

# A study of resilience training for student paramedics

<b>Submission date</b> 01/10/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/11/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Research indicates that paramedics carry an increased risk for depression and a severe stress condition called posttraumatic stress disorder (PTSD) due to the nature of their work. Past research has identified early predictors of these problems in student paramedics. A training programme has been developed that aims to prevent these problems from developing by modifying the predictors linked to their onset. The study aims to evaluate if study paramedics benefit from resilience training, which programme best helps student paramedics, and if the interventions are associated with improvements in physical health.

### Who can participate?

Students aged 18 to 65 years who are training to be paramedics and who are in years 1, 2 or 3 of their paramedic programme.

### What does the study involve?

Participants complete questionnaires about depression and post-traumatic stress. Eligible participants are invited to complete a longer set of questionnaires that measure levels of wellbeing, resilience and stress and to answer a few questions about stress symptoms over the telephone with the research assistant. Participants are randomly allocated to one of the two internet-based courses which will start within a few weeks or to standard practice. Participants allocated to standard practice are offered the course after two years. Participants are invited to give a blood sample (1 teaspoon) and six saliva samples collected upon awakening, 15, 30 and 60 minutes after awakening, and at 12 noon and 8 pm. Samples are collected before the course (or standard practice), immediately after, 12 and 24 months post course (or standard practice). Blood samples are analysed for a marker of inflammation called C-reactive protein. Saliva samples are analysed to measure a stress hormone called cortisol. The main phase of the course is 6 weeks. Over the course of the interventions, participants are asked to complete questionnaires at five time points: before the intervention, after the intervention, six, 12 and 24 months after the intervention.

### What are the possible benefits and risks of participating?

Participation could lead to improvements in resilience and mental wellbeing. Also, participation will help guide improvements to the course before it is made more widely available. There are

no risks associated with completing the questionnaires or the interventions or receiving standard practice or taking saliva samples. There are common risks associated with taking blood. It can be uncomfortable and result in fainting, localised pain, or bruising.

Where is the study run from?

The study takes place at University of Brighton, University of Worcester, Bournemouth University, Oxford-Brookes University and University of Hertfordshire.

When is the study starting and how long is it expected to run for?

October 2017 to December 2020

Who is funding the study?

MQ, Transforming Mental Health: Mental Health Research Charity (UK)

Who is the main contact?

Dr Jennifer Wild

## Contact information

**Type(s)**

Public

**Contact name**

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**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

PREVENT-PTSD/Protocol V1

## Study information

**Scientific Title**

Preventing PTSD, depression, and associated health problems in student paramedics: A randomised controlled trial of internet-delivered cognitive training for resilience (iCT-R)

**Study objectives**

Compared to Mind-Online and standard practice, internet-delivered cognitive training for resilience (iCT-R) will lead to:

1. Fewer cases of PTSD and Major Depression (including subsyndromal PTSD and MD) and less PTSD and MD symptomatology at follow-up
2. Greater improvement in secondary outcome measures (resilience, rumination, hormone and immune function, smoking, weight gain, alcohol use, symptoms of anxiety, and sleep problems, psychological distress, wellbeing)
3. Smaller costs per QALY gained

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Medical Sciences Inter-Divisional Research Ethics Committee at the University of Oxford, 17/08/2017, ref: R44116/RE001

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet**

See study outputs table

**Health condition(s) or problem(s) studied**

Prevention of PTSD and depression, including subsyndromal PTSD and depression.

**Interventions**

Participants complete questionnaires about depression and post-traumatic stress. They are not able to take part if the questionnaires suggest that they may have one of these problems and would benefit from treatment. If this is the case, the researcher talks with the participant and gives them suggestions about what may be helpful, such as visiting their GP or accessing other local services. Participants are able to take part if the questionnaires suggest that they do not have depression or post-traumatic stress. Eligible participants are invited to complete a longer set of questionnaires that measure levels of wellbeing, resilience and stress and to answer a few questions about stress symptoms over the telephone with the research assistant.

Once they have completed these, they will be randomly allocated to one of the two internet-based courses which will start within a few weeks or to standard practice. Participants allocated to standard practice are offered the course after two years. Participants are invited to give a blood sample (1 teaspoon) and six saliva samples collected upon awakening, 15, 30 and 60 minutes after awakening, and at 12 noon and 8 pm. Samples are collected before the course (or standard practice), immediately after, 12 and 24 months post course (or standard practice). Blood samples will be analysed for a marker of inflammation called C-reactive protein. Saliva samples are analysed to measure a stress hormone called cortisol. The main phase of the course is six weeks. If participants are allocated to either of the internet-based courses they work through the internet programme modules in the comfort of their home with support from a wellbeing coach via SMS or email, depending on their preference.

There are three training programmes:

1. Internet-delivered cognitive training for resilience (iCT-R). This training consists of six online modules, which cover helpful and unhelpful thinking, dwelling, helpful and unhelpful attention, then vs now training, dealing with worry and developing a blueprint.
2. Mind-Online covers dealing with stress, sleep problems, anger, depression, post-traumatic stress disorder and mindfulness.
3. Standard practice refers to training-as-usual, information on wellbeing and stress that is provided to students as part of their university programme.

