

# Treating PTSD and alcohol use disorder simultaneously

<b>Submission date</b> 18/01/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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 Linköping, 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 Söderström-Königska Sjukhemmet, Karolinska Institutet/Stockholm County Council, Psykiatrifonden.

Who is the main contact?

Åsa Magnusson, sponsor, principal investigator, PhD, psychiatrist, is the main contact. She can be reached at [asa.magnusson@ki.se](mailto:asa.magnusson@ki.se)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Åsa Magnusson

### ORCID ID

<https://orcid.org/0000-0002-4263-1957>

### Contact details

Rosenlunds sjukhus  
EWA-mottagningen  
Box 179 03  
Stockholm  
Sweden  
118 95

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

## **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 measure**

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.

## **Secondary outcome measures**

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.

**Overall study start date**

25/01/2016

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

150

**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 Dependency Disorders

Rosenlunds sjukhus

EWA-mottagningen

Box 179 03

Stockholm

Sweden

11895

## Study participating centre

### PRIMA Maria Oppenvård

Wollmar Yxkullsgatan 25, 1 tr

Stockholm

Sweden

118 50

## Study participating centre

### Universitetssjukhuset i Linköping

CSAN, Psykiatriska kliniken, ingång 27, plan 9, Universitetssjukhuset

Linköping

Sweden

581 85

# Sponsor information

## Organisation

Rosenlunds sjukhus [Rosenlund Hospital]

## Sponsor details

Rosenlunds sjukhus

EWA-mottagningen

Box 179 03

Stockholm

Sweden

118 95

**Sponsor type**

Hospital/treatment centre

## 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

**Publication and dissemination plan**

Once the study is completed a manuscript outlining it and its results will be submitted for publication in a peer-reviewed journal.

**Intention to publish date**

31/03/2022

**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?
<a href="#">Results article</a>		01/07/2025	16/07/2025	Yes	No

