engager

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Engager

Evaluation of a complex intervention (Engager) for prisoners with common mental health problems, near to and after release – Full trial**.**

STUDY PROTOCOL

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Study Sponsor: Devon Partnership NHS Trust
Chief Investigator: Professor Richard Byng (University of Plymouth)

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1 SIGNATURE PAGE

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3 LIST OF ABBREVIATIONS

AE	Adverse Event
CBT	Cognitive Behavioural Therapy
CI	Chief Investigator
CMHP	Common Mental Health Problem
ConSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRN	Clinical Research Network
CTU	Clinical Trials Unit
CJS	Criminal Justice System
DMC	Data Monitoring Committee
DPT	Devon Partnership NHS Trust
FPE	Formative Process Evaluation
GCP	Good Clinical Practice
GP	General Practitioner
IAPT	Improving Access to Psychological Therapies
ICH GCP	International Conference on Harmonisation of Good Clinical Practice
IOMI	Intermediate Outcomes Measurement Instrument
ITT	Intention to Treat
MCID	Minimally Important Difference
NIHR	National Institute of Health Research
NOMS	National Offender Management Service
NRES	National Research Ethics Service
PenCTU	Peninsula Clinical Trials Unit
PNC	Police National Computer
PNOMIS	Prison National Offender Management Information System
PPI	Patient and Public Involvement
PSC	Programme Steering Committee
PSI	Patient Information Sheet
PTSD	Post Traumatic Stress Disorder
QALY	Quality Adjusted Life Year
R&D	Research and development
RCT	Randomised controlled trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOP	Standard Operating Procedure
SPCR	Surveying Prisoner Crime Reduction
SUSAR	Suspected Unexpected Serious Adverse Reaction
TOG	Trial Oversight Group
TSC	Trial Steering Committee
UKCRC	United Kingdom Clinical Research Collaboration

4 STUDY SUMMARY

Study Title	Evaluation of a complex intervention (Engager) for prisoners with common mental health problems, near to and after release – Full trial
Study Design	A two centre parallel group randomised controlled trial with parallel economic and process evaluations.
Study Participants	Prisoners with common mental health problems within 4-20 weeks from release.
Intervention	Usual care plus receipt of the Engager Intervention
Control	Usual care alone
Study duration	35 months
Nº of participants	280 participants will be randomised to either the Intervention (n=140) or Control (n=140) arm.
Setting	2 investigator centres: Plymouth and Manchester
Aims	To conduct a randomised controlled trial to assess the effectiveness and cost effectiveness of the Engager Intervention plus usual care vs. usual care alone in prisoners with common mental health problems before and up to six months following release from prison.
Specific objectives	• To compare levels of psychological global distress between intervention and control participants. • To compare the number of subjective met and unmet need in relation to accommodation, education, work/money/benefits, family/friends/company/intimacy, physical and mental health, safety to self and self-care, safety to others, and leisure activities between intervention and control participants. • To compare substance use and subjective view of addiction between intervention and control participants. • To compare levels of recidivism between intervention and control participants. • To compare generic health related quality of life between intervention and control participants. • To compare the cost of health, social care, and criminal justice service utilisation between intervention and control participants. • To compare subjective experience of care received between intervention and control participants. • To compare perceived helpfulness of services engaged with between intervention and control participants. • To complete a parallel process evaluation: - To determine the degree to which the core mechanisms of the intervention were delivered - To evaluate the extent to which the core mechanism of the intervention produced the intended outcomes - To identify aspects of the intervention and delivery that could be improved. - To explore unintended consequences of the intervention.
Primary Outcome	• The CORE Outcome Measure (CORE-OM) measured at 6 months post release from prison

Secondary Outcomes	• Assessment of subjective met and unmet need using the Camberwell Assessment of Need – Forensic Version (CAN-FOR) • Change in objective social domains (accommodation, education, employment and benefits) • Drug and alcohol use using the Treatment Outcomes Profile • Drug and alcohol subjective dependence using the Leeds Dependence Questionnaire • Service utilisation using an adapted version of the Client Service Receipt Inventory (CSRI) • Perceived helpfulness of services using the adapted version of the CSRI • Generic health related quality of life using the EQ-5D-5L questionnaire • Well-being related quality of life using the ICE-CAP-A questionnaire • Experience of care using the Brief Inspire questionnaire • Change in trust, hope and motivation using the Intermediate Outcomes Measurement Instrument (IOMI) • Psychological distress using the CORE-10 • Recidivism based on data from the Police National Computer (PNC)
Inclusion Criteria	• Men with prison sentences of up to and including two years. • Having between 20 and 4 weeks remaining to serve. • Identified as having or likely to have common mental health problems (Depression, Anxiety, PTSD); • Willing to engage with treatment services and research procedures. • Being released to the geographical area of the study
Exclusion Criteria	• Remand population. • Women (numbers are smaller, and prisons are remote; resettlement needs are different). • Serious and enduring mental disorder and/or on the caseload of the prison in-reach team. • Active suicidal intent requiring management under the safer custody process. • Primary personality disorder who are on the caseload of the Offender Personality Disorder Pathway programme. • Present a serious risk of harm to the researchers or intervention practitioners • Unable to provide informed consent

5 BACKGROUND AND RATIONALE

People in contact with all stages of the Criminal Justice System (CJS), but especially prisoners, have a high prevalence of mental health problems. Rates of 50-90% have been found among prison populations both in the UK[1-3] and internationally[4]. In England and Wales, a major Office of National Statistics survey conducted in 1997[5] found the following:

- Personality Disorder: 64% in male sentenced prisoners, 78% in male remands.
- Neurotic disorders (mainly depression and anxiety): 40% in male sentenced prisoners, 55% in male remands; female prisoners exhibited significantly higher levels: 63% and 76%, respectively.
- Drug dependency: 43% in male sentenced prisoners, 51% in male remands; and similar levels for women.
- Hazardous alcohol use: 63% in male sentenced prisoners, 58% in male remand prisoners.
- Functional psychosis: 7% of male sentenced prisoners, 10% of male remands, and 14% of female prisoners.

High levels of self-harming behaviour and suicidal thoughts were also reported. Indeed, the risk of suicide for male offenders leaving prison is eight times the national average[6]. Cognitive deficits are common[7] and post-traumatic stress disorder (PTSD) is particularly over represented within the prison population[5]. Our previous research[8] indicates on-going high rates of anxiety and depression (47% reach likely caseness for anxiety, PTSD or depression, of these 32% are still 'cases' after release). For these common mental health problems (CMHPs), as well as personality disorders and substance misuse there is substantial co-morbidity[8,9].

In addition to mental health problems, offenders have a wide range of personal and social problems. Offenders frequently lead chaotic lives, typically including homelessness, unemployment, and broken relationships with their partners and children. In our previous study[10], 37% reported problems with their family relationships; the majority of the sample were unemployed or on long term sickness benefit (65% in prison and 70% in the community sample); and 26% had on-going legal or criminal justice issues. These results echo previous surveys of prisoners, including the 1991 National Prison Survey[11], the 2001 national resettlement survey[12,13], the 2002 Social Exclusion Unit Report[14] on short-term prisoners, and the on-going Surveying Prisoner Crime Reduction (SPCR) study, based on regular interviews with a cohort of prisoners before and after release[15]. For example, two-thirds reported that they had been unemployed before going into custody, and 37% reported that they needed help finding somewhere to live on release[15]. These issues tend to be the focus of offenders' own concerns, indicating that addressing such issues may prove crucial and also provide motivation for change.

The cost of not addressing these issues is high. Those serving short-term sentences place a considerable burden on society. The rate of re-offending for short-sentence prisoners is 58%[16], and in 2010 the costs of an average domestic burglary were estimated at £3,925 and serious wounding at £25,747 [17]. Therefore, the potential benefits to individuals and communities, as well the financial savings, are great.

There are complex relationships between mental health, substance misuse, social exclusion, and criminal behaviour. However, these tend to be studied separately and interventions to

address them are frequently developed and delivered in isolation. One of the underpinning principles of this intervention will be to break down barriers and incorporate integrated multi-agency working within the intervention, particularly between health and criminal justice sectors.

Prison healthcare is often provided by separate primary care, drug and alcohol, and, for severe mental health problems, in-reach teams. Opiate substitution services are now generally available in prison and mechanisms for achieving continuity post-release are increasingly in place. In-reach teams for mental health have faced considerable challenges[18], but have improved care for those with psychosis and there is now evidence to support the development of pathways of care on release[19].

For offenders, provision of care for common mental health problems is limited, and we have found psychological therapy to be virtually absent in prison and community settings[10]. The prison environment complicates diagnostic assessment[3], and for some a lack of stressors may reduce anxiety. The focus of hard pressed prison health care is on immediate concerns, rather than longer term planning on release. Improving Access to Psychological Therapies (IAPT) services in prisons are still in the early stages of development and face significant challenges. Discontinuity of care on release is the norm[20].

