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Is a talking therapy, called psychodynamic interpersonal therapy, clinically and cost effective for women who self-harm in prison?

Submission date
11/02/2019

Recruitment status
Not yet recruiting

Registration date
13/02/2019

Overall study status
Ongoing

Last Edited
08/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Self-harm is an important, growing problem in prisons, especially for women. Only 5% of prisoners are women but they carry out over a quarter of prison self-harm. There are many reasons for self-harm, such as managing distress, trying to control emotions and self-punishment. People who self-harm are more likely to attempt suicide than those who do not. Although self-harm rates are high, there are currently no treatments which have been properly tested in prisons. This study aims to see if a talking therapy developed with women and prison staff for prisoners who self-harm, Psychodynamic Interpersonal Therapy (PIT), will lead to less self-harm and be value for money for the NHS and improve the lives of women who self-harm in prison.

Who can participate?
Women who are in prison, who have self-harmed in the last month and who have been on an 'ACCT' in the last 6 weeks can take part. ACCT stands for Assessment Care in Custody and Teamwork and is a prison-based system used to monitor people who are at risk of self-harm.

What does the study involve?
Participants are allocated by chance to the treatment group or a control group. Women who receive the treatment undertake 4-8 50-minute sessions of psychodynamic interpersonal therapy (PIT), either face-to-face or digitally. In PIT, people discuss their feelings, their relationships and how their past has influenced them. The aim is to help them find new ways to manage emotions and relate to others. Women in the control group receive any treatments which are currently on offer in the prison.

What are the possible benefits and risks of participating?
The PIT intervention may help reduce self-harm thoughts and feelings and may lead to a decrease in self-harm behaviour. We cannot promise that participants will receive PIT or that the research will help individual participants but the information from the research might help treat other women prisoners who self-harm in the future. Talking about self-harm may be upsetting.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
August 2018 to November 2028

Who is funding the study?
National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 38762

Study information

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

Acronym
WORSHIP III Version 1

Study objectives
Psychodynamic interpersonal therapy is clinically and cost effective for women who self-harm in prison.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 02, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, Tel: +44 (0)131 536 9000, Email: Joyce.Clearie@nhslothian.scot.nhs.uk, 23 /10/2018, ref: 18/SS/0118

Study design
Randomized; Interventional; Design type: Treatment, Complementary Therapy, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Prison/detention

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Self-harm

Interventions
Randomisation will be at the individual level by block randomisation with randomly varying block sizes, stratified by prison. Participants are randomised to the PIT treatment or the control group (usual care, not having PIT) and outcomes are compared. Therapy will be delivered by supervised trainee Clinical/Forensic Psychologists and Psychiatrists. Psychodynamic Interpersonal Therapy (PIT) will last for 4-8, 50-minute sessions, depending on women's preferences. The duration of the intervention is 4-8 session over 8 weeks. Follow up is 8 weeks post baseline and 12 weeks post baseline. The trialists are interested in whether PIT reduces self-harm incidents and its effects on other outcomes such as self-esteem and wellbeing. They are also interested in whether PIT reduces the financial costs associated with self-harm.

Intervention Type
Other

Primary outcome measure

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) checked for double entry; Timepoint(s): 8 weeks

Secondary outcome measures

Current secondary outcome measures as of 25/07/2019:
1. Demographic characteristics e.g. age, ethnicity, number of children and location of the children, educational background, past experience of the care system, abuse, neglect and domestic violence, measured using the bespoke WORSHIP III demographic and personal history questionnaire at baseline
2. Any undiagnosed mental illness, assessed using the Prison Screening Questionnaire (PriSnQuest) at baseline
3. Mental health history including past diagnoses, assessed using the bespoke Mental Health History (MHHQ) questionnaire at baseline
4. Self-harm history assessed using a bespoke Self-harm History questionnaire at baseline
5. Presence of borderline personality disorder, assessed using MacLean Screening Instrument for Borderline Personality Disorder (MSI-BPD) questionnaire at baseline
6. Depression assessed using the Beck Depression Inventory questionnaire at baseline, 8 weeks and 12 weeks
7. Hopelessness assessed using the Beck Hopelessness Scale questionnaire at baseline, 8 weeks and 12 weeks
8. Self-esteem assessed using the Rosenberg Self-Esteem Scale questionnaire at baseline, 8 weeks and 12 weeks
9. General well-being assessed using the Warwick-Edinburgh Mental Well-Being Scale questionnaire at baseline, 8 weeks and 12 weeks

