Greater Manchester Mental Health NHS Foundation Trust

Women Offenders Repeat Self-Harm Intervention Pragmatic Trial (WORSHIP III)

DELETE AS APPROPRIATE:

- **This protocol has regard for the HRA guidance and order of content**

This project was funded by the National Institute for Health Research Health Technology Assessment (HTA) Programme (project number 16/111/51). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR, NHS or the Department of Health.

RESEARCH REFERENCE NUMBERS

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ISRCTN Number:	ISRCTN10115835
SPONSORS Number:	X334
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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date: 17/06/19

....

Name (please print):

.....Sarah Leo .....

Position: .....

Head of Research & Innovation Office .....

Chief Investigator:

Date: 17/06/19

Signature: ....

Name: (please print):

.....Prof Kathryn Abel .....

Statistician:

Date: 17/06/19

Signature
:.....

Name: (please print):

.....Prof Richard Emsley .....

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LIST of CONTENTS

LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

ACCT	Assessment, Care in Custody and Teamwork
AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
CSO	Clinical Studies Officer
CTU	Clinical Trials Unit
DMEC	Data Monitoring and Ethics Committee
EDC	Electronic Data Capture
GCP	Good Clinical Practice
HMPPS	Her Majesty's Prison and Probation Service
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
MOJ	Ministry of Justice
NHS R&D	National Health Service Research & Development
NOMIS	National Offender Management Information System
OMU	Offender Management Unit
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
PIT	
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TAU	Treatment as usual

TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

TRIAL SUMMARY

Trial Title	Women Offenders Repeat Self-Harm Intervention Pragmatic Trial	
Internal ref. no. (or short title)	WORSHIP III	
Trial Design	Pragmatic RCT	
Trial Participants	Women in prison who self-harm or have recently self-harmed; prison and healthcare staff who work with women who self-harm in prison	
Planned Sample Size	Recruit 264 individually randomised women prisoners (retain 210, with predicted 20% attrition) 56-84 prison/healthcare staff	
Treatment duration	4-8 weeks	
Follow up duration	12 weeks	
Planned Trial Period	1st August 2018 – 31st January 2023	
	Objectives	Outcome Measures
Primary	To compare the effects of Psychodynamic Interpersonal Therapy (PIT) versus usual treatment (TAU) on incidents of self-harm	The number of incidents of self-harm within the intervention period, measured via prison and healthcare records and self-report
Secondary	To compare the effects of PIT versus usual treatment on key psychological measures: suicidal ideation, depression, hopelessness, self-esteem and wellbeing, on the level of harm resulting from self-harm incidents, on the frequency of self-harm thoughts, and on the participant's ACCT status.	Beck's Scale for Suicide Ideation (BSS) Beck's Depression Inventory (BDI-II) Beck Hopelessness Scale (BHS) Rosenberg Self-Esteem Scale (RSE) Warwick-Edinburgh Mental Well-Being Scale (WEMWS) Self-reported level of harm resulting from self-harm incidents cross referenced with data from the prison records and SystmOne Self-reported self-harm thoughts Likert scale (in the diary)

		Prison ACCT documents
Economic Analysis	To compare the cost effectiveness of PIT versus TAU by performing a within trial economic analysis followed by economic modelling of potential future costs	HRQoL (EQ-5D-5L/SF-12)
Process Evaluation	To understand the experiences of women receiving PIT and TAU and those of staff working with them and to understand any problems with implementation of PIT.	Individual qualitative interviews with women prisoners and focus groups with staff Therapy Satisfaction Questionnaire with the intervention group
Therapy Quality Assurance	To determine if delivery of PIT by supervised trainee clinical psychologists, forensic psychologists (trainee and qualified) and psychiatrists (trainee and qualified) is successful in terms of: therapists' competence/adherence; and therapist satisfaction with supervision	PIT competency/adherence measure Supervision satisfaction questionnaire

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research Health Technology Assessment Programme	£1,434,089.80

ROLE OF TRIAL SPONSOR AND FUNDER

Department of Health definition of a sponsor: An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them, by agreement, amongst the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities that are relevant to the study.

Summary of Sponsor Responsibilities:

- taking responsibility for putting and keeping in place arrangements to initiate, manage and fund the study
- confirming that everything is ready for the research to begin
- satisfying itself the research protocol, research team and research environment have met the appropriate scientific quality assurance standards
- satisfying itself the study has ethical approval before relevant activity begins
- allocating responsibilities for the management, monitoring and reporting of the research
- ensuring that appropriate arrangements are in place to approve any modifications to the design, obtaining any regulatory authority required, implementing such modifications and making them known
- satisfying itself that arrangements are kept in place for good practice in conducting the study and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions.

For full details of sponsor definitions and responsibilities please refer to the Department of Health's Governance Framework for Health & Social Care (2nd Edition 2005).

Sponsor: Greater Manchester Mental Health NHS Foundation Trust (GMMH) will assume overall responsibility for the project. GMMH sponsorship regulations are outlined in RD SOP14 Trust Sponsorship of Research (GMMH) https://www.gmmh.nhs.uk/search/text-content/ri-standard-operating-procedures-sops-and-guidance-documents--1739

Funder: National Institute for Health Research Health Technology Assessment Programme

The role and responsibilities of the funder are outlined in the contract between the Secretary of State for Health and Greater Manchester Mental Health NHS Foundation Trust Version number: 2/18 NHS Feb 18

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Trial Steering Committee and Data Monitoring (and ethics) Committee: Information on the roles and responsibilities of these committees can be found here: www.nihr.ac.uk/funding-and-support/funding-for-research-studies/manage-my-study/governance-approvals-and-registration.htm

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Trial Management Group: The Trial Management Committee will consist of the Chief Investigator, the Trial Manager, Trial Statistician and the Key Protocol Contributors. The committee will hold monthly meetings throughout the trial to review progress against the Project Management Plan.

Protocol contributors

Prof Kathryn Abel, the CI, is Director of the Centre for Women's Mental Health, Faculty of Biology, Medicine and Health Sciences, University of Manchester and an honorary member of Greater Manchester Mental Health NHS Foundation Trust. She has expertise developing and evaluating gendered mental health services and clinical care and led WORSHIP I/II/COVER.

Dr Louise Robinson will act as co-PI on the trial. She is a Consultant Forensic Psychiatrist in secure mental health services and Honorary Senior Lecturer at FBMHS. She led a multi-site prison mental health study which resulted in recommendations for practice for Scottish prisons and was a member of the COVER research team.

Dr Kerry Gutridge, the Trial Manager, will be responsible for the day-to-day project management and oversight and will line manage the research assistants. She is Project Manager on COVER. Her PhD was on harm-minimisation for self-harm.

Dr Tammi Walker will oversee the qualitative elements of the trial. She is a Chartered Psychologist with over 12 years' experience in prison/secure mental health services. She has a PhD in women who self-harm in secure settings and was PM/qualitative lead on WORSHIP II and qualitative lead on COVER.

Dr Emma Plugge will co-manage the research assistant at University of Southampton and will act in an advisory role on the trial as an expert on prison research. She is a public health doctor with over 10 years' experience in mixed-methods research in prisons, previously conducting the largest longitudinal study of women prisoners in England.

Professor Richard Emsley will oversee the statistical elements of the trial. His research involves developing statistical methods for trials of complex interventions in mental health. He is trial statistician on 10 current RCTs in mental health, including the CRISP trial in forensic settings.

Professor Jenny Shaw will act in an advisory role on the trial as an expert in prison research. She is a Professor of Forensic Psychiatry, Consultant Forensic Psychiatrist and academic lead for the Offender Health Research Network.

Professor Annie Bartlett will co-line manage the London RA and act in an advisory role on the trial as an expert in prison research. She is a Reader in Forensic Psychiatry as well as being a qualified doctor specialising in Forensic Psychiatry.

Dr Rachel Meacock will be responsible for the health economics in the trial. She is an experienced health economist who worked on COVER.

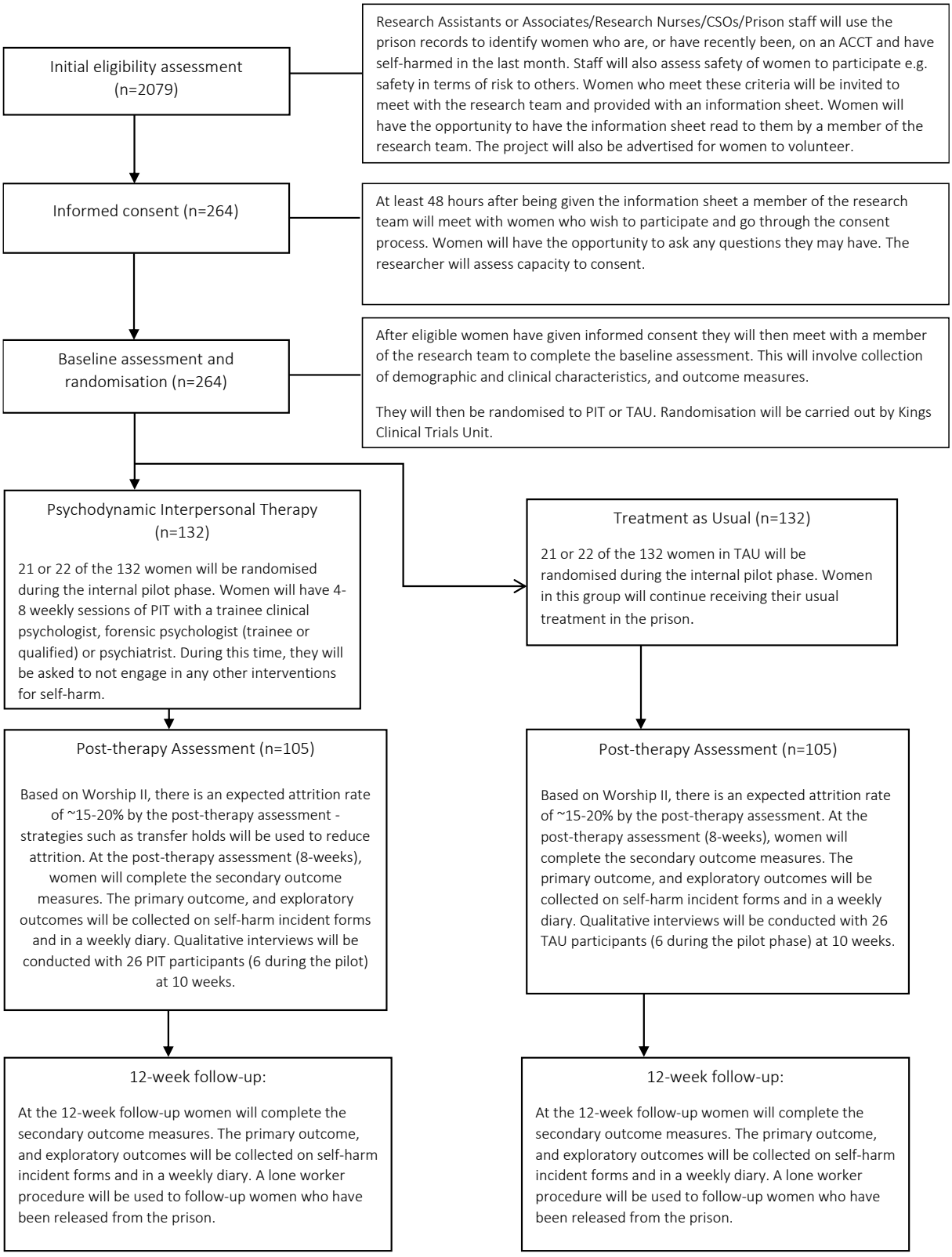
Dr Sarah Allen will help coordinate therapist recruitment and retention. She is a Consultant Clinical Psychologist and Lead Psychologist for Offender Care in Central and North West London NHS Foundation Trust.

Patient and Public Involvement:

Fiona Edgar and Tracy Millington are experts-by experience. Our experts by experience have shaped study design and edited the grant application and plain English summary. They have also suggested ways in which prisoners and staff might be involved in the research, emphasising the role of prisoners in understanding the prison system.

KEY WORDS: Prison; self-harm; women; psychodynamic interpersonal therapy; pragmatic trial

TRIAL FLOW CHART



BACKGROUND

WORSHIP III is a full-scale, randomised controlled trial to examine the clinical and cost-effectiveness of modified Psychodynamic Interpersonal Therapy (PIT) for women who self-harm in prison. Self-harm is a complex behaviour associated with acute psychological distress and increased suicide risk [1;2]. The most common self-harm methods in women's prisons are cutting or scratching, followed by strangulation [1]. Self-harm is more prevalent in women's prisons with 1987 incidents per 1000 women, compared to 399 per 1000 men, over 12 months [3].

NICE recently examined which interventions were effective for adults in the criminal justice system who self-harm. The review, limited to systematic reviews and RCTs, found no prison-based RCTs which specifically evaluated self-harm interventions with self-harm rates as the primary outcome (NICE's recommended measure [4]).

In preparation for this grant, we conducted our own systematic review of current self-harm interventions in forensic settings (women's prisons and secure hospitals) including all experimental designs. The inclusion and exclusion criteria for the review were:

Inclusion criteria:

- Include participants who were women, over the age of 18, and residing in a secure forensic mental health service or a prison.
- Examine the outcome of an intervention.
- If participants in the study included men and women, women were analysed separately.
- Measures the number of self-harm incidents as an outcome
- Report on original data.
- The paper must be written in English.
- The paper must be published.

Exclusion criteria:

- They did not include women.
- They did not measure change after an intervention, i.e. there were no pre- and post-intervention measures of outcome.
- If participants in the study included men and women, women had not been analysed separately.
- A self-harm outcome measure of incidents was not used.
- They did not report on original data.
- The paper had not been written in English.
- The paper had not been published.

The following search terms were used, to be present in the abstract or title:

(Prison* OR incarcer* OR jail* OR inmate OR police OR custody OR secure mental health OR forensic* OR remand OR felon* OR detainee OR convict*) AND

(Women OR female*) AND

(Intervention OR therap* OR treatment OR management OR medication) AND

(Self-harm* OR self harm* OR selfharm* OR self-mutilat* OR self mutilat* OR selfmutilat* OR self-injur* OR self injur* OR selfinjur* OR self-wound* OR self wound* OR selfwound* OR self-poison* OR self poison* OR selfpoison* OR parasuicid* OR non-suicid* OR deliberate self-harm* OR ligatur*)

Databases searched were those used in an earlier systematic review of treatment for women prisoners [5].

457 papers met the search criteria, with 5 meeting the inclusion criteria. In terms of study quality, no study received a high rating. One received a moderate rating [6]. The remaining four received very low ratings.

From the review, we concluded that no self-harm interventions have been robustly evaluated for women who self-harm in prison in the UK except in our WORSHIP studies (Women Offenders Repeat Self-Harm Intervention Pilots) [6].

WORSHIP I modified and examined the acceptability of brief manualised PIT for women in prison who self-harm. WORSHIP II evaluated the feasibility of running an RCT to examine modified PIT in three women's prisons and collecting follow-up data. WORSHIP II showed that it is feasible and acceptable to randomise women in prison to PIT or a control group. Our randomisation method resulted in comparable groups with similar past experiences and we found that women were unlikely to drop out because they were not in their preferred group. The pilot also demonstrated ways to reduce attrition during a clinical trial in a prison environment by including a sufficiently long sentence length as part of the inclusion criteria, using transfer holds to mitigate against women moving between prisons during therapy, seeking consent from the entire women's estate to follow up women who are transferred, providing additional, easy-read information to ensure that women are fully aware of their role in the research and allowing women who have been released, but who return to prison, to resume participation. The study also showed that it is feasible for psychiatry trainees and other allied health professionals to deliver the treatment. Finally, WORSHIP II showed that it is feasible to collect the psychological outcome measures and demonstrated the necessity to collect, and then compare, records of incidents of self-harm from multiple sources [6].

WORSHIP III seeks to build on WORSHIP I and II by conducting a fully powered, pragmatic RCT of PIT versus TAU examining clinical efficacy and cost-effectiveness. A pragmatic trial design, as recommended by NIHR reviewers, i.e. comparison of the intervention against treatment as usual, has been chosen because it is important to determine if PIT surpasses the variety of treatments commonly provided in women's prisons e.g. self-esteem and thinking skills courses, which have not been tested using gold standard methods and are not specifically designed to reduce self-harm.

