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**PARTICIPANT INFORMATION SHEET AND PRIVACY NOTICE**

**TITLE OF PROJECT:**Early Intervention EMDR Therapy (Virtual Group Traumatic Episode Protocol – VGTEP) for Front Line Health, Emergency & Social Care Workers experiencing Psychological Distress & Trauma in response to Covid-19 – A Randomized Control Trial (RCT) Study

**Invitation**

The University of Worcester engages in a wide range of research that seeks to provide a greater understanding of the world around us. At this present moment in time, the world is facing a pandemic caused by the COVID-19 Coronavirus. You are invited to be part of a study exploring the impact of a virtual group trauma treatment that will be delivered via an online platform. Before deciding if you want to be involved in this project, it is crucial that you understand why it is happening and what the implications are for you if you decide to participate. This document will explain why we are engaging in this particular research and how you might be able to assist us. If, by the end of this document, you still have any outstanding questions, please feel free to ask one of the members of the research team. Their contact details are included at the end.

**What is the purpose of the research?**

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 & Social Care Workers experiencing Psychological Distress & Trauma in response to Covid-19. This group is the target population for this research.

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

What we are particularly interested in exploring the effectiveness of the following:

1. An internationally recognized trauma treatment - EMDR therapy (endorsed by the World Health Organisation and the International Society for Traumatic Stress Studies)
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 we will be testing an online version, this is known as VGTEP. We want to determine that the treatment intervention is safe, effective, efficient and relevant.

Just to say more about EMDR Therapy, this is an evidence-based treatment for Post-traumatic Stress Disorder (PTSD) and also complex PTSD. It is a treatment intervention practiced throughout the world.

Prior to recruitment to the study we used a trauma assessment known as the Impact of Events Scale – Revised (IES-R). This uses a cut off score of 24 and above. This score is a helpful indicator as to some of potential psychological difficulties you maybe encountering presently. So, because you scored above 24 – this is the reason you were invited to participate.

Although the study is mainly looking at trauma symptoms, we are also looking at the following aspects:

* anxiety
* depression
* adverse childhood experiences
* benevolent childhood experiences
* moral injury
* Effort-reward imbalance in the workplace
* Quality of Life measure

We have calculated that it takes 9-11 minutes to complete the range of measures we are using for the study.

The design of the study will use what we call, randomization, to split the research population into two groups. The first group will receive four therapy sessions of VGTEP equal to 8-10 hours of treatment. The VGTEP treatment will consist of four sessions, run over the course of 1-week, on Monday, Wednesday, Thursday and Saturday evening between 6pm and 8pm. This is known as ‘intensive treatment’.

The second group is called a delayed treatment intervention. What this means is that for the second group, we slightly delay the treatment intervention for one month, and then we carry out exactly the same treatment as the first group. We can then compare the effect of the treatment (VGTEP) on both groups 1 and 2.

We estimate that this research project will run for a 12-months.

**Who is undertaking the research?**

The Lead Researcher for the Project is Dr Derek Farrell, who is based at the University of Worcester. Derek is an international expert in EMDR Therapy. His contact details for if you want further information are available at the end of this document.

There are several other UK-based Universities involved in this research project, including Ulster, Bath Spa, Queens, and Northumbria. Again, their contact details are available at the end of the document.

An essential partner within the research is the Trauma Recovery Network Ireland (TRN). TRN is an EMDR Therapy organization, based in Dublin, that specializes in providing early intervention trauma treatment in response to a major incident or disaster.

**Why have I been invited to participate?**

You are invited to participate in this study as you are a frontline worker, responding to the COVID-19 pandemic and have experienced an impact on your psychological health and well-being. On the Trauma Response Network – Ireland Website there is information about the study. To participate in the study all you would need to do is ‘register your interest’ by giving permission for a member of TRN Ireland to contact you. Initial contact is usually made via telephone at a time that is convenient to you.

**Do I have to take part?**

No. It is entirely up to you whether you wish to participate in the study. Hopefully, this information sheet will help inform that decision, and you are encouraged to discuss participation with others. If you choose to participate, you can withdraw from the study at any point without disclosing why.

**Who is funding the research?**

Currently, this research is unfunded.