Once released into the community, ex-prisoners with common mental health problems are, in theory, provided for by mainstream statutory services including: general practice; community mental health teams; and IAPT services. In reality few access these services; we found a mean of a mere 0.25 contacts per year with mental health specialists for those reporting common mental health problems[10].

Despite negligible uptake and high need, we have identified no systems worldwide for actively engaging offenders with common mental health problems in prison (some are screened at reception), providing initial treatment and transferring care to community teams. Also, many offenders, like others with common mental health problems complicated by co-morbidity, fall between primary care, IAPT and specialist services[21-24]. Offenders are further disadvantaged by their resistance to seeking help, to accepting mental health diagnoses and lower levels of GP registration[9,10,20]. This contrasts with well-established services and transfer of care for opiate misuse[25,26].

In a relatively small proportion of cases, psychological input and/or general support is provided by statutory or third sector resettlement services – from thinking skills 'booster' programmes delivered by probation to prisoners on licence, through to volunteer mentoring or peer mentoring services[27,28], although currently, resettlement plans typically contain limited reference to health concerns.

We maintain that mental health input for common mental health problems should be considered as a part of the range of services which can make up collaborative care directed towards social outcomes and resettlement.

The research team have developed a collaborative care intervention for prisoners with common mental health problems. This randomised controlled trial is designed to evaluate the effectiveness of the intervention we have developed.

6 AIMS AND OBJECTIVES

To conduct a pragmatic randomised controlled trial carried out in two prison sites answering the following research question:

What is the effectiveness and cost effectiveness of the Engager Intervention plus usual care compared to usual care alone in prisoners with common mental health problems before and up to six months following release from prison?

Specific objectives:

- To compare levels of psychological global distress between intervention and control participants.
- To compare the number of subjective met and unmet need in relation to accommodation, education, work/money/benefits, family/friends/company/intimacy, physical and mental health, safety to self and self-care, safety to others, and leisure activities between intervention and control participants.
- To compare substance use and subjective view of addiction between intervention and control participants.
- To compare levels of recidivism between intervention and control participants.
- To compare generic health related quality of life between intervention and control participants.
- To compare the cost of health, social care, and criminal justice service utilisation between intervention and control participants.
- To compare subjective experience of care received between intervention and control participants.
- To compare perceived helpfulness of services engaged with between intervention and control participants.
- To complete a parallel process evaluation:
  - To determine the degree to which the core mechanisms of the intervention were delivered.
  - To evaluate the extent to which the core mechanism of the intervention produced the intended outcomes.
  - To identify aspects of the intervention and delivery that could be improved.
  - To explore unintended consequences of the intervention.

7 STUDY DESIGN

Summary

This protocol describes a parallel two group randomised controlled trial with 1:1 individual participant allocation to either the Engager Intervention plus standard care (intervention group) or standard care alone (control group) with economic evaluation and parallel process evaluation.

Following identification as being potentially suitable from prison records, and recruitment into the study as a whole, prisoners will be interviewed to identify either current common mental health problems or probable common mental health problems upon release. Two hundred and eighty participants will be individually randomised to receive either the Engager Intervention in addition to usual care, or usual care alone. The Engager Intervention will be delivered for between 4 and 16 weeks in prison, and for up to 16 weeks post-release.

Outcome measure data will be collected at baseline and approximately 1, 3, 6, and 12 months following release from prison.

Setting

The study will be conducted in two regions, one in the southwest (Plymouth University) and one in the northwest (Manchester University), with participants recruited from three prisons in those regions (HMP Exeter and HMP Channings Wood in the southwest, HMP Liverpool in the northwest). Conduct of the trial in each region will be led by a local Principal Investigator supported by a research team. All research staff will have received training in Good Clinical Practice and in the requirements of the study protocol.

7.1 Outcome measures

7.1.1 Primary Outcome measure

- Psychological distress using the CORE-OM[29]

7.1.2 Secondary outcome measures

- Assessment of subjective met and unmet need across key outcome domains using the Camberwell Assessment of Need – Forensic Version (CAN-FOR)[30]
- Change in objective social domains (accommodation, education, employment and benefits)
- Drug and alcohol use using and adapted version of the Treatment Outcomes Profile (TOP)[31]
- Drug and alcohol subjective dependence using the Leeds Dependence Questionnaire (LDQ)[32]
- Service utilisation using an adapted version of the Client Service Receipt Inventory (CSRI)[33]
- Perceived helpfulness of services using the adapted version of the CSRI
- Generic health related quality of life using the EQ-5D-5L questionnaire[34]
- Well-being related quality of life using the ICE-CAP-A questionnaire[35]
- Experience of care using the Brief Inspire questionnaire [36]
- Change in trust, hope and motivation using the Intermediate Outcomes Measurement Instrument (IOMI)[37]
- Psychological distress using the CORE-10[38]
- Recidivism based on data from the Police National Computer (PNC)

CSRI data will be used alongside Engager practitioners' records, which will include contact time, location, time spent on activities such as training and supervision. This will provide cost estimates for the intervention delivery.

The primary assessment point will be 6 months post release from prison.

Procedures for collection of outcome data at each time-point are described in section 10 (Study Schedule).

7.2 Considerations for minimising bias

Participants will be randomly allocated in a 1:1 ratio to either intervention or control group arms. Randomisation will be stratified by investigator centre to ensure balance between the two treatment arms across the two investigator centres. Randomisation numbers will be computer generated and assigned in strict sequence. At the point of randomisation, participants will be allocated the next unassigned randomisation number in the sequence. To minimise selection bias, allocation will be concealed from the research team, using a centralised automatic web-based data management system at the time of allocation.

Given the nature of the intervention, it is not possible to blind participants or those involved in delivering the intervention as this is a novel intervention which individuals would not normally expect to receive or provide. Researchers were blind to trial arm allocation in the pilot study but numerous barriers to maintaining blinding were encountered. Specifically, because the researchers and intervention practitioners are both working within the confines of a prison environment, there are many occasions when un-blinding occurred in the pilot: researchers seeing practitioners with participants receiving the intervention; participants seeing the researchers around the prison and informing the researchers that they are receiving the intervention. Attempts were made to switch researchers, so that a second researcher collects follow-up data but this proved to be logistically very challenging and ultimately conflicts with previous findings in relation to building a strong researcher-participant relationship to enhance follow-up rates. Therefore, a decision was taken to accept that sufficient levels of researcher blinding would not be possible in the trial and to attempt to minimise any potential bias by protocolising collection of the primary outcome measure.

While the research interview as a whole has been developed with a level of flexibility to ensure continued engagement with offenders who have problems with reading, concentration and irritability, the primary outcome measure (CORE-OM) will be collected using a highly scripted interview, with researchers reading each question to the offenders and only deviating from this to clarify the meaning of the question when offenders indicate they do not understand the question.

7.2.1 Attrition bias

Attrition bias will be minimised by having robust trial procedures to prevent data loss and also analysing the data by intention to treat (ITT). Procedures have been developed and tested for maintaining contact with participants following their release from prison and researchers will endeavour to maintain engagement with participants in between data collection points. Prior to being released from prison, participants will provide details of how to contact them following release including, where appropriate, consent for the researchers to make contact via any organisation (e.g. probation) the participant may be engaging with. The recent introduction of the Community Rehabilitation Companies will mean that all participants will have CJS supervision in the community and it is anticipated that this will reduce the number of participants lost to follow-up. Participants will also be given a thank you payment for attending the 3, 6, and 12 month post release interviews. These payments will be in the form of high street vouchers and will be to the value of £10 for the 3 month follow-up and £20 for the 6 and 12 month follow-ups, and will only be given to participants followed up in the community and not those who are interviewed in prison. It is anticipated that these will provide an additional incentive for participants to attend follow-up interviews.

Recognising that this population can be difficult to follow-up in the community, follow-up data collection points are to occur within broad time windows, such that the 3 month follow-up will take place between 61 and 151 days post release, the 6 month follow-up between 152 and 244 days post release, and the 12 month follow-up between 304 and 483 days post release. Additionally, it has been noted during the pilot work that some participants can be lost for a period but subsequently re-emerge (possibly engaging with community services or back in prison). As such, if a participant misses a follow-up interview (e.g. at 3 months), they will continue to be included in the study until all follow-up time-points have lapsed (e.g. at 12 months). For the last data collection point, researchers will continue to try to contact participants until the end of day 483, after which those remaining out of contact will be regarded as lost.

Additionally, and in recognition that this population often lead chaotic lives, researchers will attempt to complete the CORE-10 via the telephone for those participants they can contact but who are difficult to setup an interview with (or those who fail to turn up to an appointment). However, even when the CORE-10 has been completed, researchers will continue to try to follow-up participants with a face-to-face interview.

The research team will make multiple and sustained attempts to follow-up each participant at each time point. The numbers and reasons for dropouts and losses to follow-up will be reported for each arm of the study.

7.2.2 Contamination

There is unlikely to be significant contamination between the intervention and control arms of the study, although it is theoretically possible for: trainers to train practitioners elsewhere, practitioners to pass on skills and working practices to those treating control individuals, materials such as the 'shared understanding and plan' to influence practice for control individuals, offenders to influence each other.

