

Can we carry out an online health coaching program for Canadian armed forces personnel receiving treatment for mental health?

Submission date 01/05/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/05/2022	Condition category 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

Military service impacts mental health, with existing data indicating substantial disability and career effects. CAF psychiatric clinics serve active members diagnosed with Major Depressive Disorder (MDD), Post-Traumatic Stress Disorder (PTSD), Generalized Anxiety Disorder (GAD) and other mental health challenges. Published studies indicate non-compliance with antidepressant medication in 30% - 50% of patients and psychotherapy dropout in 69% of PTSD patients (only 31% complete 8 or more therapy sessions). Online interventions that increase engagement can be important adjuncts or alternatives to in-person service. In this study we assess the feasibility of an online health coaching intervention with members of the Canadian Armed Forces (CAF) being treated by CAF psychiatrists and diagnosed with depression and anxiety disorders.

Who can participate?

Participants must be active members of the Canadian Armed Forces (CAF) who are being treated by CAF psychiatrists and diagnosed with depression and anxiety disorders.

What does the study involve?

Sixteen weeks of online access to the Nex J, Inc. Connected Wellness Program platform which is populated with 36 workbooks and 56 videos created to assist people experiencing depressive and anxiety symptoms. Participants also receive 16 weeks of phone-based personal health coaching that is administered by Registered Kinesiologists (RKIN) supervised by a registered clinical psychologist.

What are the possible benefits and risks of participating?

Benefits can include significant reductions in symptoms and related distress (depression and anxiety). There are risks that thinking about and discussing depression-anxiety symptoms can result in symptom exacerbation and intensified distress.

Where is the study run from?

York University (Canada)

When is the study starting and how long is it expected to run for?
August 2020 to March 2021

Who is funding the study?
Build in Canada Innovation Program (BCIP) (Canada)

Who is the main contact?
Prof. Paul Ritvo
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-006

Study information

Scientific Title
Feasibility of an online health coaching program for Canadian armed forces personnel receiving treatment for mental health

Study objectives

Health coaching, in combination with use of the Nex J Connected Wellness platform, is a feasible intervention for members of the Canadian Armed Forces referred for assistance due to depressive symptoms

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/02/2019, Defense Research and Development Canada Human Research Ethics Committee (no address provided; +1 (416) 635-2000, ext. 3141; HREC-CEESH-TORONTO@drdc-rddc.gc.ca), ref: 2019 - 006

Study design

Single arm interventional trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Current depressive symptoms that qualify for mild, moderate or severe symptoms

Interventions

The health coach intervention was 16 weeks in duration and followed the contents and principles of cognitive behaviour therapy, motivational interviewing and mindfulness meditation. Thirty-six workbooks were available online (24 h/7 days/week) for reading along with 56 videos and interactive experiences related to tracking walking steps (every subject received a Fitbit to use), diet (photojournalism of meals consumed), sleep (movements during sleep periods). Another intervention component consisted of secure text messaging between health coach and intervention participant. Intervention hours varied per participant but typically exceeded 16 hours/16 weeks and 2 hours/week; the hours were determined by coach supervisor and the coach. The workbooks and videos reflected multiple topics (eg, Living by Your Truths, Overcoming Wired-ness and Tired-ness, Mindfulness and Relationships, Loss and Grief, Resilience, Befriending Ourselves, Befriending Your Body With Exercise, Body Image and Mindfulness, Intimacy, Forgiveness, Overcoming Procrastination, Dealing With Negative Moods, Stress Resilience, Overcoming Performance Anxiety, and Cultivating Inspiration). The online platform used was produced and maintained by NexJ Health, Inc in Toronto, Ontario, and is the same basic platform employed in a prior studies, although it has been upgraded numerous times

in the interim. NexJ Health, Inc provided use of the NCW platform free of charge (as a research partner). Assessments were undertaken online with phone assistance at baseline, 8 weeks, 16 weeks and 6 months follow up.

Intervention Type

Behavioural

Primary outcome measure

Depression measured using the Patient Health Questionnaire (PHQ 9) at baseline, 8 weeks, 16 weeks (post intervention) and 6 months follow up

Secondary outcome measures

Measured at baseline, 8 weeks, 16 weeks (post intervention) and 6 months follow up:

1. Anxiety - The General Anxiety Disorder Questionnaire (GAD 7)
2. Post-Traumatic Stress Disorder Symptoms - the Patient Check List-5
3. Working Alliance Inventory - a brief self report questionnaire
4. The number of times one engages in mild-moderate-strenuous leisure exercise bouts of at least 15 min duration in a typical week - Godin Leisure Time Physical Activity Questionnaire
5. Alcohol Use Disorders Identification Test (WHO-AUDIT)
6. Medication adherence in patients being regularly prescribed medications for a chronic condition - Medication Adherence Rating Scale
7. Medication side effects - Frequency, Intensity, and Burden of Side Effects Rating

Overall study start date

15/08/2020

Completion date

30/03/2021

Eligibility

Key inclusion criteria

1. Canadian Armed Forces service members accessing care at the Esquimalt CFB, and Edmonton CFB experiencing depression, anxiety and/or Post-Traumatic Stress Disorder Symptoms. CAF service members will self-select for study participation, OR
2. Clinicians (i.e. general practitioners, psychiatrists, nurse practitioners, physician assistants, social workers) interested in using NexJ Connected Wellness in their clinical activity

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Total final enrolment

44

Key exclusion criteria

1. Individuals who meet DSM-V criteria for severe alcohol/substance use disorder in the past 3 months or clinically significant suicidal ideation defined as imminent intent or attempted suicide in the past 6 months
2. Co-morbid diagnoses of borderline personality disorder, schizophrenia and/or obsessive-compulsive disorder

Date of first enrolment

18/08/2020

Date of final enrolment

12/12/2020

Locations

Countries of recruitment

Canada

Study participating centre

Canadian Armed Forces - Equimalt Canadian Forces Base, Edmonton Canadian Forces Base
Naden Building 5
PO Box 17000 Stn Forces
Victoria
Canada
V9A 7N2

Study participating centre

Edmonton Canadian Forces Base
Bldg 181 Churchill Ave, CFB Edmonton
PO 10500, Stn Forces
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Sponsor information

Organisation

Build in Canada Innovation Program (BCIP)

Sponsor details

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Sponsor type

Government

Website

<https://buyandsell.gc.ca/procurement-data/tender-notice/PW-18-00856392>

Funder(s)

Funder type

Government

Funder Name

Build in Canada Innovation Program (BCIP)

Results and Publications

Publication and dissemination plan

Reporting to the CFB staff and related health professionals. Submission of platform presentation to the International Conference on Military Nursing and Healthcare, June 15, 2022, Toronto, Ontario

Intention to publish date

09/09/2022

Individual participant data (IPD) sharing plan

This is a study of members of the Canadian military. As such, extra security precautions are being adhered to. We don't expect to make available the basic (raw) datasets for security reasons that are not necessarily applicable in other datasets.

IPD sharing plan summary

Not expected to be made available