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# Reconsolidation using Rewind

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 22/01/2020 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 23/01/2020 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/05/2024 | Mental and Behavioural Disorders | |

## Plain English summary of protocol

Background and study aims
Many people who experience traumatic events are left with distressing symptoms afterwards. Post-traumatic stress disorder (PTSD) is a common mental health problem and many people are helped by talking about their experiences with a therapist. Despite this, some people still struggle with their symptoms, and so it is important that the researchers can create new ways of treating PTSD to help more people. In this study, the researchers are inviting people who are currently struggling with their mental health to receive either a new kind of talking therapy called the Rewind Technique, or to join a waiting list to then receive the usual psychological treatments used in PTSD, such as cognitive behaviour therapy (CBT) and Eye Movement Desensitisation Reprocessing therapy (EMDR). As a one-to-one talking therapy the Rewind Technique has many things in common with current therapies available on the NHS, but the therapy asks patients to address your difficult experiences in a different way. Our goal is to find out if the Rewind Technique works better than for those people who join a waiting list to receive CBT or EMDR. The researchers hope that the results will be used to bring forward new treatments for NHS patients.

Who can participate?
Anyone over the age of 18 with PTSD.

What does the study involve?
Participants will be randomly allocated to receive The Rewind Technique immediately or after an eight week delay. The researchers will collect information from participants before, during and after their courses of therapy, using a combination of interviews and questionnaires. Comparing the results before and after will allow us to see if the Rewind Technique is an acceptable treatment for those with PTSD.

What are the possible benefits and risks of participating?
There is some emerging evidence for The Rewind Technique and so it may help with PTSD symptoms. While there are no known side effects or risks of The Rewind Technique some people may find addressing their experiences distressing. Participants will be monitored throughout treatment by their therapist who can provide support. Participants are also free to leave the study at any time, without giving a reason.

Where is the study run from?
Cardiff University, UK

When is the study starting and how long is it expected to run for?
November 2019 to April 2022 (updated 11/05/2021, previously: June 2021)

Who is funding the study?
Cardiff University, UK

Who is the main contact?
Dr Laurence Astill Wright (public)
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Prof Jonathan Bisson (scientific)
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# Contact information

### Type(s)
Public

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# Additional identifiers

**EudraCT/CTIS number**
Nil known

**IRAS number**

**ClinicalTrials.gov number**
Nil known

**Secondary identifying numbers**
Nil known

# Study information

**Scientific Title**
The RETURN Study: REconsolidaTion Using RewiNd

**Acronym**
RETURN

**Study objectives**
The Rewind Technique will be superior to a waitlist control group in this crossover randomised controlled trial

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
We will have submitted ethical approval via IRAS by mid-October 2019.
Sponsorship reference number: SPON1791-19

**Study design**
Two-armed phase 2 exploratory Interventional randomized controlled trial

**Primary study design**
Interventional

**Secondary study design**
Randomised cross over trial

**Study setting(s)**
Community

**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
Post Traumatic Stress Disorder (PTSD)

## Interventions
This is a cross-over waitlist controlled RCT.
The total duration of treatment will be three 60 minute sessions. One arm of the study will start Rewind post-randomisation, with the second group remaining on a waitlist for 8 weeks, and then starting Rewind at 8 weeks following the 8 week outcome assessment.
Follow up will occur at 8 and 16 weeks.
The randomisation process will be computer-based random allocation.

The intervention will comprise three 60-minute sessions following a protocol developed by David Muss which has been modified by David Muss and the research team following feedback from therapists. This will then be administered by experienced and trained psychological therapists under the supervision of David Muss and the Cardiff and Vale Traumatic Stress Service. The participant will be introduced to the technique and the theory behind it before being asked to imagine he/she is in a cinema watching a film of her/his traumatic event as if it had been captured on CCTV. Rather than the film start at the trauma itself the person with PTSD is told the film starts before the traumatic event took place and is then followed by the regular intrusive recall which includes all the images, sounds and smells plus (if this is part of the regular recall) what could have happened next but didn't. Once the recall ends, the sufferer is (metaphorically) invited to enter the screen and at that point the film is rewound at speed back to the exact starting point (where all was well before the trauma). The forward part of the loop should not take longer than 2 minutes, the rewound part about 10 seconds. This usually requires the person with PTSD to practise the technique a few times before feeling confident it is being undertaken as intended.

## Intervention Type
Behavioural

## Primary outcome measure
PTSD symptom severity measured using the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) at 8 and 16 weeks post-randomisation

## Secondary outcome measures
Measured at 8 and 16 weeks post-randomisation (unless otherwise noted):
1. PTSD symptoms (DSM-5) measured using the PTSD Checklist (PCL-5) at the start of each treatment session
2. ICD-11 PTSD and complex PTSD symptoms measured using the International Trauma Questionnaire
3. DSM-5 depressive symptoms measured using the PHQ-9 at the start of each treatment session
4. Symptoms of generalised anxiety disorder measured using the GAD-7 at the start of each treatment session
5. Symptoms of insomnia measured using the Insomnia Severity Index
6. Health-related quality of life measured using the EQ5D-5L
7. An intervention acceptability questionnaire will be administered by the Rewind therapist at the end of the final session to gauge acceptability and feasibility of the intervention, as perceived by the participant

### Overall study start date
01/10/2019

### Completion date
01/04/2022

## Eligibility

### Key inclusion criteria
1. Adults aged 18 years or over who are fluent in English
2. Able to provide informed consent
3. Meet DSM-5 criteria for PTSD

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### Total final enrolment
40

### Key exclusion criteria
1. Current psychotic or bipolar disorder
2. Traumatic brain injury
3. Substance dependence
4. Acute suicidal ideation
5. Personality disorder
6. Learning disability
7. Previous receipt of an adequate trial of trauma-focused psychological treatment for PTSD
8. Change to the type or dosage of psychotropic medication within one month of baseline assessment

### Date of first enrolment
01/10/2020

### Date of final enrolment
01/12/2021

## Locations

### Countries of recruitment
United Kingdom

Wales

### Study participating centre
**Cardiff University**
School of Medicine
UHW Main Building
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## Sponsor information

### Organisation
Cardiff University

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medicine@cardiff.ac.uk

### Sponsor type
University/education

### Website
https://www.cardiff.ac.uk/medicine/research/divisions/psychological-medicine-and-clinical-neurosciences

### ROR
https://ror.org/03kk7td41

## Funder(s)

### Funder type
University/education

### Funder Name
Cardiff University

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Universities (academic only)

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
We will present the work at academic conferences via oral and poster presentations, and facilitating workshops, engaging practising clinicians and hoping to inform their practice. Publishing the work in a prestigious, open access academic journal will increase the publicity of our research and inform the academic debate.

### Intention to publish date
01/07/2023

### Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 28/01/2021 | 12/08/2021 | Yes | No |
| Results article | | 12/10/2023 | 10/05/2024 | Yes | No |