Cluster randomisation to prevent contamination would have been theoretically possible by randomising at a prison level, but practically not feasible because prisons are clustered together in localities, with one for new entrants, so each cluster would have several prisons. Additionally, the prison system can be subject to sudden and significant changes to prison procedures and entrants and it was estimated that a minimum of six clusters would be required in order to ensure balance, and this would have incurred prohibitive costs. However the risk of contamination is considered low, primarily because there is no alternative funded pathway for delivery of the substantive components of the intervention for those in the control arm. Engager practitioners form a separate team in prison and while other practitioners are informed about the intervention, i) they are not trained in the detail, ii) they tend not to have contact with our participants who are selected for the study using case finding iii) they don't have governance arrangements in place to follow individuals into the community.

Additionally, as Engager practitioners work within a range of local services, sometimes with men released from prison, there is the potential for the practitioners to work with men in the control arm of the study in their 'usual' job role. In such instances, it is possible that the practitioners will use some of their training and skills (e.g. mentalisation skills) to enhance their usual work. The research team will document instances where participants in the

control arm engage with services where the practitioners work, and whether the participants worked with the Engager practitioner.

In order to further mitigate risk of contamination we will give clear instructions to the intervention practitioners not to provide manuals or supplementary intervention materials to any participants not assigned in the intervention group. Trainers will also be instructed not to supply materials or recommend techniques to colleagues who may be providing usual care.

In summary we believe a cluster trial is neither necessary nor feasible and so given the study design, we do not anticipate a substantial risk of contamination, but will also put in measures to ensure it is minimised.

8 STUDY PARTICIPANTS

8.1 Participants

8.1.1 Inclusion criteria

Participants must satisfy the following criteria to be enrolled in the study:

- Men with prison sentences of up to and including two years;
- Having between 20 and 4 weeks remaining to serve;
- Those identified using screening instruments as having, or likely to have following release, common mental health problems (Depression, Anxiety, PTSD; see section 10.1.2 for details about how these problems will be identified);
- Willing to engage with treatment services and research procedures; and
- Being released to the geographical area of the study.

8.1.2 Exclusion Criteria

Co-morbid substance misuse and personality disorder are NOT exclusion criteria. Participants who meet any of the following criteria will be excluded from study participation:

- Remand population;
- Women (numbers are smaller, and prisons are remote; resettlement needs are different; research procedures developed are not feasible for this context). Research will be in male prisons only;
- Those with serious and enduring mental disorder and/or on the caseload of the prison in-reach team;
- Those with active suicidal intent requiring management under the safer custody process or prison in-reach team, and where the healthcare team managing the prisoner feels it would be detrimental. Once risk levels reduce individuals in this group will be eligible if not excluded for another reason.
- Those with primary personality disorder who are on the caseload of the Offender Personality Disorder Pathway programme.
- Those who present a serious risk of harm to the researchers or intervention practitioners.
- Those unable to provide informed consent

9 STRATEGIES FOR PATIENT IDENTIFICATION

9.1 Database search

Potential participants will be identified by researchers/ research nurses / clinical studies officers using Prison National Offender Management Information System (PNOMIS). The PNOMIS search will identify potential participants likely to be within the 4-20 week period prior to release, including a consideration of whether they are likely to be subject to the early discharge process which means release is often uncertain. Remand prisoners will not be included in the search.

Men on the caseload of the prison mental healthcare team due to serious and enduring mental health problems, and those with primary personality disorder who are on the caseload of the Offender Personality Disorder Pathway programme will also be excluded. The clinical studies officers / research nurses will be trained to maintain confidentiality.

The level of risk presented by the potential participants will also be assessed. This will include the level of risk of self-harm or suicide as well as the level of risk of harm to the researchers or practitioners (e.g. violence). This will be assessed through information contained on PNOMIS and in discussion with prison staff and will take into account the likely risk in both the prison and community settings. Potential participants who are considered to present too high a risk to either the researchers or the practitioners will be excluded. Decisions whether or not to include someone based on their level of risk will be taken by the research team at each site in conjunction with local services if needed.

In addition to the above exclusion criteria, as the day of a participant's release from prison is so important for resettlement and engagement (see 12.1 for more details of the Engager intervention) we aim to have no more than two participants being released from each investigator site on the same day.

9.2 Initial approach and provision of study information

This will occur from 20 weeks pre-release. Potential participants will be approached by a research nurse/clinical studies officer or one of the researchers working specifically on the Engager project. They will be approached verbally and then, if willing, be provided with written information about the study and an opportunity for further discussion. The researcher will read and explain the information in the invitation sheet in order to overcome any literacy problems. It is not appropriate to use Criminal Justice staff, including prison health care staff, to make the first approach because of the potentially coercive (or perceived coercive) nature of the relationship in the prison environment.

10 STUDY SCHEDULE

This section describes the conduct of the study in chronological order, detailing procedures for data collection at each of the time points. A tabulated summary of the study schedule is given in Table 1 below. This section does not describe collection of process evaluation data. Conduct of the process evaluation is described in section 14.

Table 1: Tabulated summary of study schedule

		Screening	Baseline	Allocation	Pre-release	Post-release from prison			
TIMEPOINT		t_0	t_1		-1 wk t_2	+1 mth t_3	+3 mth[3] t_4	+6 mth t_5	+12 mth t_6
ENROLMENT:									
Eligibility screen		X							
Informed consent		X							
PHQ-9		X							
GAD-7		X							
PTSD-Screening Questionnaire		X							
Historical screen for past CMHPs		X							
Allocation[1]				X					
INTERVENTIONS:									
Intervention Group:	***Engager Intervention***	♦———	———	———	———	———	———	———♦	
	Usual care	♦———	———	———	———	———	———	———	———♦
Control Group:	***Usual care***	♦———	———	———	———	———	———	———	———♦
ASSESSMENTS:									
CORE-OM Questionnaire			X			X	X	X	X
CORE-10[2]						X	X	X	X
CANFOR – Short Version			X				X	X	X
Adapted CSRI (including medication)			X		X		X	X	X
Objective social outcomes (eg housing)			X					X	X
Treatment Outcomes Profile (TOP)			X				X	X	X
Leeds Dependence Questionnaire			X					X	X
EQ-5D-5L Questionnaire			X				X	X	X
ICE-CAP-A Questionnaire			X				X	X	X
Intermediate Outcomes Measurement Instrument (IOMI)			X					X	X
Standard Assessment of Personality (SAPAS)			X						
Neurodevelopmental Symptoms Rating Scale			X						
Trauma Questionnaire			X						
Contact Sheet			X		X	X			
Brief Inspire Questionnaire					X		X	X	X
Police National Computer Offending Data			X						X
SAFETY MONITORING:									
Adverse event reporting		♦———	———	———	———	———	———	———♦	

[1] Allocation will be performed using a web-based system provided by the CTU, usually within 2 days of completing the screening interview.

[2] CORE-10 will only be completed if it is not possible to complete the CORE-OM Questionnaire.

10.1 Baseline visit

10.1.1 Consent Process

Following the initial approach, if a potential participant expresses an interest in taking part in the study, a meeting will be arranged between the researcher and the potential participant where the researcher will explain the project in more detail. This meeting may take place immediately after the initial approach, but the potential participant can take longer (a minimum of 24 hours) to consider if they want to take part if necessary.

The researcher will give the participant a copy of the Participant Information Sheet (PIS). The researcher will read and explain the information in the PIS, showing sensitivity to the high levels of literacy difficulties in this population.

The researcher will explain what participation in the study involves and how much time will be involved. The researcher will ensure that the potential participant fully understands what randomisation means and that they have an equal chance of being randomised to either the Engager Intervention Group or the Control Group. They will also explain that participation is voluntary, that they can withdraw at any time and at any point and that their decision to participate, or not, will have no adverse effect on the care that they receive or their other legal rights. The researcher will also discuss the arrangements to ensure confidentiality (and limits of this) and data protection. Throughout this process, the potential participant will be given an opportunity to ask questions. Potential participants will be made aware of circumstance in which confidentiality would be broken.

Having had the opportunity to discuss their involvement in the study and ask questions about it, potential participants will be asked to sign the Consent Form if they are willing to take part. The consent form will be explained to the participant before they sign it and the researcher will sign the form after it has been completed by the participant. A copy of the signed consent form will be given to the participant and a copy will be retained by the researcher.

Once written informed consent has been obtained, the participant will be invited to begin the screening interview.

The reason for interviewing people so shortly after the initial approach is because of the chaotic nature of the prison environment, the difficulties in working around the prisons' security needs (which take priority at all times), and the very short notice periods over which people can be moved around the prison estate. Potential participants who wish to have longer to consider their involvement will be interviewed within a week of initial approach and will be given at least one day to consider whether they wish to participate.