RATIONALE

Rising rates of self-harm and a lack of evidence on the effectiveness of psychological therapy for self-harm in women's prisons makes this research highly relevant and timely. A recent Ministry of Justice White Paper acknowledges the need for a 'robust evidence base' to address prison self-harm. Currently-evaluated community treatments are likely to require significant adaptation for prison use [7], therefore, our proposal will test the clinical and cost effectiveness of a psychodynamic interpersonal therapy (PIT) which we have modified for self-harming women in prison with their input. This aligns well with Government priorities, clinical need and with the NIHR HTA remit since it tests the clinical and cost-effectiveness of an intervention which may be of immediate benefit.

Most women in prison have extensive victimisation histories, often describing multiple trauma [8]. Offender Assessment System data suggest that 59% of women in prison have had relationship

problems, including poor childhood experiences and family relationships, and abuse [9]. In a forensic mental health setting, 42% of self-harm incidents were attributed to current interpersonal conflicts [10]. This creates an ongoing need for cost-effective interventions responsive to these specific problems.

PIT is a promising intervention as it is designed for people whose problems arise from relationship disturbances [11]. It is an evidence-based psychological treatment shown to reduce suicidal ideation and self-reported self-harm in adult outpatients [12; 13; 14] and is particularly effective for those reporting childhood trauma [15]. PIT involves conversational sessions focusing on the patient's emotional life, their relationships and how problems managing their emotions might stem from difficult past events. PIT helps patients to understand, tolerate and resolve interpersonal problems learning new ways to manage emotions and relate to others.

WORSHIP III will be an RCT of modified PIT, adapted for women in prison with extensive stakeholder involvement; and piloted for feasibility/acceptability. Based on the pilot [6], we hypothesise that PIT will reduce self-harm thoughts, leading to significantly fewer incidents. The pilot showed promising reductions in suicidal ideation, depression and hopelessness. Given the knowledge gap, the trial will provide an important scientific contribution towards improving the management of a pressing clinical problem.

Of 3968 women in prison in England/Wales [16] at any one time, approximately one third self-harm. Nearly 9000 women pass through prison every year; [17] this means that evidence-based interventions have the potential to benefit several thousand women annually. Furthermore, if benefits are sustained, this is likely to have positive effects on their families in the community. In addition, fellow prisoners who do not self-harm may be adversely affected [18] as well as staff who witness a high level of self-harm [19; 20]. Therefore, effective treatment is likely to have a positive effect on wellbeing of the wider prison community. An intervention which lessens the burden on staff, as well as women in prison, is particularly important given the current discontent of prison officers with conditions in UK prisons [21].

Assessment and management of risk

Women prisoners in the trial

All research in the Women's Estate needs approval from Her Majesty's Prison and Probation Service (HMPPS) who state that researchers must disclose the following things:

- Behaviour that is against prison rules
- Information that either indicates a risk or harm to yourself or others
- Information on previously undisclosed illegal acts or plans to commit a new
- crime
- Information that raises concerns about terrorist, radicalisations, or security issues.
- information about poor or unacceptable practices by the prison staff or by an outside organisation

As such, we are required to disclose information on issues such as ongoing abuse of a child or adult, and information on intention to self-harm or commit suicide. This requirement will be made explicit to participants during consent. If participants do not agree to these disclosures they will not be able to take part in the research. We have followed this guidance in all previous research in prisons over the last 20+ years and, as far as we are aware, the potential for disclosure rarely prevents women from participating. It is our understanding from WORSHIP II that the women find disclosure of risk a containing element of their relationship with the therapist/researcher which indicates that they are taking the woman's complex needs seriously and are committed to protecting them and other people from harm. Disclosures are made to all relevant departments in the prison including Safer Custody staff, healthcare staff, personal officers and the Offender Management Unit (OMU). All these personnel have

considerable experience managing personal disclosures in a sensitive and supportive manner. Researchers or therapists will be provided with a template risk disclosure form to complete if they identify a risk.

Initially we encourage women to disclose to staff any risks themselves. If they do not want to do this, we ask for their permission to inform staff. If they refuse both options, we are obliged to inform someone without their consent. This final option rarely occurs.

As an additional precaution, we shall also seek the women's consent to send a letter about their participation to their prison GP and mental health team and add a page about participation to their ACCT folder and information about participation to their case notes on NOMIS, so professionals are aware that they are involved with the project and can contact the research team if they have any concerns. If the women are on an active ACCT, the Assessment, Care in Custody and Teamwork process for self-harm, we shall be required to add information to the participant's ACCT folder outlining any issues relating to risk raised in either the research or therapy sessions. Notes will also be added to the participant's SystmOne healthcare records and their NOMIS case notes concerning any risk. Any women involved in the intervention will also be included on the agenda for any prison or healthcare Safe Interventions or complex needs meetings to ensure that their safe involvement in the trial is discussed in these forums.

The research will involve discussing self-harm. This might draw out experiences that may be of a sensitive and upsetting nature. Responding ethically to this may require the researchers to take either, or both, formal and informal measures to support participants. In considering an appropriate response to prisoner participants, the research team must work within the restrictions posed by their environment. Thus, the research team must draw upon existing support mechanisms already available to prisoners within the prison itself. If the researcher/therapist observes that a prisoner is upset during the research project (s)he will seek permission to speak to Safer Custody staff at the relevant prison immediately; she will then contact the Trial Manager who will coordinate any follow up procedures with relevant members of the prison staff, e.g. healthcare, personal officers and OMU.

Participants will also be able to follow the usual mechanisms which are already in place in the event that they become upset or distressed about any issue. Women will be able to contact their personal officer, psychology team, mental health staff, or a representative from the chaplaincy department. If a woman is distressed and likely to self-harm the prison will follow their usual procedure implementing the ACCT process.

It is also recognised that participants may become upset or distressed during the intervention sessions, interviews or focus groups. In the event of this, the research team will draw upon the approach outlined in Holloway (2000) who advises that in such circumstances the role of the researcher is one of emotional containment [22]. Holloway advocates offering participants the possibility to take a short break and then be guided by them as to whether or not to continue with the session. Therapists will draw on the containment skills they have learnt during the PIT training and will discuss their participant's reaction during their supervision.

If a participant is transferred during the research project, we shall contact the Safer Custody team in their new prison and the healthcare team to inform them of any risk e.g. if they are prematurely ending the therapy. We will explore whether it is possible for the participant to continue therapy if they are transferred to another study prison. We will also request permission to inform their probation service / community rehabilitation company (CRC) if they leave the prison before they complete the therapy.

Staff participating in the research

Staff will be able to access the comprehensive existing support mechanisms available to them via the HM Prison Service. These include private support and counselling support.

The research team

The main risks for the researchers and therapists relate to the prison environment and interaction with women in prison. Most members of the research team are already familiar with working in this environment and with this population, having completed other recent prison research (WORSHIP I/II, COVER). They will provide an initial orientation session for all new research assistants, CSOs, research nurses, outcome assessors and therapists so they are also familiar with working within the prison environment.

As part of the security clearance procedures for the prisons, researchers and therapists will be required to attend security training within the prisons which teaches them procedures relating to their personal safety. This includes practices such as 'signing in' to the visitors' book upon entering the main prison, rules covering restricted items and guidance on safe interaction with the women in prison. If the therapists are only delivering a small number of sessions, this induction may be delegated to experienced researchers who have themselves completed the induction.

All research and therapy will take place within a private room within the prison that is in close proximity to prison staff in case the researcher/therapist should need any assistance. The room will have an alarm.

It is recognised that some of the prisoners wishing to participate in this research may pose a risk to researchers/therapists at some times. All potential participants will be reviewed by the Safer Custody/healthcare team/OMU in the relevant prison, and any women who are deemed to present too much of a risk to work one-to-one with researchers and/or therapists will be excluded from the research, until the risk can be safely managed. Close collaboration with the Safer Custody team, healthcare and the OMU throughout the research will enable the researchers and therapists to be alert to any fluctuations in risk which could mean that it is no longer safe for a woman to be involved with the research/intervention e.g. the list of participants will be reviewed by local collaborators on a weekly basis.

If researchers are following up women in the community, a lone worker protocol will be followed. See the copy of this policy in the Master File/Site File.

Finally, the research team recognise that undertaking research with women in prison who self-harm may involve discussion of sensitive and emotional issues. Therefore, the researchers and therapists will receive supervision from senior members of the research team and/or in-house clinical supervisors for the duration of the project.

OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

Primary objective

- To compare the effect of modified PIT versus TAU on the number of incidents of self-harm at 8 weeks.

Secondary/Exploratory objectives

- To compare the effects of PIT versus TAU on key psychological measures: suicidal ideation, depression, hopelessness, self-esteem and wellbeing, on the level of harm resulting from self-harm incidents, on the frequency of self-harm thoughts, and on the participant's ACCT status at 8 weeks.

Outcome measures

Primary outcome

The primary outcome is the total number of self-harm incidents in the 8-week period from baseline. We shall also be measuring the total number of self-harm incidents in the 12-weeks from baseline. All self-harm which takes place at a specific time point will count as one incident. For example, if someone cuts themselves on their neck and arm at the same time this will count as one incident; however, if they cut themselves at two different times, in the same day, this will count as two incidents e.g. when there is a gap of 30 minutes between incidents. This approach is consistent with the way incidents of self-harm are recorded on SystmOne and the prison self-harm records e.g. the self-harm incidents log/ACCT/NOMIS/F213.

The primary outcome will be a composite of self-harm incidents derived from self-report, medical databases (SystmOne) and prison databases or paper records (NOMIS; F213 forms, ACCT folders, self-harm incidents logs; daily officer's logs) checked for double entry. This approach was recommended in Borschmann et al (2017) who conclude that relying on one data source for self-harm incidents in incarcerated adults could substantially under-ascertain the actual number of events [23]. Self-harm acts will be recorded on the self-harm incidents logs (participants, prison and SystmOne) and then checked for double entry before they are entered into the CTU database. The date and time of each self-reported incident will be recorded to allow cross-checking with medical and prison records, which record self-harm incidents by date and time, to check for duplication.

Both the intervention group and the control group will be asked to complete a weekly self-harm incidents' log (participants) outlining the number of times they have self-harmed since the last entry. All participants (in control and intervention arm) will be able to self-complete the log, at the end of one week, or complete the log with a research assistant. We will explore with each prison recruiting trusted peers to assist with log completion if the women have low literacy.

Secondary outcomes

Becks Scale for Suicide Ideation [24]: a 19-item instrument measuring intensity, duration and specificity of thoughts about committing suicide. The BSS has high internal consistency (0.89) and high inter-rater reliability (0.83) [24].

Becks Depression Inventory [25]: a 21-item scale measuring symptoms of depression. The BDI-II has high internal consistency and a retest reliability ranging from 0.73 to 0.96 [26].

Beck Hopelessness Scale [27]: a 20-item self-report inventory designed to measure three major aspects of hopelessness: feelings about future, loss of motivation and expectations. The BHS has high concurrent validity (.86) and high reliability (α = .91) [27].

Rosenberg Self-Esteem Scale [28]: a 10-item Likert scale with items answered on a four-point scale – from strongly agree to strongly disagree. The scale measures self-esteem and has been used in prison research [29]. Internal consistency ranges from .77 to .88 and test-retest reliability ranges from .82 to .85 [29].

Warwick-Edinburgh Mental Well-Being Scale [30]: a 14-item scale of mental well-being covering subjective well-being and psychological functioning, in which all items are worded positively and address aspects of positive mental health. The WEMWBS has high internal consistency (α = .91) and test-retest reliability (0.83) [30].

ACCT: The Assessment, Care in Custody and Teamwork (ACCT) process is a prison-based system for self-harm monitoring and management. We will record whether the participant is taking part in the ACCT process at 8-weeks and at 12 weeks.

Exploratory outcomes

Level of harm resulting from self-harm incidents: Following Hawton et al [1], the level of harm resulting from self-harm incidents will be measured as follows: incidents will be classified as resulting in a high level of harm when they involve loss of life, resuscitation in prison, an overnight stay in hospital, external hospitalisation on life support or a combination of these. A medium level of harm will be defined as external hospitalisation other than life support (NOT an overnight stay) and a low level of harm will be defined as any episode not needing resuscitation or external hospitalisation. The level of harm will be recorded by the individual on the self-harm incidents' log (participants), for non-fatal incidents, and cross referenced with data recorded in the self-harm incidents logs (prison and SystmOne) . Any deaths will be reported in the self-harm incidents logs (prison and SystmOne). For each participant, we shall calculate an average level of harm across all incidents.

Self-harm thoughts: Self-harm thoughts will be measured in a weekly diary on a Likert Scale. Women will be asked to report how often they have had thoughts of self-harm since the due date for their last weekly diary (not at all; almost never; sometimes; almost always; all the time).

Table of outcomes.

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective To compare the effect of modified PIT versus TAU on incidents of self-harm	Self-harm incidents (composite of self-report and prison/healthcare records)	8-week post baseline (primary outcome); 12-weeks post baseline
Secondary/Exploratory Objectives To compare the effects of PIT versus TAU on key psychological measures: suicidal ideation, depression, hopelessness, self-esteem and wellbeing, on the level of harm resulting from self-harm incidents, on the frequency of self-harm thoughts, and on the participant's ACCT status.	Becks Scale for Suicide Ideation Becks Depression Inventory Beck Hopelessness Scale Rosenberg Self-Esteem Scale Warwick-Edinburgh Mental Well-Being Scale Prison ACCT documents Self-reported self-harm thoughts Likert scale (in the diary) Self-reported level of harm resulting from self-harm incidents cross referenced with prison records and SystmOne	8-weeks post baseline; 12-weeks post baseline
Process Evaluation	Therapy Satisfaction Questionnaire	10 weeks post baseline

TRIAL DESIGN

Pragmatic randomised controlled trial

The trial will include an internal pilot which will run over 9 months in four prisons with 6 months' recruitment and an additional three months for follow up. During the pilot, we shall aim to recruit 43 women to demonstrate that we can achieve the required numbers in the full trial period. These figures fit with our predicted recruitment rates. The predicted figures have been calculated based on the number of women who will pass through HMP Styal, HMP New Hall, HMP Bronzefield, and HMP Downview depending on their size and the recruitment rate achieved in WORSHIP II. HMP Downview has been added to the pilot, as an amendment, as a recruitment site and also as a follow-on therapy site as women are frequently transferred from HMP Bronzefield to HMP Downview and we have agreement from our therapists that they will continue therapy in HMP Downview if a woman is moved (due to their close proximity).

Progression rules for the pilot will follow a traffic light system where red indicates intractable issues that cannot be remedied, amber indicates there are potentially remediable issues and green indicates that there are few concerns regarding the success of the trial [31]. We shall use the following criteria for each colour:

- Red: Recruitment < 60% of required numbers. Consider stopping the trial with the Trial Steering Committee and NIHR.
- Amber: Recruitment 60%-80% of required numbers. We shall submit a rescue plan approved by the Trial Steering Committee outlining steps that will improve recruitment to ensure that the sample size is achievable.
- Green: Recruitment 80-100% of required numbers. We shall continue to the full trial.

Progression criteria for women randomised to the intervention are:

- Red: Less than 50% of intervention group complete the intervention as intended (i.e. at least 4 sessions within the timeframe with before and after data) Consider stopping the trial with the Trial Steering Committee and NIHR.
- Amber: 50%-80% of intervention group complete the intervention as intended. Submit a rescue plan approved by the Trial Steering Committee outlining steps that will improve completion as intended.
- Green: 80-100% of intervention group complete the intervention as intended. Continue to full trial.

TRIAL SETTING

Multicentre: Women's prisons in England/Wales. 7-9 prisons will be recruitment and treatment sites and 3-5 additional prisons will be follow up sites only. A list of the participating sites can be found in the Master file and Site files. Research in prisons requires HMPPS National Research Committee approval (https://www.gov.uk/government/organisations/her-majestys-prison-and-probation-service/about/research) and Governor approval. We have provisional agreement from study prisons and HMPPS have agreed to facilitate access.

