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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

Registration date
12/05/2022

Overall study status
Completed

Last Edited
12/05/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Single arm interventional trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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. M edication side effects - Frequency, Intensity, and Burden of Side Effects Rating

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

Funder(s)

Funder type
Government

Funder Name
Build in Canada Innovation Program (BCIP)

Results and Publications

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