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Treating PTSD and alcohol use disorder simultaneously

Submission date
18/01/2019

Recruitment status
No longer recruiting

Registration date
06/03/2019

Overall study status
Completed

Last Edited
16/07/2025

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
Posttraumatic stress disorder (PTSD) is triggered by severe trauma. It is characterized by intrusive memories or nightmares, avoidance, hyperarousal and negative changes in cognition and mood. PTSD is common and occurs more often in women than in men (8-16 vs 4-8%). PTSD often occurs simultaneously with alcohol dependence (AD), also referred to as moderate to severe alcohol use disorder (AUD). There is effective treatment for PTSD. Prolonged exposure (PE) is one such effective treatment for PTSD. It is a manual based treatment, a type of trauma focused cognitive behavioral therapy (CBT). It has been adapted for individuals with both PTSD and substance use disorders (SUD). This new treatment is called “Concurrent Treatment of PTSD and Substance Use Disorders Using Prolonged Exposure" (COPE) and combines PE with CBT for SUD, i.e. relapse prevention (RP). RP is frequently used in the treatment of AUD.

The overall aim of this research project is to evaluate COPE in out-patient care for women with PTSD and moderate to severe AUD. The study evaluates the hypothesis that COPE will lead to greater reductions in PTSD and AUD symptom severity than RP, i.e. that COPE will be better than RP.

Who can participate?
Up to one hundred and fifty treatment-seeking women, aged >18, diagnosed with current PTSD and moderate to severe AUD will be recruited.

What does the study involve?
The study consists of three consecutive phases for each participant:
1. Screening and randomization, carried out over the course of three to four visits, including diagnostic assessment and randomization to receive COPE or RP,
2. CBT, 12 sessions of COPE or 12 sessions of RP, typically one a week,
3. follow-ups, at sessions 6 and 12, and six and nine months post baseline.

What are the possible benefits and risks of participating?
Participants will receive treatment for PTSD and AUD (COPE) or AUD (RP) respectively and their symptoms will be carefully monitored. Should further treatment be necessary post study treatment, such treatment or a referral to another health care provider will be provided.

Previous studies have shown these treatments to be safe and effective, but side effects such as temporarily worsening symptoms may occur. Should this occur, staff at the study site will provide care and support.

Where is the study run from?
The study is run from the EWA unit and PRIMA Maria in Stockholm and the University hospital in Linkoping, Sweden. The EWA unit is the lead centre.

When is the study starting and how long is it expected to run for?
The study started in 2016 and ran until May 2021.

Who is funding the study?
The study is funded by research grants from Systembolagets Alkoholforskningsrad, Stiftelsen Soderstrom-Konigska Sjukhemmet, Karolinska Institutet/Stockholm County Council, Psykiatrifonden.

Who is the main contact?
Asa Magnusson, sponsor, principal investigator, PhD, psychiatrist, is the main contact. She can be reached at asa.magnusson@ki.se

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
A randomized controlled trial of Concurrent treatment of PTSD and Substance Use Disorders using Prolonged Exposure (COPE) and Relapse Prevention (RP) in women with PTSD and Alcohol Use Disorder.

Acronym
The COPE & RP study

Study objectives
Our hypotheses are:
1. That COPE will reduce PTSD symptoms more than relapse prevention (RP), i.e. that COPE will be better than RP
2. That COPE will reduce alcohol consumption more than RP, i.e. that COPE will be better than RP

The co-primary objectives of the study are to determine whether COPE, in women with co-morbid PTSD and moderate to severe AUD, will:
1. Reduce PTSD symptoms, measured as change from baseline, to sessions 6 and 12 and six and nine months after baseline, compared to RP (measured using the Clinician-Administered PTSD Scale (CAPS))
2. Reduce alcohol use, measured as change from baseline in alcohol consumption per week (grams per week) and heavy drinking days (HDD) from baseline to session 6 and 12 and six and nine months after baseline, compared to RP (measured using the Time Line Follow Back (TLFB))

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stockholm Ethical Review Board, 13/04/2016, ref. 2016/4:4, 2016-06-22, 2016/1250-32.

