Testing the efficacy of a mental health education program for military recruits

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/10/2016		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/10/2016	Completed	[X] Results		
Last Edited 31/10/2019	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

The Canadian Armed Forces recognize the importance of maintaining good mental health among personnel. The Road to Mental Readiness (R2MR) mental health education and training program was developed and launched to help military members maintain good mental health throughout their career. All Canadian Armed forces non-commissioned member recruits receive R2MR mental health training during Basic Military Qualification training. These key components or objectives are aimed at increasing knowledge about mental health, teaching stress management skills, and changing negative attitudes towards mental health service use. The aim of this study is to assess how well mental health training works with respect to mental health and well-being, resilience, training performance, and attitudes.

Who can participate?

Anglophone and Francophone Canadian Armed forces non-commissioned member recruits partaking in the Basic Military Qualification (BMQ) training at Canadian Forces Leadership and Recruit School

What does the study involve?

Anglophone platoons are randomly allocated to receive the R2MR mental health education /training conducted either at the beginning or later on in BMQ. Francophone platoons are allocated to R2MR mental health training conducted at the beginning of the BMQ. All participants complete questionnaires assessing current mental health and well-being, resilience, performance, and attitudes at three times over the course of the BMQ training. Time commitment for this study is 80 minutes at each of the three assessments (start, mid-point and end of the BMQ).

What are the possible benefits and risks of participating?

This study will provide information on how well mental health training works within a military context. The results of this study will indicate how well mental health training works and whether it needs to be changed to better meet the needs of Canadian Armed Forces recruits. There are no known risks associated with this study.

Where is the study run from? Saint-Jean-sur-Richelieu, Québec, Canada

When is the study starting and how long is it expected to run for? May 2016 to December 2018

Who is funding the study?
Canadian Forces Health Services

Who is the main contact? Dr Deniz Fikretoglu

Contact information

Type(s)

Scientific

Contact name

Dr Deniz Fikretoglu

Contact details

1133 Sheppard Ave. W Toronto Canada M3K 2C9

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2016-021

Study information

Scientific Title

Testing the efficacy and effectiveness of the Road to Mental Readiness (R2MR) mental health training program during basic military qualification

Study objectives

The Road to Mental Readiness (R2MR) mental health training program at Basic Military Qualification (BMQ) has three objectives:

- 1. To increase basic mental health literacy
- 2. To teach stress management skills
- 3. To change attitudes and intentions towards mental health service use The overall objective of this study is to assess the efficacy of R2MR in improving psychological

health, psychological resilience, attitudinal and performance outcomes for Canadian Armed Forces (CAF) Non-Commissioned Member (NCM) recruits.

The trialists hypothesize that:

- 1. R2MR will have a beneficial effect on psychological health
- 2. R2MR will have a beneficial effect on psychological resilience
- 3. R2MR will have a beneficial effect on attitudes towards and intentions for mental health service use
- 4. R2MR will have a beneficial effect on performance in BMQ training
- 5. R2MR's beneficial effects will be in the very small-to-medium range
- 6. R2MR's beneficial effects will diminish over time, from immediately post-intervention to short-term follow-up

The trialists hypothesize in an exploratory fashion, that:

- 1. Stress management and mental health literacy will mediate the effects of R2MR
- 2. Some socio-demographic variables such as sex and education will moderate the effects of R2MR

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human Research Ethics Committee (HREC), Defence Research & Development Canada - Toronto, 21/06/2016, ref: 2016-021

Study design

Anglophones: Single-centre double-blinded group randomized control trial design Francophones: Single-centre group non-randomized/uncontrolled longitudinal (pre-post-post) observational study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Psychological well-being

Interventions

Incoming Anglophone platoons will be assigned, using blocked randomization, to either the Intervention (i.e., receiving R2MR early on in the BMQ) or a delayed intervention control (i.e.,

receiving R2MR later on in BMQ). R2MR involves participants attending a 160-minute class about mental health literacy, stress management skills, and attitudes towards mental healthcare. Baseline measures will be collected at the beginning, mid-point, and end of the BMQ training.

In the observational study of Francophone recruits, all Francophone platoons will receive R2MR at the beginning of BMQ. The data collection schedule will be identical to the Anglophone study.

Intervention Type

Behavioural

Primary outcome measure

The following measures will be collected at the beginning (week 2), mid-point (week 5), and end (week 9) of the BMQ training:

- 1. Psychological health, measured using the Patient Health Questionnaire, Kessler Psychological Distress Scale, and Subjective Units of Distress Scale
- 2. Psychological resilience, measured using the Connor-Davidson Resilience Scale and Test of Performance Strategies
- 3. Mental health service use attitudes and intentions, measured using the Canadian Armed Forces Mental Health Service Use Questionnaire and R2MR Program Evaluation Form

Secondary outcome measures

Training graduation rate, indicated by performance in the BMQ course at week 9 (completion of the BMQ)

Overall study start date

01/05/2016

Completion date

31/12/2018

Eligibility

Key inclusion criteria

Group randomized controlled trial:

- 1. Anglophone
- 2. Canadian Armed Forces non-commissioned member recruits
- 3. Partaking in the Basic Military Qualification training at Canadian Forces Leadership and Recruit School
- 4. Ages 16-65, inclusive

Parallel observational study:

- 1. Francophone
- 2. Canadian Armed Forces non-commissioned member recruits
- 3. Partaking in the Basic Military Qualification training at Canadian Forces Leadership and Recruit School
- 4. Ages 16-65, inclusive

Participant type(s)

Other

Age group

Adult

Sex

Both

Target number of participants

53 platoons (approximately 60 members in each platoon)

Total final enrolment

2831

Key exclusion criteria

N/A

Date of first enrolment

01/10/2016

Date of final enrolment

31/05/2018

Locations

Countries of recruitment

Canada

Study participating centre Saint-Jean-sur-Richelieu, Québec

Canada

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Sponsor information

Organisation

Canadian Forces Health Services

Sponsor details

1745 Alta Vista Drive Ottawa Canada K1A 0K6

Sponsor type

Government

ROR

Funder(s)

Funder type

Government

Funder Name

Canadian Forces Health Services

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

30/06/2019

Individual participant data (IPD) sharing plan

Participant level data will not be disclosed in order to ensure confidentiality for study participants. Data will be held by Defence Research and Development Canada.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/10/2019	31/10/2019	Yes	No