*10.1.2 Screening for Common Mental Health Problems (**t_0**)*

The primary purpose of the screening interview is to identify participants currently experiencing common mental health problems. However, it is recognised that, for some individuals, being in prison can provide a relief from the stresses of living in the community. Our pilot work in Engager1 has shown that some individuals may not present as suffering from a current mental health problem but reach threshold for anxiety or depression on release. To address this issue, we have included a screening measure to establish whether participants have experienced common mental health problems in the previous two years, whether those problems impacted on their day-to-day functioning, and whether they are

likely to experience similar problems on release from prison. By including this measure within the screening interview we aim to capture as many men as possible who are likely to experience common mental health problems when they are released from prison.

The researcher will deliver the screening interview in a narrative conversational format. The questions from the following measures will be read out to participants:

- PHQ-9[39]
- GAD-7[40]
- PTSD Screening Questionnaire[41]
- Historical Common Mental Health Problem Screen

Additional questions are asked to confirm that the participant is not currently being treated for severe mental illness, including schizophrenia, psychosis, or bipolar disorder, and whether they have seen a mental health worker for these problems while they have been in prison.

A participant will be considered suitable for the study if the screening interview for common mental health problems indicates that they:

- have a common mental health problem as indicated by a score of 10 or more on either the PHQ-9 or the GAD-7, or 3 or more on the PTSD screening questionnaire.

Or

- have experienced a common mental health problem during the past two year which prevented them from functioning normally in everyday tasks, and which is likely to be a problem for them following release.

And

- They are not currently being treated for schizophrenia, psychosis, or bipolar disorder.

In most instances, the researcher will be able to assess whether or not a participant 'passes' the screening interview for common mental health problems. Where this is possible and the participant does not meet the criteria to proceed to the trial, the researcher will inform the participant of this and thank them for their time. If the participant does meet the criteria to proceed to the trial, the researcher will inform them of this, remind them of what participation in the study involves, and continue with the baseline data collection if the participant is happy to continue. Alternatively, if the participant would prefer not to continue with the session, the researcher will arrange another time to carry out the baseline data collection.

There are likely to be instances where the researcher is not certain whether or not the participant 'passes' the screening interview for common mental health problems. For example, the participant may indicate that he has been seen by (or referred to) the mental health in-reach team but not know why, and it may be necessary for the researcher to check with the mental health team whether the participant is suitable for inclusion in the trial. In these situations, the researcher will inform the participant that he has completed the screening questionnaire and another meeting will be set up to inform him of the outcome. The researcher will be open and honest with the participant about the need to clarify any information.

10.1.3 Baseline data collection (t_1)

The researcher will normally continue with the baseline data collection following screening, and additional sessions can be arranged to meet the needs of individual participants.

The researcher will continue to deliver the baseline data collection interview using the narrative conversational format developed in our pilot work. The questions from the CORE-OM, the primary outcome, will be read out to participants in a precise and consistent manner. Questions from other measures are incorporated into a specially constructed flexible interview which avoids duplication of subject matter in order to reduce disengagement or irritability:

- Camberwell Assessment of Need – Forensic Version (CAN-FOR) – Adapted
- Client Service Receipt Inventory – Adapted
- Objective social outcomes
- Treatment Outcomes Profile (TOP)
- Leeds Dependence Questionnaire
- EQ-5D
- ICE-CAP
- Intermediate Outcomes Measurement Instrument (IOMI)
- Standardised Assessment of Personality – Abbreviate Scale (SAPAS)
- Neurodevelopmental Symptoms Rating Scale
- Trauma questionnaire

Data will be recorded in the Baseline Care Report Form (CRF).

In addition to the baseline data collection, the researcher will complete a contact sheet for each participant. This will include contact numbers and addresses provided by the participant, as well as a list of services they are likely to be in contact with post-release. This sheet will be completed in collaboration with the participant and the participant will sign the form to confirm they give the research team permission to contact them via the relevant services.

10.1.4 Randomisation process

Randomisation will be achieved by means of a web-based system created by Peninsula Clinical Trials Unit (PenCTU). Once the participant has completed the screening interview and baseline data collection interview, the researcher will access the randomisation website using a unique username and password. The website will require entry of the study site, participant initials and participant age before returning the participants' unique randomisation number and allocation (Engager Intervention or Control).

10.1.5 Communicating allocation

Confirmation that randomisation has been performed will be communicated in an un-blinded fashion to the investigator site staff and key members of the central research team. Communication will be achieved via emails automatically generated by the randomisation website.

A researcher (usually the same researcher who conducted the baseline interview) will visit the participant in prison to deliver a letter informing the participant of whether they have been

randomised to the Engager Intervention or Control group. The researcher will go through the letter with the participant, ensuring that they understand which group they are in. Experience has shown that continuity of researcher has a positive effect on participants' continued engagement and out-weights concerns around maintaining blinding.

10.1.6 Provision of referral information to intervention practitioners

The intervention practitioners will be sent, via email from the Clinical Trials Unit, a pseudo-anonymised 'referral form' for each participant randomised to the Engager Intervention. The referral form will contain the participant unique ID number, along with anticipated release date and area, and the earliest release date (this is the date that they become eligible for home detention curfew, if applicable). The referral form will also include information on the participants' screening questionnaire responses and some researcher notes regarding the presentation of the participant (e.g. anxious) and what his main concerns are. In effect the information from the research screening process is used to construct data similar to that which might be obtained in the current prison reception screen or a future pre-release screen.

*10.1.7 Pre-release data collection (**t_2**)*

The researcher will meet with the participant usually within the week prior to release. During this meeting, the researcher will confirm the contact information provided at baseline and make any amendments to the information (e.g. change of phone number).

The researchers will complete the service use table from the adapted CSRI to collect information on any services that the participant has used since the baseline data collection interview. The researchers will also ask participants to complete the Brief Inspire Questionnaire

10.2 Time 3: follow-up: 1-month outcome measure collection (*t_3*)

At approximately 1 month post-release, the researcher will contact the participant. This data collection point can be completed via a phone call, but will preferably be done face-to-face to support continued engagement.

The questions from the following measure will be read out to participants:

- CORE-OM

The researcher will discuss the 3-month follow-up in detail and agree the best way to contact the participant for that appointment, depending on a range of scenarios, and changes to modes of follow up. Obtain any new mobile phone number if contact had been made without an up to date mobile contact. Data collection of the outcome measures will be utilised in analysis, but the main objective of the meeting is to sustain engagement and plan further contact.

10.3 Time 4: follow-up: 3-month outcome measure collection (*t_4*)

The 3-month follow-up can take place between 61 and 151 days post-release, although researchers will endeavour to complete data collection close to the 3 month (90 day) point.

Researchers will arrange to meet the participant at a convenient location in the community. Where possible, interviews will be conducted in the premises of services that the participant is engaging with in order to minimise risk to the researcher. Where this is not possible, researchers will arrange to conduct the interviews in a suitable location in the community and adhere to the Lone Working policy and be accompanied by a Buddy as an additional safeguard.

The researcher will remind the participant of the information sheet and consent, drawing attention to data confidentiality and instances of disclosure where the researcher would need to breach confidentiality.

As with the baseline data collection, the researcher will continue to deliver the follow-up data collection interview using narrative conversational format. The questions from the following measures will be read out to participants:

- CORE-OM
- Camberwell Assessment of Need – Forensic Version (CAN-FOR) – Adapted
- Client Service Receipt Inventory – Adapted
- Treatment Outcomes Profile (TOP)
- EQ-5D
- ICE-CAP
- Brief Inspire Questionnaire
- Experience of Engager Intervention – Part A (Intervention participants only)

If the researcher is in contact with a participant but experiences problems in setting up a follow-up interview, or if the participant fails to attend a follow-up appointment, the research will attempt to complete the CORE-10 via phone call with the participant. Regardless of whether the CORE-10 has been completed, the researcher will continue to try to conduct a face-to face follow-up interview with the participant until the end of the follow-up window.

10.4 Time 5: follow-up: 6-month outcome measure collection (t_5)

The 6-month follow-up can take place between 152 and 244 days post release, although researchers will endeavour to complete data collection close to the 6 month point (182 days).

Researchers will arrange to meet the participant at a convenient location in the community as per 3 month follow up. The questions from the following measures will be read out to participants:

- CORE-OM
- Camberwell Assessment of Need – Forensic Version (CAN-FOR) – Adapted
- Client Service Receipt Inventory
- Objective social outcomes questionnaire
- Treatment Outcomes Profile (TOP)
- Leeds Dependence Questionnaire
- EQ-5D
- ICE-CAP
- Intermediate Outcomes Measurement Instrument

- Brief Inspire Questionnaire
- Experience of Engager Intervention – Part B (Intervention participants only)

As with the 3-month follow-up, the CORE-10 will be completed when it is difficult to arrange a face-to-face interview.

10.5 Time 6: follow-up: 12-month outcome measure collection and collection of reconviction data (t_6)

The 12-month follow-up can take place between 304 and 483 days post release from prison, although researchers will endeavour to complete data collection close to the 12 month post (365 days).