**What will it mean for me if I choose to participate?**

If you choose to participate in the study, then a member of the research team will contact you to arrange for an initial telephone consultation. This meeting will provide you with an opportunity to discuss any questions or queries you may have regarding the research project.

During the research, you are asked to complete some questionnaires several times throughout the investigation. This data will assist the research team in monitoring your progress during the treatment, and also for some time afterward. We check these measures after one, three and six months. These checks are known as a follow-up (FU). These measures will be carried out by the Trauma Response Network Ireland. As mentioned earlier, we estimate that these measures will take 9-11 minutes to complete.

The treatment itself (VGTEP) will consist of four online sessions of approximately 2 -2/5 hours in duration. During each session, there will be two EMDR therapists present; one will lead; the other will be in a supportive role. Each session will be led by a different EMDR therapist. We call this therapist rotation. Each group will consist of six other research participants.

The VGTEP treatment four sessions will run over the course of 1-week, on Monday, Wednesday, Thursday and Saturday evening between 6pm and 8pm. This is known as Intensive Trauma Treatment.

For this study, each of the EMDR therapists are highly trained mental health workers with many years of experience of using EMDR therapy, alongside many other psychological treatment interventions to treat various clinical populations.

The online treatment platform that we are using for the research is ZOOM. Using Zoom allows us to record each of the VGTEP sessions. By recording the treatment sessions, this then helps to ensure that the treatment is applied correctly. An international expert in VGTEP then checks these recordings. We call this a treatment fidelity check. These recordings are then destroyed once the fidelity checks have been completed.

After the fourth VGTEP session, you will be asked to repeat the same questionnaires completed at the start of the treatment. We will ask you to repeat these measures on three further occasions; after 1-month, 3-months and 6-months.

**Who has oversight of the research?**

For this research to proceed, it must be approved by the University of Worcester in line with its Research Ethics Policy. The University of Worcester acts in compliance with the General Data Protection Regulation [GDPR] Act (2018). For more on our approach to Information Assurance and Security visit:

<https://www.worcester.ac.uk/informationassurance/index.html>.

This research, in compliance with GDPR (2018), ensures that any data is:

1. processed lawfully, fairly and in a transparent manner
2. collected only for specified, explicit and legitimate purposes, and not be further processed in any way incompatible with those
3. adequate, relevant and limited to what is necessary concerning the purposes for which it is processed
4. accurate and, where appropriate, kept up-to-date
5. not kept as identifiable data for longer than necessary for the purposes concerned
6. processed securely

**Will the information collected in this study be kept confidential and anonymous?**

All information collected in this study will be entirely anonymous and unidentifiable. No individual information will be reported. Only the research team will have access to this documentation.

During the VGTEP sessions you will be allocated into a group with five other participants. During the treatment sessions research participants may disclose personal information. It is imperative that confidentiality and nondisclosure is maintained. This will be reinforced by the VGTEP Therapists at the start of each session. This aspect will be included in the Participant Consent Form.

**What happens if the VGTEP intervention is not suitable for me?**

If the VGTEP intervention becomes too challenging, or overwhelming, or there is a need to drop out of the study, then 1:1 support will be made available, on a pro-bono basis, by Mirabilis Health in Glengormley, Northern Ireland under the Clinical Leadership of Professor Paul Miller – Consultant Psychiatrist. This is a service which offers expert mental health services including Consultant Psychiatrists, Clinical Psychologists, Mental Health Nurses and Registered Psychotherapists

**What will happen to my results?**

It is anticipated that the results of this study will inform the research evidence-based surrounding effective trauma treatments. The research findings will also be reported in peer-reviewed scientific journals and presented at international research conferences.

During the project, all data / information will be kept securely in line with the University’s Policy for the Effective Management of Research Data and its [Information Security Policy](https://www.worcester.ac.uk/informationassurance/content_images/Information_Security_Policy_v_1.1_July_2017%281%29.pdf).

The findings from the research project will be used in the following ways:

* To use the research data and anonymised information gathered from participants in the research project to seek new knowledge and understanding that can be derived from the information we have gathered.
* To summarise this information in written form for the purposes of dissemination (through research reports, conference papers, journal articles or other publications).
* Any information disseminated / published will be at a summary level and will be fully anonymised. There will be no way of identifying your individual personal information within the published results.
* To use the summary and conclusions arising from the research project for teaching and further research purposes. Again, any information used in this way will be at a summary level and will be fully anonymised. There will be no way of identifying your individual personal information from the summary information used in this way.