PARTICIPANT ELIGIBILITY CRITERIA

Trial Participants – Women in Prison

Inclusion criteria (as piloted in WORSHIP I and II)

- The participant is a remand or sentenced woman in prison who is on an ACCT currently or has been on an ACCT in the last 8 weeks. ACCT refers to the Assessment Care in Custody and Teamwork process which is used in prisons for self-harm monitoring and management. The ACCT process is started when women are at risk and often experiencing thoughts of self-harm. It is designed to target people who are at risk of self-harm repetition.
- The participant is a woman in prison who has self-harmed in the last month.
- The participant is 18 years or over. The intervention has been piloted with adults as women under 18 may have different needs.
- The participant has been screened for date of release or trial and has a minimum of 8 weeks left in prison, at baseline, to complete the intervention sessions

Exclusion criteria

- The participant is currently involved in another psychological intervention in the prison establishment which has aims that overlap with PIT, e.g. it is designed to address their distress or self-harm via a talking therapy approach or they are booked to start an overlapping therapy during the 12-week study period
- The participant lacks capacity to consent to research participation. This assessment will be made by experienced researchers in collaboration with prison staff and healthcare staff and will be based on the principles behind the Mental Capacity Act (2005).
- The participant is too distressed/unwell to participate in research. This decision will be based on consultation with Safer Custody/healthcare staff and their case manager and psychiatrist (if they have one). For example, women who are at a very high risk of suicide may be excluded as they will be too distressed to engage effectively with therapy.
- The participant currently poses a high risk to the researchers or the therapists. This criterion is only for people who pose an imminent risk of violence which would mean that the researchers/therapists are in danger of physical harm. People will be assessed based on their current risk rather than their past behaviours. Assessment will be made by the Safer Custody and OMU team in consultation with the researchers, the participants case manager, and mental health in-reach. Once the risk has subsided women may be eligible to participate if they fit the other criteria.

Staff Participants

Inclusion Criteria

- Have worked with women involved in the intervention.

Exclusion Criteria

- Staff with no experience working with women involved in the intervention will be excluded from participating**.**

TRIAL PROCEDURES

Following consent, the women prisoners will complete the Eligibility Form (designed to ensure the accuracy of the screening process) and the baseline measures (Demographic and Personal History Questionnaire; PriSnQuest; bespoke Mental Health History Form (Self-Report); bespoke Self-harm

History Questionnaire; bespoke Alcohol and Drug History Form (Self-Report); McLean Screening Instrument: Borderline Personality Disorder (MSI-BPD) ; BSS; BDI-II; BHS; RSE; WEMWBS) and the health economics measures (EQ-5D-5L; SF-12) with a research assistant or associate/CSO/research nurse. The bespoke Mental Health History Form (Self-Report) and the Bespoke Alcohol and Drug History Form will both be cross checked with information extracted from SystmOne. This combined approach shall be used to increase the accuracy of the information by ensuring that we are not relying solely on one information source. The research assistant or associate/CSO/research nurse will also complete the NOMIS Baseline Record Sheet using the prison database. This covers details of the participant's offence e.g. whether the offence was violent or non-violent, sentence (if applicable) and release date. To classify offences as violent or non-violent please refer to the Offence Classification Sheet.

Following the baseline assessments, participants will be randomised using an online randomisation system provided by the Clinical Trials Unit at Kings College London to PIT or usual treatment. Participants randomised to the intervention arm will receive 4-8, 50-minute sessions of PIT. The research assistant will share relevant baseline information with the therapists from the baseline questionnaires and database searches using the Background History of Participant Form. The number of therapy sessions will be determined by ongoing need, identified by the participants and agreed by the therapist.

The treatment will be provided on a weekly basis in a room in the prison's Safer Custody suite or an alternative private room within prisons that do not have a Safer Custody suite. If women are unable to leave the wing or are on segregation we will seek permission to complete the therapy/research measures in those locations. PIT will be delivered by qualified doctors training in psychiatry qualified psychiatrists, and third year trainee clinical psychologists or forensic psychologists. The treatment group will not engage in any other talking therapies which address their distress or self-harm during the intervention period. Participants randomised to usual treatment will continue to receive any treatments that are provided to them in the study prison. Details of the therapists delivering the intervention need to be entered into the Therapist Database. If the therapists finish their training during the research they will still be able to deliver therapy.

During the study period (12-weeks), all participants will complete a weekly diary and the Self-Harm Incidents' Log (Participants), alone, with a trusted peer, or with the research assistant. They will also complete the Concomitant Therapies Form with a research assistant. The diary will include any thoughts of self-harm that have occurred since the last diary date, and any life events which have influenced their self-harm (including the time spent outside their cell). The Self-Harm Incidents' Log (Participants) will include incidents of self-harm in the last week and the severity of the incidents of self-harm. The Concomitant Therapies Form will contain information on any new therapy that has been started during the study period. Information in the Self-Harm Incidents' Log (Participants), will be cross checked with information from prison records (e.g. self-harm incidents databases) and SystmOne using the relevant Self-Harm Incidents' Logs. Concomitant Medications will be recorded from SystmOne on the Concomitant Medications Form. If the participant is unable to provide the relevant details for the concomitant therapies this information will be checked using the relevant prison or healthcare databases. We shall also collect the dates and duration of time that women spent on a basic regime during the intervention period from NOMIS on the Basic Regime Data Collection Form.

At 8-weeks and 12-weeks, all participants will complete the secondary outcome measures (BSS; BDI-II; BHS; RSE; WEMWBS) and the health related quality of life scales (EQ-5D-5L; SF-12) and we shall record on the ACCT Status Form whether or not they are participating in the ACCT process.

If a participant is transferred part way through the research, we will seek permission from the receiving prison to complete the ongoing measures (e.g. concomitant medication) and the follow up measures. This will require local access to prison and healthcare databases. We will seek permission from the

participant in the consent process to contact their probation office / CRC for help to locate the women to try to complete ongoing and follow up measures.

We shall also collect resource use data using an adapted version of the Secure Facilities Service Use Schedule [32] developed by the research team (designed to capture any information pertinent to self-harm). Resource use data will be extracted by research assistants or associates/healthcare staff/prison staff. The resource use information can be found on a variety of prison databases and paper-based records. For example, NOMIS (for information such as contact with professionals from outside the prison), detail officer's logs (for time spent with staff), the F213 injury log and near miss forms (for constant observation and other responses to self-injury), in Safer Custody records and ACCT folders (for provision of alternative clothing), SystmOne healthcare records (for information on physical (e.g. wound) treatment and mental health input), the bed watch booklet (for information on bed watches) and the Alpha lists (for information on time on segregation). Resource use information is not recorded in the CTU database and needs to be entered onto the Resource Use Database.

Process evaluation interviews will be completed with 52-60 women prisoners (26-30 from the intervention group and 26-30 from the control group) at 10-weeks. 12-20 of these interviews will take place during the pilot and will be used to determine if there are any problems with participation which need to be addressed before the full-scale trial. In the full trial, interviews will be designed to explore the opinions of participants on PIT or TAU; and any problems they encountered in relation to implementation of the intervention in the prison. Staff process evaluation focus groups will be undertaken in all prisons (N=7; 8-12 participants per group) to explore their perceptions of TAU or PIT, for example, how they believe it affects the wellbeing of women in their care and any problems they encountered in relation to implementation of the treatment in their prison. We shall also complete process evaluation interviews with the research staff and therapists.

Recruitment

Participant Identification and screening

Trial Participants – women in prison

The Research Assistants or Associate/Research Nurses/CSOs/Safer Custody staff will screen prison records (e.g. on NOMIS; ACCT records (paper and databases); Detail Officer's Logs and Self-Harm Incidents Logs) to determine if the women prisoners are over 18, have been on an ACCT in the last8 weeks, have self-harmed in the last month and have at least 8 weeks remaining in the prison at baseline. The list of eligible women will then be reviewed by their Safer Custody/healthcare/OMU staff, and their case manager or psychiatrist if relevant, to determine with them whether the women are currently too distressed/unwell to participate in the research and whether the women pose a high risk to the researchers/therapists and should be excluded. The staff will also let the research team know if the women are currently undertaking any talking therapies or courses in the prison or due to start any during the study period. As part of the research the research team will be completing a full maping of all the current therapies/courses that women are offered within prison. This will involve telephone interviews using the TIDieR checklist [33] and interviews with prison and healthcare staff. This mapping will be completed by medical students or graduates. The research team will use information from this mapping to assess if the course/therapy overlaps with the aims of PIT and to publish the first review of therapy across all the women's estate. The mapping will include identifying talking therapies which are designed to affect the secondary outcome measures e.g. by improving well-being and self-esteem. Women who are already completing other therapies/courses which meet these criteria, or are due to start any during the study period, will be excluded although they will be eligible to take part once the other therapy has finished if they meet the inclusion and exclusion criteria. Eligible women will be invited to a meeting with a member of the research team who will describe the research and provide them with a participant information sheet and summary of the therapy. For women with low literacy, all written information will be read to them during this appointment and recorded so a member of the research team can witness

that the document was read in full. They will be given at least 48 hours to consider taking part in the research. Ideally, this screening will be undertaken by members of the research team since, in WORSHIP II, we found that staff often acted as 'gate-keepers' for recruitment; often trying to safeguard the research team against 'aggressive, troublesome or manipulative' women, which could cause bias in recruitment.

Following advice from the Confidential Advisory Group, we contacted senior members of HMPPS who are responsible for Information Governance and compliance with GDPR/Data Protection to seek approvals to legitimise our access to the database. This has resulted in a data sharing agreement being signed by the deputy director of Her Majesty's Prison and Probation Service. The agreement can be found in the Masterfile.

We shall keep a record of all ineligible participants including their age and ethnicity and the reason that they were ineligible for participation. We shall also keep a record of any women who refuse to take part following screening and the reason for refusal (when given). Re-screening of the ineligible women will take part at regular intervals (e.g. once every week) as participants' eligibility may change e.g. a participant's distress and risk to researchers may reduce. For women who consent to take part in the research, information on eligibility will be entered into the CTU database.

Publicity posters and leaflets will also be posted around each prison and adverts will be placed in prison newsletters/papers. We shall also explore with each prison whether it is possible for leaflets to be sent to all prisoners' cells including people who are on the segregation unit to ensure that everyone has an equal chance of participation. The research will be advertised on prison radio and at recruitment events in the prison. We shall approach Samaritan Listeners and women prisoners who work in Safer Custody for their help advertising the research to their peers. We shall also visit different locations in the prison to speak directly to staff and run coffee mornings/lunchtime 'meet and greets' to raise awareness of the research. All advertising will detail how the women can contact the research team to see if they are eligible to participate in the research. This method of recruitment will be used in addition to screening since prison records may not capture all people who have self-harmed in the last month due to some women hiding their self-harm from staff.

Staff Participants

We shall visit different locations in the prison to speak directly to staff, so they are familiar with the research and will run Coffee Mornings/Lunchtime 'meet and greets' to raise awareness of the research. Adverts and posters will be placed in areas of the prison that staff frequent with contact details, so they can hear more about the project. We will also send a global email to all staff advertising the research. We shall attend full staff briefings or other staff meetings and present the research to staff. Staff for the focus groups will be approached directly by members of the research team regarding participation. This may include face-to-face contact or emails.

Payment

To ensure that payment does not act as an incentive for involvement in the research, participants will not receive individual payment for taking part. Participants in the prison will receive a small token gift to thank them for their time. The gift will be decided in consultation with Safer Custody staff from the prisons and will include items such as toiletries. Women will be informed about this small gift in the participant information sheet. Each recruiting prison will receive a gift at the end of the research up to the value of £100. The nature of this gift will be decided in consultation with Safer Custody and will contain items for women in the prison such as books, art and craft materials. Released women will receive a £20 gift voucher if they meet the team to complete the follow up measures in the community. We shall also reimburse any incurred travel expenses. Details of this reimbursement have been intentionally omitted from the participant information sheet to avoid misleading participants in prison that they will receive any kind of payment for taking part in the research. Details of the gift voucher will only be provided to

participants who have agreed to be contacted in the community at the time they are contacted for follow up. We shall give women in the community a £20 voucher to compensate for the inconvenience of meeting with the researcher in their own time at a public location and for the time taken out of their day to complete the questionnaires. All the women will have consented to community follow up when they were in prison. The voucher will be used in lieu of payment for their time. The amount of the voucher was decided in reference to the amount we pay our experts-by-experience on the project (i.e. £10 per hour). This should cover the time taken to complete the questionnaires and travel time. We chose to pay the participants an equivalent amount to the experts-by-experience, so it compensates for the participant's time but does not mean that the participants are coerced into completing the follow up interviews.

Consent

Consent for participation in the research will be sought by the research assistants or associate/CSOs/research nurses associated with the project. All people who seek participants' consent will act in accordance with the study protocol, the principles of good clinical practice (GCP) and the Declaration of Helsinki. All people who are authorised to take consent will be recorded in the Delegation Log. Although initial screening will be carried out without prior consent, we will seek consent from the women prisoners to examine their prison and healthcare notes for all the additional data to be collected during to the research e.g. primary outcome data and resource use data. During the consent process we will collect contact details for the women in case they are released early from the prison, and shall seek to contact them via their probation office or their Community Rehabilitation Company (CRC). If the participant is released part way through the therapy, we will let their probation officer know about their involvement. We shall also seek the women's consent for a transfer hold to be enacted so they remain in the study prison during the intervention period. We shall seek consent to contact the women in another prison if they are transferred despite this. To ensure that the prison and healthcare staff are aware of their participation we shall seek consent to send a letter to the participant's prison GP and mental health team and record participation in the research in the participant's ACCT records and on NOMIS and SystmOne. We will also seek permission to tell the woman's personal officer that they are taking part in the research project and Safer Custody, healthcare and OMU staff. We shall also seek consent to add information about risk to their ACCT records, NOMIS and SystmOne and to discuss risk with relevant staff. This will include alerting healthcare to any undiagnosed mental illness which is revealed during the research interviews or therapy. These measures are necessary safeguarding and women who do not agree will be unable to take part in the research.

All participants will provide written informed consent before participation in any of the research procedures. A photocopy of this consent form will be added to the participant's medical notes along with a page outlining the study title, acronym, version number and date of the relevant PIS and the date that consent was obtained. These documents will also be given to the Forensic Team for secure filing.

The PIS will outline the participants' right to refuse participation without giving reasons. It will also explain to participants that they are free to withdraw at any time from the trial without giving reasons and without prejudicing any further treatment. At baseline, participants will be asked to provide consent for any data that has been collected up to the point of withdrawal to be used after withdrawal. If participants do not consent to this retention, all data will be destroyed. This will apply to all participants in the trial, however, staff in the focus groups will be informed that it may not be possible to destroy their data if they withdraw from the focus group.

The PIS and consent forms for the women prisoners taking part in the trial will outline that participation in the research will not affect the women's parole, the standard of care they receive in the prison or any other aspect of their life in prison in any way. It will also outline circumstances when the researchers/therapists will have a duty to disclose information to prison staff. The research team will be required to disclose the following information to all the relevant departments in the prison:

- Behaviour that is against prison rules
- Information that either indicates a risk or harm to yourself or others
- Information on undisclosed illegal acts or plans to commit a new
- crime
- Information that raises concerns about terrorism, radicalisation, or security.
- information about poor or unacceptable practices by prison staff or by an outside organisation

The team are also required to report information about risk of harm to self to healthcare/ mental health in-reach. Any risks identified will also be reported to the Trial Manager. Women will be encouraged to disclose these risks to staff themselves, if they do not want to do this, we will ask for permission to inform staff; if both options are refused, researchers will inform the prison without consent.

All participants will be made aware of these reporting requirements and if they do not agree to these disclosures they will not be able to take part in the research.

The PIS and all advertising materials will outline how participants can contact the research team to obtain further information about the trial.

Where a participant is required to re-consent or new information is required to be provided to a participant, the trial manager will ensure this is done in a timely manner. The trial manager's responsibility for informing the participants will be outlined in the Delegation Log.

Because of low literacy in prison, all women invited to participate in the trial will be offered the opportunity to have the PIS read aloud to them by a member of the research team. In these circumstances a witness will confirm that the information has been read out accurately.

