not)



Engager2 – Which outcome?

Mental health

Symptoms

Caseness – meet criteria or not

Mental wellbeing – resilience, hope, empowerment

Key behaviours – substance misuse, self harm, offending

Social status – work, housing, training

Who should decide?

Should intervention dictate outcomes?

Engager2 – selecting outcomes

Step 1 – Single step Delphi to rank domains

Step 2 – Cohort 1 –

3x20 comparison of measures

Mental health, social inclusion, substance use

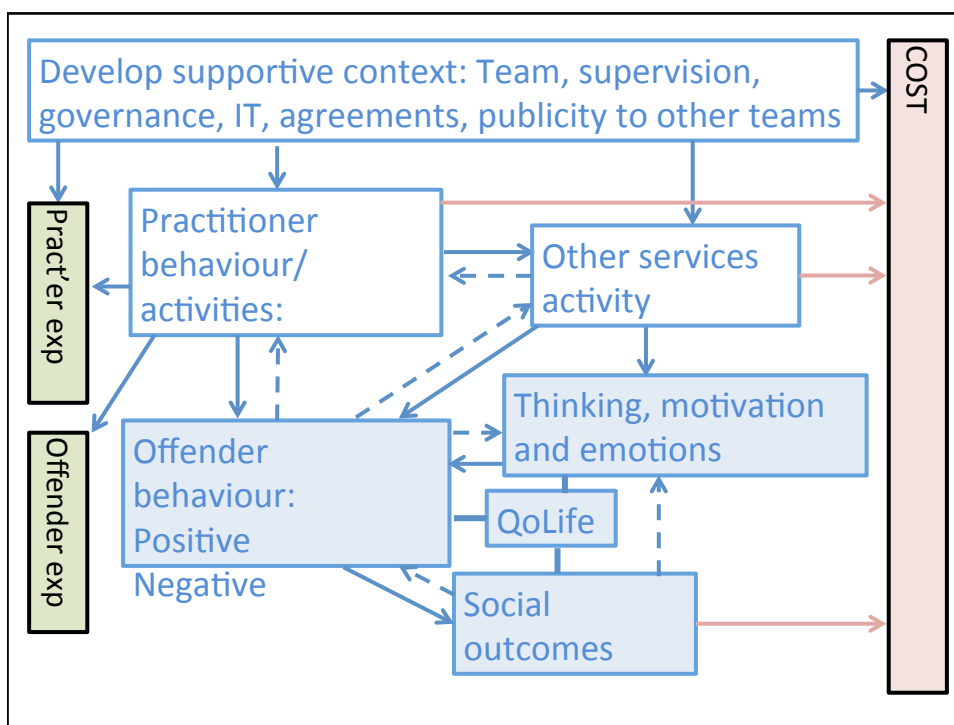
Step 3 – Consensus group

Familiarise problem

Expert advice on trials/psychometrics

Decisions:

- Mental health vs social vs composite (need)
- CORE-OM not PHQ-9
- Split between CORE-OM and CAN-FOR
- Decision based on psychometrics



Engager2 – Putting it into practice

Intervention delivery issues:

- Intervention utilises existing practitioner skills and requires thoughtful decisions not 'replication'
- Intervention requires local services to be aligned to maximise effect
- Need to get up and running and optimised
- Need to ensure fidelity 'keeps on track'
- Need to understand about post trial implementation (or adaptation if negative result)

Engager2 – Putting it into practice

Intervention delivery platform:

- A manual describing actions for practitioners and supervisors
- A training programme for supervisors and practitioners – addressing skills and differences from practice as normal
- Three levels of supervision
- Team meetings to plan for weeks ahead, keep learning
- A set of organisational agreements and informal liaison
- Other equipment – Guardian alarms, laptops
- Review, reflection and audit to assess fidelity
- 6 monthly joint site meetings to keep up morale and coherence across sites

Engager – Process evaluation

What happens?

What is delivered? How does it relate to ideal model (fidelity)?

How does it work?

What supports delivery? What extra is added? Are core mechanisms working in the way we think?

Revisit what are the core mechanisms/ CMOs?

Engager – Process evaluation

Methodological strategies

1. Describe what happened in relation to trial outcomes:
 - Measure components (eg through the gate)
 - Mechanisms (eg trust generated by 'through the gate', 'practical support, or 'showing cares') and relating to personal context
 - Qualitative for depth understanding – interviews, observation, conversation analysis

Engager – Process evaluation

Methodological strategies

2. Moderator-mediator regression analysis

Moderators:

- Demographics,
- Criminal Justice History,
- Impulsivity, cognitive function

Mediators:

- Intervention components delivered - external
- Other services delivered - external
- Generic individual processes – trust, hope, etc
- Intervention mechanism activated – eg trust following practical support

Qualitative for depth understanding

Thanks you and discussion

- **Your ideas for 3rd quantitative strategy**
- **How does this relate to tropical disease and health care in the south?**

Engager – sample size

Range of uncertain parameters which define sample size:

- Standard deviation
- Change we want to detect/intervention is capable of delivering
- Retention rates

CORE- OM Number per group		Standard deviation		
		5.5	6.5	7.5
Change to be detected	5	26	36	48
	4.5	32	44	59
	4	40	56	74
	3.5	52	73	97