Researchers will arrange to meet the participant at a convenient location in the community as per 3 and 6 month follow up. The questions from the following measures will be read out to participants:

- CORE-OM
- Camberwell Assessment of Need – Forensic Version (CAN-FOR) – Adapted
- Client Service Receipt Inventory
- Objective social outcomes questionnaire
- Treatment Outcomes Profile (TOP)
- Leeds Dependence Questionnaire
- EQ-5D
- ICE-CAP
- Intermediate Outcomes Measurement Instrument
- Brief Inspire Questionnaire

As with previous follow-ups, the CORE-10 will be completed when it is difficult to arrange a face-to-face interview.

Reconviction data will be collected for the 12 months post release from prison. This information will be requested from the Ministry of Justice and will not involve any additional contact with the participants. It can take up to six months for data on new convictions to be recorded onto the Ministry of Justice system. Therefore, this information will be requested after participants have been released for a minimum of 18 months.

10.6 Duration of participant involvement

Each recruited participant is expected to be involved in the study for up to a maximum of 89 weeks from the screening interview to the final follow-up (up to 20 weeks pre-release plus up to 69 weeks post release). A sample of participants (trial participants and practitioners) may participate for longer if selected for process evaluation interview (see section 14). The study will end on completion of data collection for the last participant entered into the study.

11 DISCONTINUATION / WITHDRAWAL

It is recognised that many of the participants will have chaotic lifestyles and it will be a challenge to maintain their engagement with both the intervention and the research elements

of the study. Our pilot work has demonstrated that these men are not always contactable, but often re-emerge at a later stage. For instance, during the pilot work, the research team were unable to contact a number of participants at one month post release from prison, but were able to contact them at 3 or 4 months post release.

The intervention is targeted at men who are characterised by high levels of re-offending and it is significant that, in the pilot study, many of the men who were not contactable at 1 month post release were contactable at 3 months post release because they had returned to prison.

11.1.1 Return to prison

Return to prison is not a reason for automatic withdrawal from the study. Any participant who returns to prison will continue to be included in the research and, where possible, the researchers will conduct follow-up interviews in the prison where they are detained. If a participant is returned to a prison in England or Wales other than the three included in the study, the researchers will try to arrange to visit the participant in their host prison to conduct any follow-up interviews.

The location of the follow-up interview (prison or community) will be factored into the analysis.

11.1.2 Follow-up problems

In order to maximise the follow-up rate at each of the time periods, broad time frames have been assigned to each of the follow-up assessments. In addition, if a participant cannot be contacted and misses the 1, 3, and/or 6 month follow-up assessments, they will not be withdrawn from the study and researchers will continue to try to contact them until the end of the 12 month follow-up window. Lastly, in order to maximise the number of participants providing data at follow-up, researchers will try to administer the CORE-10 via phone for those participants that are difficult to follow-up with a face to face interview.
Both of these data collection methods will be addressed within the statistical analysis plan.

12 INTERVENTION

12.1 Description

Key elements of Engager model
General psycho-social

- Mentalisation informed approach as a support for the components listed below
- Use of existing practitioner skills (e.g. coaching, solution focused therapy, behavioural activation, Cognitive Behavioural Therapy [CBT])

Pre-release

- Practitioner to initiate engagement.
- Manage expectations and prepare for endings from the outset: ensure understanding of remit of intervention and role.
- Develop a shared understanding of an individual's emotional, social and behavioural goals and links between emotional, thinking, behaviour and social outcomes - developed by supervisor and practitioner alongside the individual
- Goals developed and refined with reference to the shared understanding

- Develop a shared plan to achieve the individual's goals - developed by the individual and practitioner with regular supervision to ensure that goals are realistic and appropriately prioritised.
- Plan to achieve goals created from resources (practitioner skills; individual, family and community; peer, mentor and volunteer support; other professionals and agencies) identified to provide support.
- Work towards attainment of goals that can be achieved in prison
- Mobilise resources both in prison and the community – involving liaison with other agencies, peer support, families as appropriate
- Preparation for release: through the gate work
- Review shared understanding and update shared plan pre-release – print out for offender and share with other agencies
- Maintain engagement.

Day of release

- All day support if required.

Post release

- Renew contact and re-engage
- Review shared understanding and update shared understanding and plan – or complete if unable in prison
- Liaise with community services and align plans (engager shared plan and other agencies plans) if required.
- Support the individual to re-enter the community and engage with services.
- Maintain engagement.
- Review the shared understanding and plan.
- Prepare the individual for the end of the therapeutic relationship.
- Work with the individual to take responsibility for self-care.
- Plan ending and liaise with community organisations to set up possible continuation of care

12.2 Delivery

In order to help ensure delivery we have developed a strong 'implementation platform'. The rationale is to ensure a supportive environment for practitioners to work in, clarity about what they are expected to do, training and support to ensure they continued to work in the way outlined within the model. The supportive environment was seen as particularly important, as it would not always be possible to have practitioners based within existing teams, and because the model of care and scope of practitioners working within and outside prisons is distinct from any health care teams working currently.

Participants randomised to receive the Engager intervention will for between 4 and 16 weeks before release, and the intervention will continue for up to 16 weeks post release from prison. The length of the intervention is flexible depending on the needs of individual participants. All participants will receive the intervention for 8 weeks post release, but for those who still need support, the intervention can continue for a further 8 to 12 weeks, although this will be at a lower intensity.

Overall components

The components of the implementation platform include:

- A manual describing actions for practitioners and supervisors;
- A training programme for supervisors and Engager practitioners;
- A programme of supervision put in place for prison and community care;
- A set of organisational agreements;
- Other equipment and tools.

Manual

A comprehensive manual has been written to guide practitioners and supervisors to following components of the intervention.

Training

The practitioners taking on the role of Engager Practitioners may have no formal training as therapists. They will not necessarily be from the Increasing Access to Psychological Therapies (IAPT) programme, as originally anticipated, but instead come from a variety of backgrounds, primarily the substance misuse services and social inclusion services from the third sector. They will have experience of some combination of coaching, problem solving, solution focused therapy or motivational approaches. Supervisors will be experienced in making psychological formulations and carrying out psychological therapy (no specific modality is stipulated).

Practitioners and supervisors will be trained in the logic and rationale of the model, and will receive additional training in mentalisation based approaches, one of the psychological approaches for which there is evidence to support practitioners to work with individuals who have extreme changes in emotion, typical of those with personality disorder (anger, anxiety, despondency).

Supervision

Supervision is known to be key for successful implementation within research trials of complex interventions and is also an integral part of collaborative care, one of the underpinning models for the intervention. Our model of supervision has been strengthened from that originally anticipated. Supervisors work alongside the practitioners in the prison, supporting them to create a shared understanding (psychological and social formulation) and then provide ongoing supervision, particularly in the community, in a model more traditional to collaborative care. A supervision agreement has been developed for all supervisors to follow. The supervisor at each study centre will take on a management lead function and as a part of this role will ensure data related to fidelity of the model is aggregated to be shared within the team. In addition, team supervision incorporates informal peer-to-peer discussions and formal monthly meetings attended by members of the research team, to provide the form of ‘meta supervision’ (personal correspondence, Linda Gask) required to ensure fidelity. A brief team meeting will also happen weekly.

Organisational agreements

A set of organisational agreements has been put in place in order to ensure individual practitioners receive a supportive context and are able to practice safely. These include honorary contracts for individuals to be able to work as part of other organisations, information sharing agreements, and less formal agreements to house and support practitioners with desk space, computers, etc. It is worth noting that the work required to set these up was considerable, amounting to approximately four months of an experienced individual, half time.

Other components

A range of other physical objects important to the delivery of the intervention have been developed. These include worksheets for practitioners to work with individuals (also forming the appendix to the manual), mobile phones, safety alert systems (Guardian 24), and office and desk space.

12.3 Withdrawal from intervention

Lack of response to contact will not be taken as an indication for withdrawal. Practitioners will continue to make contact. Withdrawal from the intervention can however be initiated at any time by the participant. Those withdrawing from the intervention will still be included in follow-up unless they also ask to be withdrawn from the research.

12.3.1 Return to prison

If any participant randomised to the Engager Intervention returns to prison whilst still receiving the intervention, then the practitioners will, where possible, continue to deliver the intervention before and after release. If the participant is unlikely to be re-released within 16 weeks of their original release date then the Engager practitioners will contact the participant and work with them to facilitate engagement with services in prison and support their mental health. If the participant is likely to be re-released within 16 weeks from their original release date, the Engager practitioner will make contact and revisit the shared plan and continue the intervention through to release and for up to 16 weeks from original release date.

13 CONTROL GROUP

Individuals in the control group will receive treatment as usual. In prison they will be able to access primary care, mental health and substance misuse services in the standard way. They will also receive support from criminal justice and any other third sector organisations in the standard way. Our previous research has shown that they are very unlikely to receive specialist mental health care but are likely to receive substance misuse care if opiate dependent and may attend GPs to obtain anti-depressants.