If you wish to receive a summary of the research findings or to be given access to any of the publications arising from the research, please contact the lead investigator: d.farrell@worc.ac.uk

**How will my data be stored and how long will it be stored for?**

Video data of the VGTEP sessions will be deleted once the treatment fidelity checks have been carried out. Your consent form will be kept within the University of Worcester. All electronic data are stored on a double password-protected computer at the University of Worcester. All data will be stored following the University of Worcester guidelines and GDPR (2018) and kept for as long as possible subject to any legal restrictions on preservation.

The data will initially be collected in the Republic of Ireland by the Trauma Response Network. The data will eventually be transferred to the University of Worcester for data analysis. At this stage the research team as no means of identifying any of the research participants. The data will be transferred via an encrypted, password protected USB by use of a courier service as a registered (and tracked) parcel.

**How can I find out what information you hold about me?**

You have certain rights concerning the personal information the University holds about you. For more information about Individual Rights under GDPR (2018) and how you exercise them, please visit <https://www.worcester.ac.uk/informationassurance/requests-for-personal-data.html>.

**What happens next?**

Please keep this information sheet. If you do decide to take part, please either contact the researcher using the details below.

**Thank you for taking the time to read this information.**

If you decide you want to take part in our project, and we hope you do, or if you have any further questions, then please contact Dr. Derek Farrell – d.farrell@worc.ac.uk.

Equally you can contact Johnny Moran - Trauma Response Network Ireland National Co-ordinator: johnny@openmindcentre.ie

If you have any concerns about the project at this point or any later date, you may contact the researcher (contact as above). However, if you would like to speak to an independent person who is not a member of the research team, please contact Michelle Jellis at the University of Worcester, using the following details:

**Michelle Jellis**

Secretary to Research Ethics Panel for College of Business, Psychology, and Sport

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**Person responsible for this document:**

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* Gus Murray – President of EMDR All-Ireland: gusmurray18@gmail.com
* Johnny Moran – Trauma Response Network Ireland National Co-ordinator: johnny@openmindcentre.ie

**Additional Resources:**

**HSE**Health Services Executive   <https://www2.hse.ie/coronavirus/>

**HSE**  Counselling in Primary Care   01 6637403

**HSE**  National Counselling Service    1800234111

**MyMind**

Online counselling service
Visit [mymind.org](https://mymind.org/)
hq@mymind.org

**Shine**

Remote support and an outreach service to people  by phone and email.
Visit [shine.ie/covid-19](https://www.shine.ie/covid-19/)
phil@shine.ie

**Suicide or Survive (SOS)**

Free online wellness workshops and programmes
Visit [suicideorsurvive.ie](https://suicideorsurvive.ie/)

**Samaritans**

Emotional support to anyone in distress or struggling to cope.
Freephone 116 123 every day 24 hours a day
jo@samaritans.ie

**Pieta House**

Telephone and text-based support counselling for people who are suicidal or engaging in self-harm.
Freephone 1800 247 247 every day 24 hours a day
Text HELP to 51444 - standard message rates apply
Visit [pieta.ie](https://www.pieta.ie/)

**Aware**

Information and support to anyone over 18. Issues relating to mood or the mood of a friend or family member, or who has depression or bipolar.

Freephone support line 1800 80 48 48 10am to 10pm every day
supportmail@aware.ie
Visit [aware.ie](https://www.aware.ie/)

**Crisis Text Line Ireland**

Confidential messaging support service
Text TALK to 086 1800 280 every day 24 hours a day .

**Mental Health Ireland**

Information and support for people who experience mental health difficulties
Information line 01 284 1166 from 9am to 5pm Monday to Friday
Visit [mentalhealthireland.ie](https://www.mentalhealthireland.ie/)
info@mentalhealthireland.ie

**GROW Mental Health Recovery**

Information line 1890 474 474
Six-week guide on coping with COVID19, consisting of podcasts, practical resources and information.
Visit [grow.ie](https://grow.ie/)
info@grow.ie