ISRCTN16493616 https://doi.org/10.1186/ISRCTN16493616

A study of resilience training for student paramedics

Submission date	Recruitment status	[X] Prospectively registered
01/10/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/10/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/11/2023	Mental and Behavioural Disorders	[ ] 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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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

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Wellington Square
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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?
Participant information sheet	version 2.0	11/08/2017	15/11/2023	No	Yes
Protocol article		31/12/2018	15/11/2023	Yes	No