Participants will only be included in the research if they have capacity to consent to involvement. Assessment of capacity to consent will be undertaken by the trained research assistants or associate/CSOs/research nurses in accordance with the principles of the Mental Capacity Act (2005) and in consultation with Safer Custody and healthcare staff (where necessary).

For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:

- understand the purpose and nature of the research
- understand what the research involves, its benefits (or lack of benefits), risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision.
- be able to make a free choice
- be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
- where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected

Where a participant is able to consent but later becomes incapacitated, the participant will be suspended from the study. If their capacity returns they will be given the opportunity to re-enter the study. When a participant is formally withdrawn from the study, by their own choice or due to ongoing incapacity, identifiable data already collected with consent will be retained and used in the study, if they consented to retention at baseline. No further data will be collected, or any other research procedures carried out, on or in relation to the participant.

Randomisation

Kings Clinical Trials Unit will build a randomisation system. Randomisation will be at the individual level by block randomisation with randomly varying block sizes, stratified by prison. The trial manager/RAs will access the randomisation system, randomise the participants and receive randomisation alerts and will inform the other researchers and the therapists of the allocation for each participant.

Blinding

Blinding of trial participants and care providers is not possible due to obvious differences between the interventions. It is not practical for the research assistants/research associate to be blind as they will need to coordinate the delivery of the therapy in their study prisons. The outcome assessors who collect the post intervention data (8-weeks) and follow-up data (12-weeks) will be blind to the intervention groups. Outcome assessors will include trained Research Nurses/CSOs/volunteers/peer mentors/ students. These outcome assessors will be security trained so they can enter the prison independently to complete their assessments and will have no other involvement in the research. The trial manager will ensure that outcome assessment takes place at a time and in a location of the prison which will avoid the assessors interacting with the RAs and therapists in a way that could reveal any participant's allocation. If a participant is transferred to a remote site which cannot be accessed by the outcome assessors, they will be followed up by a research assistant who is unaware of their randomisation status. E.g. the RA from London will follow up the RA from Manchester's participants.

Emergency Unblinding

Emergency unblinding should not be necessary as the investigators and therapists will not be blinded and will be able to respond to any serious adverse events in accordance with the protocol.

Baseline data

The following baseline data will be collected in a 1-hour interview with a research assistant/associate/research nurse/CSO:

- The Eligibility Form will be competed to double check that participants fit the inclusion/exclusion criteria
- The bespoke WORSHIP III Demographic and Personal History Questionnaire designed to collect baseline variables which may have an effect on the participant's self-harm, such as separation from children.
- The Prison Screening Questionnaire (PriSnQuest) [34] is a questionnaire developed to screen for possible serious mental illness within a criminal justice setting.
- The bespoke Mental Health History Form (Self Report) is designed to record people's mental health diagnoses and history, including previous contact with services, their past medication use, details about their most recent episode of self-harm, and previous support they have received for their self-harm (cross referenced with SystmOne).
- The bespoke Alcohol and Drug History Form (Self Report) designed to capture the participant's history of drug and alcohol use and any past treatment (cross referenced with SystmOne).
- The bespoke Self-Harm History Questionnaire details the types of self-harm women have used in the past, whether they have used these types of self-harm in prison, whether they have used

the types of self-harm in the last year and the frequency of each type of self-harm in the last year.

- MacLean Screening Instrument for Borderline Personality Disorder (MSI-BPD) [35], a questionnaire which assesses whether the person is displaying signs of BPD; a common diagnosis in women prisoners who self-harm [4].

- All secondary outcome measures (BSS; BDI-II; BHS; RSE; WEMWBS)

- The health economics measures (EQ-5D-5L; SF-12).

Trial assessments

- Participants will be asked to complete a weekly diary which assesses self-harm thoughts and life events which may affect people's self-harm, including the amount of time that the participant has spent outside their cell. The diary will be self-completed by the participant, with a peer mentor or completed with a research assistant.

- Participants will be asked to complete a weekly Self-Harm Incidents' Log (Participants) which will record acts of self-harm and the severity of these acts. The log will be self-completed by the participant, with a peer mentor or completed with a research assistant. This will be cross referenced with prison and healthcare records using the Self-Harm Incidents' Logs (prison and SystmOne).

- Participants will be asked to complete a weekly Concomitant therapies form. The forms will be completed with a research assistant. This will be cross referenced with prison and healthcare records, if necessary.

- The research assistant will complete the Concomitant Medications Log on a weekly basis using SystmOne.

- Post intervention assessments at 8-weeks will be collected during a 1-hour interview with a blinded outcome assessor and will include all secondary outcome measures (BSS; BDI-II; BHS; RSE; WEMWBS) and the health related quality of life measures (EQ-5D-5L; SF-12).
- The participant's ACCT status will be recorded by the research assistant.
- Participants randomised to receive PIT will be asked to complete the Therapy Satisfaction Questionnaire at 10 weeks with an unblinded member of the research team.
- We shall also collect from NOMIS the amount of time that each participant spent on a basic regime from baseline to 8 weeks.

Long term follow-up assessments

- Participants will be asked to complete a weekly diary which assesses self-harm thoughts and life events which may affect people's self-harm, including the amount of time that the participant has spent outside their cell. The diary will be self-completed by the participant, with a peer mentor or completed with a research assistant.

- Participants will be asked to complete a weekly self-harm incidents' log (participants) which will record acts of self-harm and the severity of these acts. The log will be self-completed by the participant, with a peer mentor or completed with a research assistant. This will be cross referenced with prison and healthcare records.

- Participants will be asked to complete a weekly Concomitant Therapies Form. The forms will be completed with a research assistant. This will be cross referenced with prison and healthcare records, if necessary.

- The research assistant will complete the Concomitant Medications Log on a weekly basis using SystmOne.

- Long-term follow up assessments at 12-weeks will be collected during a 1-hour interview with a blind outcome assessor and will include all secondary outcome measures (BSS; BDI-II; BHS; RSE; WEMWBS) and the health related quality of life measures (EQ-5D-5L; SF-12).
- The participant's ACCT status will be recorded by the research assistant.
- We shall also collect from NOMIS the amount of time that each participant spent on a basic regime from 8 weeks to 12 weeks.

Prison-level data collection

We shall collect the following information on the Prison-Level data collection form:

- The average amount of time that women spend outside their cells for each of the study prisons in one week
- Whether the prison provides an in-cell telephone service.

Qualitative assessments

12-20 individual interviews (6-10 from the control group and 6-10 from the intervention group) will be completed with pilot women at 10-12-weeks to determine if there are any issues or problems with participation which need to be addressed before the full-scale trial. These interviews are designed to help to inform the decision regarding progression, for example, if a rescue plan is necessary.

During the full-scale trial, process evaluation interviews will be completed with 40 women prisoners (20 from the intervention group and 20 from the control group) at 10-12-weeks. These interviews will be designed to explore the opinions of the participants on PIT or TAU and any problems they encountered in relation to the implementation of the intervention in the prison. Staff process evaluation focus groups will be undertaken in all prisons (N=7; 8-12 per group) to explore their perceptions of TAU or PIT, for example, how they believe it affects the wellbeing of women in their care and any problems they encountered in relation to implementation of the treatment in their prison.

We will invite the therapists, research assistants and the outcome assessors to take part in individual qualitative process evaluation interviews.

Withdrawal and termination criteria

Women will be removed from the research if they wish to withdraw e.g. if they are finding participation too distressing. All women who withdraw will be asked to provide a reason. In WORSHIP II we found that approximately 65% of the women were happy to disclose why they no longer wished to participate

(even though, ethically, they are not required to provide a reason). From these data, we might determine whether drop-out was as a result of prison factors e.g. transfer, release or their response to the therapy e.g. not feeling a benefit.

All adverse events will be recorded and discussed according to the process laid out in the standard operating procedures (described below). The research team will seek advice from the research management group, steering group, data management and ethics committee and prison regarding stopping the intervention with individual prisoners if an adverse event or serious adverse event is caused by participation in the research. Serious adverse events will also be discussed with the sponsor and, on advice, reported to the REC.

Any decision about a temporary halt or early termination of the research will be discussed by the research management group and steering group in the first instance. The rationale for the halting or early termination will be recorded in the project master file and site files and discussed with the sponsor. Discussion will involve consideration of follow-up measures, if any, that need to be taken for safety reasons.

If a decision is made to request a temporarily or terminal the trial, notification of the substantial amendment will be submitted for ethical review including follow up safety measures, if necessary. All other relevant bodies will be notified of any decision to halt or terminate, e.g. any healthcare providers, the prison and HMPPS.

TRIAL TREATMENTS

The health technology being assessed is Psychodynamic Interpersonal Therapy. Psychodynamic Interpersonal Therapy is a model, developed by Hobson (1985), which uses the client–therapist relationship as a tool for resolving interpersonal problems [11]. PIT differs from Interpersonal Therapy in that it is less focused on formal diagnosis, the concept of illness and symptom resolution [36]. Instead, the therapy ‘draws on traditional psychodynamic concepts like conflict, avoidance of painful feelings, and the re-enactment of problematic patterns of relating, acquired early in life, in current relationships’ [37]. The treatment focuses on two basic needs that are often in conflict: (i) the need for a coherent and positive sense of self; and (ii) the need to retain relatedness with other people, particularly attachment figures [37]. Both PIT and IPT have an interpersonal emphasis, are present focused and collaborative, however PIT uses distinct techniques designed to create a safe and trusting relationship that enables the client to tolerate their anxiety about recognising their 'hidden' feelings and help them to begin to accept them as part of their experience.

The PIT model stresses a strong working alliance; key features include staying with feelings, picking up cues and working in the ‘here and now’. The therapist assumes a negotiating style and is open to correction. The purpose is to engage the client in a conversation that moves slowly to deeper and deeper levels. The therapist aims to ‘develop a mutual feeling language that puts the client’s experiences into words in an emotionally vivid way’ [37]. Metaphor is used wherever possible to connect images to underlying feelings, for example, the metaphor of a ‘spring’ can be used to explore a client’s feelings of tension and frustration [38]. These metaphors are ‘designed to amplify feelings and expand the client’s understanding of them’ [37]. Statements are chosen instead of questions and are expressed in the form of hypotheses. These are cautious but informed guesses or interventions that the therapist makes about the client’s inner world. Many of the constituents are non-specific but together they form a definable therapy that is relatively easy to learn and understandable to clients [6].

The therapists in the research will be using an adapted version of PIT. The adaptation of the intervention, and its delivery, took place during WORSHIP I and II. Originally, PIT was a 4-session intervention which had been delivered to people in the community who repeatedly self-harm and attend A&E. In its original form, PIT is not designed to be either specific to women, or gender sensitive. Neither is it designed to

be used with prisoners who have complex histories including domestic abuse, sexual assault and childhood neglect. Any version of PIT delivered in prison needs to be mindful of the women's difficult histories and address problems specific to being incarcerated, such as loss of contact with their family or prison-based conflict.

Following consultation with women in prison and staff in WORSHIP I, the intervention training and supervision were adapted so they had more emphasis on our target group e.g. prison-specific case studies were used during the training, and supervision emphasised women's experiences of incarceration. During the PIT sessions with women prisoners, the therapists were encouraged to acknowledge the likely sources of trauma in women's lives both as precipitants, as well as maintaining factors in their self-harm. At the beginning of sessions, therapists specifically identified with clients such possible traumatic and triggering events; events which were considered particularly difficult for some of the prisoners to manage. For example, they discussed the links between being separated from children, being abused or perceived as abused by other prisoners, being frightened in the first night or first weeks of imprisonment and being isolated for long periods in cells alone as powerful potential triggers for self-harm.

A goodbye letter for the end of treatment was also developed and successfully piloted in WORSHIP II. The goodbye letter reviews why the client initially entered therapy and what they hoped to achieve. It describes the process and progress of this and how understanding and change were achieved as well as describing areas of 'stuckness'. It details how the relationship developed and how this and other aspects might have contributed to change. The letter highlights deepened and new understandings as well as obstacles that became apparent. Additionally, the content includes the on-going impact of therapy once it is finished and how the client can hold on to the positive aspects and remain mindful of the relational pulls and patterns that might get in the way of progress. It strongly attempts to validate the multiple experiences in therapy. It names or lists aspects that have been identified to help or provide some alternative relief from the previously established problematic patterns. WORSHIP II showed that these letters were a useful tool in PIT for imprisoned women and might help to sustain the positive benefits of therapy long after it has finished [39]. The intervention delivery will also account for the possibility that women may suddenly leave therapy before completion, for example because of transfer or release. In each session, the therapist recognised and acknowledged with women the possibility that it could be their last session.

PIT will be delivered by qualified doctors training in psychiatry, qualified psychiatrists, and third year trainee clinical psychologists or forensic psychologists. Studies show that PIT can be used by trainee therapists with the support of senior supervision. They can be taught to use it quickly and easily [40]. All the trainees who deliver PIT will already have experience working with vulnerable women since the clinical psychology trainees will have completed at least 2 years training prior to their involvement in the research, the forensic psychology trainees and qualified therapists will already be working within the prison system or will have two years clinical experience, and the psychiatry trainees are fully qualified doctors training to be consultant (often forensic) psychiatrists. All therapists will attend a bespoke, two-day, face-to-face training course in PIT with prison-specific elements and will be tested for PIT competence at the end of the training using an observed role play. Training will be delivered by experienced trained psychiatrists/psychologists including the CI. Treatment competency and adherence will be monitored by weekly or fortnightly supervision from an experienced psychiatrist or clinical/forensic psychologist. In WORSHIP II, we found that a flexible supervision model worked well with therapists being able to choose between individual face-to-face sessions, groups supervision or supervision via Skype, depending on preferences and availability. This form of supervision was also approved by The Royal College of Psychiatrists. All therapists will receive weekly or fortnightly supervision lasting 30-60 minutes. Therapists will also be provided with a PIT therapy manual, a summary of the PIT model, guidance on structuring their sessions, ingredients for the goodbye letters and a template to complete at the end of the therapy to add to the participant's SystmOne notes so the outcome of the therapy can

be shared with the healthcare team. The outcomes of the therapy will also be shared with the forensic team, with the women's consent. Participants will still be able to take part in the intervention if they refuse to share the outcomes with the forensic team.

All therapy sessions will be digitally recorded so the therapist can review their sessions and share details of their sessions with their supervisor. The sessions will only be recorded with the consent of the participant. The first therapy session recording for each PIT participant will be reviewed by an independent PIT rater to test for adherence to the PIT model. If the review of the first session demonstrates difficultly with PIT compliance the independent rater will also review the fourth session. We shall also test adherence to the PIT manualised treatment and therapist competency by purposefully selecting 10% of the PIT participants' recordings for assessment (n=13, 10% of the 132 people randomised to PIT). Purposive sampling will ensure that recordings from all of the prisons are scrutinised as well as recordings from a range of therapists from different professional backgrounds. The recordings will be reviewed by an independent assessor with PIT training using a standardised adherence/competency scale [41]. For each PIT participant's recordings, we will rate the first and fourth session in the therapy. The selected recordings will also be blindly assessed by a member of the research team who is competent in PIT to test for consistency. The majority of the rating will take place in the pilot to ensure that we identify any problems with adherence and competence early on. Therefore, we will rate 8 participants' PIT recordings in the pilot and 5 in the main study. In addition to the supervision, we shall set up a private WhatsApp group for the therapists to discuss their experiences remotely with their peers. At the end of their time with the research team all the therapists will complete the Supervision Satisfaction Questionnaire. Some participants may be uncomfortable completing therapy with a male therapist. In these circumstances they will be able to request a female therapist.

Delivery by trainees is advantageous for several reasons. A trainee model helps to reduce NHS excess treatment costs; develops capacity within the psychotherapy workforce and increases the availability of PIT. To ensure that the intervention can be successfully implemented following the research period, we need to provide a model of delivery that is low cost, scalable and sustainable. Trainee delivery costs significantly less than delivery by a consultant psychiatrist or a fully trained clinical psychologist and, once the infrastructure is in place, trainee placements can continue to be offered in the study prisons and expanded to the other prisons in the women's estate.