14 PROCESS EVALUATION

The Process Evaluation will be conducted in parallel with the trial and will adopt a mixed methods, realist informed, approach.[42] During the development and piloting of the Engager intervention we produced and refined a theoretically informed, and evidence based, logic model of the ways in which the intervention was understood to work, [43] which we intend to test in the process evaluation. The logic model included the core components of the intervention that the practitioners were asked to deliver, the key mechanisms of impact (i.e. how what the practitioners were doing was understood to produce the desired outcomes), and the anticipated outcomes.[44]

Process Evaluation Specific Objectives:

- To determine the degree to which the core components of the intervention were delivered and the key mechanisms of the intervention occurred;
- To evaluate the extent to which the core components and key mechanisms of the intervention produced the intended outcomes;
- To explore any unintended consequences of delivering the intervention;
- To identify aspects of the intervention and delivery that could be improved;
- To identify any aspects of intervention delivery that require additional input from practitioner teams when the research team is no longer in place;
- To develop an understanding of how to deliver the intervention in real world settings (training, supervision, meta-supervision).

Data Collection

The data collection methods were developed, and refined for acceptability, in the pilot trial Formative Process Evaluation and include:

- Semi-structured interviews, with a purposively selected sub-sample of participants, some on one occasion and some at regular intervals throughout their participation in the trial;
- Semi-structured interviews with Engager practitioners and supervisors throughout the trial;
- Semi-structured interviews with other practitioners, and team leaders, in other services about their perceptions of, and interactions with, The Engager practitioners, participants and the intervention;
- Semi-structured interviews with family/partners/friends of participants receiving the Engager intervention;
- Audio-recordings of practitioner group supervision sessions;
- Audio-recordings of selected practitioner-participant interactions;
- Engager practitioner records and notes;
- Quantitative outcome measures, contained within the CRF, and also being used as part of the main trial outcomes
- Ethnographic field notes recorded by the Process Evaluation researchers.

Data Analysis:

The framework analysis methodology, which we developed and applied in the Formative Process Evaluation, will be utilised and extended to collate and interrogate the Process Evaluation data.[45] The deductive components of the framework will be informed by the logic model's key mechanisms of impact; that is the ways in which we understand the intervention to be working. Inductive components of the framework will be surfaces as part of the

analytical process. At the end of this analytical process, the logic model of the key mechanisms of impact of the intervention will be revised.

The Process Evaluation researchers will be distinct from the researchers collecting outcome measures. They will contribute to the qualitative, and therefore more subjective, data collection and the overall analysis. A 'critical friend' researcher, external to the outcome measure and delivery teams, will facilitate the Process Evaluation researchers' opportunity to self-reflexively explore how their presence effects their data collection and experiences in the field which may influence their analytical processes.[44] When the Process Evaluation data and analysis can contribute to refining ongoing fidelity to the Engager model, it will be fed back directly to the intervention delivery team. When the Process Evaluation data and analysis concerns the outcomes of interest, the data will be shared after the trial database has been locked down and initial statistical analyses have been carried out.

If the main trial does not demonstrate that the intervention is effective, additional analysis of the qualitative data will be conducted using thematic methods to explore possible explanations for this,[46] and to glean any additional learning that may have application to other studies with socially marginalised populations and/or those with mental health needs.

15 SAFETY REPORTING

15.1 Definitions

Adverse Event (AE)
Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in participants **whether or not related to any research procedures or to the intervention.**

Seriousness
Any adverse event will be regarded as serious if it:

i. results in death;
ii. is life threatening;
iii. requires hospitalisation or prolongation of existing hospitalisation;
iv. results in persistent or significant disability or incapacity ; or
v. consists of a congenital anomaly or birth defect

An adverse event meeting any one of these criteria will be a **Serious Adverse Event (SAE)**.

Relationship
The expression 'reasonable causal relationship' means to convey, in general, that there is evidence or argument to suggest a causal relationship. The research team will assess the causal relationship between reported events and trial participation according to the standardised guidance given below:

Relationship	***Description***
Unrelated	*There is no evidence of any causal relationship*
Unlikely	*There is little evidence to suggest there is a causal relationship (e.g. The event did not occur within a reasonable time after administration of the trial treatment/procedure). There is another reasonable explanation for the event (e.g. The participant's clinical condition, other concomitant treatment).*
Possible	*There is some evidence to suggest a causal relationship (e.g. Because the event occurs within a reasonable time after administration of the trial treatment/procedure). However, the influence of other factors may have contributed to the event (e.g. The participant's clinical condition, other concomitant treatments).*
Probable	*There is evidence to suggest a causal relationship and the influence of other factors is unlikely.*
Definitely	*There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.*

15.2 Reportable events

Any non-serious adverse events (regardless of relatedness) will not be reported in this study.

15.2.1 Reporting Serious Adverse Events

In this study, all SAEs will be reported to the CI regardless of relatedness within 24 hours of the PI (or authorised delegate) becoming aware of the event. A record of all SAEs will be kept in the Trial Master File All SAE's deemed to have a causal relationship to trial participation will be reported to the Sponsor and Clinical Trials Unit (CTU) within 24 hours of the CI being informed. The CTU will maintain a register of all reported SAE's. The CI will make a decision on expectedness of all related SAE's. SAE's that are related and unexpected are to be reported to NRES within 15 days. The relevant R&D department will also be informed.

15.3 Processing serious adverse event forms

15.3.1 Processing events for independent adjudication

All SAE's deemed to have a causal relationship to trial will be reported to the Data Monitoring Committee (assume we are having one).

Detailed guidance for the reporting and processing of SAEs will be provided to study personnel by the Engager research team in a separate work instruction.

16 DATA MANAGEMENT

16.1 Study Numbering

Each participant will be allocated a unique study number on consenting to the study and will be identified in all study-related documentation by their trial number and initials.

16.2 Data Collection

Data will be recorded on study specific data collection forms (CRFs), usually by the research team at each site. All persons authorised to collect and record trial data at each site will be listed on the study site delegation logs, signed by the relevant PI. Source data will include all data recorded straight into the CRF.

Audio files and transcriptions of the data will be collected by the Process Evaluation Team, comprising Engager team co-applicants and collaborators.

16.3 Data entry

Completed CRFs will be checked and signed at the research sites by a member of the research team before being sent to the CTU. Original CRF pages will be posted to the CTU at agreed timepoints for double-data entry on to a password-protected database, with copies retained at the relevant study site.

All forms and data will be tracked using a web-based trial management system. Double-entered data will be compared for discrepancies using a stored procedure. Discrepant data will be verified using the original paper data sheets.

16.4 Data Confidentiality

Participant names and addresses will be collected for the purpose of managing questionnaires, intervention delivery and process evaluation interviews. The names, phone numbers and address of participants' family members, partners, and friends will also be collected when provided by participants as a means of contacting them once they have been released from prison. Hard copies will be stores in a locked cabinet at each research site, separate to all other study data, with access limited to members of the research team. Investigators will ensure that the participants' anonymity is maintained on all other documents. The details of family members, partners and friends provided by participants to facilitate contact post-release will also be stored on the secure CTU database. Within the CTU, anonymised and identifiable study data will be stored separately, to prevent the identification of participants from research records, in locked filing cabinets within a locked office. Electronic records will be stored by the CTU in a SQL Server database, housed on a restricted access, secure server maintained by the University of Plymouth. Data in the database will be backed up daily by the University of Plymouth web team and will be accessible for up to 6 months. The website will be encrypted using SSL. Data will be collected and stored in accordance with the Data Protection Act 1998. Direct access to the trial data will be restricted to members of the research team and the CTU, with access granted to the Sponsor on request. Access to the database will be overseen by the CTU data manager and trial coordinator. Copies of original study data retained at study sites will be securely stored for the duration of the study prior to archiving. Audio recordings will be stored on a restricted access, secure server at the University of Plymouth.

16.5 Archiving

Following completion of trial data analysis, the Sponsor will be responsible for archiving the study data and essential documentation in a secure location for a period of 5 years after the

end of the trial. No trial-related records should be destroyed unless or until the Sponsor gives authorisation to do so.

17 DATA ANALYSIS CONSIDERATIONS

17.1 Sample Size

We plan to recruit and randomise a total of 280 prisoners in order to detect a statistically significant and clinically meaningful between group differences in mental health outcomes using our primary outcome CORE-OM based on an intention to treat analysis

In our pilot work the standard deviation (SD) for CORE-OM was 5.6. However, larger clinical studies have reported larger SDs of approximately 7.5[47]. For CORE-OM, 5.0 points is the accepted Reliable Change Index[48] in service evaluations[49]. In contrast, 2.5 points is seen as the upper limit of what would be considered a change compatible with equivalence (Personal communication, Professor Michael Barkham) in trials comparing two interventions. Other trials using the CORE-OM for mental health interventions versus treatment as usual or waiting list controls have achieved mean between group differences in change score of between 3.5 and 7.8[50, 51].

Given the uncertainty, in both SD and the appropriate minimally important difference (MCID) for the CORE-OM, we calculated sample sizes for different scenarios based on the range of values for these two parameters (see Table below).

