Reconsolidation using Rewind

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
22/01/2020		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2020	Completed Condition category	[X] Results		
Last Edited		[] 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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Contact information

Type(s)

Public

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Scientific

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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 Ouestionnaire
- 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

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UHW Main Building
Heath Park
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Sponsor information

Organisation

Cardiff University

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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 protocol	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		28/01/2021	12/08/2021	Yes	No
Results article		12/10/2023	10/05/2024	Yes	No