The control group will receive the usual treatment available in their study prison. We shall record all interventions each participant in the control group receives during the intervention period. We shall also request details of the content of the interventions from each prison, in our mapping, to assess whether they contain elements which are specifically designed to address distress or reduce rates, severity or thoughts of self-harm.

To gain an understanding of usual treatment, we conducted a brief informal mapping of Safer Custody and healthcare delivery across the Women's Estate. We found that most prisons have prisoners who are trained as listeners by a local branch of the Samaritans. The listeners are available 24/7 and can provide a confidential listening service to women in distress, including those who are at risk of self-harming. Constant supervision, hourly checks and half hourly checks are also used to manage women who are identified as being at high risk of self-harm; sometimes this involves placing the prisoners in a cell with a Perspex or transparent door. Distraction packs, to help women manage self-harm thoughts, are supplied in over half of the women's prisons; these vary in quality but tend to include colouring books, puzzles and stress balls. There are also bespoke schemes run through Safer Custody in different prisons. For example, HMP New Hall runs a Wellbeing programme which allows Safer Custody staff to spend additional time with high-risk women. HMP Bronzefield carries out a similar programme in the form of a 1-to-1 support service. HMP Send run a Wellbeing programme via the gymnasium which aims to give prisoners an outlet to deal with their problems through exercise. HMP Askham Grange, HMP Drake Hall and HMP Low Newton all have a designated space that women can use when they are feeling particularly anxious, in the form of a Calm room, Care room and Sensory room, respectively.

In terms of healthcare interventions, provision ranges from low-intensity talking therapy to complex psychiatric interventions. Most of the prisons offer Cognitive Behavioural Therapy (CBT), trauma-focused approaches and group-based therapies although they are unlikely to be specifically targeted for self-harm. Dialectical Behavioural Therapy or DBT informed-therapy is offered in at least seven prisons. DBT is designed for treatment of borderline personality disorder but contains elements which are specifically targeted at self-harm. Two prisons provide specialised services for women with personality disorders, e.g. the 'Options' service at HMP Downview, which delivers DBT, and the 'ADAPT' team at HMP Styal. ADAPT is part of the Offender Personality Disorder (OPD) pathway which is aimed at offenders with severe personality disorder who pose a high risk of harm to others or of reoffending in a harmful way [42]. One of the main aims of the ADAPT team is to increase the confidence and competency of a wide range of prison and partner agency staff to support women who have personality difficulties to improve their psychological health and wellbeing and reduce reoffending. The ADAPT team, therefore, works closely with staff (rather than providing individual or group therapy for women) and provides training, supervision and reflective practice for prison staff, as well as joint development of formulations involving prisoners and staff. The model of the ADAPT service is that of mainly psychologically-informed consultation, support and liaison with prison staff of all grades and disciplines. Various other initiatives are offered in individual prisons e.g. the 'Reader Project' in HMP New Hall which uses approved texts to open discussion about emotion, self-esteem, talk about death and grief, whilst building women's confidence and literacy skills. None of the treatments that are currently run in prison has been modified to be targeted at self-harm and its underlying problems specifically; and none has been formally evaluated; let alone using an RCT design. All prison-based initiatives depend on availability of trained staff and are currently under-resourced [7].

ADVERSE EVENTS

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant including occurrences which are not necessarily caused by or related to the intervention or research.
Adverse Reaction (AR)	An untoward and unintended response in a participant. In this case, this refers to adverse reactions to the research and adverse reactions to the therapy. The phrase "reaction to the research or therapy" means that a causal relationship between an intervention/research and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out. All cases judged by either the CI or the Sponsor as having a reasonable suspected causal relationship to the intervention or research qualify as adverse reactions.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires an admission to hospital or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect

	Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the intervention or research, based on the information provided.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A serious adverse reaction which was unexpected,

Operational definitions for AEs

The WORSHIP III study investigates the use of PIT with vulnerable high-risk women in prison who self-harm. WORSHIP III not only undertakes research in a high-risk environment, but also may recruit women in prison very early into their admission to a prison. Both these factors mean our participants are likely to self-harm in the context of the study period and self-harm is our primary outcome. In the context of this study, therefore, self-harm is an expected event. As such, we do not necessarily consider that self-harming behaviour represents an adverse event. A number of complex intersecting variables are associated with risk of an individual undertaking self-harming behaviour. All of our participants are women who have very recent histories of self-harming behaviour in response to life circumstances. Therefore, to determine whether an incident of self-harm needs to be investigated and reported during the study we follow the procedure outlined below.

Adverse Events Process

Each participant's personal officer, Safer Custody, healthcare and the OMU will be informed that the participant is taking place in the study. They will be asked to report any changes to a participant's self-harm behaviour to the research team. Changes may include increased frequency of self-harm, a change in the method of self-harm (e.g. to a more risky type) and undertaking self-harm that: results in death; is life threatening; requires an admission to hospital or prolongation of existing hospitalisation; results in persistent or significant disability or incapacity; or is medically significant, i.e. requires intervention to prevent any one of the above outcomes. The research assistant will also be monitoring the participant's self-harm on a weekly basis and can alert the trial manager if they notice any changes in the self-harm behaviour.

Prison and healthcare staff will also be asked to report to the team any non-self-harm adverse events. The research assistant will also ask the participants each week if they have experienced any new health problems, aside from self-harm incidents, so they can be investigated to see if they are adverse events. These adverse events will be recorded on the paper Adverse Events Form Not Self-Harm and entered into the CTU database Adverse Events Log.

If a research assistant is notified of an Adverse Event, or they identify an Adverse Event, they must notify the trial manager immediately (or a nominated proxy if the trial manager is on leave). All adverse events should be recorded in the Adverse Events Reporting spreadsheet. All adverse events that are

self-harm will be recorded on the Self Harm Adverse Events Log and entered on the Self-harm Incident's log on the CTU database. They should be recorded in the participants SystmOne medical notes and on NOMIS.

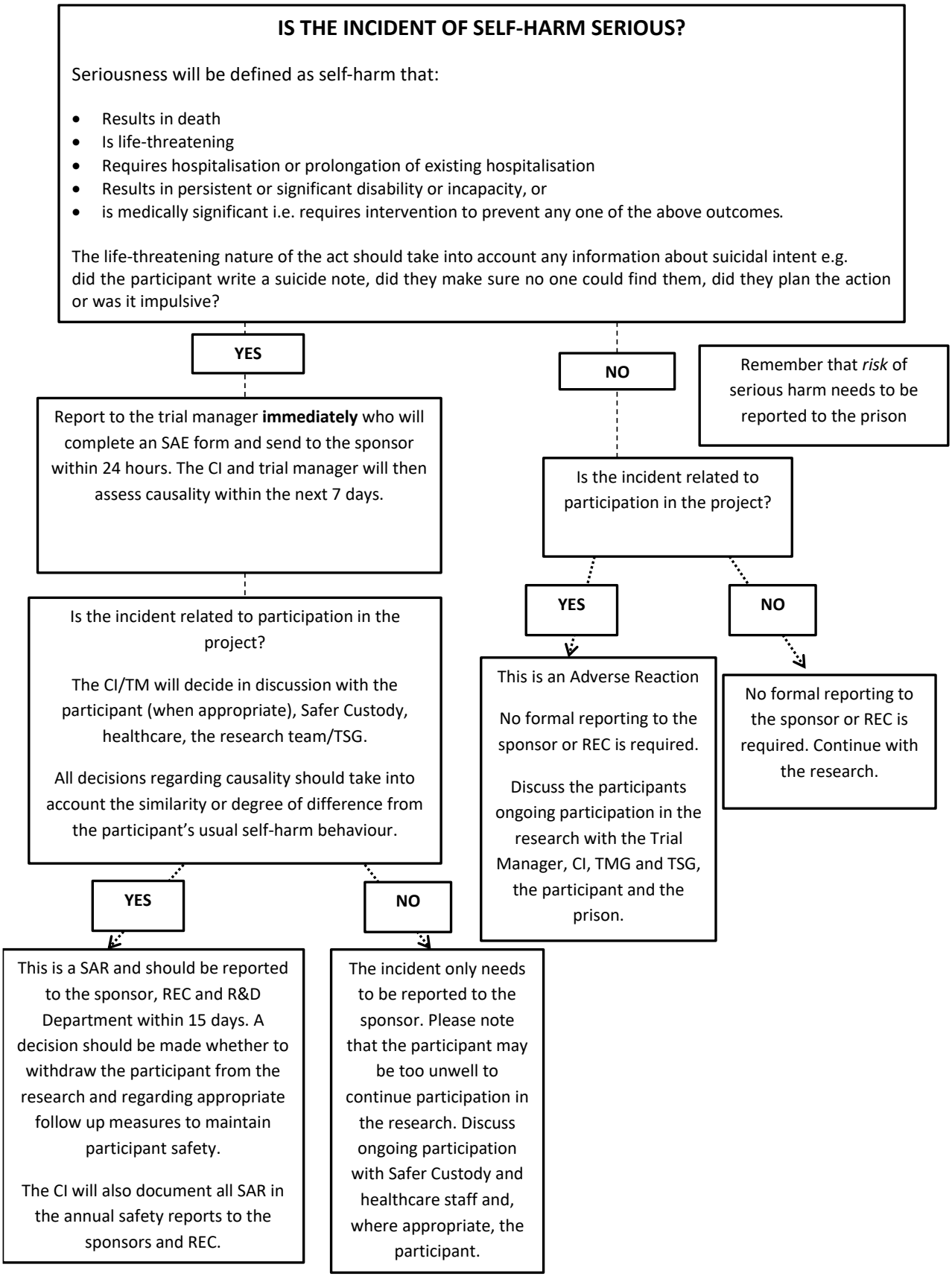
The trial manager (together with the PI/Co-PI) will need to determine the severity of the self-harm AE. The term "severe" is often used to describe the intensity (clinical severity) of a specific event. This is not the same as "serious", which is a regulatory definition based on patient/event outcome. For example, a headache may be severe but not serious, while a minor stroke is serious but may not be severe. Example criteria for grading severity:

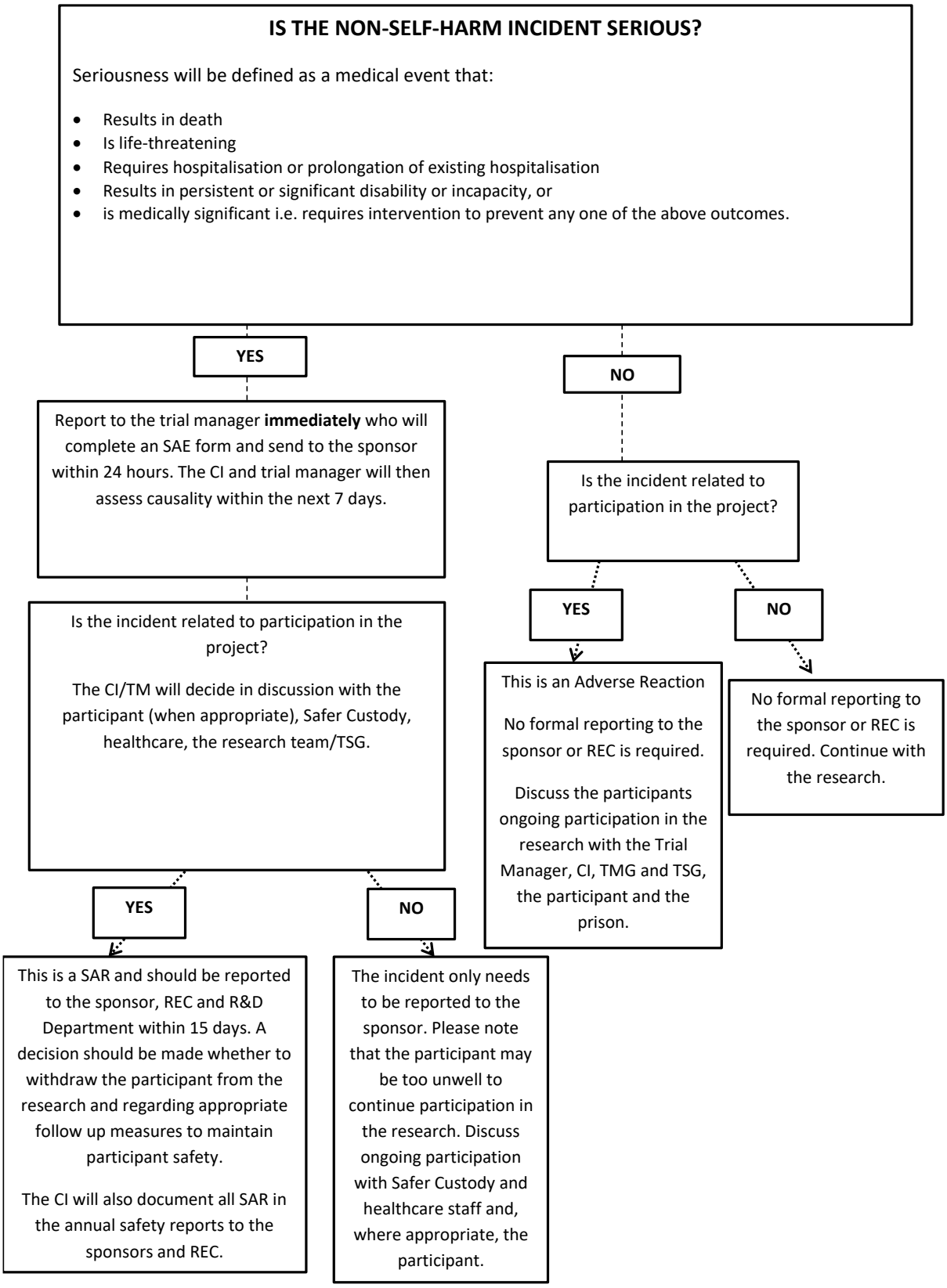
- Mild: asymptomatic or mild symptoms, diagnostic observations only, no intervention indicated. Not interfering with everyday activities/functioning.
- Moderate: an event that is sufficiently discomforting to interfere with normal everyday activities. Minimal, local or non-invasive intervention indicated.
- Severe: an event that prevents normal everyday activities. Medically significant but not immediately life-threatening. Admission to hospital or prolongation of hospitalisation indicated.

The adverse events procedure is the responsibility of the trial manager in consultation with the PI.

All AEs will be investigated to see if they are an AR, a SAE, a SAR, or a SUSAR. All Serious Adverse Events will be reported on the Incidents Response Form (following investigation these events may be reclassified as SAR or SUSARs which have additional reporting requirements). We will use the flow charts below to aid with the classification and reporting of Adverse Events for Self-Harm and Non-Self-Harm.

If a participant is transferred during the study, we will contact staff at the receiving prison and ask them to report any potential adverse events to the research team. If women are released, we will send them a letter asking them to contact us if they experience any adverse events.


IS THE INCIDENT OF SELF-HARM SERIOUS?
Seriousness will be defined as self-harm that:
Results in death
Is life-threatening
Requires hospitalisation or prolongation of existing hospitalisation
Results in persistent or significant disability or incapacity, or
is medically significant i.e. requires intervention to prevent any one of the above outcomes.
The life-threatening nature of the act should take into account any information about suicidal intent e.g. did the participant write a suicide note, did they make sure no one could find them, did they plan the action or was it impulsive?
YES
NO
Remember that risk of serious harm needs to be reported to the prison
Report to the trial manager immediately who will complete an SAE form and send to the sponsor within 24 hours. The CI and trial manager will then assess causality within the next 7 days.
Is the incident related to participation in the project?
YES
NO
This is an Adverse Reaction
No formal reporting to the sponsor or REC is required.
Discuss the participants ongoing participation in the research with the Trial Manager, CI, TMG and TSG, the participant and the prison.
No formal reporting to the sponsor or REC is required. Continue with the research.
Is the incident related to participation in the project?
The CI/TM will decide in discussion with the participant (when appropriate), Safer Custody, healthcare, the research team/TSG.
All decisions regarding causality should take into account the similarity or degree of difference from the participant's usual self-harm behaviour.
YES
NO
This is a SAR and should be reported to the sponsor, REC and R&D Department within 15 days. A decision should be made whether to withdraw the participant from the research and regarding appropriate follow up measures to maintain participant safety.
The CI will also document all SAR in the annual safety reports to the sponsors and REC.
The incident only needs to be reported to the sponsor. Please note that the participant may be too unwell to continue participation in the research. Discuss ongoing participation with Safer Custody and healthcare staff and, where appropriate, the participant.