Previous secondary outcome measures:
1. Demographic characteristics e.g. age, ethinicity, number of children and location of the children, educational background, past experience of the care system, abuse, neglect and domestic violence, measured using the bespoke WORSHIP III demographic and personal history questionnaire at baseline
2. Any undiagnosed mental illness, assessed using the Prison Screening Questionnaire (PriSnQuest) at baseline
3. Mental health history including past diagnoses, assessed using the bespoke Mental Health History (MHHQ) questionnaire at baseline
4. Self-harm history assessed using the Adapted Deliberate Self-Harm Inventory (DSHI) questionnaire at baseline
5. Presence of borderline personality disorder, assessed using Zanarini Borderline Personality Disorder (ZBPD) questionnaire at baseline
6. Depression assessed using the Beck Depression Inventory questionnaire at baseline, 8 weeks and 12 weeks
7. Hopelessness assessed using the Beck Hopelessness Scale questionnaire at baseline, 8 weeks and 12 weeks
8. Self-esteem assessed using the Rosenberg Self-Esteem Scale questionnaire at baseline, 8 weeks and 12 weeks
9. General well-being assessed using the Warwick-Edinburgh Mental Well-Being Scale questionnaire at baseline, 8 weeks and 12 weeks

Overall study start date

01/08/2018

Completion date
30/11/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/07/2019:
For women participating in the randomised controlled trial and qualitative follow-up (as piloted in WORSHIP I and II):
1. 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 month. 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.
2. The participant is a woman in prison who has self-harmed in the last month.
3. The participant is 18 years or over. The intervention has been piloted with adults as women under 18 may have different needs.
4. 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

For staff participating in the qualitative follow-up:
Have worked with women involved in the intervention

Previous inclusion criteria:
For women participating in the randomised controlled trial and qualitative follow-up (as piloted in WORSHIP I and II):
1. Remand and sentenced women in prison who are on an ACCT currently or have been on an ACCT in the last month. 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
2. Women who have recently self-harmed in the last month
3. Women will be 18 years or over. The intervention has been piloted with adults as women under 18 may have different needs.
4. Women will be screened for date of release or trial and will need to be in the prison for a minimum of 8 weeks to complete the intervention sessions.
5. Women 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.

For staff participating in the qualitative follow-up:
Have worked with women involved in the intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 264; UK Sample Size: 264

Key exclusion criteria
Current exclusion criteria as of 25/07/2019:
For women participating in the randomised controlled trial and qualitative follow up:
1. 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
2. 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).
3. The participant is too distressed/unwell to participate in research. This decision will be based on consultation with Safer Custody/healthcare staff. 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.
4. 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 and mental health in-reach. Once the risk has subsided women may be eligible to participate if they fit the other criteria.

For staff participating in the qualitative follow-up:
Staff with no experience working with women involved in the intervention

Previous exclusion criteria:
For women participating in the randomised controlled trial and qualitative follow up:
1. Women who lack capacity to consent to research participation will be excluded from the research. 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).
2. Women who are too distressed/unwell to participate in research will also be excluded. This decision will be based on consultation with Safer Custody/healthcare staff. 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.
3. Women who have less than 8 weeks left in prison will also be excluded as they will be unable to complete the entire course of treatment.
4. Women who currently pose a high risk to the researchers or the therapists will also be excluded from the research. 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 team in consultation with the researchers and mental health in-reach. Once the risk has subsided women may be eligible to participate if they fit the other criteria.
5. Women will be excluded if they are already involved in another psychological intervention within the prison establishment that has aims which overlap with PIT, e.g. it is designed to address their distress or self-harm via a talking therapy approach.

For staff participating in the qualitative follow-up:
Staff with no experience working with women involved in the intervention

Date of first enrolment
01/10/2025

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HMP Styal
Wilmslow
United Kingdom
SK9 4HR

Study participating centre
HMP New Hall
Dial Wood
Flockton
Wakefield
United Kingdom
WF4 4XX

Study participating centre
HMP Bronzefield
Woodthorpe Road
Ashford
United Kingdom
TW15 3JZ

Study participating centre
HMP Send
Ripley Road

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GU23 7LJ

Study participating centre
HMP Downview
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Sutton
United Kingdom
SM2 5PD

Study participating centre
HMP Foston Hall
Foston
Derby
United Kingdom
DE65 5DN

Study participating centre
HMP Eastwood Park
Falfield
Wotton-under-Edge
United Kingdom
GL12 8DB

Study participating centre
HMP Drake Hall
Eccleshall
United Kingdom
ST21 6LQ

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Sponsor details
Bury New Road
Prestwich

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United Kingdom
M25 3BL
+44 (0)161 358 1689
Annya.Sekula@gmmh.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/111/51

Results and Publications

Publication and dissemination plan
The protocol will be available when published. Dissemination will happen throughout the grant and in the year after the grant ends.

Intention to publish date
30/11/2029

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No