Study design
A multi-center randomised controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-traumatic stress disorder and alcohol use disorder

Interventions
12 sessions of Concurrent Treatment of PTSD and Substance Use Disorders Using Prolonged Exposure (COPE), integrated cognitive behavioural therapy (CBT) for PTSD and substance use disorders (SUD) will be compared with control 12 sessions of relapse prevention (RP), i.e. CBT for SUD. The twelve sessions are to be delivered weekly, but may be given over a maximum of 20 weeks. Follow-ups will occur at sessions 6 and 12 as well as six and nine months post baseline. Participants will be randomised 1:1 to the different arms. Randomisation is provided by an organization independent from the researchers.

Intervention Type
Behavioural

Primary outcome(s)

1. PTSD symptom severity will be measured using the Clinician-Administered PTSD Scale (CAPS-5) at baseline, sessions 6 and 12 and six and nine months post baseline.
2. Alcohol consumption per week (grams per week) and heavy drinking days (HDD) will be measured using the Timeline Follow Back (TLFB) at baseline, sessions 6 and 12 and six and nine months post baseline.

Key secondary outcome(s))
1. AUD symptom severity will be measured using the AUD section of the MINI International Neuropsychiatric Interview (MINI) at baseline, sessions 6 and 12 and six and nine months post baseline.
2. Biomarkers of alcohol use (phosphatidylethanol (PEth), aspartate amino transferase (ASAT), alanine amino transferase (ALAT), gamma glutamyl transpeptidase (GGT), mean corpuscular volume (MCV) will be measured using blood samples at baseline, sessions 6 and 12 and six and nine months post baseline.
3. Biomarkers of stress (cortisol in hair) will be measured using hair samples at baseline, session 12 and six and nine months post baseline.
4. The association between genetic variation (e.g. CNR1, FAAH) and treatment response will be measured using blood samples at baseline.
5. Functioning in important areas such as work and relationships will be measured using the Addiction Severity Index – Self Report Form (ASI-SR) at baseline, session 12 and six and nine months post baseline.
6. The effect of treatment on health care consumption will be measured using the Questionnaire on Medical consumption and Productivity losses associated with Psychiatric Illness (TiC-P) at baseline, session 12 and six and nine months post baseline.
7. The association between general mental ability (GMA) and treatment response will be measured using the GMA test Matrigma at baseline, session 12 and six and nine months post baseline.
8. The association between personality and treatment response will be measured using NEO Five-Factor Inventory-3 (NEO-FFI-3) at baseline, session 12 and six and nine months post baseline.
9. The association between treatment credibility/expectancy and treatment response will be measured using the Credibility/Expectancy Questionnaire (CEQ) at baseline, sessions 1, 6, 12 and six and nine months post baseline.
10. The association between working alliance and treatment response will be measured using the Working Alliance Inventory (WAI-S) at baseline, sessions 1, 6, 12 and six and nine months post baseline.

Completion date
10/05/2021

Eligibility

Key inclusion criteria
1. Female
2. Aged 18 years or older
3. Current PTSD and moderate to severe AUD, according to DSM-5 and clinical assessment

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
90

Key exclusion criteria
1. Current moderate to severe SUD, other than alcohol and nicotine, according to DSM-5
2. Current or not stably treated psychosis
3. Suicidal or homicidal ideation deemed to be in need of treatment before study treatment can start
4. Current medication, which may affect the study outcome, and which is deemed impossible to discontinue for the duration of the study, primarily AUD medication
5. Insufficient memory of the trauma (assessed using the CAPS-5)
6. Dissociation which is more difficult or affects the subject more than her PTSD
7. Somatic or psychiatric illness where it is deemed to not be in the subject's best interest to participate in the study
8. IQ < 70

Date of first enrolment
13/04/2016

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Sweden

Study participating centre
The EWA unit at The Stockholm Centre for Depencency Disorders
Rosenlunds sjukhus
EWA-mottagningen
Box 179 03
Stockholm
Sweden
11895

Study participating centre
PRIMA Maria Oppenvård
Wollmar Yxkullsgatan 25, 1 tr
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118 50

Study participating centre
Universitetssjukhuset i Linkoping
CSAN, Psykiatriska kliniken, ingang 27, plan 9, Universitetssjukhuset
Linkoping
Sweden
581 85

Sponsor information

Organisation
Rosenlunds sjukhus [Rosenlund Hospital]

Funder(s)

Funder type
Research council

Funder Name
Systembolagets Alkoholforskningsrad

Funder Name
Stiftelsen Soderstrom-Konigska Sjukhemmet

Funder Name
Karolinska Institutet/Stockholm County Council

Funder Name
Psykiatrifonden

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be available as the current ethics approval does not allow it.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2025	16/07/2025	Yes	No