IS THE NON-SELF-HARM INCIDENT SERIOUS?
Seriousness will be defined as a medical event that:
Results in death
Is life-threatening
Requires hospitalisation or prolongation of existing hospitalisation
Results in persistent or significant disability or incapacity, or
is medically significant i.e. requires intervention to prevent any one of the above outcomes.
YES
NO
Report to the trial manager immediately who will complete an SAE form and send to the sponsor within 24 hours. The CI and trial manager will then assess causality within the next 7 days.
Is the incident related to participation in the project?
YES
NO
This is an Adverse Reaction
No formal reporting to the sponsor or REC is required.
Discuss the participants ongoing participation in the research with the Trial Manager, CI, TMG and TSG, the participant and the prison.
No formal reporting to the sponsor or REC is required. Continue with the research.
Is the incident related to participation in the project?
The CI/TM will decide in discussion with the participant (when appropriate), Safer Custody, healthcare, the research team/TSG.
YES
NO
This is a SAR and should be reported to the sponsor, REC and R&D Department within 15 days. A decision should be made whether to withdraw the participant from the research and regarding appropriate follow up measures to maintain participant safety.
The CI will also document all SAR in the annual safety reports to the sponsors and REC.
The incident only needs to be reported to the sponsor. Please note that the participant may be too unwell to continue participation in the research. Discuss ongoing participation with Safer Custody and healthcare staff and, where appropriate, the participant.

Recording and reporting of SAEs and SARs

All SAEs occurring from the time of written informed consent until 60 days post cessation of trial treatment must be recorded on the Incident Response Form and emailed to the Sponsor within 24 hours of the research staff becoming aware of the event. Once all resulting queries have been resolved, the finalised Incident Response form should be posted to the sponsor and a copy to be retained on site.

For each SAE the following information will be collected:

- Full details (including all medical terms and the body system affected) and case description
- Event duration (start and end dates, if applicable)
- Severity
- Causality (i.e. relatedness to intervention), in the opinion of the investigator
- Category of seriousness
- Action taken
- Outcome of any action taken
- Whether the event would be considered anticipated.

Any change of condition or other follow-up information should be emailed to the Sponsor as soon as it is available or at least within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached.

Following investigation, the SAE may be reclassified as SAR or SUSAR which have additional reporting requirements. All SARs will be reported to the Sponsor, HRA and R&D department and REC within 15 days. If the event is a SUSAR reporting needs to be completed within 7 calendar days.

GMMH Trust SOP will be used to report any adverse events from the trial therapy. A Steering Group set up for management of the trial and the DMEC will regularly review issues for any trends to safeguard study participants. Any issues will be reported using Trust DATIX system for escalation and management.

Responsibilities

Principal Investigator (PI) and trial manager will be responsible for:

1. Investigating all AEs and ARs assigning seriousness and causality and providing an opinion on whether the event/reaction was anticipated
2. Ensuring that SAEs, SARs and SUSARs are recorded and reported to the relevant organisations (e.g the sponsor, REC, and HRA) in line with the requirements of the protocol, the Trust, the REC, and the HRA.
3. Central data collection and verification of AEs, ARs, SAEs and SARs according to the trial protocol onto a database and recording the AEs, ARs, SAEs and SARs in the Master File.
4. Reporting safety information to the independent oversight committees identified for the trial (Data Monitoring Committee (DMC) and / or Trial Steering Committee (TSC).
5. Instigating safety measures in response to AEs, SAEs, ARs, SARS, and SUSARs.
6. Quarterly review of all adverse events occurring in the study to identify any trends and reporting to the Sponsor and DMEC/TSG as appropriate.
7. Reporting adverse events to the research assistant or healthcare team so they can record the details of the adverse events in the participants medical records (e.g. how the adverse event was identified, date and time, duration (if ended), severity, treatment, outcome, and any action re the therapy (if appropriate).

Trial Steering Committee (TSC):

In accordance with the Trial Terms of Reference for the TSC, periodically reviewing safety data and liaising with the DMEC regarding safety issues.

Data Monitoring and Ethics Committee (DMEC):

In accordance with the Trial Terms of Reference for the DMEC, periodically reviewing overall safety data, provided as interim reports, to determine patterns and trends of events, or to identify safety issues which would not be apparent on an individual case basis.

Notification of deaths

Deaths should be reported to the sponsor immediately.

Reporting urgent safety measures

If any urgent safety measures are taken the CI/Trial Manager/Sponsor shall immediately telephone the REC, and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC of the measures taken and the circumstances giving rise to those measures.

STATISTICS AND DATA ANALYSIS

Sample size calculation

An opportunity sample of 264 women will be recruited to the research. The sample size is powered to detect a minimal important clinical difference of 33% reduction in self-harm incidents over 8 weeks. This clinically significant difference is based on Hawton et al's systematic review of the efficacy of psychological and pharmacological interventions designed to reduce self-harm repetition [43]. From MOJ prison data, the average number of self-harm episodes over 8 weeks in the control group was 6.65 [3]. We modelled this with a Poisson distribution (mean and variance=6.65) and used Monte Carlo simulations with 1000 simulations to estimate the power for a range of sample sizes, with power defined as the proportion of estimated p-values less than 0.05 for null hypothesis testing (treatment effect is 0), against an alternative hypothesis (33% reduction in the log of the outcome). With 5% significance, to obtain 90% power, we will require 105 per group for the primary analyses. Based on WORSHIP II [6] we estimate 20% attrition so will recruit 132 per group at baseline. This level of attrition is not expected in the primary outcome, due to availability of prison data and the fact that self-reported incidents will be measured on a weekly basis, but allows for attrition in the secondary outcomes.

We expect that there will be several potential therapists because we are using trainees as well as qualified professionals. This means that each therapist will see a small number of participants each (mean≈6.6). In turn, we expect that the ICC will be small (though no estimates are available to inform our calculations), and since the number of participants per cluster is also small, the corresponding design effect indicates a small increase to the sample size would be required to take into account this clustering. We anticipate that this will be balanced by accounting for baseline prognostic factors in our statistical models, and that 90% power will be maintained with lower than 20% attrition rate for the primary outcome. We shall include a random effect for each therapist within the statistical analysis models.

Planned recruitment rate

The predicted figures have been calculated based on the number of women who will pass through each of the prisons, depending on their size and the recruitment rate achieved in WORSHIP II. The predicted figures (confirmed by HMPPS) are calculated as follows:

There are ~3895 women in prison at any one time. Of these women, the following estimated numbers are in each of the study prisons (based on published MOJ statistics [44], except Bronzefield which is based on figures provided by the prison as the MOJ figures were published before the closure of Holloway) and each prison contains the following percentage of the prison population (prison capacity/total capacity of the women's estate x 100):

	Number of Women	**Percentage of the prison population**
Styal	**486**	**12.47%**
New Hall	**425**	**10.91%**
Bronzefield	**640**	**16.43%**
Send	**282**	**7.24%**
Downview	**355**	**9.11%**
Eastwood Park	**442**	**11.34%**
Foston Hall	**344**	**8.83%**

~9000 women pass through prison each year [17]. Given the capacity of the study prisons we can predict that the following number of women will pass through the study prisons in 1 year (total number of women who pass through prison x proportion of the prison population in the individual prison:

Styal (9000 x 0.1247)	**1122**
New Hall	**982**
Bronzefield	**1479**
Send	**652**
Downview	**820**
Eastwood Park	**1021**
Foston Hall	**795**

WORSHIP II recruited 28 people in 6 months across 3 prisons with approximately 1450 women passing through during that time. From this, we can anticipate a recruitment rate of 2%. Based on this recruitment rate, in the 6-month pilot (with 3 months follow up) we can recruit:

Styal (1122/12 x 6) x 0.02	**11**
New Hall	**10**
Bronzefield	**14**
Downview	**8**
Total	**43**

The intervention period will last for 24 months (21 months recruitment and 3 months follow up). This means that during the intervention periods we should be able to recruit the target of 221 additional people based on the following recruitment calculation for each prison:

Styal (1122/12 x 21) x 0.02	39
New Hall	34
Bronzefield	52
Send	23
Downview	29
Eastwood Park	35
Foston Hall	29
Total	241

The predicted figures were calculated for 7 research sites, however, we will be seeking permission for 9 sites to be main study sites in case we encounter any problems in the study prisons and need to add an additional site a short notice. If we only include 7 sites in the research some of the prisons listed above may be replaced with other prisons. For the list of Currently Active Prisons please see the Masterfile.

Summary of baseline data and flow of patients

Index Offence	Violent
	Non-Violent
Prison Status	Sentenced
	Remand
Sentence Length	Mean, SD
Ethnicity	White
	Mixed
	Asian
	Black
	Other
Marital Status	Single, never married or civil partnered
	Married, civil partnered or in a relationship
	Separated, divorced or widowed, including from civil partner
Receive Visits	Yes
	No
Children	Yes
	No
Number of Children	Mean, SD
Location of Children	With family
	In care

	Living independently
	Other
	Unknown
Age Participant left School	Mean, SD
Past experience of a care placement	Yes
	No
Past experience of being on ‘at risk’ register	Yes
	No
Past experience of parental neglect	Yes
	No
Past experience of domestic violence	Yes
	No
Past experience of sexual abuse as a child	Yes
	No
Past experience of sexual abuse as an adult	Yes
	No
Past experience of prison	Yes
	No
Past psychological treatment for drug addiction	Yes
	No
Past psychological treatment for alcohol addiction	Yes
	No
Past medication for drug addiction	Yes
	No
Past medication for alcohol addiction	Yes
	No

Number of times in prison	Mean, SD
Past experience of Schizophrenia	Yes
	No
Past experience of Depression	Yes
	No
Past experience of Anxiety	Yes
	No
Past experience of Bipolar disorder	Yes
	No
Past experience of Personality Disorder	Yes
	No
Past experience of Obsessive Compulsive Disorder	Yes
	No
Past experience of Post-Traumatic Stress Disorder	Yes
	No
Past experience of Eating Disorder	Yes
	No
Past contact with psychiatric services	Yes
	No
Age of first contact with psychiatric services	Mean, SD
Past admission to a mental health unit	Yes
	No
Number of psychiatric admissions	Mean, SD
Past experience of detention under the Mental Health Act	Yes
	No
Number of mental health admissions under the Mental Health Act	Mean, SD
Longest Hospital Admission	Mean, SD
Past medication - Antidepressants	Yes
	No

Past medication – Antipsychotics	Yes
	No
Past medication – Anti-anxiety	Yes
	No
Past medication – Mood stabilisers	Yes
	No
Age of first self-harm	Mean, SD
Past hospitalisation for self-harm (mental health hospital)	Yes
	No
Past hospitalisation for self-harm (general hospital)	Yes
	No
Number of self-harm hospital admissions	Mean, SD
Past talking therapy for self-harm	Yes
	No
Number of different types of self-harm in the past	Mean, SD
MIS-BPD	Mean, SD

Following CONSORT principles, we shall report all participant flow.

Statistical analysis plan

Analyses of the quantitative data will use an intention-to-treat (ITT) approach with analysis of randomised participants, regardless of non-compliance with protocol. Analyses will post-date final follow-up assessments, with consideration of potential biases from loss to follow-up. The primary outcome (number of incidents of self-harm at 8 weeks) will be analysed using a mixed Poisson model that adjusts for pre-specified baseline covariates and includes a random effect for therapist (since there are multiple therapists per site).

Secondary outcomes will be analysed using a linear mixed model over all repeated measures. Time will be included as a categorical factor, as well as a time*treatment interaction. We will estimate the effect at 8 and 12 weeks separately and report these as an adjusted mean difference.

We can explore possible subgroup effects (particularly around ethnicity, see above) using a treatment by covariate interaction in the fixed part of the model. We are not powered to detect significant interactions and are not currently pre-specifying any potential subgroups.

As secondary analyses, we shall explore a dose-response relationship using randomisation as an instrumental variable for number of sessions received. If there are significant effects on secondary outcomes which are also potential mechanisms (e.g. hopelessness, self-esteem), we shall perform a mediation analysis to test if these account for any observed treatment effects on the primary outcome using causal mediation approaches.

The sensitivities of all treatment effect estimates to missing outcome data will be explored; these models will explore the robustness of the treatment estimates to whatever small amount of missing data there is. The main analysis will use all available data that we believe are valid under the assumption of missing at random. We shall then use a suite of sensitivity analysis to explore the robustness of the primary analysis to departures from assumptions, including all randomised participants. If required, sensitivity analyses will include multiple imputation, and imputing a range of values for missing data under missing not at random assumptions.

Qualitative Analysis

Qualitative data will be analysed using framework analysis following the methods set out by Gale et al (2013) [45]. Framework analysis is designed to be used in applied policy and health research which has highly focused aims and structured topic guides [46]. The approach seeks to systematically identify commonalities and differences within qualitative data sets, examining the relationship between different parts of the data, and resulting in descriptive or explanatory conclusions clustered around themes [45]. In Framework Analysis, the researchers develop a matrix which is used to code the data in a structured manner. The matrix approach enables researchers to compare and contrast data across participants and within the individual participant's account [45]. It is particularly useful when a multi-disciplinary team are working on the analysis and facilitates constant comparative techniques across large data sets [45]. The analysis will be completed in NVivo using their framework matrices facility. Following familiarisation with the data at least two researchers will independently code and categorise the first few transcripts. They will then meet and compare codes so they can develop a working analytic framework. The framework is then applied to subsequent transcripts using existing categories and codes. Each category will contain an 'other' code to avoid ignoring data that does not fit with the working framework [45]. Data is then charted into a matrix by summarising the data by category from each of the transcripts. Memos are used to record interpretations of the data throughout the charting stage. Following charting, interpretation of the full data set involves interrogation of theoretical concepts, mapping connections between categories and exploring explanations for emerging phenomena.

In assessing the quality of the qualitative data that will be collected in this study, several factors will be considered. Credibility or confidence in the data will be gained by the research teams prolonged engagement with the data [47]. We shall use the following methods to ensure credibility: i) Triangulation ii) Respondent validation iii) Transparency & reflexivity iv) Generating & assessing alternative explanations/conclusions v) Highlighting negative or discrepant information.

Consistency will be maintained by keeping an audit trail and this will involve asking colleagues not involved in the study to check over the research team's decision and analysis processes. Transferability (neutrality) will be evaluated by providing the raw data to a colleague so they are able to interpret how

themes have emerged. Lastly, dependability will involve showing that the findings are consistent and could be repeated. The team comprises several researchers with extensive qualitative experience.

Economic evaluation

Measures

- A bespoke resource use collection tool adapted from the SFSUS and refined in consultation with prison staff.
- **EQ-5D-5L [48]:** a generic preference-based measure covering five domains of health-related quality of life (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Test-retest reliability is high and ranges from 0.78 to 0.87, with convergent validity at 0.64 [49].
- **SF-12:** a shortened version of the SF-36 [50], consisting of twelve questions covering eight dimensions of health: physical functioning, role limitations - physical, bodily pain, general health, vitality, social functioning, role limitations - emotional, and mental health. Test-retest reliability ranges from 0.76 to 0.89 and relative validity ranges from 0.43 to 0.93 [49].

The within trial economic analysis will estimate incremental cost-effectiveness of PIT versus TAU to evaluate whether implementation represents cost-effective use of NHS resources at NICE's £20,000 – 30,000 per quality-adjusted life year (QALY) threshold. For the primary analysis, the UK social tariff will be applied to completed EQ-5D-5L health state profiles to estimate QALYs gained between baseline and follow-up using the area under the curve method. Following collection of health and service usage using the adapted version of the SFSUS form, incremental costs per QALY gained will be estimated. Intention-to-treat analyses and bootstrapping will be used to calculate uncertainty around estimates.

Secondary analysis will use the SF-6D, derived from the SF-12, to calculate the incremental cost-per-QALY using this alternative measure of health-related quality of life (HRQoL). The incremental cost per self-harm incident averted will also be calculated.