Sample size (for each group) based on different values of SD and MCID for the CORE-OM*

		Standard deviation (SD)		
		5.5	6.5	7.5
Change to be detected (MCID)	5.0	26	36	48
	4.5	32	44	59
	4.0	40	56	74
	3.5	52	73	97

*At 90% power and 2-sided alpha of 5%

Based on the conservative scenario of a MCID of at least 3.5 and a common SD of 7.5 (a moderate effect size of 0.47) we will require CORE-OM data on 97 participants in each group at 90% power and 5% alpha.

We have observed a 63% and 55% level of outcome attrition in our Engager I and pilot trials. However, based on learnings from the pilot trial and collaboration with the new community rehabilitation companies who supervise all prison leavers for one year, we believe we can realistically reduce the attrition to 30% or less at six months follow up. We will therefore need to recruit 140 participants per group, a total sample size of 280.

17.2 Statistical analysis

All quantitative data analyses will be conducted and reported in accord with Consolidated Standards of Reporting Trials (CONSORT) recommendations. We will closely monitor the process of data collection during the trial and provide a flow diagram summarising, by group, the numbers approached, recruited, randomised, followed-up/lost to follow up, and outcome completion.

Primary analyses will be conducted on an intention to treat basis (i.e. according to randomised group) and compare primary and secondary outcomes at 6-month follow up between randomised groups on those with complete data sets. Outcomes will be compared using linear regression based methods adjusting for baseline outcome scores and stratification variables. Where necessary, outcomes will be transformed to ensure good regression model fit. A secondary analysis will compare primary and secondary outcomes between groups at all follow up time points using a repeated measures approach. Reasons for missing data (including loss to follow up and participant drop out) will be documented and the baseline characteristics of those with and without missing data compared. Using different assumptions for missing data, we will undertake sensitivity analyses using various imputation models and compare between group results to the completers primary analysis. In addition, given that we expect a proportion of participants may provide a CORE-10 (but not the primary outcome of CORE-OM) we will seek to undertake a sensitivity analysis comparing the between group effect size for the CORE-10 versus CORE-OM. We explore the possibility of conducting a secondary per protocol between group comparisons. If possible, this will be based on a pre-defined minimum level of intervention receivership and using CACE analysis methods. The analyst will be blinded to group allocation and undertaken using STATA v.13.

A detailed statistical analysis plan (SAP) will be prepared before any data analysis is conducted. The SAP will be agreed with the TSC/DMEC.

18 HEALTH ECONOMICS EVALUATION

The cost-effectiveness of the intervention to increase engagement and access to services, and improve mental health outcomes will be assessed, compared with service access and support as usual, using the economic model developed in the pilot phase populated with the trial outcomes and resource use data up to 6-months post-release from prison. It will be conducted from a public sector perspective, initially with the same time horizon as the RCT, and primarily using a cost-consequence approach. Within the cost-consequence approach the estimated incremental costs will be compared with:

- The number of people provided with the service/intervention
- The incremental differences in the main RCT self-reported health outcomes –CORE scores, and EQ-5D-5L and ICE-CAP social preference weights.
- Incremental differences in the number of ex-prisoners who: have resettled; are in employment; have no re-convictions; are not homeless.
- Estimated lifetime gains in Quality-Adjusted Life-Years (QALYs) – presuming the persistence of any short-term measured gains and the inclusion of estimated gains associated with social inclusion outcomes such as effective resettlement, increased employment, or reduced re-conviction rates.

The cost of providing the intervention will be based on a combination of process of care data collection and intervention practitioner care records and diaries (bottom-up costing approach), and the total costs of service provision (top-down costing). Both deterministic and probabilistic sensitivity analysis will be conducted to explore uncertainty in the model assumptions and parameters, with exploration of key sources of structural uncertainty where feasible.

The analyses will be conducted according to current guidance (ISPOR) on best practice for conducting and reporting model-based economic evaluation, and as much as possible to be consistent with the analytical approach used in the statistical analysis of the effectiveness outcomes of the RCT.

19 DATA MONITORING AND QUALITY ASSURANCE

The PI (or authorised delegate) will check completed CRF's for missing data or obvious errors before the forms are sent to the CTU. Data will be monitored centrally for quality and completeness by the CTU and every effort will be made to recover data from incomplete forms where possible. The CTU data manager will oversee data tracking and data entry and initiate processes to resolve data queries where necessary. The trial manager will devise a monitoring plan specific to the study which will include both central monitoring strategies and study site visits as appropriate.

Participating sites will be required to permit the trial manager or deputy, or representative of the sponsor, to undertake study-related monitoring to ensure compliance with the approved study protocol and applicable Standard Operating Procedures (SOPs), providing direct access to source data and documents as requested.

All study procedures will be conducted in compliance with the protocol and according to the principles of the International Conference on Harmonisation Good Clinical Practice (ICH GCP). Procedures specifically conducted by the CTU team (e.g. randomisation, data entry, data management) will be conducted in compliance with CTU standard operating procedures (SOPs).

20 STUDY ORGANISATIONAL STRUCTURE

Responsibility for the trial is assumed by the CI (Prof. Richard Byng) who will ensure its timely completion. The Principal Investigators in each centre will be responsible for managing all aspects of the study at their site.

Data Management services will be provided by the UKCRC-registered PenCTU. PenCTU will also allocate a senior trial manager to provide mentoring support to the Engager trial manager.

20.1 Trial Oversight Group (TOG)

A TOG including the CI, trial manager, trial statistician, health economist, process evaluation team, PIs, and other relevant personnel (e.g. other clinical colleagues, CTU data manager and patient representatives) will meet regularly throughout the duration of the trial to monitor progress, resolve day-to-day problems, oversee development of documentation and forms, monitor participant recruitment and follow-up, review the budget, discuss analysis, results, draft reports and dissemination. The TOG will meet at least every quarter. The CI, PIs and trial management team will also have teleconference meetings on a monthly basis.

20.2 Programme Steering Committee (PSC) responsibility

The Programme Steering Committee (see Appendix 2 for list of members) for the Engager programme has formally agreed to adopt the role of Trial Steering Committee (TSC) for the study and will oversee the conduct and safety of the trial. A charter describing the role and function of the committee specific to this study will be developed and agreed prior to, or soon

after, study commencement. The Committee includes an independent chair, independent members, a Patient and Public Involvement (PPI) representative and the CI. Representatives from both the Sponsor and funding organisations will be invited to study-related elements of the PSC meetings as observers. The PSC meet at least annually. Minutes of the PSC meetings will be sent to the Sponsor.

20.3 Data Monitoring Committee (DMC)

An independent Data Monitoring Committee will meet at least annually during the trial to oversee data issues relating specifically to patient safety and ethics, and will report to the TSC. The DMC is chaired by an independent clinician and comprises one other independent clinician and one independent statistician. SAEs will be reported on a quarterly basis to the DMC and all Suspected Unexpected Serious Adverse Reactions (SUSARs) will be reported to the DMC as they occur. Detailed operating procedures for the DMC will be agreed before the start of the study and incorporated into the DMC charter.

21 DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

The PI and the Sponsor will permit trial-related monitoring, audits, regulatory inspections and REC review by providing appropriate bodies (e.g. PenCTU, REC etc.) direct access to source data.

22 RESEARCH GOVERNANCE

22.1 Sponsor

The study Sponsor is Devon Partnership NHS Trust.

22.2 Ethics and NHS approvals

The study will be conducted in accordance with the Research Governance Framework for Health and Social Care, Second edition (2005). The study will be sponsored by Devon Partnership NHS Trust (DPT) and approved by a recognised NHS REC, and the Trust Research and Development (R&D) Departments for each site. The study will be adopted by the NIHR Clinical Research Network (CRN).

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP. Any amendments to the protocol will be submitted for REC approval as appropriate.

On request, the Chief/Principal Investigators will make available relevant trial-related documents for monitoring and audit by the Sponsor, and the relevant Research Ethics Committee.

Annual progress reports will also be submitted to the REC using the recognised National Research Ethics Service (NRES) template. An end-of-trial declaration will be provided to the REC within 90 days of trial conclusion or within 15 days of trial termination in the event the trial is prematurely terminated.

22.3 National Offender Management Service (NOMS) approvals

The study will be approved by the National Offender Management Service.

23 STATEMENT OF INDEMNITY

This is an NHS-sponsored research trial. If an individual suffers negligent harm as a result of participating in the trial, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an ex-gratia payment may be considered in the event of a claim.

24 PUBLICATION POLICY

A publication plan will be developed outlining any publications and manuscripts that will be developed for peer reviewed journals. The development work may also be presented at national and international conferences.

25 FINANCE

The Engager study is funded by the NIHR as part of a Programme Grant of Applied Research (RP-PG-1210-12011).

The research is sponsored by the Devon Partnership NHS Trust, represented by Mr Tobit Emmens, Managing Partner, Research and Innovation.

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27 APPENDICES

Appendix 1: Descriptions of outcome measures

Patient Health Questionnaire-9 (PHQ-9)[39]
The PHQ-9 is a nine item scale used to measure depression based directly on the nine diagnostic criteria for major depressive disorder in the DSM-IV (Diagnostic and Statistical Manual Fourth Edition). Participants are asked to rate each item on a 4-point Likert scale from 0 (not at all), 1 (several days), 2 (more than half days) and (nearly every day). The total score is the sum of the individual items.

Generalised Anxiety Disorder–7 (GAD-7)[40]
The GAD-7 is a standardised screening tool and severity measure of generalised anxiety disorder. Participants are asked to rate each item on a 4-point Likert scale from 0 (not at all), 1 (several days), 2 (more than half days) and 3 (nearly every day). The total score is the sum of the individual items.

Post-Traumatic Stress Disorder Scale (PTSD)[41]
The scale measures whether a person is presenting with PTSD symptoms as a result of a traumatic experience. The scale is based on four main symptom of PTSD of which two must be present.

Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM)[29]
The widely-used CORE Outcome Measure is a 34 item scale that measures psychological distress. It comprised of four domains, including subjective well-being (4 items); depression and anxiety symptoms (12 items); general, social and close relationship functioning (12 items); and 6 items concerning risk of harm to self or others. Respondents rate each of the items with regard to how they have been feeling over the previous week. Each item is rated on a 5-point Likert Scale, with eight of the items being reverse scored.

Normative data have been established for clinical and non-clinical populations, and the measure appears reliable and sensitive to clinically significant change. Since its development in 1998, the CORE-OM has been widely used in primary care services and it exhibits good psychometric characteristics. Although its use in forensic and prison settings is limited, it has been used and evaluated in these settings and functions satisfactorily.

The authors of the CORE-OM recommend computing a clinical score by dividing the sum the score on each of the completed items by the number of completed items, and multiplying by ten. This yields a score between 0 and 40. A clinical score of 10 or more is suggested to be indicative of psychological distress.

Clinical Outcome in Routine Evaluation – 10 item version (CORE-10)[39]
The CORE-10 is a brief outcome measure comprising 10 items drawn from the CORE-OM. It includes items from the four domains of the CORE-OM (well-being, depression and anxiety symptoms, functioning, and risk). Respondents rate each of the items with regard to how they have been feeling over the previous week. Each item is rated on a 5-point Likert Scale. A clinical score can be calculated by multiplying the average item score by 10.

Normative data has been established for clinical and non-clinical samples. Clinical scores on the CORE-10 significantly correlate with clinical scores on the CORE-OM (r=0.94 in a clinical sample and r=0.92 in a non-clinical sample).

Camberwell Assessment of Need – Forensic Version (CAN-FOR)[30]
The CAN-FOR-S is an individual needs assessment tool designed to identify needs, across a range of domains, of people with mental health problems who are in contact with forensic services. The domains cove a broad range of health, social, clinical, and functional needs.

Although the original CAN-FOR had 25 items, we have removed the items relating to psychotic symptoms, information on condition and treatment, sexual expression, telephone, transport, and treatment. These items were considered less relevant to the participants in the current study.

On each of the items, the participant is asked whether they likely to have any problems in the particular area when they get released. If the response indicates no problem, then additional questions are asked to establish whether this is because they are receiving help in this area. The researcher then rates each of the 19 items on a 3-point scale, where 0 = no need, 1 = met need, and 2 = unmet need. The number of 1s and 2s on each of the items can be summed to provide a total number of met and unmet needs across the domains.

Treatment Outcomes Profile (TOP)[32]
The TOP is a tool designed to measure change and progress in key areas of the lives of people being treated in drug and alcohol services. In addition to actual drug and alcohol use over the preceding four week, the measures captures information on risk taking behaviour, criminal activity, and health and social functioning. However, much of this information is being collected in other outcome measures and therefore only the section relating to drug and alcohol use is being used in the current study. However, we have expanded on the list of substances to include 'legal highs' and other substances known to be commonly used.
The total number of days abstinent over the preceding four weeks is the dependent variable.

Leeds Dependence Questionnaire (LDQ)[33]
The LDQ is a 10-item scale that measures dependence during periods of substance use or abstinence. The LDQ is an indicator of how addicted a person is and, therefore, how difficult it will be to achieve a positive outcome. Each of the 10 items are rated on a 4 point Likert scale and scored 0-3. The total LDQ score is the sum of the item scores and ranges from 0 to 30. A score of less than 10 is indicative of low dependence and a score of greater than 22 suggests high dependence, with scores from 10-22 regarded as indicating medium dependence.

Client Service Receipt Inventory (CSRI) – Adapted[34]
The adapted CSRI is a measure deigned to capture a broad range of services that participants engage with. For each contact, the table captures the name of service, whether the contact was in prison or the community, the number and duration of contacts, the nature of the contact (e.g. face-to-face, phone call) and who the contact was initiated by. All contacts with health, social care, education and third sector organisations are recorded.

Perceived Helpfulness of Services
The subjective rating of how helpful a participant feel a service has been is captured within the CSRI table. For each service contact, the participant is asked to rate on a scale of 1 to 7 how helpful they thought the service had been (1=not helpful at all, to 7=very helpful).

EQ-5D-5L [35]
The EQ-5D is a standardised measure of health status designed to provide a measure of health for clinical and economic appraisal. The scale comprised 5 items, each containing five statements indicating different degrees of health problem (e.g. no pain, slight pain, moderate pain, severe pain, extreme pain). Participants are required to tick which statement best describes their health on that day.

ICEpop CAPability measure for Adults (ICE-CAP-A)[36]
The ICECAP-A is a measure of capability for the general adult population for use in economic evaluations. Unlike the EQ-5D it focuses on wellbeing defined in a broader sense rather than just health. The format of the ICECAP-A is similar to the EQ-5D. The scale comprises 5 items, each containing four statements indicating different degrees of a problem. Participants are required to tick which statement best describes their quality of life at the moment.

INSPIRE[37]
INSPIRE is a measure designed to assess a service user's experiences of the support they receive from a mental health worker for their recovery. The Relationship section assesses the relationship between the service user and the mental health worker. It comprised 7 items that are scored on 5-point Likert scale. The Relationship score is calculated by summing the score on each of the items (0-4) to give total score ranging from 0-28. This is multiplied by 3.571 to give a score between 0 and 100.

Intermediate Outcome Measurement Instrument (IOMI)[38]
The IOMI an instrument of outcomes designed to measure positive change along an offender's pathway to an offence-free future and in the long term reductions in reoffending. The instrument covers categories including agency/self-efficacy, hope, impulsivity/problem solving, motivation to change, resilience, interpersonal trust, wellbeing. The participant is asked to rate each item on a 5-point Likert scale from 0 (strongly disagree), 1 (disagree), 2 (neutral), 3 (agree), and 4 (strongly agree), items 4, 10, 14 and 16 are reversed. The scores for each category are calculated as instructed by the table below and the overall score is the sum of all 20 items.

Agency/Self-efficacy	Add scores to questions 8, 13 and 20
Hope	Add scores to questions 4, 10 and 16
Impulsivity/Problem solving	Add scores to questions 2, 5 and 18
Motivation to change	Add scores to questions 15, 17 and 21
Resilience	Add scores to questions 7 and 14
Interpersonal trust	Add scores to questions 1, 3, 6 and 11
Wellbeing	Add scores to questions9, 12 and 19

Trauma History Screen (THS)[51]
The Trauma History Screen (THS) is a very brief measure of exposure to high magnitude stressor (HMS) events and of events associated with significant and persisting post-traumatic distress (PPD). The measure assesses the frequency of HMS and PPD events, and it provides detailed information about PPD events.

Standard Assessment of Personality (SAPAS)[52]
The SAPAS is an 8 item screen for personality disorder. Participants are asked to rate each item No (0) or Yes (1); the total score is the sum of all 8 items.

Head Injury Survey
The survey is used to gather information on any previous head injuries, including cause and severity based on the number of minutes of unconsciousness.

Adapted Rivermead Post-concussion Symptoms Questionnaire[53]
This is a 6 item version of the Rivermead Post-concussion Symptoms Questionnaire (Cognitive domain: Poor concentration & Taking longer to think; Affective domain: Depressed & Frustrated; Somatic: Headaches & Fatigue). All are scored on a 5 point Likert scales (0 = not at all, 1 = a little bit; 2 = moderately, 3 = quite a bit, 4 = severe).

Appendix 2 – Members of the Programme Steering Committee

Chair – Professor Pamela Taylor

Chief Investigator – Professor Richard Byng

Other members to be confirmed.

Appendix 3 – Member of the Data Monitoring Committee

To be confirmed.

Appendix 32 - Gantt chart

Year	2015					2016												2017												2018									
Study Month	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65
Month	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Study set-up																																								
Ethics submission																																								
R&D approvals																																								
Recruitment to trial																																								
Intervention in prison																																								
Intervention in community																																								
Baseline Assessments																																								
3 Month Follow-up																																								
6 Month Follow-up																																								
12 month follow-up																																								
Process evaluation																																								