ISRCTN35772940 https://doi.org/10.1186/ISRCTN35772940

Complex trauma psychoeducational intervention for female offenders

Submission date
07/10/2013

Recruitment status
No longer recruiting

Registration date
15/01/2014

Overall study status
Completed

Last Edited
14/04/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study to assess the effectiveness of psychoeducational interventions in female offenders with complex trauma. Our aim is to explore how effective a staged approach is to stabilising negative behaviours and trauma symptoms. We will want to look at a range of individual differences to see whether this has any impact on the outcome. The study's findings should help to improve the well-being of female offenders, particularly those in custody, as well as other survivors of trauma and abuse.

Who can participate?
Women, age 1870 years, who are currently in prison in Scotland and who have a history of abuse and trauma.

What does the study involve?
The participants will be randomly allocated either to a group-based intervention called Survive & Thrive or a waiting list group. Everybody on the waiting list will be offered a chance to participate in Survive & Thrive if they want to. Participants will be interviewed to assess their level of trauma as well as their experiences of abusive and adverse circumstances throughout their lives. The intervention consists of 10 sessions delivered over 5 weeks. Questionnaires are given at week 0, week 5 and at follow-up intervals at week 9 and 17 and should help record the progress participants make.
At the end of the study, we will compare the amount of behavioural change and other improvements in participants in both the intervention and waiting list groups.

What are the possible benefits and risks of participating?
There may be benefits to those taking part in the intervention. There will also hopefully be benefits to those female prisoners in the future because the results of the study are likely to help our understanding of appropriate treatment for female offenders and survivors of abuse in the future. The main risk of participating is that it could be upsetting for some women. Therefore, Survive & Thrive does not ask participants to talk about their own abusive experiences. Participants will also receive any further assistance from mental health staff should they need it.

Where is the study run from?
The study has been set up by Edinburgh Napier University in collaboration with the Scottish Prison Service. Participants will be recruited from HMP Cornton Vale and HMP Greenock, which are part of the Scottish Prison Service estate. The study will be conducted at HMP Cornton Vale, Scotland, UK.

When is the study starting and how long is it expected to run for?
The recruitment is expected to start in January 2014. Participants will be enrolled at various times over a period of two years.

Who is funding the study?
Survivor Scotland (UK).

Who is the main contact?
Mr Adam Mahoney, Adam.Mahoney@sps.pnn.gov.uk
Professor Thanos Karatzias, T.Karatzias@napier.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Adam Mahoney

Contact details
Psychology Department
HMP Cornton Vale
Cornton Road
Stirling
United Kingdom
FK9 5NU
-
Adam.Mahoney@sps.pnn.gov.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
138344

Study information

Scientific Title

The effectiveness of a Stage 1 psychoeducational intervention versus waiting list to stabilise complex interpersonal trauma symptomatology in female offenders

Study objectives
1. Is a Stage 1 psychoeducational intervention effective for the stabilisation of traumatic symptomatology in a prison setting?
2. Is a Stage 1 psychoeducational intervention acceptable to female offenders in a prison setting?
3. What are the factors that enhance the effectiveness and acceptability of such an intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Scottish Prison Service, 13/06/2013
2. East of Scotland Research Ethics Service (EoSRES) REC 1, 15/11/2013, REC ref: 13/ES/0111

Study design
Randomized controlled trial and qualitative interviews

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Interpersonal trauma

Interventions
Participants will be randomly allocated to either a treatment group (Survive & Thrive: Psychoeducational material for complex and interpersonal trauma) or a waiting list intent-to-treat group.

Baseline assessments will assess trauma history and level of complex trauma symptomatology to establish eligibility.
Baseline measures:
1. Traumatic Antecedents Questionnaire Revised version 3 (TAQ, van der Kolk, 2010)
2. Self-Report Instrument for Disorders of Extreme Stress (SIDES-SR: van der Kolk, 2002)
3. Young Schema QuestionnaireShort Form 3 (YSQ-S3: Young, 2005)

A university-based statistician will assist with the randomisation of all eligible participants. Participants will be assessed blindly by the research assistant on four occasions: before treatment, post treatment as well as at 1 month and 3 months follow up. Therefore, the last assessment will be at week 17. Assessments will be conducted by means of standardised scales.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Behavioural Assessment Checklist measured at weeks 0, 5, 9 and 17

Secondary outcome measures
1. Difficulties in Emotional Regulation Scale (DERS; Gratz & Roemer, 2004).
2. Posttraumatic Stress Disorder (PTSD) Checklist Civilian Version (PCL-C: Blanchard et al., 1996)
3. The Dissociative Experiences Scale (DES II; Carlson & Putnam, 1993)
4. Hospital Anxiety and Depression Scale (HADS: Zigmond and Snaith, 1983)

Measured pre and post intervention, and at 1 month and 3 months follow-up.

Overall study start date
01/01/2014

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Being willing to participate voluntarily and to give written consent
2. Having experienced childhood or adulthood negative life events
3. Aged 1870 years old
4. Being able to cope with the demands of the interviews

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
92

Total final enrolment
44

Key exclusion criteria
1. Unwilling to participate or unwilling to give written consent
2. Unable to cope with the demands of the interview because of mental or physical illness

Date of first enrolment
01/01/2014

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
HMP Cornton Vale
Cornton Rd
Stirling
United Kingdom
FK9 5NU

Sponsor information

Organisation
Edinburgh Napier University (UK)

Sponsor details
c/o Professor Thanos Karatzias
Head of Research Support
Sighthill Campus
Edinburgh
Scotland
United Kingdom
EH11 4BN

Sponsor type
University/education

Website

http://www.napier.ac.uk

ROR
https://ror.org/03zjvnn91

Funder(s)

Funder type
Charity

Funder Name
Survivor Scotland (UK) (Ref No. BPS/SPS 1)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/09/2019

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		01/07/2020	14/04/2021	Yes	No
HRA research summary			28/06/2023	No	No