A preference-based measure of HRQoL is needed to calculate QALYs for use in the cost-effectiveness analysis. The EQ-5D and SF-12 were selected as they are two of the most commonly used generic preference-based measures (Brazier et al. 2014). Whilst the EQ-5D is the measure preferred by NICE, there is concern as to whether it is appropriate for use in people with mental health problems [51]. In situations where there is doubt over the content validity of the EQ-5D, NICE suggest that an alternative HRQoL measure may be used.

Given the lack of evidence concerning the appropriateness of the EQ-5D for the population under study, we have opted to also collect the SF-12. The measure will not be refined in the pilot. Instead, the EQ-5D will be used as the primary outcome in the cost-effectiveness analysis, with a sensitivity analysis performed using the SF-12 (converted to the SF-6D) to examine the influence of parameter uncertainty on our estimates.

We shall examine the levels of missing data and correlation between changes from baseline to follow-up for both HRQoL measures with the other primary and secondary outcome measures collected to investigate the acceptability and relevance of the EQ-5D and SF-12 to the population under study. This will provide evidence on the suitability of these measures for economic evaluations in this setting.

The new 5L version of the EQ-5D was developed because of concerns over the lack of sensitivity to change of the original EQ-5D-3L. Whilst the NICE interim position statement, supports the continued use of the 5L descriptive system, it currently recommends using the 3L valuation set to derive all utility values via the

Hernandez Alava et al. mapping function (see point 6). This leaves open the option to perform the analysis using the 5L valuation set if NICE recommendations, which are due to be reviewed in August 2018, have changed by the time of analysis. If their recommendations remain unchanged, we shall perform the analysis using the Hernandez Alava et al. mapping function to derive 3L utility values as advised in the current position statement.

Information on the resource use by each participant and the resources required to deliver the intervention will be collected and included in the analysis. Supervision of the trainees has been included in the excess treatment costs, on the advice of the Mental Health Trust. These costs will be included in the economic analysis and we shall record the grade of the supervisor, duration of the session and the number of sessions of supervision.

To supplement this within-trial analysis, economic modelling of potential future costs and benefits of PIT versus TAU will be performed. This will be done in accordance with the ISPOR-SMDM good research practices guidelines for economic modelling [52]. The conceptualization phase will determine the structure and approach to be used based on consultation with subject experts on the team [53]. Impacts beyond prison will be incorporated using available wider evidence on the costs and HRQoL associated with self-harm episodes/treatments currently provided outside of the prison estate such as the evidence reviewed by NICE (2011) [4].

DATA MANAGEMENT

Data collection tools and source document identification

Source Documents

The source documents for the research will be as follows:

- The CRF
- Paper Diaries
- Paper questionnaires/scales (The Demographic and Personal History Questionnaire; the bespoke Mental Health History Form (Self-Report and Database Report), The bespoke Alcohol and Drug History Form (Self-Report and Database Report), the Bespoke Self-Harm History Questionnaire, PriSnQuest,; MSI-BPD; BSS; BDI-II; BHS; EQ-5D-5L; SF-12; RSE; WEMWBS; self-harm incidents logs; Concomitant Therapies Form; concomitant medications log; NOMIS baseline record sheet; ACCT status form; therapy attendance log; adverse events log)
- Prison databases and paper-based records (e.g. NOMIS; ACCT records; Business Hub records; F213; Detail Officer's logs; self-harm incidents report forms; near miss forms; Safer Custody records; bed watch booklets; education department records; Alpha lists)
- Health care records (e.g. SystmOne)
- Audio recordings of qualitative interviews and focus groups

The data from the source documents will be entered into the web based electronic data capture (EDC) system, the resource use database and the therapist database.

Data handling and record keeping

All paper based personal data (e.g. consent forms) will be stored in a locked filing cabinet at the University or NHS Trust sites (University of Manchester/Greater Manchester NHS Foundation Trust, Central and North West London NHS Foundation Trust and University of Southampton) or in a locked location in the study prison. The location of the filing cabinets will be in an area of the building that can

only be accessed using an identity card or key. All personal data will be stored separately from paper-based research data (e.g. the CRF and the scales) and from participant identification codes (which link the research data to the personal data e.g. participant numbers and names). The participant identification codes will also be stored on a password-protected drive on University or Trust Servers, accessed via password protected computers.

Electronic research data (from the scales/diary) will be saved on a web based electronic data capture (EDC) system designed, using the InferMed Macro 4 system, by King's Clinical Trial Unit (KCTU). The EDC will be created in collaboration with the CI, Trial Manager and Trial Statistician and maintained by the KCTU for the duration of the project. It will be hosted on a dedicated secure server within KCL.

The Trial Manager will request usernames and passwords from the KCTU. Database access will be strictly restricted through user-specific passwords to the authorised research team members. It is a legal requirement that passwords to the EDC are not shared, and that only those authorised to access the system are allowed to do so. If new staff members join the study, a user-specific username and password must be requested via the Trial Manager from the KCTU team and a request for access to be revoked must be requested when staff members leave the project. Study site staff experiencing issues with system access or functionality should contact the Trial Manager in the first instance.

No identifiable data beyond participant initials and date of birth will be entered on the EDC or transferred to the KCTU. No data will be entered onto the EDC system unless a participant has signed a consent form to participate in the trial. Source data will be entered on to the EDC by authorised staff e.g. the research assistants, typically within 7 days of data collection, by going to www.ctu.co.uk and clicking the link to access the MACRO 4 EDC system. A full audit trail of data entry and any subsequent changes to entered data will be automatically date and time stamped, alongside information about the user making the entry/changes within the system.

The Trial Manager or a delegate will undertake appropriate reviews of the entered data for the purpose of data cleaning and will request amendments as required. The trial manager will also be responsible for providing interim reports to the DMEC. At the end of the trial, the Trial Manager or a delegate will review all the data for each participant and the PI will provide electronic sign-off to verify that all the data are complete and correct. At this point, all data can be formally locked for analysis.

Upon request, KCTU will provide a copy of the final exported dataset to the Trial Statistician for analysis as appropriate.

Resource use data and data on the therapists will be stored separately at the University and NHS Trust sites in accordance with the data storage process outlined above.

Copies of the audio recordings of the research interviews be stored in password protected files on a password-protected drive on University or Trust Servers, accessed via password protected computers. Once the audio files have been stored on the computers the original files will be deleted from the digital recorders. The copies of the audio files will then be sent to a transcription service for transcription. Transcription of the audio files will be done by an approved external service that complies with data protection regulations, following advice from University data protection experts. All audio files and transcripts transferred electronically will be password-protected. The transcription company will sign an agreement that any audio files/transcripts in their possession will be stored on an encrypted space and the data contained in the files/transcripts will be kept confidential. The audio files and transcripts will be saved under participant identification codes only. Once transcription is complete the audio files, saved on the transcriber's computer or at the University/Trusts, and will be deleted.

The therapy sessions will also be recorded on digital recorders. A copy of the audio files of the therapy sessions will temporarily be stored in a password-protected file at the NHS location where each therapist works so they can review the tape and refer to them during supervision. The therapist will also send a copy of the audio recordings to the study sites (Universities/Trusts) for storage. Once the research team

confirm that they are in receipt of a functioning copy of the audio recording the therapists will be instructed to delete the original copy from the digital recorder. The digital recorder will be locked in a secure room at the therapist's place of work, as will any hand written notes taken during/after the therapy. A purposive selection of the therapy recordings, stored at the study sites (Universities/Trusts) will be used for competency/adherence rating. Copies of the randomly selected audio files will be sent electronically to the competency/adherence rater using password protected attachments. Any audio files will be stored by the competency/adherence rater on a secure work server in password protected files. The audio files, stored by the competency/adherence rater and the research team, will be deleted after they have been rated or it has been decided that they will not be part of the sample that is rated.

Some of the therapists work within a prison. These therapists may be unable to save a copy of the audio recordings to their work computer as audio is disabled. They may also not be able to email the audio files to locations outside the prisons. In these circumstances the therapists will keep the audio recording on the digital recorder in the prison until they have listened to the audio/discussed the audio with their supervisor. The research team will then collect the recorders and take them to the research organisations to transfer the audio files to the secure servers.

Data protection and patient confidentiality

All of the research team and therapists will comply with the requirements of the Data Protection Act 2018 and with the General Data Protection Regulation with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The Chief Investigator will be the data custodian.

Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections in line with participant consent.

Archiving

The paper Masterfile for the project will be archived at the Greater Manchester Mental Health Foundation Trust. The electronic Masterfile will be retained on the University of Manchester shared drive and then transferred onto a media drive. From the media drive, the electronic Masterfile will be added to the trust electronic archives.

Personal data: Consent forms will be retained as essential documents for 5 years from the end of the study, but items such as contact details in the community will be deleted as soon as they are no longer needed.

Research Data: In accordance with the guidelines of Greater Manchester Mental Health Foundation Trust the research data will be stored for at least 15 years.

See https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/ for any updates on Data Protection and Information Governance and also see https://www.gmmh.nhs.uk/privacy-notices-gdpr for the sponsor's privacy notices.

MONITORING, AUDIT & INSPECTION

The Monitoring team from the NIHR will keep in touch via webinars, regular and ad hoc progress reports, teleconferences and hub visits. The research team will be required to submit progress reports to the NIHR roughly every six months.

The NIHR have created an online form that provides the information they need to:

- review progress against a project plan
- review the impact of any issues
- identify any need for additional support

Reasonable requests to amend due dates of reporting tasks will be considered. If the research team need a change to a deadline they should open discussions with the NIHR research manager as early as possible.

The research team will be sent a reminder approximately four weeks before the progress report is due and all reports must be submitted on the appropriate template.

The online form to complete and submit the latest project progress report can be accessed via the NETSCC MIS website at https://netscc-mis.nihr.ac.uk

For the monitoring requirements for the TSG and DMC see Research Governance Guidelines for the TSG and DMC in the Master File.

See also Greater Manchester Mental Health NHS Foundation Trust Research and Development SOP Procedure for Onsite Monitoring Visit 1st July 2015 in the Master File.

ETHICAL AND REGULATORY CONSIDERATIONS

Research Ethics Committee (REC) review & reports

Before the start of the trial, approval will be sought from a REC for the trial protocol, informed consent forms and other relevant documents e.g. advertisements and GP information letters. Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the trial and NHS R&D departments and HMPPS approve the amendment. All correspondence with the REC will be retained in the Trial Master File. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. It is the Trial Manager's responsibility to produce the annual reports as required. The Trial Manager will notify the REC of the end of the trial. If the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Peer review

The study underwent independent peer review by research experts in the area by the National Institute for Health Research prior to the Chief Investigator receiving funding for this project.

Public and Patient Involvement

Women prisoners have always been at the centre of our working practice at CWMH and we have won NIHR awards in recognition of this. We have an expert by experience as a co-applicant of the research, Fiona Edgar. She will work together with our research assistants and service user research group to finalise protocols, produce study materials, assist with the analysis of qualitative data and disseminate research findings during the work piece and following it at conferences and in prisons. In Manchester, Fiona Edgar will work closely with Tracy Millington, an established member of the service user research group whom we are training so she can be a named co-applicant on research bids in the future. Tracy recently won a University of Manchester Faculty Patient and Public Involvement and Engagement Award, for her involvement in the COVER project. We will also recruit and train four new service user researchers to work alongside the RAs in London and Oxford. Ongoing consultation and involvement throughout the research will allow us to avoid making erroneous assumptions about women's experiences of prison and self-harm

and communicate as effectively as possible. Consultation with, and guidance from, expert by experience service users will ensure that the research can be conducted as planned in women's prisons. This approach has been used successfully in previous NIHR-funded research, WORSHIP II and COVER.

All our service user researchers will be members of the research management group. As in our previous studies, we shall involve current prisoners in our steering group to be held in prison at least one a year and an independent expert by experience. The steering group will also involve experts from relevant charities, for example, Women in Prison and Self Injury Support. Members of these charities already collaborate with the research team.

Our current service user researchers will receive direct support and supervision from the Trial Manager and additional supervision from LR and KA where required. The Trial Manager will also ensure that there is appropriate guidance and support for other experts-by-experience as required, with each new member of the service user research group receiving a half day training programme when they begin the research. Training will include: an explanation of the PPI role; the value of their contribution; introduction to the project; exercises to help develop skills; opportunities to ask questions.

Protocol compliance

Prospective, planned deviations or waivers to the protocol are not allowed under the UK regulations on Clinical Trials and must not be used e.g. it is not acceptable to enrol a participant if they do not meet the eligibility criteria or restrictions specified in the trial protocol.

Accidental protocol deviations can happen at any time. They must be documented adequately on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase. The sponsor of a clinical trial will notify the REC in writing of any serious breach of

(a) the conditions and principles of GCP in connection with that trial; or
(b) the protocol relating to that trial, as amended from time to time, within 7 days of becoming aware of that breach

Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

The CI, Trial Manager and all protocol contributors do not have any financial or other competing interests.

Indemnity

See the NHS Indemnity (Arrangements for Clinical Negligence Claims in the NHS) document and the University of Manchester Indemnity document in the Master File.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The

amendment will be completed by the Trial Manager/RAs and reviewed by the CI. The Trial Manager will determine whether the amendment is substantial or non-substantial in consultation with the Sponsor.

The REC will provide a response regarding the amendment within 35 days of receipt of the notice. HMPPS also need to be notified about substantial amendments in case the amendment affects their opinion of the trial. Amendments will also be emailed to all NHS R&D offices for participating sites, so they can assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

A log of all amendments will be included in the trial Masterfile and the Site Files.

Guidance on the categorisation of amendments can be found on the HRA website. http://www.hra.nhs.uk/resources/after-you-apply/amendments/

Post-trial care

The participants in the intervention group will complete the entire treatment during the research, unless they are unexpectedly released or transferred to a prison without study therapists. The research team has established relationships with HMPPS deputy director of the women's estate and health care commissioners from NHS England, who have agreed to facilitate implementation of the therapy if it is shown to be clinically and cost effective. The study is designed create a sustainable service by establishing clinical psychology/forensic psychology placements and psychiatry cases which can be continued after the research has ended.

Access to the final trial dataset

The CI, Trial Manager and Statistician will have access to the final trial dataset. Other members of the research team will be allowed access if a formal request describing their plans is approved by the steering group.

DISSEMINATION POLICY (all NIHR policy has been extracted from NIHR guidance documents shared during project set-up – original documents can be found in the Master File and Site Files)

The protocol

Once the research team have signed the contract, a summary of the project details - including the protocol - will be made available on the NETS website. It is a DH requirement that a protocol is published for every project.

The protocol will be part of the pack that is considered alongside the draft final report by reviewers and will be published as part of the agreed final report. It is therefore important that this document is kept up to date throughout.

Requests to change the study protocol during the lifetime of the project should be submitted to the NIHR research manager for approval prior to implementation.

The project datasets

The datasets arising from the trial will be protected by know-how, copyright and database rights (which are automatic rights and do not need to be registered). The copyright for the foreground IP will be held by GMMH.

Reports

Draft final report: At the end of the trial data will be analysed and a final trial report will be prepared. The draft final report will be due two weeks after the end of the contract. Approximately six months before the draft final report (DFR) is due, the NIHR team will send the research team an email with links to the

Information for Authors and other templates. Approximately three months before the due date they will contact the team to confirm arrangements for its submission.

The process from receipt of the draft final report to its final publication typically takes around a year, during which time the report will be subjected to external review and editorial scrutiny. Reviewers are appointed three months before the DFR due date and will be given a time frame for receipt and review of the report. Once the report has been to the reviewers it will also be reviewed by the NIHR Journals Library editors. Following the receipt of feedback from the reviewers and the editors, the research team will be asked to submit the revised report within four weeks. Following review of the revised report, further iterations of the report may be requested. Once the editors have signed it off the report will be sent to an external production house for copyediting, typesetting and proofreading. The DH will be notified of the planned publication of the report and it will be published following expiry of the 28-day notification period.

The NIHR advise that the research team make the appropriate plans and/or arrangements for this period, particularly in the light of the fact that a substantial part of the funding award is withheld pending final publication.

Frequent causes of delays for publications are from delivery of incomplete reports resulting in additional revisions, delays in acquiring permissions for reproduced work or errors within the referencing. For further information or guidance regarding the report please contact the NIHR Journals Library team at journals.library@nihr.ac.uk

Overdue reports: The research team should note that contractual penalties may be applied for any report that becomes overdue.