Over the course of the interventions, participants are asked to complete questionnaires at five time points: before the intervention, after the intervention, six, 12 and 24 months after the intervention. The questionnaires take 20 minutes to complete at all time points except at 6 months post-intervention, when they take just 10 minutes to complete.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Diagnoses of post-traumatic stress disorder (PTSD) and major depression (MD) are measured using the Structured Clinical Interview for DSM-5 – PTSD and MD modules at baseline, six weeks, one and two year follow up
2. PTSD and MD symptomatology are measured using the PTSD Symptom Checklist (PCL-5) and the Patient Health Questionnaire (PHQ-9) at baseline, six weeks, six months and one and two year follow-up

## **Secondary outcome measures**

1. Resilience is measured using the Connor Davidson Resilience Questionnaire (CD-RISC) and the Resilience Scale (Wagnild & Young, 1993) at baseline, six weeks and one and two year follow-up
2. RRumination is measured with the Ruminative Response Scale (brooding subscale) and the dwelling subscale of the RIQ at baseline, six weeks, and one and two year follow-up
3. Responses to intrusive memories are measured using the Response to Intrusions Questionnaire (RIQ) at baseline, six weeks and one and two year follow-up
4. Symptoms of anxiety are measured using the Generalized Anxiety Disorder 7-item Scale (GAD-7) at baseline, six weeks and one and two year follow-up
5. Smoking and alcohol use are measured with the Smoking and Alcohol Use (unpublished) at baseline, six weeks, and one and two year follow-up
6. Weight and height are measured with the Weight and Height Questionnaire (unpublished) at baseline, six weeks and one and two year follow-up

7. Sleep quality and duration is measured with the Insomnia Severity Index at baseline, six weeks and one and two year follow-up
8. Psychological distress is measured with the General Health Questionnaire (GHQ-12) at baseline, six weeks and one and two year follow-up
9. Well-being is measured with the WEMWBS at baseline, six weeks and one and two year follow-up
10. Levels of cortisol will be assessed by ELISA assay analysis on samples collected upon awakening, 15, 30, and 60 minutes after awakening, and at 12 noon and 8 pm at baseline, six weeks, and one and two year follow-up
11. High sensitivity C-reactive protein levels will be measured using an enzyme-linked immunosorbent assay in fasting serum samples collected at baseline, six weeks and one and two year follow-up
12. Quality adjusted life years are determined with the EuroQoL (EQ-5D-5L) administered at baseline, six weeks, one and two year follow-up
13. Costs associated with psychiatric illness are being measured with the Trimbos/iMTA Questionnaire for Costs associated with Psychiatric Illness (TiC-P) and the Client Service Receipt Inventory measured at baseline, six weeks and one and two year follow-up

**Overall study start date**

13/01/2016

**Completion date**

30/01/2021

## Eligibility

**Key inclusion criteria**

1. Aged 18 and above
2. In years 1, 2 or 3 of student paramedic training
3. Access to internet
4. Willing to be randomly allocated

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

570

**Key exclusion criteria**

Current symptoms of PTSD or Major Depression requiring treatment.

**Date of first enrolment**

16/10/2017

**Date of final enrolment**

30/09/2018

## **Locations**

**Countries of recruitment**

United Kingdom

**Study participating centre**

**University of Brighton**

United Kingdom

BN1 9PH

**Study participating centre**

**University of Worcester**

United Kingdom

WR2 6AJ

**Study participating centre**

**Bournemouth University**

United Kingdom

BH1 3LT

**Study participating centre**

**University of Hertfordshire**

United Kingdom

AL10 9AB

**Study participating centre**

**Oxford-Brookes University**

United Kingdom

OX3 0FL

## **Sponsor information**

**Organisation**

University of Oxford

**Sponsor details**

Wellington Square  
Oxford  
England  
United Kingdom  
OX12JD

**Sponsor type**

University/education

**ROR**

<https://ror.org/052gg0110>

**Funder(s)****Funder type**

Charity

**Funder Name**

MQ: Transforming Mental Health

**Alternative Name(s)**

Mental Health Research, MQ: Transforming Mental Health, MQ

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

The results of the trial will be submitted for publication by September 2021.

**Intention to publish date**

30/09/2021

**Individual participant data (IPD) sharing plan**

The data will be stored in the data repository (UK data archives <http://www.data-archive.ac.uk>) only if the journal to which the publication is submitted requires that the data be stored in the repository. If the journal requires this, then the data to be stored will be numerical aggregate data with no personal identifying information whatsoever. Only anonymised aggregate data would be stored, if required. The data that would be stored would be the following: the condition of the participant (e.g, mixed digital group intervention, digital only or the wait-list condition) and baseline, post-intervention and follow-up sum scores of the primary and secondary outcome measures. The trialists will not make available any personal identifying information, such as age, years of education, marital status or any other personal identifying information. Participants who will be recruited into the trial will be required to consent to the storage of anonymised data in this form and this is included in the consent form. To gain access to the data, the UK data archives requires the individual requesting access to be a registered user. To be a registered user, the individual must work for a registered organisation, such as the University of Oxford or other registered universities. The timing of availability would be one year after the end of the study. There are no ethical risks for the storage of the data in this form.

## IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 2.0	11/08/2017	15/11/2023	No	Yes
<a href="#">Protocol article</a>		31/12/2018	15/11/2023	Yes	No