

Eye movement desensitization and reprocessing group therapy for frontline and emergency workers in response to the COVID-19 pandemic

Submission date 05/07/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/07/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/04/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

As the coronavirus (COVID-19) pandemic spreads throughout the world, it is generating widespread anxiety, fear, stress, and trauma. People are experiencing a widespread disruption in their lives. One of the populations that this research is particularly interested in is front line health, emergency and social care workers experiencing psychological distress and trauma in response to COVID-19. The aim of this study to explore the effectiveness of an internationally recognized trauma treatment Eye Movement Desensitization and Reprocessing (EMDR) therapy (endorsed by the World Health Organisation and the International Society for Traumatic Stress Studies), delivered in a group format intensively using an online platform. The researchers want to determine whether the therapy is safe, effective, efficient and relevant. EMDR therapy is an evidence-based treatment for Post-Traumatic Stress Disorder (PTSD) and complex PTSD and is practised throughout the world.

Who can participate?

Front line health, emergency and social care workers (aged 18 years and above) experiencing psychological distress and trauma in response to COVID-19

What does the study involve?

Participants are randomly allocated into two groups. The first group will receive four therapy sessions of online group EMDR therapy equal to 8-10 hours of treatment. The treatment will consist of four sessions, run over the course of 1 week, on Monday, Wednesday, Thursday and Saturday evening between 6 pm and 8 pm. This is known as 'intensive treatment'. The second group receives a delayed treatment intervention, which is exactly the same treatment as the first group but 1 month later. The researchers can then compare the effect of the treatment on both groups.

What are the possible benefits and risks of participating?

The benefits of taking part in the study are that it contributes towards a better understanding of

early intervention psychological treatments, and how treatment can be offered as video-conference psychotherapy.

Where is the study run from?
Trauma Recovery Network (Ireland)

When is the study starting and how long is it expected to run for?
June 2020 to February 2022

Who is funding the study?
1. Trauma Response Network Ireland (Ireland)
2. EMDR All Ireland Association (Ireland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CBPS19200030-R2

Study information

Scientific Title

Early intervention eye movement desensitization and reprocessing therapy (virtual group traumatic episode protocol) for front line health, emergency and social care workers experiencing psychological distress and trauma in response to COVID-19 – a randomized control study

Acronym

VGTEP RCT

Study objectives

As the coronavirus (COVID-19) pandemic spreads throughout the world as a highly infectious disease-causing severe acute respiratory symptoms, it is also generating widespread anxiety, fear, stress and trauma. Both the virus, and the subsequent management of the pandemic – including social isolation and physical distancing, distressing symptoms, hospitalisation, and for some, death, creates a powerful trauma ripple effect. People are experiencing widespread disruption to their normal lives. Those at the acute end being frontline/emergency/ keyworkers in health and social care.

This is a contemporaneous, clinical research project under the auspices of Eye Movement Desensitization and Reprocessing (EMDR) All Ireland/Trauma Recovery Network Ireland in conjunction with five UK Higher Education Institutions: University of Worcester, Queens University – Belfast, Ulster University, Bath Spa University and Northumbria University. Its primary research participant group are frontline/emergency/keyworker health and social care workers in response to the COVID-19 pandemic with particular focus upon its impact in the Republic of Ireland (ROI).

The research focus is that of psychological trauma experienced by the research participant group and the impact of an early intervention using an empirically supported psychological treatment intervention. Ostensibly, this is a feasibility study, however, it also represents a groundbreaking collaboration of many academic institutions, under the auspices of EMDR All Ireland, in addressing the psychological wellbeing and mental health of frontline/emergency /keyworkers in regard to psychological trauma as a direct consequence of COVID-19, whilst at the same time acknowledge the importance of social distancing.

The primary focus of this research relates to the psychological health and well-being of the target population.

The research is interested in exploring the effectiveness of the following:

1. An internationally recognized trauma treatment - EMDR therapy endorsed by the World Health Organization (2013) and the International Society for Traumatic Stress Studies (2019)
2. Delivered in a group format
3. Delivered intensively
4. Using an online platform

This EMDR Group intervention is known as the Group Traumatic Episode Protocol (GTEP). As the researchers will be testing an online version, this is known as VGTEP. They want to determine that the treatment intervention is safe, effective, efficient and relevant.