Information for authors

Further guidance on writing the draft final report can be found on the Information for Authors webpage https://www.journalslibrary.nihr.ac.uk/information-for-authors/ . This guidance is regularly updated and will change during the lifespan of the project. The research team need to make sure they are using the most up to date guidance when drafting the report. For an interactive route map to help with the preparation and submission of the report, including information on the post-submission processes, webinar recordings and video guidance on permissions, please see:

www.journalslibrary.nihr.ac.uk/information-for-authors

Dual publication

If the research team are intending to publish an article based on the report they should review the guidance at:

www.journalslibrary.nihr.ac.uk/information-for-authors/dual-publication

The NIHR suggest the authors should plan to submit the article well in advance of your report's publication and let the NIHR know as soon as possible about any submissions. The research team will need to ensure that they only assign non-exclusive rights in any copyright agreements that they sign and that they do not reproduce large sections of identical text in the article and report. The report should be an original account of the research.

Additional Information from the NIHR related to the draft final report:

A group of scientists and editors have formed the STARD (Standards for Reporting of Diagnostic Accuracy) Initiative, to provide a method for improving reporting quality and accuracy of diagnostic studies. Information on this initiative and the documents involved can be down loaded from the STARD website. The NIHR request that the research team include the checklist (available from http://ibooked.no/stard-statement.html) as a separate appendix to the final report.

The National Screening Committee (NSC) is enthusiastic to discuss the report when it is published. The committee has requested that the NIHR should ask the research team (and all other authors of reports initiated by the Population Screening Panel) to address a number of key criteria/questions. Information regarding the criteria/questions which they would like the research team to respond to and then include as an appendix to the final report can be found at http://www.screening.nhs.uk/criteria

Publications and other dissemination

The key outputs of the research are:

1. Evidence demonstrating whether PIT is clinically and cost-effective
2. Clinical/forensic psychology trainee placements and accredited psychiatry short cases
3. A prison-adapted PIT training course and manual for future delivery
4. Qualitative data on successful ways to implement PIT within prisons.

Throughout the research and beyond, we shall follow the NIHR guidelines for study dissemination [54] In accordance with the NIHR policy the women prisoners will be at the centre of our dissemination process, and outcomes will be discussed in detail with our experts-by-experience and shared with our participants and other women within the prisons. When the research is complete, the aim is to roll out PIT across women's prisons, if it is shown to be clinically and cost effective. We have a detailed dissemination plan to raise awareness of the research to maximise the likelihood that the research will influence policy and practice. We shall be working in close collaboration with Her Majesty's Prison and Probation Service and Health and Justice Team at Public Health England during the study. They have both provided letters of support for the research and agreed for us to present the work at various stages to the Women's Prison Advisory Group, on which the CI and Trial Manager are advisory members, and which otherwise comprises senior members of HMPPS, PHE and NHS, the key bodies developing and implementing policy in this area. Through these contacts, and the Clinical Research Network, we shall share targeted outputs for practitioners, commissioners and service managers. The CI is an NIHR Senior Investigator and will use some of her SI resources specifically for targeted dissemination events such as a Manchester Women's Conference which she has been running biennially for the past decade.

We have established partnerships with national and international communities of practice, e.g. Worldwide Prison Health Research and Engagement Network, the Offender Health Research Network, the Prison Reform Trust, Self-Injury Support and with Lady Grosvenor (OneSmallThing). We shall use these partnerships to exchange knowledge and raise awareness and shall develop new partnerships through conferences/networking.

We understand the service context of our research and intend to recruit influential opinion leaders to act as champions, facilitated by existing links with the Board of Prison Governors and Safer Custody Leads. These contacts will assist with dissemination to prison staff e.g. via the Prison Governors' and Safer Custody meetings, which we already attend.

We shall work with established experts-by-experience and current prisoners to develop lay research summaries to share with participants and other women prisoners e.g. by publishing in Inside Times. Mindful of low literacy, we shall also run dissemination events in the study prisons and share our findings via National Prison Radio.

We shall submit papers to high-impact peer-reviewed international journals, including the HTA journal, and present findings at academic/professional conferences. To engage a larger audience, our progress/findings will be shared via our project website and social media. We shall also explore innovative ways to disseminate the research using film or mixed media and via local art projects such as the SICK! Festival.

We shall review the Consort Guidelines and checklist prior to generating any publications for the trial to ensure they meet the standards required for submission to high quality peer reviewed journals etc. http://www.consort-statement.org/.

For all dissemination, our contract with the Department of Health requires us to do the following:

1) Notify the NIHR of all outputs. The term output is an umbrella term which includes but is not limited to: the final report; journal article; press release; media interview; conference abstract or presentation; dissemination event for research participants, newsletters or participant materials.

2) Send the NIHR a copy of the output and any information pertaining to it, at the time of submission or at least 28 days before the date intended for publication, or it being placed in the public domain, whichever is earlier.

3) Include an acknowledgement of programme funding (i.e. Programme, NIHR, and project number) and a disclaimer in all outputs. Suggested wording is provided on the NIHR Branding and Study Outputs page

https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/manage-my-study/study-outputs-and-branding.htm .

To inform the NIHR of outputs log on to their online system and use the functionality available on our public project file. General guidance on outputs can be found on the NIHR Branding and Study Outputs page, with more specific information relating to different types of output available in the NIHR Identity Guidelines PDF https://www.nihr.ac.uk/about-us/publications/NIHR_ID_Guidelines%20Version%203.pdf , along with the NIHR's branding guidelines pertaining to use of the NIHR logo.

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Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	3	19/07/2019	Dr Kerry Gutridge, Prof Kathryn Abel and Prof Richard Emsley	An ISRCTN number was added to the protocol Members of the DMEC and Steering group changed The trial flow chart in the protocol was been edited to reflect the new predicted number in the pilot Due to delays receiving HMPPS approval, changes to the data collection following CTU review and the sudden loss of a research assistant we are behind schedule to start the research, the pilot was adaoted to start in September 2019 instead of May 2019. A fourth prison was added to the pilot. We also have agreement that therapists can work in both Bronzefield and Downview so therapy can be continued if they are

				transferred. We adjusted the recruitment targets in the protocol to reflect these changes. We also changed one of the main study prisons to HMP Eastwood Park rather than HMP Drake Hall as this prison has the largest self-harm rate nationally. We also added a sentence in the protocol to reflect the fact that the prison sites may change. We have requested permission to recruit in 9 prisons in case we encounter any recruitment problems at specific sites. The screening questionnaire was replaced by the eligibility form and reflects the revised inclusion/exclusion criteria. The wording of the inclusion and exclusion criteria was refined so that they result in clear yes/no answers on the CTU database. We also moved the inclusion criterion re other treatments to the exclusion to avoid the confusion of a double negative in the data collection forms. We specified that the participant needs to have 8-weeks left in the prison at baseline rather than screening and added that we need to check if participants are booked on clashing courses/treatments as well as currently taking them. We also specified in the protocol that therapies which overlap with the aims of PIT include therapies which are designed to affect the secondary outcomes e.g. Self-Esteem Courses. During CTU development, we edited questions on the bespoke baseline measures Demographic and personal history questionnaire: To aid data entry and following discussions during database development, we included detailed category options for ethnicity and marital status and additional possible locations for the women's children. We also moved the information on drug and alcohol use to a separate Alcohol and Drug History form and the self-harm information to the Mental Health History Form. On the Mental Health History Questionnaire we added extra categories for past diagnoses, refined the questions on past mental health admissions for clarity, included questions about past medication usage, added additional detail regarding hospitalization for past self-harm and the details of the participant's last self-harm incident e.g. adding category options for self-harm and added questions on past therapy. We also created a Mental Health History Form (database) which can be used to double check the mental health history for the participants. This replaced the NOMIS and SystmOne baseline record sheet. We replaced the DSHI as a baseline measure with a bespoke Self-Harm History Questionnaire. The DSHI was created to measure non-suicidal self-harm only and it also did not include methods of self-harm commonly found in prison. For these reasons we co-developed a new measure with experts-by-experience which was refined during consultation with prison staff and women prisoners.

				Following consultation with the author of the ZAN-BPD we replaced this form with the McLean Screening Instrument: Borderline Personality Disorder. This change was made because the new form is designed specifically for baseline assessment whereas the ZAN-BPD is designed to check changes in Borderline PD traits. We created the NOMIS Baseline Record Sheet to replace the NOMIS and SystmOne baseline record sheet. We edited the Background History of Participants form, which is passed to the therapists, to reflect the changes in the baseline measures. We have created two brand new Case Report Forms for the baseline and ongoing assessments and the outcome assessments. We removed all the scales and scoring from the forms on the advice of the CTU who stated that the participant need to see an original copy of the forms. Self-reported self-harm incidents will not be collected in a daily diary now. Instead, we created a separate Self-Harm Incidents Log (participants). This change was made so that the CTU database is clear and consistent. The separate self-report self-harm form is necessary as the self-report self-harm data is combined with self-harm data from healthcare and prison records, whereas the other information in the diary is not combined with other data. We are collecting the same data in the new form e.g. method of self-harm, date, time and treatment. Rather than using the original primary outcome data collection form, we have created two new forms to collect self-harm incidents from prison records and SystmOne (healthcare). These forms have been created so the data collection from databases matches the self-report data collection and the CTU database. Following additional consultation with the statistician during the CTU database development we have decided that it is not necessary to collect self-harm incidents in the 4 weeks before the participant's baseline and will only collect incidents during the 12-week trial period. The protocol was edited so it is clear that the health-related quality of life scales will only be used in the economic analysis and will not be used as secondary outcomes. We have included death as a high level of harm resulting from a self-harm incident. We created a Concomitant Medications Form so we can clearly collect all medications that the participants are taking and any changes to medication during the trial period. We also specified that we will only be collecting psychotropic medications and pain medications as these are the most relevant types of drugs. We created a concomitant therapy form so we can measure the types of therapy participants receive, the number of sessions and when they start and stop the therapies during the trial.

				We changed the daily diary collection to a weekly diary. We had concerns that a daily diary would overburden women and had the potential to influence their self-harm behaviour. We have edited the questions in the diary to make sure that the information is collected from the last diary due date. Originally the diary asked for information 'in the last week' but the date of diary completion may alter. The new questions allow us to identify in the CTU database when there is missing data and the exact time period that the answers refer to. Following advice from the steering group we have added a question to the diary so we can collect the amount of time the women have spent outside their cell. This information is important as it could have a bearing on their self-harm rate. We created a new basic regime form to be used with prison data sets. This is because time spent on basic regime could have a bearing on people's self-harm rates. We have created a new ACCT Status Form to ensure that we collect whether participants are on an ACCT at 8-weeks and 12-weeks, in accordance with the protocol. The protocol was changed to clarify that the research assistants will be able to follow up people transferred to remote sites blindly as they will not know the arm that the other RA's participants have been allocated to. We refined the resource use collection form in consultation with prison and healthcare personnel from the pilot prisons to ensure that it is possible to collect all the relevant data and that we know which data sets will need to be searched. Following advice from the Steering Committee, we will be collecting prison level data on the average time that women spend out of their cell in each prison and whether the prison has an in-cell telephone service (including the services that can be accessed using the phone). These are both things that could impact on self-harm rates. The protocol has been edited so it is clear that people can only take part in the research if they agree that we can disclose information about risk to prison and healthcare staff. Following consultation with the prisons we have also listed all the departments that need to be informed including healthcare, personal officers, Safer Custody and Offender Management. We have also specified that information about risk will be written in people's NOMIS case notes. All these changes follow consultation with prison staff designed to ensure that are risk reporting procedures are as robust as possible. We provided more detail in the protocol about how we will identify adverse events. Prison, healthcare staff and the research assistants will monitor the participants for changes in their self-harm behaviour which will need to be investigated as an adverse event. We have also specified that adverse events include medical changes that are not self-harm. We made it clear in the protocol that we will ask members of prison staff to notify us of any adverse events for women who are transferred to their prison and we

				have created a letter for released women so they can notify the team of any adverse events. We created two Adverse Events (for self-harm and other medical issues) so that Adverse Events are recorded in a consistent manner. We edited the protocol so we know what to do regarding database collection for women who are transferred during the trial. We will seek permission to access prison and healthcare records in the prison they are transferred to so we can continue to collect the primary outcome and the other ongoing measures. We specified in the protocol that we will be doing a full audit of usual treatment across the prison estate. This will aid our exclusion decisions and our understanding of usual treatment. We refined the fidelity rating procedure so that it is clear that it tests adherence to the model and competence. We changed the method of sampling for the therapy recordings to rate from random sampling to purposive sampling so we can ensure that our independent assessor rates recordings from all the prisons and from therapists from different backgrounds. We increased the number of recordings that will be rated in the pilot from 4 to 8 so we can rectify any problems with adherence and competence in the pilot stage. A member of the research team will also blindly rate a selection of recordings to test for consistency. The protocol was edited to make it clear the forensic psychologists who are involved in delivering the PIT may already be qualified and that the therapists can continue delivering the therapy if they qualify during the research. We specified in the protocol that all the therapy sessions will be recorded. This is so that the therapists can listen back to the recordings and share the recordings with their supervisors. Recording will only take place with the women's consent. We specified in the protocol that participants can request a female therapist if they are unhappy doing the therapy with a male. We edited the guidance for the structure of therapy to include rules regarding lateness and missed appointments. If people are late or miss an appointment for unavoidable prison factors, they will make up the time/session. If they are late of miss an appointment by choice this will be addressed within the therapy and the time will not be made up. This is in accordance with standard psychotherapy practice in the community. We specified in the protocol that assessment of competency following training is via an observed role play. We specified that supervision needs to be 30-60 minutes long We created a therapy attendance log to record the therapy appointments. We made it explicit in the protocol and consent form that the outcomes of the therapy will be shared with the healthcare team and requested that the outcomes can be

				shared with the forensic team. This distinction has been made as some women are reluctant to share medical data with the forensic team in case it affects their parole. People will still be able to take part in the research if they do not consent to outcome sharing with the forensic team. We edited the template for the therapists to complete at the end of PIT so it is consistent with the Therapy Manual. We specified in the revised protocol that the Therapy Satisfaction Questionnaire will be completed at 10-weeks so it can be completed alongside any qualitative interviews. We edited the summary table of baseline data in the protocol to reflect the changes in data collection We amended our data storage procedure so that therapist can temporarily store the therapy recording at their place of work so they can listen back to the recordings and share the recordings with their supervisor. We removed the prison specific self-harm services from the leaflet and any advice concerning self-harm from the leaflet. This is so the information does not clash/contradict advice that is currently offered within the prisons We edited the PIS to include the fact that therapists may be forensic staff who already work in the prison, to reflect the new loss of capacity procedure, to specify that information will be shared with the Offender Management Team and so that it is explicit that we will be sharing the outcomes of the therapy with the healthcare team. We also amended contact details on the form. We specified in the protocol that the PIS will be witnessed. This will involve recording the session being sent to the trial manager so they can arrange for the recording to be witnessed. We do not have the capacity within the team for a person to sit in on every session. The protocol was amended to clarify that people who lose capacity during the research will not automatically be withdrawn but their participation will be suspended until capacity returns (if it does). We edited the consent form so that it contains the new guidance on loss of capacity, all the staff that risk information will be shared with, sharing the outcomes of the therapy with healthcare and the option for sharing the outcomes with the forensic team. We have requested that participant initials are added to the consent form as these are needed for the CTU database. As some of the questions on the consent for are mandatory for participation, and others are not, we have created a Consent Procedure document for the RAs so they know which boxes need to be ticked to proceed. We revised the briefing for prison staff so that it reflects the changes to the protocol. We edited the letters so they are consistent with the protocol and current contact details We edited the follow charts for the baseline assessors and the outcome assessors to reflect the changes to the protocol.

2	3	18/07/2019	Dr Kerry Gutridge, Prof Kathryn Abel and Prof Richard Emsley	The Trusts that are responsible for New Hall and Askham Grange has changed to Bradford District Care NHS Foundation Trust and the Trust that is responsible for Foston Hall and Drake Hall has changed to Midlands Partnership Foundation Trust.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee.