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Women Offenders Repeat Self-Harm Intervention Pilot II

Submission date	Recruitment status	[X] Prospectively registered
19/12/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/12/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2020	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The female prison population is growing at a much faster rate than men in prison. Recent government policy has identified women prisoners as having special health and service needs which are currently not met. Repeated self-harm (SH) (including suicide attempts) has become a considerable problem amongst women prisoners. It is associated with psychosocial problems, depression and increased risk of suicide, which is far greater in women prisoners than women in the community. Interpersonal conflicts are the commonest cause of SH in women and nearly 50% report histories of domestic violence, and around a third, previous sexual abuse, including one incident of rape in 1 in 20 women. Women prisoners also have high rates of mental illness. Managing SH is a significant call on scarce resources. Currently, no solution for women who SH in prison have been evaluated; none focuses explicitly on women's needs and no methodology for follow up has been developed. In this study, we developed and began evaluating a targeted intervention for SH using Psychodynamic Interpersonal Therapy (PIT) which focuses on resolving women's interpersonal and emotional difficulties which drive them to harm themselves. The researchers have tested how feasible and acceptable it is to deliver PIT in a prison and now want to find out how well PIT works for women prisoners with a recent history of repeat self-harm.

Who can participate?
Female prisoners aged 18-65 who have committed an act of self-harm in the previous month

What does the study involve?
Participants are randomly allocated to receive 4-8 sessions of PIT or control therapy (AC) after they have completed the initial assessments. Women's thoughts of suicide and SH, and the number and severity of SH events are assessed at the start of the study, after therapy and 6 months later. The study tests out methods of following women for 6 months and tests ways to collect information on the use of prison resources resulting from women's SH.

What are the possible benefits and risks of participating?
This study may reduce suicidal thoughts and risk, and improve female prisoners' self-harm behaviour. Secondary benefits of this will be to improve safety and quality of life for female offenders, help the prison system improve care and treatment and provide women with equal opportunity to get SH therapies. The potential risk to women who participate in the PIT

treatment group may be that if they explore their interpersonal problems perhaps for the first time this may bring out their negative past experiences and feelings, worsen their distress which could subsequently increase their self-harming behaviours. However, by engaging in a short-term therapy which focuses on women's distress, we hope to help women offenders self-manage their SH longer term.

Where is the study run from?
Styal, Foston Hall and Newhall prisons (UK)

When is study starting and how long is it expected to run for?
January 2013 to June 2015

Who is funding the study?
Research for Patient Benefit Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11830

Study information

Scientific Title
Women Offenders Repeat Self-Harm Intervention Pilot II

Acronym
WORSHIP II

Study objectives
1. In the Psychodynamic Interpersonal Therapy (PIT) intervention group, levels of self-harm and suicidal ideation will be reduced further than those of the participants in the active control group.
2. By engaging female offenders in a short-term intervention which focusses on women's distress, we hope to help female offenders self-manage their self-harm in the longer term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Essex, 25/06/2012, ref: 12/EE/0179

Study design
Randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Mental Health Research Network - Suicide and self-harm

Interventions
Active control (AC): AC comprises a basic control for women being taken out of their cells and having non prison staff company for a set period of time per week. Thus, women prisoners will be taken out of their cell once a week for 50 minutes by the Research Assistant and can engage in activities such as card games, reading magazines or practical topics (e.g. money management). No personal support/active listening is undertaken; women are told they cannot talk about emotional topics.

PIT, Psychodynamic Interpersonal Therapy (PIT) involves identifying and helping resolve interpersonal difficulties that exacerbate psychological distress. Specialist psychiatry trainees,

from Manchester Mental Health & Social Care Trust will come into the prison to deliver this intervention. Sessions will be weekly and last for 50 minutes. Permission will be sought from participants for the sessions to be audio-recorded. Therapy will be monitored.

Followed up at 6 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Beck's Scale for Suicidal Ideation measured at baseline, post-therapy and at 6 month follow-up

Secondary outcome measures
1. Beck's Depression Inventory measured at baseline, post-therapy and at 6 month follow-up
2. Suicide Attempt Self-Injury Interview measured at baseline, post-therapy and at 6 month follow-up
3. The Prison Screening Questionnaire measured at baseline
4. Therapy satisfaction questionnaire measured post-therapy
5. Zanarini Rating Scale for Borderline Personality Disorder measured at baseline

Overall study start date
17/12/2012

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Women offenders aged over 18 years old
2. On an ACCT (Assessment, Care in Custody and Teamwork)
3. Self-harmed in the previous month
4. The female prisoners will also be screened for date of release or trial
5. If on remand they will need to have a minimum of 6 weeks to complete sessions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
UK Sample Size: 140

Key exclusion criteria
1. Women currently at serious risk of harm to others or suicide
2. Moderate to severe learning disability or without capacity to consent
3. Women who don't speak English
4. Women who are currently receiving a therapeutic intervention in prison

Date of first enrolment
01/01/2013

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme ref: PB-PG-0610-22176

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/03/2017	13/08/2020	Yes	No