Research Questions:

1. Is Early Intervention EMDR Group Therapy (VGTEP) a relevant and effective treatment intervention for frontline/emergency/keyworkers in the Republic of Ireland (ROI), who experience psychological trauma in response to COVID-19 with regards to both recruitment &

retention to the study?

2. Is Early Intervention EMDR Group Therapy (VGTEP) a safe, effective and efficient treatment intervention for frontline/emergency/keyworkers in ROI, who experience psychological trauma in response to COVID-19 with regards to trauma sequelae and co-morbid symptoms?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/07/2020, University of Worcester (College of Health, Life and Environmental Sciences, Research Office, St John's Campus, University of Worcester, Worcester, UK; +44 (0) 1905 542767; ethics@worc.ac.uk), ref: CBPS19200030-R2

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-traumatic stress disorder

Interventions

The research will utilise a randomised control trial design (RCT) of two cohorts using a delayed treatment intervention:

Experimental Cohort 1: EMDR therapy VGTEP Treatment (four sessions of 2 to 2.5 hours duration which equates to 8-10 hours of treatment intervention) in a 1-week period

Control Cohort 2: Treatment as Usual (TAU) (4 weeks) + Delayed intervention of EMDR therapy VGTEP. Treatment will also be over a 1-week period.

EMDR therapy - group intervention (group traumatic events protocol) delivered as a video-conference psychotherapy

Intervention Type

Other

Primary outcome(s)

1. Subjective levels of distress or disturbance measured using the Subjective Unit of Disturbance/ Distress (SUD) scale at pre, post, 1-month and 6-month follow-up
2. Severity of anxiety symptoms measured using the Generalized Anxiety Disorder Assessment (GAD-7) at pre, post, 1-month and 6-month follow-up
3. Severity of depression symptoms measured using the Patient Health Questionnaire (PHQ-9) at pre, post, 1-month and 6-month follow-up
4. Core features of PTSD and CPTSD measured using the International Trauma Questionnaire (ITQ) at pre, post, 1-month and 6-month follow-up

Key secondary outcome(s)

1. Imbalance between work effort and reward measured using the Effort-Reward Imbalance Questionnaire (ERI) at pre, post, 1-month and 6-month follow-up
2. Perceived transgressions, betrayals, or violations to an individual's moral code measured using the Moral Injury Event Scale (MIES) at pre, post, 1-month and 6-month follow-up
3. Health status measured using the EQ-5D at pre, post, 1-month and 6-month follow-up
4. Exposure to adverse childhood experiences measured using the Adverse Childhood Experience International Questionnaire (ACE-IQ) at pre timepoint only
5. Exposure to benevolent factors in childhood measured using the Benevolent Childhood Experiences Score (BCEs) at pre timepoint only

Completion date

01/02/2022

Eligibility

Key inclusion criteria

1. Adults (aged 18 years and above)
2. Front line health, emergency & social care workers experiencing psychological distress & trauma in response to COVID-19
3. Currently in active employment
4. Symptoms indicative of psychological distress and impact of psychological well-being and functioning
5. Impact of Events Scale-Revised Score of 24 and above

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

136

Key exclusion criteria

1. Currently not in active service
2. Currently in receipt of psychiatric or psychological treatment
3. Suicidal ideation

Date of first enrolment

01/07/2020

Date of final enrolment

30/06/2021

Locations

Countries of recruitment

Ireland

Study participating centre

Trauma Recovery Network

Dublin

Ireland

A96 KE47

Sponsor information

Organisation

Trauma Response Network Ireland

Funder(s)

Funder type

Charity

Funder Name

Trauma Response Network Ireland

Funder Name

EMDR All Ireland Association

Results and Publications

Individual participant data (IPD) sharing plan

All the raw data for the study has been placed in an international repository at <https://osf.io/ty7xe/>

IPD sharing plan summary

Stored in repository

Study outputs

Output type

[Results article](#)

[Participant information sheet](#)

Details	Date created	Date added	Peer reviewed?	Patient-facing?
	23/03/2023	18/04/2023	Yes	No
	07/07/2020	04/08/2021	No	Yes