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An evaluation of a new resilience intervention for emergency workers

Submission date	Recruitment status	[X] Prospectively registered
25/10/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/11/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/11/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Emergency services personnel work in high-pressure environments and are regularly exposed to stressful incidents. There are a small number of programmes available to increase their resilience to stress, but they do not work very well. The factors that increase the risk of mental ill health have been identified and a new programme has been developed to change these risk factors. The aim of this study is to test the new programme to determine whether or not it improves wellbeing and resilience to stress.

Who can participate?
Adults aged 18 to 67 who work in one of the four emergency services: police, fire and rescue, ambulance, and search and rescue

What does the study involve?
Participants complete questionnaires about depression and anxiety. 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. Participants are then randomly allocated to one of three groups. The first group receive the new programme, which consists of four modules to complete online which take about 20 minutes per week, and four group sessions two hours each in length covering the main topics linked to maintaining resilience. Group sessions take place at one of the four Mind sites: Peterborough and Fenland, Tyneside, Wirral, or London (City, Hackney and Waltham Forest). The programme is delivered over four weeks. The second group receive the digital-only programme, which consists of completing online modules about mental health and wellbeing, taking about 30 minutes per week over four weeks. The third group are put on a waiting list and receive no treatment for four months and then receive the new programme afterwards. Over the course of the programmes, participants complete a number of questionnaires assessing their mental wellbeing and life satisfaction at three times: before the programme, after the programme, and at 3-month follow-up. The questionnaires are short and

take about 30 minutes to complete before the programme, and 20 minutes after the programme and at follow-up. We also ask participants to complete a very brief questionnaire every week. A sample of participants is invited for in-depth interviews after the programme.

What are the possible benefits and risks of participating?
Participants may experience improvements in wellbeing. Also, participation will likely guide future programmes to improve wellbeing and resilience in high-risk occupations. There are no risks associated with taking part.

Where is the study run from?
The study takes place at one of the four Mind sites: Peterborough and Fenland, Tyneside, Wirral, or London (City, Hackney and Waltham Forest).

When is the study starting and how long is it expected to run for?
October 2016 to April 2017

Who is funding the study?
Mind, the mental health charity (UK)

Who is the main contact?
Dr Jennifer Wild

Contact information

Type(s)
Public

Contact name
Dr Jennifer Wild

ORCID ID
https://orcid.org/0000-0001-5463-1711

Contact details
Department of Experimental Psychology
University of Oxford
South Parks Road
Oxford
United Kingdom
OX1 3UD

Additional identifiers

Protocol serial number
WILD/NEF/MIND/REVISED RESILIENCE/102016

Study information

Scientific Title
A randomised controlled trial to evaluate a new resilience intervention for emergency workers

Study objectives
Compared to the placebo and wait-list control conditions, the new resilience intervention will lead to greater:
1. Satisfaction with life
2. Wellbeing
3. Awareness of mental health management tools
4. Mindful attention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Sciences Inter-Divisional Research Ethics Committee, 14/10/2016, ref: R47862/RE001

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Emergency workers will be randomly allocated to receive one of the following three interventions:
1. The new resilience intervention, which consists of four digital modules covering four main topics linked to maintaining resilience (attention training, dwelling, dealing with difficult emotions and transforming worry). It is delivered over four weeks. Each week the participant completes a digital module lasting 15/20 minutes, and attends a linked group session at one of four local Mind centres lasting 2 hours with a break. The group session covers experiential exercises, work in pairs and group discussion. It is delivered over 4 weeks.
2. The digital-only intervention, which consists of reading material about mental health and wellbeing delivered over 4 weeks.
3. The wait-list condition; participants will receive the new resilience intervention 4 months later.
The mental wellbeing and life satisfaction of participants in each condition are compared at baseline, 4 weeks later, and at 3-month follow-up.

Intervention Type
Other

Primary outcome(s)
Measured at baseline, post-intervention and at 3 month follow-up:
1. Wellbeing, measured with the Warwick Edinburgh Mental Wellbeing scale and the ONS Wellbeing questions (item 1)
2. Mindful attention, measured with the Mindful Attention and Awareness Scale

Key secondary outcome(s))
Measured at baseline, post-intervention and at 3 month follow-up:
1. General health, measured with the General Health Questionnaire - 12-item version
2. Self-reported resilience, measured with statements about resilience with Likert response options
3. Overall level of satisfaction, measured with statements about life satisfaction with Likert response options
4. Awareness of mental health management tools, measured with questions about knowledge of mental health management tools with Likert responses
5. Rumination, measured with statements about dwelling with Likert response options
6. Mental health (depression and anxiety), measured with the 9-item Patient Health Questionnaire (PHQ-9) and the 7-item Generalised Anxiety Disorder (GAD-7) scale

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Adults aged 18 to 67
2. Fluent in English
3. Work in one of the four emergency services: police, fire and rescue, ambulance, and search and rescue

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Participants who are depressed or suffering from PTSD and who require treatment for these conditions

Date of first enrolment
02/11/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
Tyneside and Northumberland Mind
NE8 4QL

Study participating centre
Mind in the City, Hackney and Waltham Forest
E9 7SN

Study participating centre
Wirral Mind
CH41 5DL

Study participating centre
Peterborough & Fenland Mind
PE2 7BW

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Mind, the mental health charity

Results and Publications

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		01/11/2016	01/11/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes