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Feasibility Findings from a Pilot Group Randomized Control Trial on the Road to Mental Readiness (R2MR) Program

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Defence Research and Development Canada
Scientific Report
DRDC-RDDC-2018-R003
March 2018

Canada

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Abstract

Background: Conducting Randomized Control Trials (RCTs) in military operational and training settings poses special challenges. Thus, it is important to assess the feasibility of RCTs in pilot studies.

Objective: A pilot study was completed to assess the feasibility of two related studies: a Group RCT (GRCT) to test the efficacy of the Road to Mental Readiness (R2MR) mental health education and training program among Anglophone Non-Commissioned Member (NCM) recruits and a parallel non-randomized, uncontrolled pre-post-post study among Francophone NCM recruits.

Methods: Eight Anglophone platoons and two Francophone platoons were recruited for the pilot with a total of 536 potential participants. Three data collection sessions took place in week 2, 5, and 9 of Basic Military Qualification (BMQ). At each data collection session participants completed questionnaires assessing their psychological health and resilience as well as their attitudes towards mental health service use. In the efficacy arm of the pilot with Anglophone participants, platoons randomized to the intervention condition received R2MR in week 2 of their BMQ (after the first data collection session); platoons randomized to the control condition received R2MR in week 9 of their BMQ (after the last data collection session). In the effectiveness arm of the pilot with Francophone participants, both platoons received R2MR in week 2 of their BMQ (after the first data collection session). Feasibility issues examined included participation rates, attrition rates, participant demographics, missing data, problems with randomization, scheduling, blinding, contracting, data collection, data linkage and management, as well as possible threats to data validity.

Results: Out of a possible 536 recruits, a total of 452 (354 Anglophone) participated in the initial week 2 baseline data collection session (84.33%). Of those 452 participants, 332 (261 Anglophone) completed all three data collection sessions (73.45%). In the efficacy arm with Anglophone platoons, there was not a significant difference in attrition between the intervention and the control group. There were a few issues around randomization and scheduling where the assessment sessions did not respect the randomization scheme, or sessions had to be rescheduled and the data collection team was not informed. These issues were resolved quickly and procedures were implemented for communicating changes. There was an instance of possible unblinding of participants, which led to additional training for study staff in charge of data collection. Some potential threats to data validity were noted, for instance the late evening timing of assessment sessions, participants' difficulty understanding and/or complying with the instructions of some of the study measures, participants' decreasing motivation to complete repeated measures over the course of the study, and concerns around data entry. A number of adjustments were made to the study procedures to minimize the effects of these threats.

Conclusions: As the Canadian Armed Forces (CAF) moves towards testing mental health interventions such as the R2MR in RCTs, it will be important to increase awareness of and capture lessons learned about feasibility. This pilot study is the first GRCT on a mental health intervention in the CAF and provides novel information about feasibility issues that may be of use to future researchers.

Significance to Defence and Security

This pilot study assesses the feasibility of a larger Group Randomized Control Trial (GRCT) which will evaluate the Road to Mental Readiness (R2MR) mental health education and training program. The information contained in this report is valuable for other researchers working in military training or operational settings and for the design of future Randomized Control Trials (RCTs).

Résumé

Contexte : Effectuer des essais contrôlés randomisés (ECR) dans le cadre d'une formation et d'opérations militaires représente une difficulté particulière. Il est donc important d'évaluer la faisabilité des ECR lors d'études pilotes.

Objectif : On a mené une étude pilote pour évaluer la faisabilité de deux études connexes : un ECR par grappes pour évaluer l'efficacité du programme d'éducation et de formation en santé mentale d'En route vers la préparation mentale (RVPM) auprès des recrues militaires du rang (MR) anglophones et une étude avant-après non contrôlée et non randomisée menée en parallèle auprès des recrues MR francophones.

Méthodes : Huit pelotons anglophones et deux francophones ont été choisis pour l'étude pilote, soit un total de 536 participants potentiels. Trois séances de collecte de données ont eu lieu durant les semaines 2, 5 et 9 de la Qualification militaire de base (QMB). Au cours de chaque séance, les participants ont rempli un questionnaire d'évaluation de leur santé psychologique, de leur résilience, ainsi que de leur attitude face à l'utilisation des services en santé mentale. Dans le volet efficacité de l'étude pilote menée auprès des participants anglophones, les pelotons randomisés du groupe d'intervention ont reçu la formation sur RVPM durant la semaine 2 de leur QMB (après la première séance de collecte de données), les pelotons randomisés du groupe témoin ont reçu la formation sur RVPM durant la semaine 9 de leur QMB (après la dernière séance de collecte de données). Dans le volet efficacité de l'étude pilote menée auprès des participants francophones, les deux pelotons ont reçu la formation sur RVPM durant la semaine 2 de leur QMB (après la première séance de collecte de données). Les problèmes de faisabilité examinés incluaient le taux de participation, le taux d'attrition, les renseignements démographiques sur les participants, les données manquantes, les problèmes de randomisation, l'établissement du calendrier, le recours à l'insu, la passation de marché, la collecte, le couplage et la gestion des données, ainsi que les menaces potentielles à leur validité.

Résultats : Parmi les 536 participants potentiels, un total de 452 (354 anglophones) ont pris part à la séance initiale de collecte de données de la semaine 2 (84,33 %). Sur ces 452 participants, 332 (dont 261 anglophones) ont participé aux trois séances de collecte de données (73,45 %). Dans le volet efficacité parmi les pelotons anglophones, il n'y avait pas de différence significative dans l'attrition entre le groupe d'intervention et le groupe témoin Quelques problèmes relatifs à la randomisation et à la planification sont survenus parce que les séances d'évaluation ne respectaient pas le schéma de randomisation, ou bien parce que les séances devaient être reportées et que l'équipe de collecte des données n'en avait pas été informée. Les problèmes ont été résolus rapidement et des procédures ont été mises en œuvre afin de communiquer les changements. Une possible levée de l'insu a donné lieu à une formation supplémentaire du personnel de l'étude responsable de la collecte des données. On a noté certaines menaces potentielles à la validité des données, par exemple, les séances d'évaluation tenues en fin de soirée, les participants qui avaient de la difficulté à comprendre les instructions de certaines mesures de l'étude ou à s'y conformer, la diminution de la motivation des participants à exécuter des mesures répétées pendant la durée de l'étude et les préoccupations entourant la saisie des données. Un certain nombre de corrections ont été apportées aux procédures de l'étude pour minimiser les répercussions de ces menaces.

Conclusions : Tandis que les Forces armées canadiennes (FAC) se préparent à évaluer les interventions en santé mentale telles que le RVPM dans les ECR, il importe d'accroître la sensibilisation aux leçons

retenues concernant la faisabilité et leur consignation. Cette étude pilote, le premier ECR par grappes d'une intervention en santé mentale dans les FAC, fournit de nouveaux renseignements sur les problèmes de faisabilité qui pourraient s'avérer utiles aux futurs chercheurs.

Importance pour la défense et la sécurité

Cette étude pilote fournit une évaluation de la faisabilité d'un plus grand ECR par grappes qui permettra d'évaluer le programme d'éducation et de formation en santé mentale d'En route vers la préparation mentale (RVPM). L'information contenue dans le présent rapport s'avère précieuse pour les autres chercheurs qui travaillent dans le cadre d'une formation et d'opérations militaires, ainsi que pour la conception de futurs ECR.

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1 Introduction

1.1 Background

The Road to Mental Readiness (R2MR) mental health education and training program was developed at the request of the Chief of Military Personnel (CMP) and the Canadian Armed Forces (CAF) Surgeon General to help military members maintain good mental health throughout their career. Key components of R2MR are 1) increasing mental health literacy, 2) teaching stress management skills, and 3) changing negative attitudes towards mental health service use.

Short-term and long-term outcomes that are assumed to result from the uptake of the three key components of R2MR include 1) lower psychological distress in the short term and lower incidence and severity of mental health problems in the long-term, 2) higher psychological resilience, 3) higher help-seeking intentions and behaviours when mental health problems do arise, and ultimately, 4) improved military (training and operational) performance outcomes. R2MR needs to be tested for efficacy in order to determine if (and to what extent) beneficial changes in these outcomes of interest are indeed taking place, and whether they are maintained over time from immediate post-intervention to longer-term.

R2MR at Basic Military Qualification (BMQ) represents military members' first exposure to R2MR and as such provides the foundation upon which all subsequent mental health training is built. Therefore, ensuring that R2MR is efficacious at BMQ is critical for the success of all mental health training in the CAF.

Randomized Control Trials (RCTs) are the gold standard for establishing the efficacy of interventions such as R2MR. In RCTs participants are randomly assigned to a treatment or control condition. Random assignment provides three important advantages over non-randomized designs:

> First, when properly implemented, it eliminates selection bias, balancing both known and unknown prognostic factors, in the assignment of treatments. Without randomisation, treatment comparisons may be prejudiced, whether consciously or not, by selection of participants of a particular kind to receive a particular treatment. Second, random assignment permits the use of probability theory to express the likelihood that any difference in outcome between intervention groups merely reflects chance. Third, random allocation, in some situations, facilitates blinding the identity of treatments to the investigators, participants, and evaluators, possibly by use of a placebo, which reduces bias after assignment of treatments. (Page 2) [1].

Alternative designs (i.e., observation studies, non-random quantitative assignment of treatment) may be justified when random assignment is unethical or impractical; however, compared to alternative research designs, RCTs have higher internal validity and higher statistical power [2]. In settings where pre-existing clustering or grouping of individuals is present, where the intervention is delivered at the group (not the individual) level, and where there is "the risk of contamination"—whereby group members randomized to the intervention condition could influence those randomized to the control condition through sharing the active ingredients of the intervention—it is more appropriate to randomize subjects at the group level, i.e., to conduct a Group Randomized Control Trial (GRCT) [3]–[6].

Conducting GRCTs in military training settings such as the BMQ pose special challenges and there are a number of factors that can affect feasibility. First, study procedures must fit into pre-existing training and operational requirements. The BMQ is 12 weeks long and the Canadian Forces Leadership and Recruit School (CFLRS) runs more than 60 BMQ courses per Fiscal Year (FY). To manage this pace of training, platoons are paired up into twin (i.e., 2 platoons at a time), triplet (i.e., 3 platoons at a time), or quadruplet (i.e., 4 platoons at a time) "sister platoons" when starting their training. Any randomization scheme that is used in a GRCT must respect this scheduling requirement. While a training calendar at the beginning of a FY specifies such pairings, it is not unusual for a given platoon to be cancelled due to low numbers etc. Such last-minute changes require adjustment to the randomization scheme and thus constant communication between the CFLRS and the study team is critical over the course of a GRCT. Second, while sister platoons that start their training on the same date have very limited contact with each other, steps must be taken to ensure blinding of the participants, training staff, and data collection staff. In a training context where word spreads quickly, concrete steps may need to be employed and evaluated to ensure blinding is successful.

Third, despite the shortening duration of the BMQ in recent years, CFLRS is asked to include in the BMQ an increasing number of courses, classes, and training components. This leaves very little time during the day to fit in data collection sessions. Data collection sessions scheduled at the end of a long day can pose threats to participant motivation, attention, and data quality. Fourth, the BMQ is physically and mentally taxing. A previous study conducted by Defence Research and Development Canada (DRDC) – Toronto Research Centre found that recruits reported sleeping an average of only 5.2 hours per night and experienced abnormal to severe fatigue. As a result, recruits demonstrated reduced cognitive effectiveness and motivation [7], [8]. Thus, regardless of the timing of the data collection sessions, study procedures must be in place to help study participants be aware of their cognitive state and the possible influence of this on accurate reporting/data quality.

Further, in order to prevent disruption to the larger BMQ training, the scheduling of the intervention and the data collection sessions needs to be done by the school's Standards/Scheduling Division. The Scheduling Division has a changing cadre of military members, all of whom must be knowledgeable about study design requirements for timing of the intervention and data collection sessions. Last-minute changes to the day-to-day training schedule are not uncommon. Such changes pose potential threats to study design and validity as the GRCT requires precise timelines for intervention delivery and the multiple data collection sessions; with a minimum and maximum permitted amount of time between sessions. Thus constant vigilance is required to ensure that all of the scheduling requirements of the GRCT design are met for each platoon.

Due to these unique challenges, a pilot study to test the feasibility of the larger GRCT on R2MR at CFLRS (and in fact in any military training or operational setting) is critical.

1.2 Pilot and Feasibility Studies

The terms pilot study and feasibility study are often used interchangeably. They both attempt to determine if a larger study could be done, if it should proceed, and how it should proceed. Pilot studies have an additional component of duplicating the intended design of the larger study on a smaller scale [9]. A pilot study can be defined as "a version of the main study that is run in miniature to test whether the components of the main study can all work together" (pg. 5) [10]. Feasibility studies look at if a study could be run in theory while pilot studies look at if a study could be run in practice. While a pilot study may share the same design as the main study, the purpose of conducting a pilot study is not to evaluate

the same outcomes as the main study, but to gather information about the feasibility of conducting the main study, and to inform the planning of the main study [11].

Prior to commencing the full R2MR GRCT, there was a need to conduct a pilot study to assess the feasibility of the study design and to refine the procedures and methods. There are many important aspects of a study to consider during pilot work including the study process, resources, management, outcomes, and the intervention itself [5], [11]. Previous pilot work has already been completed focusing on the content and delivery of the R2MR intervention [12]–[17] but these studies cannot inform the design of the GRCT. This pilot study is external to the larger study and data collected will not be used in the analysis for the main GRCT. External pilot studies allow for the design of the main study to be changed if necessary based on the findings of the pilot [5]. Pilot studies are especially important to conduct prior to GRCTs because these designs are very complex and resource-intensive. Pilot work helps to prevent resources (money and time) being wasted on poorly designed studies and increases the likelihood of success of the main study.

1.3 Objectives

1.3.1 Overall Aim

The overall aim of the current pilot study is to assess the feasibility of a larger GRCT which will evaluate the efficacy of the R2MR mental health education and training program and its impact on outcomes of interest including psychological distress, psychological resilience, help-seeking intentions and behaviours, and military (training and operational) performance.

1.3.2 Pilot Study Objectives

In order to be able to access the feasibility of the larger GRCT there are a number of pilot study objectives:

1. Assessing participation rates and attrition rates.
2. Assessing participant demographics and determining if these are significantly different between participants and non-participants.
3. Assessing missing data rates and determining if these are significantly different across conditions.
4. Testing and refining the randomization and scheduling procedures to ensure the intervention and the data collection sessions are delivered at the appropriate times.
5. Testing and refining the procedures required to ensure the participants, platoon instructors, data collection staff, and the principal investigator all remain blind to platoon condition.
6. Ensuring the necessary mechanisms are established for utilizing external contractors.
7. Testing and refining the data collection procedures and materials.
8. Establishing -and refining as needed- the procedures for data management, including data linkage to other recruit administrative and research databases.
9. Identifying possible threats to data validity.

2 Methods

2.1 Participant Recruitment and Procedures

The target participant population for the larger GRCT is all new Anglophone recruit platoons arriving at the CFLRS for BMQ training. In any given calendar year, 75% or more of the incoming NCM platoons are Anglophone. Francophone platoons are excluded from the larger GRCT (please see the study protocol for full justification [18]). However, to help provide some evidence of the effectiveness of R2MR for Francophone platoons at BMQ, there is a non-randomized, uncontrolled parallel effectiveness study among Francophone platoons while the GRCT among the Anglophone platoons is running. Both Anglophone and Francophone platoons were included in the pilot phase as we wanted to test the feasibility of both the GRCT among Anglophone platoons and the parallel non-randomized, uncontrolled pre-post-post study among Francophone platoons.

The pilot phase of the study included ten platoons who started their BMQ training in October and November 2016. These platoons were ideal for a pilot phase because their training schedule made them ineligible to participate in the larger study. These platoons paused their training and went home for three weeks for the winter holidays while platoons in the larger study will complete their training without interruption. Thus, the platoons that started their training in late Oct–Nov differed from all other platoons in the CFLRS training calendar in ways that can potentially influence study outcomes. Eight of the pilot platoons were Anglophone and two were Francophone.

All members of the selected BMQ platoons were eligible to participate and there were no exclusion criteria. Some recruits going through BMQ training pause their training due to not meeting fitness requirements, getting injured or falling sick. Once ready to resume their training, these recruits may then be moved into a new platoon that is different than the platoon that they started their BMQ training in (i.e., the recruits "get recoursed"). This poses obvious problems for GRCTs as recoursed recruits may move from intervention to control groups (and vice versa). For this reason, we decided to remove recoursed recruits from the efficacy analyses to be conservative, although we collected data from them. We decided to collect data from recoursed recruits in order to be able to conduct sensitivity analyses to determine whether removing the recoursed recruits made a difference to efficacy results or not.

Each platoon in the pilot study completed data collection as a group in a classroom at CFLRS in Saint-Jean-Sur-Richelieu Quebec. In the initial week 2 baseline data collection session, the data collection staff explained the purpose of the study and provided an Information Sheet and an Informed Consent Form. Participants were also given a letter which explained that the study had been endorsed by their commanding officer. Participants were then given a chance to ask any questions they had before signing the Informed Consent Form.

2.2 Design

2.2.1 Anglophone GRCT Design

The design for the Anglophone pilot followed the design of the larger GRCT (Figure 1). Participating platoons were randomly assigned to either the intervention or control group. For both groups, there were three data collection sessions (week 2, week 5 and week 9 of the BMQ). The intervention group received

R2MR in week 2 of the BMQ (after their first data collection session) and the control group received R2MR in week 9 of the BMQ (after their last data collection session). The timing of assessment sessions and R2MR delivery was based on practicality issues (e.g., R2MR delivery being part of standard training in week 2, limited recruit availability after week 9 due to training exercises away from CFLRS) as well as advice from CFLRS (e.g., week 5 being particularly challenging and thus an ideal time to examine beneficial effects of R2MR). See Table 1 for assessment and intervention dates.

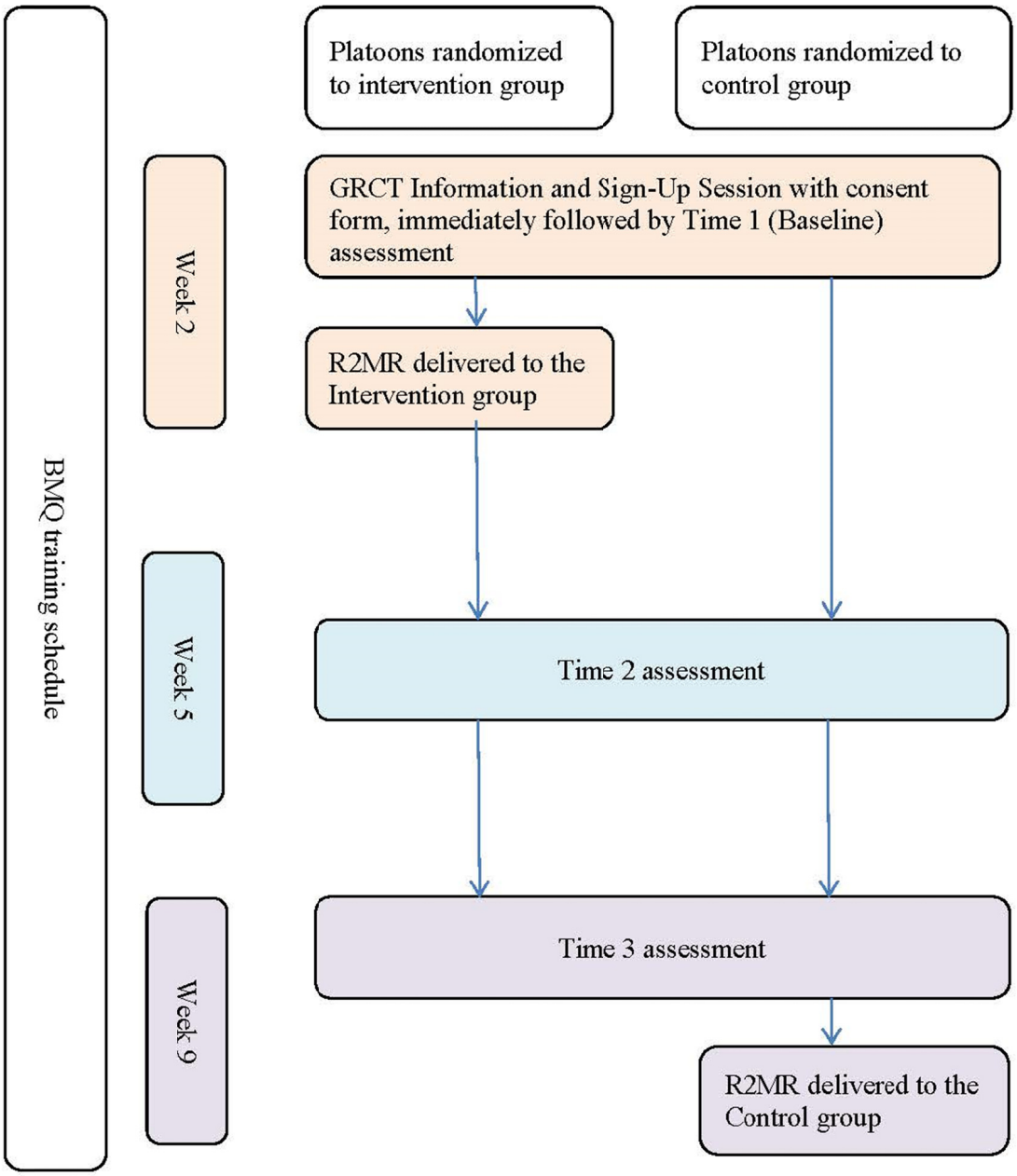

Figure 1: *Overview of the design of the Anglophone GRCT.*

Table 1: *Pilot dates for Anglophone Platoons.*

Platoon Number	BMQ Start Date	Condition	Data Collection Time 1 (T1) Date	R2MR Date	Data Collection Time 2 (T2) Date	Data Collection Time 3 (T3) Date
182	10/31/2016	Control	11/10/2016	01/27/2017	11/30/2016	01/24/2017
183	10/31/2016	Intervention	11/08/2016	11/09/2016	11/29/2016	01/25/2017
186	11/07/2016	Control	11/16/2016	02/02/2017	12/07/2016	01/31/2017
187	11/07/2016	Intervention	11/15/2016	11/18/2016	12/06/2016	02/01/2017
188	11/07/2016	Control	11/17/2016	02/01/2017	12/05/2016	01/30/2017
189	11/14/2016	Intervention	11/22/2016	11/24/2016	01/12/2017	02/06/2017
190	11/14/2016	Intervention	11/23/2016	11/25/2016	01/11/2017	02/08/2017
191	11/14/2016	Control	11/24/2016	02/09/2017	01/12/2017	02/07/2017

2.2.2 Francophone Parallel Effectiveness Study Design

The larger Francophone parallel effectiveness study will not be randomized and instead all platoons will be in the intervention condition. Thus both Francophone platoons in the pilot were placed in the intervention condition. They completed baseline data collection in the second week of their BMQ. Later that same week, they received R2MR training. They completed Time 2 and Time 3 data collection sessions in week 5 and week 9, respectively. See Figure 2 for study design and Table 2 for data collection and intervention dates.

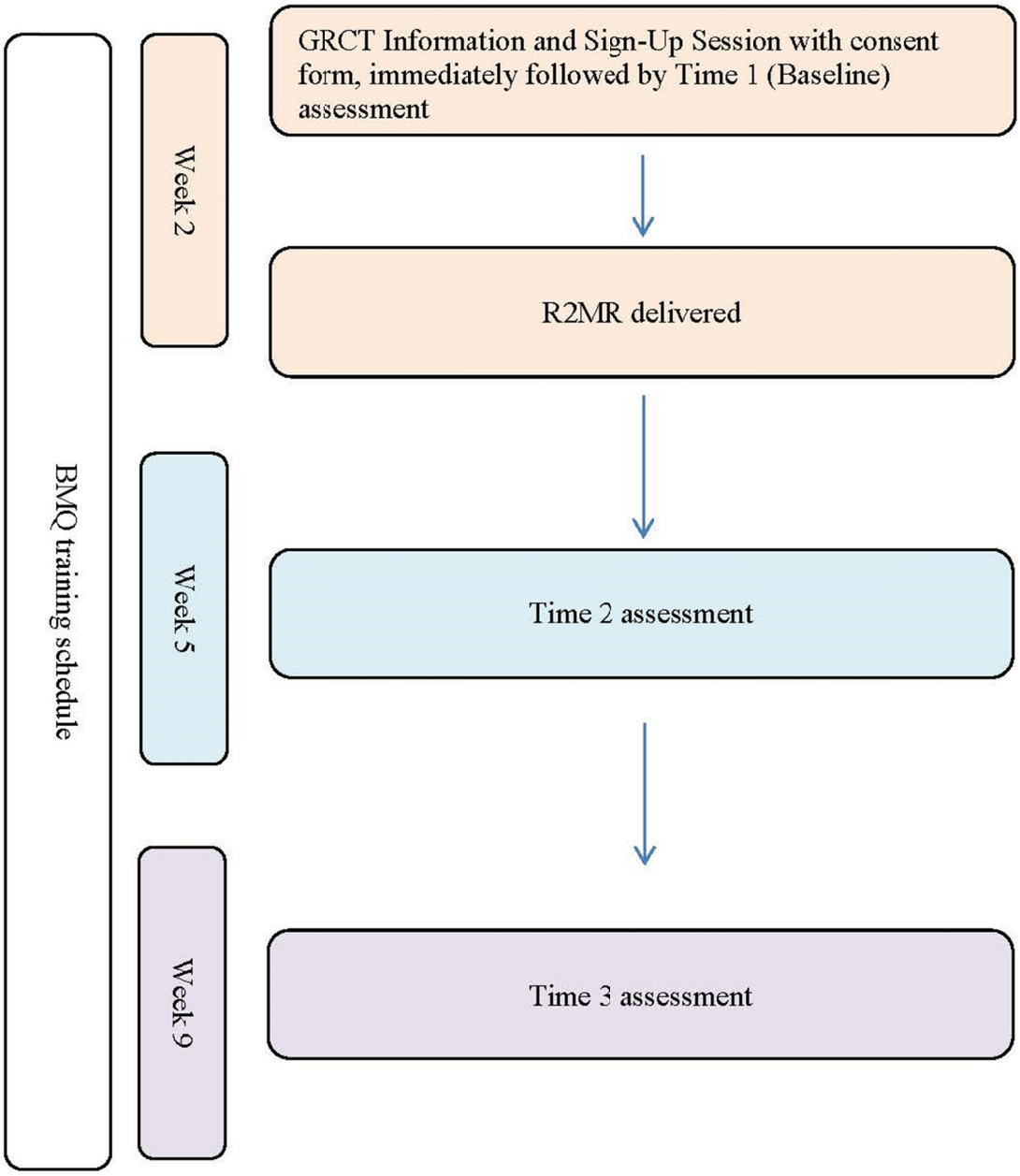

Figure 2: *Overview of the design of the Francophone Parallel Effectiveness Study.*

Table 2: *Pilot dates for Francophone Platoons.*

Platoon Number	BMQ Start Date	Condition	Data Collection T1 Date	R2MR Date	Data Collection T2 Date	Data Collection T3 Date
184	10/31/2016	Intervention	11/09/2016	11/10/2016	12/01/2016	01/26/2017
185	10/31/2016	Intervention	11/07/2016	11/09/2016	11/28/2016	01/24/2017

2.3 Randomization

For the eight Anglophone platoons in the efficacy arm of the pilot study, blocked randomization was utilized. Block randomization divides platoons into blocks with the same size (2n, n is an integral), then randomizes platoons in each block so that the same number of platoons (n) are assigned to group 1 (i.e., intervention) and 2 (i.e., control). Thus, for the pilot, four platoons were in the intervention condition and four platoons were in the control condition. The randomization scheme was created by the biostatistician (A.L.) and provided to the school several months ahead of time to facilitate scheduling of the intervention and the data collection sessions. Both of the pilot Francophone platoons in the effectiveness arm of the pilot study were automatically placed in the intervention condition.

2.4 Allocation, Implementation, and Blinding

The main Anglophone GRCT and the pilot study were designed to be triple-blinded, meaning that the principal investigator (D.F.), the data collection staff, and the participants needed to be shielded from information regarding intervention assignment. To achieve blinding and allocation concealment, the sequence of the intervention assignment for the GRCT was created by the study statistician (A.L.) and was relayed to CFLRS staff in charge of scheduling and the Toronto study monitor (K.B.) several months prior to the start of data collection. Other staff at CFLRS were not aware of the larger study or the pilot.

2.5 Outcome Measures

2.5.1 Efficacy and Effectiveness Outcomes

R2MR has multiple mental health education and training objectives. Data were collected to assess four main areas:

1. Psychological health

   Psychological health will be measured with the PHQ-9 (Patient Health Questionnaire) [19], K-10 (Kessler Psychological Distress Scale) [20], SUDS (Subjective Units of Distress Scale) [21], and GAD-7 (Generalized Anxiety Disorder Scale) [22] questionnaires.

2. Psychological resilience

   Psychological resilience will be measured with the CD-RISC (Connor-Davidson Resilience Scale) [23].

3. Mental Health Service Use (MHSU) attitudes and intentions

   MHSU attitudes and intentions will be measured by the CAF-MHSUQ (Canadian Armed Forces Mental Health Service Use Questionnaire) [24].

4. BMQ performance and graduation rate

   BMQ performance data will be accessed only for those participants who provided additional consent for us to access their CFLRS administrative data. In addition to graduation status, a number of performance measures will be examined including the FORCE (Fitness for Operational Requirements of Canadian Armed Forces Employment) evaluation and weapons drills.

A separate report will address the findings for these effectiveness and efficacy outcomes. The primary focus of this report is to address feasibility outcomes.

2.5.2 Feasibility Outcomes

Feasibility of the larger GRCT and parallel study was assessed across 9 main areas:

1. Participation rates and attrition rates

   For this GRCT, participants will be asked to complete multiple data collection sessions which requires a significant amount of time in an already busy BMQ schedule. They will be completing the same questionnaires multiple times, some of which are quite lengthy, which could lead to frustration. It is important to track participants over the course of a repeated measures GRCT and to examine participant feedback to get a good understanding of study acceptability and expected attrition for the larger trial.

   Participation rates and attrition rates at each time point are important for estimating the parameters needed to conduct a power analysis. This information is used to estimate how long the main trial will need to run to reach an acceptable level of power to find the expected results. Participation and attrition rates also provide some information about the generalizability of the findings to the larger population.

   One of the biggest challenges in running a repeated measures GRCT in the CFLRS BMQ setting is the fact that recruits do not necessarily remain in the same platoon for their entire BMQ. As stated previously, recruits get recoursed out of their intake platoon for a variety of reasons, including physical injury, illness, personal reasons, inability to pass mandatory physical fitness testing, or inability to keep up with other (non-physical) BMQ requirements [25]. When a recruit is in multiple platoons over the course of their BMQ it becomes very difficult to determine when he/she was exposed to the R2MR/intervention. For instance, a recruit could start his/her BMQ in an intervention platoon and finish in a control platoon. It is also possible for a recruit to complete the entire study in the same platoon, but for him/her to have had spent time in a different platoon prior to the start of the study (where he/she may have received R2MR). Due to the research team's inability to fully assess and control exposure to the intervention in these recruits, they will be removed from analyses. For the purpose of this report, recourse status was determined through a combination of self-report and administrative data provided by CFLRS.

Participation rates were calculated for each Anglophone and Francophone data collection session, after recoursed recruits were removed from the sample. At the beginning of each T1 session, the data collection staff counted the number of people in the room, which was used as the denominator to calculate participation rate. The nominator was the number of eligible (non-recoursed) recruits who chose to participate and submitted a valid consent form. This method was deemed to be more accurate than using the official platoon size provided by CFLRS as the denominator for several reasons: first, the official number represents the platoon size at day 1 of the BMQ and we know that platoon size changes over the course of the BMQ (due to recruits releasing or being recoursed), and second, recruits who are officially in a platoon may still miss a given data collection session for various reasons. Asking CFLRS to determine the actual platoon size on each assessment date for each platoon was considered to be too labour-intensive and time consuming for the CFLRS staff. For T2 data collection sessions, the participation rate was the percentage of T1 participants who also completed T2. For T3 sessions, the participation rate was the percentage of T1 participants who also completed T3.

2. Participant demographics

   We collected demographic information from participants including gender, age, education, ethnicity, self-reported general physical health, and self-reported general mental health. Non-participants were asked to voluntarily provide this basic information. We assessed if study participants differed significantly from non-participants. The generalizability of a GRCT is compromised if there are systematic differences between the participants and non-participants.

3. Missing data

   In GRCTs, it is important to ensure that rates of missing data are low, especially for the key outcomes of the study, and that rates of missing data do not differ across the study (intervention versus control) conditions. Furthermore, rates of missing data typically increase over the course of multiple assessments sessions. We examined missing data rates at T1, T2, and T3 and examined whether these rates are comparable across the study conditions.

4. Randomization and scheduling

   In GRCTs, it is imperative to examine the study procedures put in place to ensure adherence to the study design. If mistakes are made in the timing of the intervention (i.e., R2MR) or the three data collection sessions, this could result in a substantial loss of data. Because block randomization is used in the proposed R2MR GRCT, mistakes with a given platoon will lead to the loss of data not just for that platoon but for all the platoons that are in the same block.

   Toronto staff monitored the scheduling of the intervention (i.e., R2MR) and the data collection sessions for any instances when the randomization scheme was not adhered to (R2MR scheduled at the wrong time; e.g., R2MR scheduled in week 9 for an intervention platoon) or when data collection sessions did not adhere to the study design (data collection scheduled incorrectly in relation to R2MR; e.g., T3 data collection scheduled after R2MR for a control platoon).

5. Blinding

   It is vital to ensure that blinding is maintained for the GRCT. Knowledge of condition assignment by the participants could introduce multiple sources of bias. Being aware of condition assignment can impact the expectations of the participants or the attitude and behaviour of the instructors and investigators [26]. Testing the procedures to maintain blinding prior to the start of the main GRCT helps to minimize the loss of data which would occur if platoons were required to be removed from the study due to unblinding. Toronto staff monitored and investigated any and all instances of suspected unbinding of recruits, CFLRS staff and instructors, or contractors in charge of the data collection.

6. Contracting

   External contractors needed to be used for printing study materials (Information Sheet, Informed Consent Forms, Questionnaire Packets, and Endorsement Letters) and running data collection sessions, due to the large volume of printing and the frequency with which data needed to be collected (3–4 times per week). There can be various obstacles and delays in contracting mechanisms which we note below in the Results section.

7. Data collection

   We created standard data collection scripts for Time 1, Time 2, and Time 3. These scripts included orienting the potential participants to the study objectives and procedures, and highlighting key information regarding their rights as research participants. Piloting the data collection scripts and questionnaire booklets was important in order to gain a sense of whether participants understood what is being asked of them and if the instructions were clear. Spontaneous questions and comments from participants were noted.

8. Data management and data linkage

   We wanted to evaluate how well data management procedures including data entry and data quality checks worked during the pilot. We also wanted to explore whether we could successfully link participant data across multiple time points as well as across supplementary research and administrative databases (i.e., CFLRS administration data, the Recruit Health Questionnaire, (RHQ), Canadian Forces Aptitude Test (CFAT), and the Trait Self Descriptive Personality Inventory (TSD)).

9. Threats to data validity

   Research staff involved in the data collection were asked to observe and take note of anything that came up during the data collection which could potentially impact data validity.

2.6 Analytical Methods

2.6.1 Main GRCT Sample Size

GRCTs (compared to RCTs) have reduced statistical power due to the clustered nature of the data. To take this into consideration, we incorporated Intra-Class Correlation Coefficients (ICCs) into our power analysis. Before the starting of the GRCT, we estimated the needed sample size for the GRCT using data

from previous research with NCM recruits [27]. It was recently updated using the data from this pilot study [28]. Results were very similar across the two reports. Both the reports concluded that a year and half data collection is needed to recruit enough NCM recruits to provide sufficient statistical power for detecting the hypothesized effects of all outcomes. Specifically, the findings from the updated power analysis were that 60 platoons would provide sufficient power for all outcomes of interest. This was a conservative estimate which assumed low participation rates (an average of 28 people per platoon, or 70% of a 40 person platoon) and no platoon-level covariates.

2.6.2 Pilot Sample Size

Pilot studies are small in nature. This pilot study was not intended to be sufficiently powered to address the main GRCT outcomes (Section 2.5.1) or to be representative of the future trial population. Sample size for the pilot study was primarily determined by practicality issues. This study was unable to begin until another large study—Project Horizon—at CFLRS had completed data collection with the recruit population, in the Fall of 2016. At that time there were 10 platoons remaining in the calendar year which were different from all other platoons because the three week holiday break (when recruits leave CFLRS and go home) occurred during their BMQ. This made them ineligible for the main GRTC. Stopping after the 10 platoons impacted by the holiday break meant that all eligible platoons starting their BMQ in the 2017 calendar year could be utilised for the larger GRCT. Based on previous research with the same population we expected that 10 platoons would be sufficient to examine feasibility outcomes (Section 2.5.2) [13]. Additionally, based on conversations with CFLRS staff, there was hesitation to push back the start date of the larger GRCT any further.

2.6.3 Intended Statistical Analysis for Assessing the Efficacy of R2MR

The analytical approach for the larger GRCT is detailed in the study protocol [18]. Mixed effects models will be utilized to account for the clustered nature of the data. Mixed linear models (assuming random intercepts and slopes to account for platoon level differences) will be used for continuous variables. Generalized linear mixed models will be utilized for binary variables. A Scientific Report for the preliminary analysis of the efficacy of R2MR using the pilot data is under review [29]. Given the very limited sample size of the pilot data (including a total of 8 Anglophone platoons), we noted in the report that the results should be interpreted with great caution and should not be used for hypothesis testing of the efficacy of R2MR.

3 Results and Discussion

3.1 Participation Rates and Attrition Rates

3.1.1 Anglophone Participation Rates and Attrition Rates

Out of a possible 427 potential participants, a total of 354 (82.90%) agreed to participate in the study and completed T1 data collection. Of those original 354 participants, 296 completed T2 data collection (83.62%) and 278 completed T3 data collection (78.53%). Two attrition rates were calculated (T1 to T2, and T1 to T3). The overall attrition rate for T1–T2 was 58/354 (16.38%) and the overall attrition rate for T1–T3 was 76/354 (21.47%). See Table 3 for participation rates and attrition rates for individual platoons.

Table 3: *Pilot participation rates and attrition rates for Anglophone Platoons.*

Platoon	Condition	T1 Participation Rate	T2 Participation Rate	T3 Participation Rate	T1–T2 Attrition Rate	T1–T3 Attrition Rate
182	Control	46/58 (79.31%)	43/46 (93.48%)	41/46 (89.13%)	3/46 (6.52%)	5/46 (10.87%)
183	Intervention	44/58 (75.86%)	31/44 (70.45%)	34/44 (77.27%)	13/44 (29.55%)	10/44 (22.73%)
186	Control	47/56 (83.93%)	37/47 (78.72%)	34/47 (72.34%)	10/47 (21.28%)	13/47 (27.66%)
187	Intervention	51/57 (89.47%)	39/51 (76.47%)	36/51 (70.59%)	12/51 (23.53%)	15/51 (29.41%)
188	Control	45/53 (84.91%)	42/45 (93.33%)	39/45 (86.67%)	3/45 (6.67%)	6/45 (13.33%)
189	Intervention	41/49 (83.67%)	36/41 (87.80%)	32/41 (78.05%)	5/41 (12.20%)	9/41 (21.95%)
190	Intervention	40/51 (78.43%)	38/40 (95.00%)	38/40 (95.00%)	2/40 (5.00%)	2/40 (5.00%)
191	Control	40/45 (88.89%)	30/40 (75.00%)	24/40 (60.00%)	10/40 (25.00%)	16/40 (40.00%)

3.1.2 Anglophone Participant Flow: Intervention

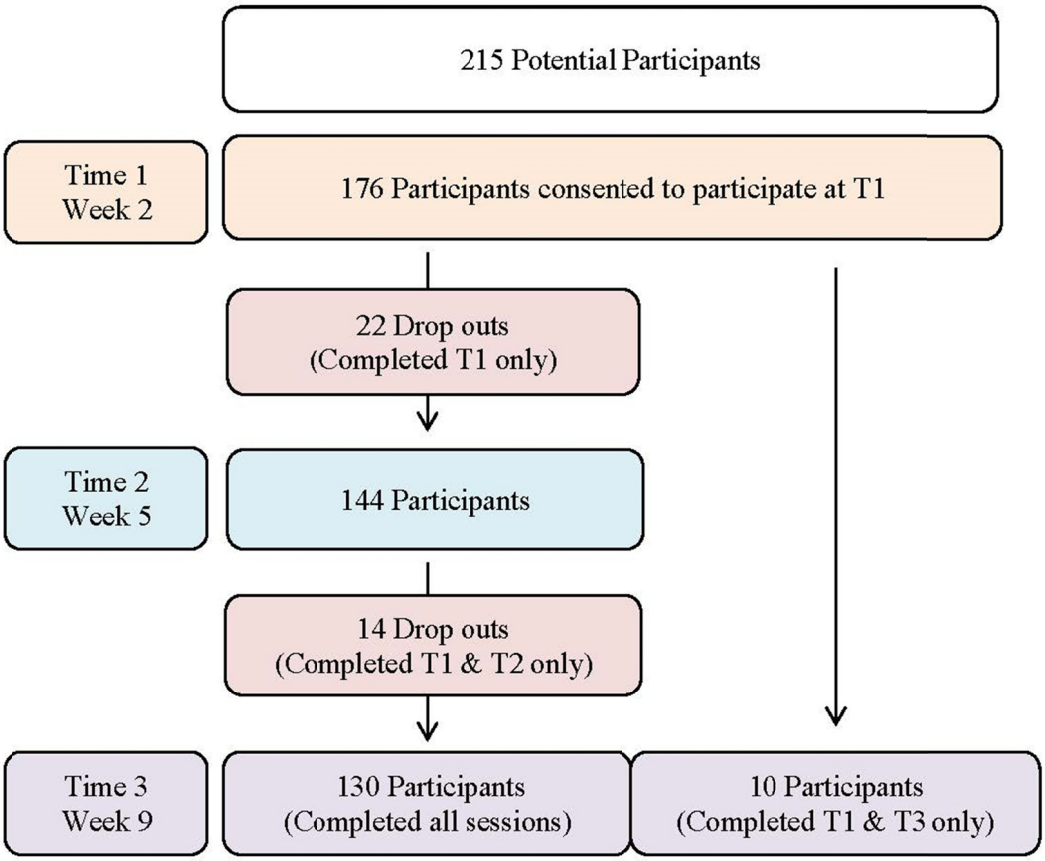

Figure 3: *Anglophone participant flow for intervention condition.*

3.1.3 Anglophone Participant Flow: Control

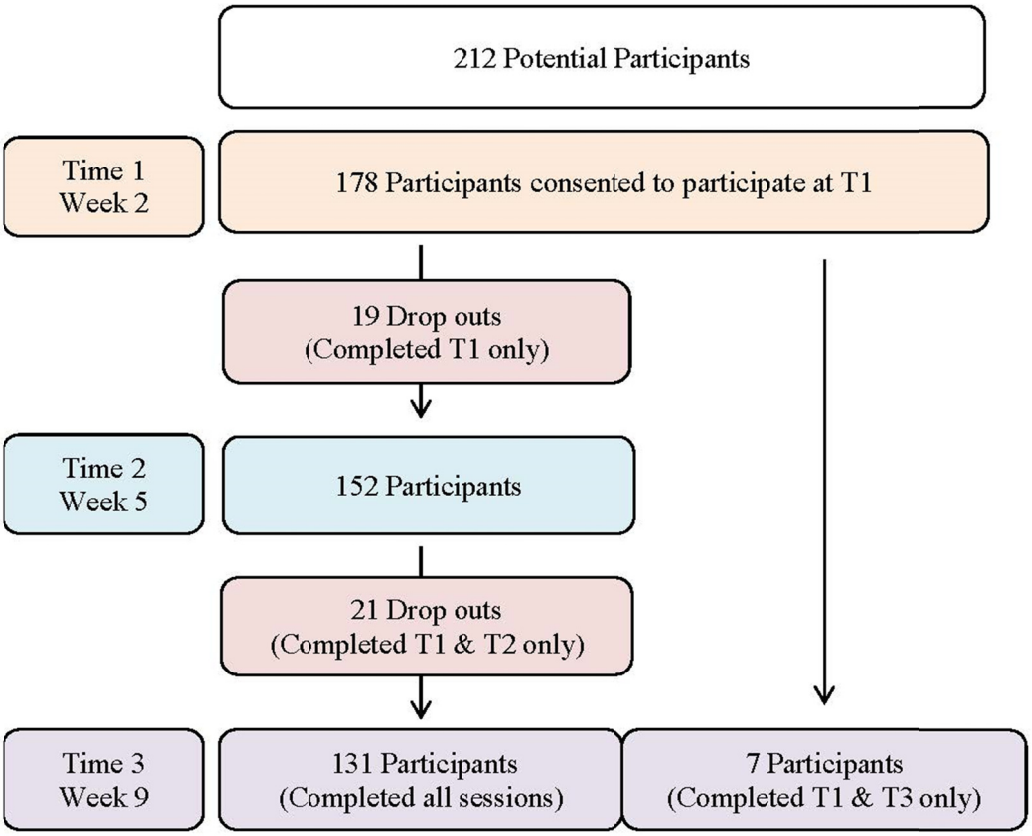

Figure 4: *Anglophone participant flow for control condition.*

3.1.4 Francophone Participation Rates and Attrition Rates

Out of a possible 109 potential participants, a total of 98 (89.91%) agreed to participate in the study and completed T1 data collection. Of those original 98 participants, 87 completed T2 data collection (88.78%) and 71 completed T3 data collection (72.45%). Two attrition rates were calculated (T1 to T2, and T1 to T3). The overall attrition rate for T1–T2 was 11/98 (11.22%) and the overall attrition rate for T1–T3 was 27/98 (27.55%). See Table 4 for participation rates and attrition rates for individual platoons.

Table 4: *Pilot participation rates and attrition rates for Francophone Platoons.*

Platoon	T1 Participation Rate	T2 Participation Rate	T3 Participation Rate	T1–T2 Attrition Rate	T1–T3 Attrition Rate
184	47/53 (88.68%)	42/47 (89.36%)	33/47 (70.21%)	5/47 (10.64%)	14/47 (29.79%)
185	51/56 (91.07%)	45/51 (88.24%)	38/51 (74.51%)	6/51 (11.76%)	13/51 (25.49%)

3.1.5 Francophone Participant Flow

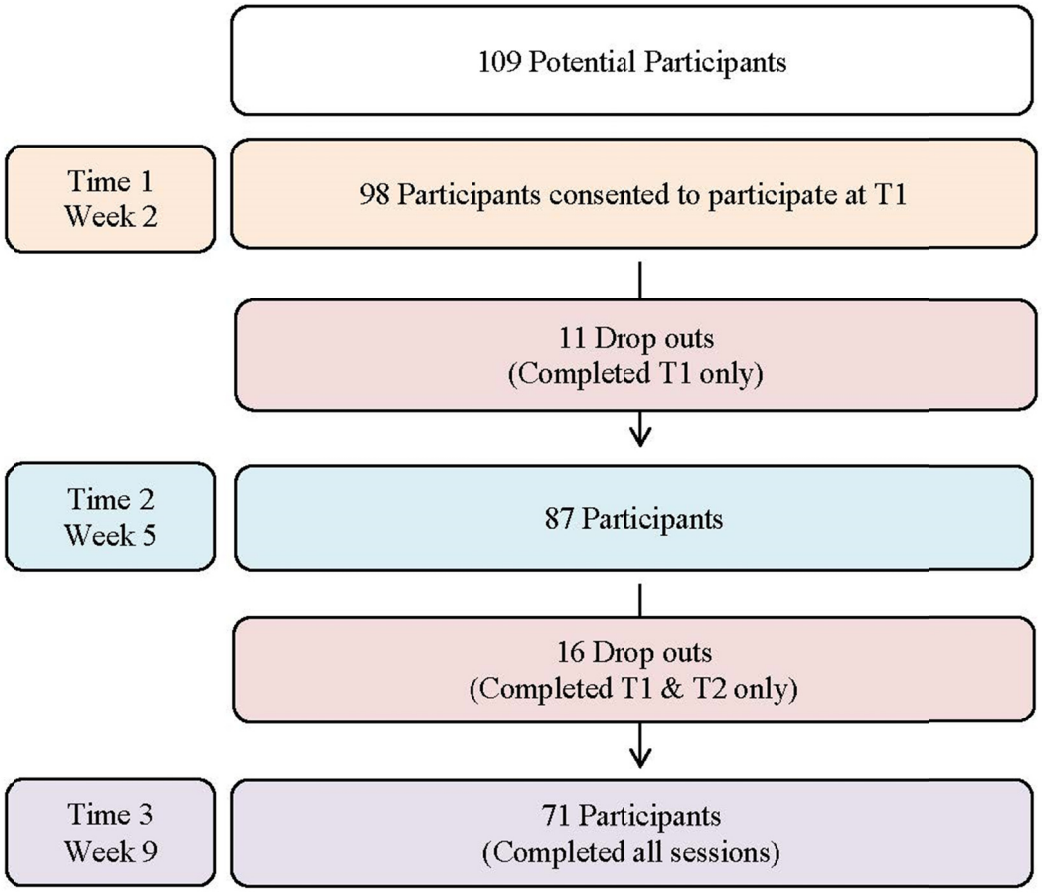

Figure 5: *Francophone participant flow.*

3.2 Missing Data and Participant Demographics

3.2.1 Missing Data

Rates of missing data are provided for Anglophone participants in the intervention condition (Table 5), Anglophone participants in the control condition (Table 6), and Francophone participants (Table 7). Rates of missing data were not significantly different between Anglophone participants in the intervention condition versus the control condition. Descriptive analyses indicate a trend for participants to be more likely to leave questions blank at later data collection time points, and near the end of the questionnaire at each data collection time point. These patterns of missingness are common in survey research.

Table 5: *Rates of missing data for Anglophone participants in the intervention condition.*

	Missing Rate T1 (%)	**Missing Rate T2 (%)**	**Missing Rate T3 (%)**
Age	0	N/A	N/A
Gender	0	N/A	N/A
Education	0	N/A	N/A
Ethnicity	0	N/A	N/A
Physical Health	0	N/A	N/A
Mental Health	0	N/A	N/A
Shipley	0	N/A	N/A
SUDS score	0.57	2.08	4.29
K-10 total score	0.57	0.69	5.71
GAD total score	1.14	0	2.86
PHQ-9 total score	1.70	0.69	5.00
Resilience (CD-RISC) total score	0.57	0	2.14
Attitude (MHSU)			
Instrumental attitude	5.68	4.86	5.00
Affective attitude	5.68	14.58	8.57
Intention	1.70	10.42	7.86
Self-efficacy	4.55	14.58	9.29
Control	4.55	14.58	9.29
Subjective norms	2.27	11.81	7.86
Overall	3.98	3.47	8.57

Table 6: *Rates of missing data for Anglophone participants in the control condition.*

	Missing Rate T1 (%)	**Missing Rate T2 (%)**	**Missing Rate T3 (%)**
Age	0	N/A	N/A
Gender	0	N/A	N/A
Education	1.12	N/A	N/A
Ethnicity	0	N/A	N/A
Physical Health	1.12	N/A	N/A
Mental Health	1.69	N/A	N/A
Shipley	0	N/A	N/A
SUDS score	0	3.29	1.45
K-10 total score	0	1.32	0.72
GAD total score	0	1.32	1.45
PHQ-9 total score	0.56	1.97	0.72
Resilience (CD-RISC) total score	0	0.66	1.45
Attitude (MHSU)			
Instrumental attitude	7.30	7.89	3.62
Affective attitude	7.87	9.87	6.52
Intention	3.93	9.21	5.80
Self-efficacy	6.18	9.21	8.70
Control	5.62	9.87	8.70
Subjective norms	5.06	9.21	6.52
Overall	5.62	5.26	7.97

Table 7: *Rates of missing data for Francophone participants.*

	Missing Rate T1 (%)	**Missing Rate T2 (%)**	**Missing Rate T3 (%)**
Age	0.00	N/A	N/A
Gender	0.00	N/A	N/A
Education	0.00	N/A	N/A
Ethnicity	0.00	N/A	N/A
Physical Health	0.00	N/A	N/A
Mental Health	0.00	N/A	N/A
Shipley	0.00	N/A	N/A
SUDS score	2.04	2.30	2.82
K-10 total score	1.02	1.15	1.41
GAD total score	2.04	0	1.41
PHQ-9 total score	2.04	0	1.41
Resilience (CD-RISC) total score	2.04	0	0
Attitude (MHSU)			
Instrumental attitude	14.29	6.90	9.86
Affective attitude	7.14	5.75	7.04
Intention	5.10	2.30	4.23
Self-efficacy	7.14	2.30	4.23
Control	6.12	2.30	4.23
Subjective norms	6.12	2.30	4.23
Overall	5.10	4.60	4.23

3.2.2 Participant Demographics

For the Anglophone participants, there were no significant differences on demographic variables between those in the intervention condition compared to those in the control condition (Table 8). Non-participants were asked to voluntarily provide basic demographic information. We were able to obtain these data from 24 Anglophones and 5 Francophones. Despite the small sample size available, we compared Anglophone participants to Anglophone non-participants and found no significant differences (Table 9). Due to the very small sample size, demographic information for Francophone non-participants is not provided in this report in order to protect anonymity and avoid potential identification.

Table 8: *Anglophone participant demographics by condition.*

	Intervention	**Control**
Gender (n, %)		
Male	142 (80.68%)	154 (86.52%)
Female	34 (19.32%)	24 (13.48%)
Age (Mean, SD)	23.66 (5.71)	23.98 (5.93)
Completed education (n, %)		
Less than high school diploma	6 (3.41%)	10 (5.68%)
High school diploma or a high school equivalency certificate	97 (55.11%)	92 (52.27%)
Trade Certificate or Diploma	30 (17.05%)	21 (11.93%)
College, CEGEP, or other non-university certificate or diploma	27 (15.34%)	38 (21.59%)
At least some University*	16 (9.09%)	15 (8.52%)
Ethnicity (n, %)		
White	150 (85.23%)	144 (80.90%)
Other*	26 (14.77%)	34 (19.10%)
Self-reported general mental health (n, %)		
Excellent	28 (15.91%)	26 (14.86%)
Very Good	68 (38.64%)	63 (36.00%)
Good	50 (28.41%)	69 (39.43%)
Fair	27 (15.34%)	14 (8.00%)
Poor	3 (1.70%)	3 (1.71%)
Self-reported general physical health (n, %)		
Excellent	16 (9.09%)	12 (6.82%)
Very Good	45 (25.57%)	44 (25.00%)
Good	78 (44.32%)	91 (51.70%)
Fair	33 (18.75%)	28 (15.91%)
Poor	4 (2.27%)	1 (0.57%)

*Categories were collapsed for the purpose of this report to protect anonymity and avoid potential identification of participants in small categories.

Table 9: *Anglophone participant and non-participant demographics.*

	Participants	Non-participants
Gender (n, %)		
Male	296 (83.62%)	22 (91.67%)
Female	58 (16.38%)	2 (8.33%)
Age (Mean, SD)	23.82 (5.81)	23.96 (4.81)
Completed education (n, %)		
Less than high school	16 (4.55%)	1 (4.17%)
High school or non-university certificate or diploma*	305 (86.65%)	20 (83.33%)
At least some University*	31 (8.81%)	3 (12.50%)
Ethnicity (n, %)		
White	294 (83.05%)	18 (75.00%)
Other*	60 (16.95%)	6 (25.00%)
Self-reported general mental health (n, %)		
Excellent	54 (15.38%)	3 (12.50%)
Very Good	131 (37.32%)	9 (37.50%)
Good	119 (33.90%)	12 (50.00%)
Fair	41 (11.68%)	0 (0.00%)
Poor	6 (1.71%)	0 (0.00%)
Self-reported general physical health (n, %)		
Excellent	28 (7.95%)	5 (20.83%)
Very Good	89 (25.28%)	6 (25.00%)
Good	169 (48.01%)	12 (50.00%)
Fair	61 (17.33%)	1 (4.17%)
Poor	5 (1.42%)	0 (0.00%)
*Categories were collapsed for the purpose of this report to protect anonymity and avoid potential identification of participants in small categories.		

3.3 Randomization and Scheduling Procedures

Following multiple meetings with CFLRS Scheduling, Standards, and Research coordinator staff, the randomization scheme for the pilot study was created by the biostatistician (A.L.) and provided to CFLRS several months in advance. CFLRS BMQ training schedules (which contain information on the timing of R2MR and the three assessment sessions) were available online approximately 8 weeks in advance. It was the responsibility of the Toronto study monitor (K.B.) to use this internal CFLRS online information to ensure that R2MR and the three data collection sessions were scheduled at the correct times for each platoon according to the study design.

Overall, the randomization and scheduling procedures worked well. At the same time, the pilot study showed that the study monitor role was indeed very important. There was an instance where the study

monitor needed to contact CFLRS to have a session moved because a platoon in the control condition had been scheduled to receive R2MR in week 2 instead of week 9. While it is beyond the scope of this report to capture instances of problems with randomization and scheduling beyond the pilot, we can anecdotally report that similar problems continue to occasionally come up and need to be corrected by the study monitor. This role is therefore being maintained for the larger study, which is ongoing.

An issue also arose where CFLRS had re-scheduled a data collection session after publishing the online schedule. There was no procedure in place for informing the study monitor that a change had been made. The study monitor discovered the change on her own but if this hadn't have been the case then a data collection session could have been missed. Two procedures were put into place as a result: 1) the scheduling department at CFLRS was requested to contact the study monitor directly with any changes to the R2MR or data collection sessions, 2) the study monitor was required to double-check all schedules on a weekly basis to ensure previously scheduled sessions had not changed.

3.4 Contracting

Given the expected duration of the study and the large number of questionnaire booklets needing to be printed, it was impractical for DRDC Toronto to print and deliver all of the study materials to CFLRS; an external printing company was utilized instead. DRDC Toronto provided the specifications and the PDF documents to be printed. The printing company mailed printed proofs to DRDC for approval and then printed all documents and shipped them directly to CFLRS. This process went very smoothly. However, in order to use this option, it was necessary to go through procurement at DRDC Toronto, receive bids, evaluate the bids received, and then enter into a contract with the chosen company. This process was very time-consuming and needed to be initiated months in advance. Additionally, the print job was completed for all pilot platoons in one batch prior to the start of the study which would not have allowed changes to be made to the printed documents if mistakes had been discovered. Another concern about printing being delivered in one batch was limited storage space available at CFLRS to store study materials.

The original intention for the pilot study was to have an external contractor run the three data collection sessions for each platoon. Two different contracting mechanisms were explored simultaneously and of these only one (adding a new task to an existing Standing Offer with a defence contractor) met the task requirements. However, contracting was slow and there were additional delays in getting contractors started with data collection at CFLRS, for instance, delays in obtaining security clearances for the contractors. Security clearance is required in general for defence contractors but in the case of this GRCT is also required so that contractors can be allowed unescorted on CFLRS property. Security clearances for subcontractors added further delays. After task authorization, time required to obtain security clearances was about 8 weeks.

Due to the above issues, the contractors were not able to assist with the pilot data collection until T3 data assessment sessions. Instead, the study monitor (K.B.) and other DRDC employees completed all T1 and T2 data collection sessions. The Toronto employees could not be blind to platoon condition/allocation which is required in the larger study. As a result, procedures to ensure that data collection staff remain blind to platoon condition/allocation could not be tested for the larger study. The plan for the larger GRCT is to have contractors do 100% of the data collection. The study monitor will obtain scheduling information directly from the posted online schedules and will provide a data collection schedule to the contractors on a weekly basis, stripping any and all information about platoon condition in these communications.

Another concern was that due to delays in starting the pilot study, T3 data collection for the pilot study was running parallel to T1 data collection of the larger study. Since the contractors were not in place until the start of the main study, any issues that could potentially arise with the contractors not being able to complete the tasks they were assigned could not be discovered prior to the start of the main study and if and when such issues arose, had to be corrected very quickly. Running the pilot T3 and study T1 sessions in an overlapping schedule also made the data collection very complicated for the contractors partly because the pilot and study phases used slightly different materials. In any applied setting such as the military training setting at CFLRS, there are multiple and, at times, competing objectives: the objectives of the study team were to test all study procedures as fully as possible which would normally have required delaying the start of the study phase until all pilot data collection had been completed and contractors had been sufficiently observed in their data collections role. However, the objective of CFLRS is to try and compress the duration of the R2MR GRCT as much as possible as the randomization, the data collection (totalling six 40-minute blocks of training time during the BMQ), and scheduling place a significant burden on an already busy scheduling and standards division. Given prior concerns regarding these burdens from CFLRS, and the hesitation of CFLRS to greenlight the larger GRCT in the past, the decision was made to not delay the larger study. Based on both prior DRDC experience working with the contractor and contractor training and skill set, we assumed that no major problems with contractors would be uncovered during the pilot in meeting data collection demands. This was indeed the case, the contractors, all Master's or Ph.D. level researchers with multiple years of experience working on defence research projects, following a brief training and orientation phase, quickly took over data collection with success.

A naïve recommendation for future studies would be to ensure that a strong contracting mechanism is established far in advance so that external resources can be accessed in a timely manner when there are insufficient internal resources to handle the workload. However, it should be noted that the exploration of the two contracting mechanisms for the current pilot and subsequent GRCT trial started *years* in advance. Thus, a more helpful recommendation would be to address procurement and contracting mechanisms at the agency level so that contracts can be put into place for project data collection in a more timely manner, something that is being addressed as part of a wider agency level capability review.

3.5 Blinding

The larger GRCT study will be triple blind: the principal investigator, the data collection staff, and platoons eligible to participate in the study will all be blinded as to which condition each platoon is in. Furthermore, every effort will be made to blind all CFLRS staff other than those in charge of research coordination, and scheduling. Unfortunately, during the pilot, we were not able to fully test this aspect of the study design. As mentioned above, delays in contracting required that DRDC Toronto staff (not blind to platoon condition) run most of the data collection sessions.

We had one major incident during the pilot study in which an entire platoon and their instructor were possibly un-blinded to their condition. During T2 data collection with one of the platoons, the platoon instructor asked for more information about the study from the DRDC Toronto staff member completing the data collection. The information given in front of the class by the staff member incorrectly explained that the study has one data collection session prior to R2MR and then two follow-up sessions. This was a deviation from the carefully worded Information Sheets, Consent Forms, and data collection scripts (see Annex A and B and C) which avoided stating that there would be data collection sessions "before and after" R2MR (because the control platoons do not receive R2MR until after they have completed all T1, T2, and T3 data collection sessions). Thus, when the staff member in charge of data collection incorrectly told the

platoon instructor that the platoon should have received R2MR, the platoon instructor understandably became concerned, knowing that the platoon had not yet received R2MR; further, when questioned by the staff member doing the data collection, some recruits in the platoon thought that they had indeed not completed R2MR whereas others thought that they had. This led to further questions and discussion among study staff, the recruits, and the platoon instructor regarding whether R2MR was received or not, while the recruits were still completing the surveys. Finally, the platoon instructor looked through the platoon's full BMQ training schedule and found R2MR in week 9 (the correct timeline for the control condition).

In instances such as this where one platoon is possibly un-blinded, the unblinded platoon and the block to which it belongs in the randomization scheme should all be removed from statistical analyses to preserve the validity of the randomization and allocation. This means that mistakes with unblinding can cause significant loss of data for the study, especially if repeated over the course of the study.

Following this one instance of possible unblinding, adjustments were made to study staff training to prevent future occurrences of similar mistakes. Specifically, more time than originally planned was set aside to go over the full details of the study design and to highlight the importance of blinding. Further, the incident was discussed with the contractors in great detail to alert them to possible ways in which they could inadvertently unblind platoons to study allocation. In addition, further training was provided to the contractors on how to answer questions from participants and platoon staff about the scheduling of R2MR and the purpose of the study without revealing too many details about study design.

3.6 Data Collection Procedures and Materials

Piloting all three data collection sessions allowed us to have better estimates for how long each assessment session would take and gave us an opportunity to discover problems with data collection materials and scripts. It also gave us an opportunity to see the type of questions that participants asked during data collection, so we could better prepare the contractors on what to expect.

There were a number of issues that were discovered during data collection. One of the most significant issues was with the timing of sessions. Data collection took place in the evening (typically between 18:05–19:35 or 18:55–20:25) and participants informed us that they only had the opportunity to phone family members between 20:00–20:30. For the participants in the later evening sessions this was a major source of concern. There was also a Fire Picket each night at 19:30 which 3–4 members of each platoon were required to go to. For the larger study, it was requested that an earlier timeslot be assigned whenever possible to minimize disruptions due to the phone calls and the Fire Picket.

Another issue that became apparent was with the administration of the Shipley [30] Block Design subscale at T1. This subscale of the Shipley measures fluid cognitive ability which is the ability to "use logic and other skills to learn and acquire new information; for example, solve novel puzzles or problems" (pg. 3) [30]. This measure was included because cognitive ability was found to impact learning outcomes of R2MR [31] and thus it was important to ensure that the intervention and control groups were not significantly different on cognitive ability. The instructions for the Shipley indicate that the participants should not draw on the block images (which changes the nature of the mental rotation task) but 67 participants were found to have done so anyway during the pilot. Drawing on the Shipley in this manner, according to the test manual [30], invalidates the test and results in missing data (in the case of the pilot for approximately 15% of eligible non-recoursed participants). Changes were made to the standard data collection script to further emphasize the fact that participants should not draw on the block images and that doing so leads to invalid results.

3.7 Data Management

The pilot study gave us an opportunity to design and test data management procedures including data entry, data quality assurance, and data linkage. It was necessary to automate data entry as much as possible due to the extremely large amount of data involved in this study. The primary study will run for up to 18 months with a possible 6750 participants. Each participant will complete three data collection sessions potentially resulting in over twenty-thousand questionnaire booklets which will need to be entered by a small group of staff.

Remark Office OMR 2014 software [32] was utilized for data entry. Prior to the start of pilot data collection, templates were developed in Remark by scanning blank copies of the questionnaires and indicating values that should be assigned to multiple-choice style responses. Completed paper questionnaire packages were scanned and then the PDFs were entered into the Remark software. The multiple-choice style questions were scored by the software. Certain errors were picked up by the software (blanks and multiple answers for a single question). Research technologists went through each of these identified errors manually to correct them. Unfortunately, it was discovered that some errors were not easily identified by the software. There were some cases where the Remark template appeared to shift and was not lined up properly with the PDF scan of the data. For example, in some cases the template would be too high on the page compared to the scan. In this case the first question would appear blank (an error would be given) but the rest of the questions would line up with the wrong part of the template (question 1 of the scan would line up with question 2 of the template, etc.). In this case it was not sufficient to just fix the single error given by Remark for the first question, rather, all questions on that page needed to be fixed manually. The most concerning errors were when the template appeared to experience a glitch and two questions on the PDF scan would appear under the same template space. For example, the answer given for question 1 would also be given for question 2, while the answer for question 2 would be skipped. In these cases no error was recognized by the system. This problem was only discovered because in some cases the two questions had different response options and impossible values were being entered.

A method for data quality assurance was therefore developed which involved multiple steps. All questions were checked for impossible values and if any were discovered to have occurred due to template shifting or glitches, that entire section of the questionnaire was checked manually for each participant in that platoon. A second safeguard was put into place where a different research technologist who did not do the original entry and checking would check 10% of the questionnaires manually for accuracy.

This study required the three data collection time points to be linked for each participant. A linkage sheet was utilized for each data collection session which contained platoon number, date, Service Number (SN) of the participant, and a unique booklet number. When this linkage sheet was removed from the rest of the booklet, the booklet did not contain any identifying information. Data from the three data collection sessions could then be linked while keeping questionnaire data separate from identifying information in all electronic files. While this method was successful for the most part, an issue did arise where some participants entered a different SN across the three time points. This could have occurred for multiple reasons including participants not having correctly memorized their SN, high fatigue levels, etc. It was decided that this method, while not perfect, was still preferable to the alternative data linkage method used in previous studies where participants were required to create and remember a Personal Identification Number (PIN).

Participants were asked to provide additional consent to allow us to access their CFLRS administrative data and additional test scores including the Recruit Health Questionnaire (RHQ), the Canadian Forces Aptitude Test (CFAT), and the Trait Self Descriptive Inventory (TSD). Delays in this being provided to us occurred for reasons outside of our control, including delays in data entry, project management issues (change of staff), and competing priorities. Additional consent for data linkage was provided by 227 Anglophone participants (64.12% of the 354 non-recoursed participants) and 79 Francophone participants (80.61% of the 98 non-recoursed participants). This linkage also utilized self-reported SN and shared the same issues around inaccuracy as mentioned above. There were five instances where the SN reported by the participant could not be found in the relevant databases. Accessing these additional databases required communicating with multiple points of contact at multiple organizations.

4 Conclusion

RCTs are the golden standard in testing the efficacy of mental health interventions such as R2MR. RCTs have complex designs which make them particularly difficult to run in applied settings, such as the training and operation settings in which R2MR is given. In this first pilot RCT, we noted a number of threats to randomization, scheduling, blinding, and data validity. A number of steps were taken to address these threats including a) additional oversight by Toronto staff to double check that all sessions were correctly scheduled according to study design, b) additional oversight by Toronto staff to ensure that any changes to the data collection schedule were identified and communicated to data collection staff, c) additional training for data collection staff on the importance of blinding and not deviating from the data collection scripts, d) moving data collection sessions to earlier in the evening to address scheduling conflicts and participant fatigue, e) changes to the data collection scripts to improve instructions for the Shipley cognitive assessment, and f) additional quality assurance steps for data entry. These additional steps will help to mitigate the problems identified in the pilot phase and increase the likelihood of success for the larger GRCT. None of the problems identified in the pilot were serious enough to postpone or cancel the larger GRCT which is currently underway and expected to run from January 2017 to August 2018.

The threats identified in this pilot study are likely to exist in all CAF training and operational settings and must be taken into consideration in designing future RCTs. Future studies may benefit from having in-depth discussions prior to the start of the RCT, among the CAF military training staff, mental health education stakeholders, and researchers. These discussions and their outcomes (e.g., determining the timing of the assessment sessions that both minimizes invalid responses and disruptions to the larger military training schedules) may need to be formalized with a Memorandum of Understanding that spells out roles and responsibilities of all parties. Unfortunately, even with the kind of high level cooperation among the various stakeholders observed in the R2MR GRCT, competing priorities for each stakeholder will necessitate compromises. This was certainly the case with the current study in which late assessment sessions were moved to an earlier time by CFLRS but not as early as the research team would have liked them. In future RCTs, it will be important to track, minimize and explicitly disclose the limitations imposed by such compromises that are inherent in applied military settings.

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Annex A Information Sheet

Table A.1: *Information sheet.*

Researchers and Research Sponsors	Defence Research and Development Canada; Toronto Research Centre is conducting a study entitled *Testing the Efficacy and Effectiveness of the Road to Mental Readiness (R2MR) mental health training program during Basic Military Qualification*. This project has been approved by Defence Research and Development Canada; Toronto Research Centre's Human Research Ethics Committee (Protocol # 2016-021).
The Present Study	You will be receiving mental health training during your Basic Military Qualification (BMQ) training. The purpose of this project is to assess how well mental health training works by measuring your mental health and well-being, your resilience, your performance and your attitudes at three assessments. These assessments will take place approximately at week 2, week 5, and week 9 of the BMQ. Your time commitment for this study is 80 minutes at each of the three assessments. What do we need from you? We would like you to fill out self-report questionnaires that assess your current mental health and well-being, resilience, performance, and attitudes. We would like to ask for your permission to use your data from the questionnaires for research purposes. We would also like to link your answers to the questionnaires in this study to some data that you have already provided (or will soon provide) to the Canadian Armed Forces (CAF). Specifically, we would like to link your answers from this study to: Canadian Forces Leadership and Recruit School databases which have information on your performance during your BMQ training and graduation status, Department of National Defense (DND) personnel records containing information from the application and selection process, and another DND endorsed survey that you will be invited to complete later in your training at CFLRS (namely, the *Recruit Health Questionnaire* [RHQ] administered for the purpose of public health surveillance which includes some questions which are relevant in the context of this study).
Your Rights As A Participant	**Your participation in this study is completely voluntary and agreement to participate in this first phase of the project in no way constitutes a commitment to participate in subsequent phases of the study.** You may drop out of the study and withdraw your data from the study without prejudice or hard feelings.

Confidentiality Of Your Results	All of your results will be kept strictly confidential and will not be shared with your unit leaders/supervisors or anyone else in the CAF at the individual level. All the information and responses that you provided during this study will be kept in a secure location at Defence Research and Development Canada's Toronto Research Centre to which only researcher team members will have access. **Results communicated or reported will contain no identifying information.** The list matching your names and service numbers to the numerical codes we will assign your data will be kept separate from the questionnaires and will only be accessible to the investigators. The same procedure will be used for data linkages. Lists that match service numbers to participant numbers will be used to link data from the current study to other existing recruit administrative and research databases. **This list will be destroyed at the end of the study** and the resulting dataset will only include the numerical codes assigned to each participant. In other words, once the study is complete, no one (not even the investigators) will be able to link your responses on these questionnaires back to you. All information you provide in this survey that identifies you personally is protected by the Privacy Act. Data will be stored separately from identifier codes. Your participation will have no impact on your career.
Benefits	The results of this study will indicate how well mental health training works and whether it needs to be modified to better meet the needs of CAF recruits.
Potential Risks To You	There are no known risks associated with this study.
Who do I contact with questions about this study?	For any further questions or concerns about this project, please contact: *The Principal Investigator* for this study: Dr. Deniz Fikretoglu For questions please contact: Dr. Deniz Fikretoglu, Defence Research and Development Canada; Toronto Research Centre; phone: 416-635-2049, e-mail Deniz.Fikretoglu@drdc-rddc.gc.ca. For human research ethics issues*, Defence Research and Development Canada; Toronto Research Centre Human Research Ethics Committee Chair*, Ms. Tonya Hendricks, at 416-635-2061, e-mail HREC-CEESH-Toronto@drdc-rddc.gc.ca.

Annex B Consent Form

VOLUNTARY CONSENT FORM

Title: Testing the Efficacy and Effectiveness of the Road to Mental Readiness (R2MR) mental health training program during Basic Military Qualification (BMQ).
Protocol Number: Protocol #2016-021
Principal Investigator: Dr. Deniz Fikretoglu (Defence R&D Canada Toronto)
Co-investigators: Aihua Liu (contractor)

1. I, (name) _____hereby volunteer to be a participant in a study entitled *Testing the Efficacy and Effectiveness of the Road to Mental Readiness (R2MR) mental health training program during Basic Military Qualification.* I have read the information sheet and was given the opportunity to ask questions of the investigator(s). All of my questions concerning this study have been fully answered to my satisfaction. However, should I request additional information about this research project or have any further questions, I understand I may contact the principal investigator Dr. Deniz Fikretoglu (416-635-2049).

Involvement

2. I am aware that *I will soon be receiving mental health training and that in order to see how well mental health training works,* I am being asked to complete questionnaires assessing my current mental health and well-being, resilience, performance, and attitudes at three time points (week 2, week 5, and week 9 of the BMQ). I further understand that I am being asked to give my permission for my data from these questionnaires to be used for research purposes.

Purpose and Benefits

3. I am aware that this study will yield information on how well mental health training works. The results of this study will indicate whether course modification is necessary to more effectively improve recruits' mental health and performance outcomes.

Risks

4. I have been told that there are no known risks associated with this study. Also, I acknowledge that my participation in this study, or indeed any research, may involve risks that are currently unforeseen by Defence Research and Development Canada; Toronto Research Centre.

Confidentiality

5. I understand that my experimental data will be protected under the Government Security Policy at the appropriate designation and not revealed to anyone other than the Defence Research and Development Canada; Toronto Research Centre-affiliated Investigator(s) or external investigators from the sponsoring agency without my consent except as data unidentified as to source.

6. I understand that my name will not be identified or attached in any manner to any publication arising from this study. Moreover, I understand that the experimental data may be reviewed by an internal or external audit committee with the understanding that any summary information resulting from such a review will not identify me personally.

7. I understand that, as a Government Institution, Defence Research and Development Canada; Toronto Research Centre is committed to protecting my personal information. However, under the Access to Information Act, copies of research reports and research data (including the database pertaining to this project) held in Federal government files, may be disclosed. I understand that prior to releasing the requested information, the Directorate of Access to Information and Privacy screens the data in accordance with the Privacy Act in order to ensure that individual identities (including indirect identification due to the collection of unique identifiers such as rank, occupation, and deployment information of military personnel) are not disclosed.

8. I understand that a numerical code will be assigned to each participant and to his/her questionnaires in order to protect confidentiality. Completed questionnaire results will be kept in Excel and Statistical Package Social Sciences data files with access restricted to research personnel only and will additionally be protected using electronic password options. Once completed questionnaire results have been entered electronically in Excel and SPSS, paper copies of questionnaires will be shredded. We are asking for your Service Number below to facilitate possible data linkage to other recruit administrative and research databases. The list we will create including Names and Service Numbers will be destroyed once the data linkage has been completed.

Withdrawal

9. I understand that I am free to withdraw from the study at any time without prejudice or hard feelings. Should I withdraw my consent, my data in this research project will be withdrawn immediately.

Remuneration

10. I understand that there will be no remuneration for participation in this study.

Rights

11. I understand that by signing this consent form I have not waived any legal rights I may have as a result of any harm to me occasioned by my participation in this research project beyond the risks I have assumed. Also, I understand that I will be given a copy of this consent form so that I may contact any of the individuals mentioned below at some time in the future should that be required.

If you consent to participate, please sign and date this consent form below.
I consent to having the information I provided here today be used for research purposes, i.e., to see how well mental health training works for recruits and whether it needs to be modified to better meet the needs of recruits.

Volunteer's Name:_____

Signature:_____ Date: _____

Volunteer's Service Number:_____

Data Linkage:

We would like to link your survey responses to the other phases of the study and to other recruit databases, in order to enhance our understanding of factors related to the efficacy and effectiveness of mental health training. This data linkage also helps us avoid having to ask you the same questions twice (as part of separate studies) and minimizes the burden on you, the survey respondent. Specifically, we would like to match your information from the current study with Canadian Forces Leadership and Recruit School databases which have information on your performance during your BMQ training and graduation status, DND personnel records containing information from the application and selection process, and with some of your responses from another DND endorsed survey that you will be invited to complete later in your training at CFLRS (namely, the *Recruit Health Questionnaire* [RHQ] administered for the purpose of public health surveillance which includes some questions which are relevant in the context of this study).

This data linkage will be done strictly for CAF mental health training research purposes and information collected will never be placed in your personnel files or be used to guide decisions about your military career.

Once the link has been made all personally identifying data will be deleted.

If you consent to have your information from this survey linked to other databases (other phases of the current study, DND personnel records, CFLRS administrative databases, and the RHQ) strictly for research purposes, please check the box below.

❑ **I consent to data linkage, as outlined above.**

FOR PARTICIPANT ENQUIRY IF REQUIRED:
Should I have any questions or concerns regarding this project before, during or after participation, I understand that I am encouraged to contact Defence Research and Development Canada; Toronto Research Centre cited below. This contact can be made by surface mail at this address or by phone or email to any of the DRDC numbers and addresses of individuals listed below:

Defence Research and Development Canada; Toronto Research Centre
1133 Sheppard Avenue West
Toronto, Ontario, M3K 2C9
Principal Defence Research and Development Canada; Toronto Research Centre Investigators:

Dr. Deniz Fikretoglu, Defence Research and Development Canada; Toronto Research Centre; phone: 416-635-2049, e-mail: Deniz.Fikretoglu@drdc-rddc.gc.ca.

For research ethics issues**, Chair, Defence Research and Development Canada; Toronto Research Centre Human Research Ethics Committee:**
Ms. Tonya Hendricks, (416) 635-2061, HREC-CEESH-Toronto@drdc-rddc.gc.ca

This research has been coordinated by the DGMPRA Social Science Research Review Board, in accordance with DAOD 5062-0 and 5062-1. The SSRRB coordination # is 1580-16N.

If you decide not to participate:

We respect your decision not to participate in this study.

An important step in this study is ensuring that those recruits who participate in the study and those recruits who do not participate do not differ from each other in significant ways. By showing that participants and non-participants do not differ from each other, we can ensure that our findings apply to all recruits, not just those who participated in the study.

We would like to therefore ask for your help in providing us some basic information about yourself by filling out page 5 of the questionnaire packet only. This should take only a minute.

You can leave everything on this Consent Form blank.

It is completely voluntary to provide this information.

Annex C Data Collection Scripts

C.1 Time 1 Script

Good afternoon/evening everyone,

My name is _____. I am a researcher working for the Department of National Defence.

I am here this afternoon/evening to conduct an important study on resilience training.

Please do not start looking at the pages in front of you until I explain what we are going to be doing.

As part of your BMQ you are going to be taught a course called Road to Mental Readiness (or R2MR). This course was developed under the direction of the CAF Surgeon General. R2MR has 3 goals: increase knowledge about mental health, teach effective stress management skills, and improve psychological resilience, which is the ability to bounce back from stressful or traumatic situations. The purpose of this study is to determine if the R2MR course is working. In order to answer that question we need to know how recruits think and feel throughout their BMQ.

It is important for you to know that this study has been approved by your Commanding Officer and time has been set aside for this study in your training schedule so you will not miss anything in your BMQ by participating. The study is totally separate from your BMQ; Your leaders will not be told who choose to participate and who did not and they will not see your responses. Participation in this study is completely voluntary but is encouraged. It is only with your input that we can say for sure whether resilience training works for recruits, how well it works, and whether it needs to be modified.

I am going to walk you through each of the forms in front of you and explain everything you need to do. Please follow my instructions carefully and do not move ahead or look at anything before I tell you to. This is important because there is a portion of this study that is timed which you are not supposed to see before I tell you that you can start.

So what will we ask you to do in this study? Please take a look at first sheet in front of you called the Information Sheet. This will give you an overview of the study. I will give you a minute to read through this now.

As you can see in the second box, in this study we will ask you to fill out a survey that assesses your mental health and well-being, your resilience, your performance, and your attitudes at three time points: today, three weeks later, and towards the end of your training around week 9. Each time point you may spend anywhere from 60 to 80 minutes on the survey. These timings may be slightly different for your platoon due to the holiday break.

We would also like to link your answers to the questionnaires in this study to some data that you have already provided (or will soon provide) to the Canadian Armed Forces (CAF). The reason we are doing this is to save you time. You will be completing other questionnaires as part of your BMQ and other studies, and we do not want you to have to complete the same forms twice.

Now I need to go over some really important additional points with you on the Information Sheet. As I mentioned earlier, this study is completely voluntary. You can also drop out at any time. If you complete the session today, you are under no obligation to complete the rest of the sessions if you do not want to. Also, if you choose to participate in the study you can still refuse to answer any questions that you do not want to answer. Your data will be confidential. Everyone's booklet has a participant number which will be linked to their data. Your data will be kept separate from your personal information such as name and service number.

There are no known risks associated with participating in this study. The benefit of participating in this study is that you will be helping to determine if resilience training works and if it needs to be modified to meet the needs of future recruits like yourself.

The last section of the Information Sheet has contact information. If you have a question about the research, you can contact Deniz, and if you have any concerns about research ethics or about how this study is being conducted you can contact Tonya who is the head of the research ethics committee.

So once again, to summarize, we are here because we have been asked to look at how well resilience training meets your needs and whether or not it will help you better succeed with your recruit training here and your military career later on. But we can only do this with your help.

Now let's look at the Consent Forms, which contain the same information as the Information Sheets but in "legalese"; these forms need to be filled out. Please use a pen not a pencil for everything we do today. I will give you a minute to look over the Consent Form but please wait for my instructions before you fill it out.

Are there any questions?

If you consent to participate, please write down your name on page 1 of the Consent Form; at the bottom of page 2, write down your name, sign and date and put down your Service Number. On page 3, if you consent to linking data from other administrative databases and research studies to this study, please check the box in blue/grey. Again, we are asking for this to save you time, so you do not have to provide the same information twice.

Now go to page 3 of your booklet, please write down and fill in the bubbles for today's date, your service number, and your platoon number. Please fill in the entire bubble. If you make a mistake put an X through that bubble and then fill in the correct bubble. Next everyone can turn to page 5, now is the time to fill this Sociodemographic Questionnaire.

On page 4 of the Consent Form, you will see that for those who may not wish to participate in the study, we are still asking you to fill out a Sociodemographic Questionnaire on a voluntary basis; this is so we can say with certainty that those who participated and those who did not participate, did not differ from each other in a significant way. After you finish this one page you can quietly remain in your seat until the study is over. For those who are participating, when you finish this page please do not go on to the next page until I tell you to. We are going to be doing the timed section after this so please do not look ahead.

Is everyone finished with page 5?

Now we will be completing a problem solving test. We are interested in looking at if a person's problem solving ability in general impacts how they think about resilience. Just a reminder that this test will not impact your BMQ in any way and your BMQ staff will not get your test scores, it is purely for research purposes. You will be completing two pages of block patterns. In this task you will see an image with one or more pieces missing. Your job is to select the missing piece or pieces from the available multiple choice options. The problems on the second page are harder. These images have been flipped, rotated, and some have blank spaces to make it even more challenging. You are supposed to figure out which piece is missing in your head, meaning you are not allowed to draw on the images. Drawing on the images in fact completely invalidates the test, we can't use any of your data if you draw or make marks. You will have 10 minutes to complete BOTH pages. So when you finish the first page please start the second page right away. I will tell you when your time is up. If you have any questions during the test, please raise your hand and I will help. Are they any questions before we start? Please turn the page and start now.

Please stop working and turn the page now. From this point on, please do not return to the section you just completed or make any changes to it. You can now complete the rest of your booklet.

I want to thank everyone again for participating. You are helping to shape the R2MR program and your contributions are greatly appreciated. I will see you all again in three weeks for the next session.

C.2 Time 2 Script

Good afternoon/evening everyone,

My name is _____. I am a researcher working for the Department of National Defense.

I (or a colleague of mine) was here about three weeks ago and I (he/she) had asked you to participate in an important study looking at how well resilience training that has been put into place to help you guys during your BMQ training and later on in your military career is working. As I mentioned last time, R2MR was developed under the direction of the CAF Surgeon General. R2MR has 3 goals: increase knowledge about mental health, teach effective stress management skills, and improve psychological resilience, which is the ability to bounce back from stressful or traumatic situations.

As part of this study, three weeks ago you filled out questionnaires about your mental health and well-being, your resilience, your performance, and your attitudes. I am here today to conduct part 2 of that study which involves filling out the same questionnaires as you did three weeks ago, except for the problem solving test which you don't have to do a second time. I know it can be frustrating to answer the same questions you answered a few weeks ago but it is important because in order for us to be able to determine if R2MR is working we need to know how you are thinking and feeling throughout (emphasize) your BMQ. That's why your continued participation in this study is so important.

There may be some of you who joined this platoon after we had completed the first data collection, some of you who missed that day for other reasons such as being injured or sick. If this applies to you, and you might be interested in participating today, please raise your hand. This information sheet will explain the

study. If you want to participate you will have to fill out the consent form. I will walk you through how to fill it out after I get everyone else started.

For those of you who participated last time and are participating today, you will not be completing a second consent form because this is part of the same study, but I want to remind you of a few important things. Participating in this study is completely voluntary and you can drop out at any time. You are not obligated to complete today's session just because you completed time 1. This also means that if you complete the session today, you are under no obligation to complete the next one. Having said that, we really hope that you continue to participate—as I said before, only by having information about how you are doing throughout (emphasize) your BMQ are we able to say whether R2MR works for you or not.

If you choose to participate in the study you can still refuse to answer any questions that you do not want to answer. Your data will be confidential. Everyone's booklet has a participant number which will be linked to their data. Your data will be kept separate from your personal information such as name and service number. The study is not part of your BMQ and your leaders will not be told who choose to participate and who did not and they will not see your responses.

So once again, to summarize, we are here because we have been asked to look at how well resilience training meets your needs and whether or not it will help you better succeed with your recruit training here and your military career later on. But we can only do this with your help.

If you are participating, please open your booklet now and write and bubble in today's date, your service number, and your platoon number. Please fill in the entire bubble. If you make a mistake put an X through that bubble and then fill in the correct bubble. When you are finished with the first page you can continue filling out the rest of the booklet. Feel free to raise your hand if you have questions at any point. Any Questions?

Those of you who did not participate during the last data collection and want to participate today, please raise your hand now so I can help you with additional forms.

I want to thank everyone again for participating. You are helping to shape the R2MR program and your contributions are greatly appreciated. I will see you all again in one month for one last session to see how you are doing towards the end of your BMQ training

C.3 Time 3 Script

Good afternoon/evening everyone,

My name is _____ and I am here today to conduct the final data collection session for the study looking at the effectiveness of R2MR resilience training. As a reminder, R2MR was developed under the direction of the CAF Surgeon General and has three important goals: increase knowledge about mental health, teach effective stress management skills, and improve psychological resilience, which is the ability to bounce back from stressful or traumatic situations.

As you know, in order for us to be able to determine if R2MR is working we need to know how you are thinking and feeling throughout (emphasize) your BMQ which is why your continued participation in this study is so important.

There may be some of you who missed session 1, session 2, or both sessions for whatever reason. You are still welcome to participate today. This is true even if you chose not to participate in the earlier sessions but have changed your mind and wish to participate now. If you haven't completed either session 1 or 2, I have an information sheet which explains the study, and you will need to complete a consent form. Is there anyone who missed both previous sessions that might be interested in participating today? If you would like to participate I will walk you through how to fill out the consent form after I get everyone else started.

If you completed one or more of the previous sessions you do not need to fill out the consent form again. Once again I have to remind you that your participation in this study is completely voluntary and you are not obligated to complete today's data collection even if you have completed the previous sessions. Having said that, we really hope that you continue to participate—as I said before, only by having information about how you are doing throughout (emphasize) your BMQ are we able to say whether R2MR works for you or not.

I will also remind you that if you choose to participate in the study you can still refuse to answer any questions that you do not want to answer. Your data will be confidential. Once again, everyone's booklet has a participant number which will be linked to their data. Your data will be kept separate from your personal information such as name and service number. The study is not part of your BMQ and your leaders will not be told who choose to participate and who did not and they will not see your responses.

If you are participating, please open your booklet now and write and bubble in today's date, your service number, and your platoon number. Please fill in the entire bubble. If you make a mistake put an X through that bubble and then fill in the correct bubble If you missed session 1 or session 2 please make a brief note on this page explaining why (recoursed, injured, etc.)

When you are finished with the first page you can continue filling out the rest of the booklet. Feel free to raise your hand if you have questions at any point. Are there any questions before we start?

Those of you who have not participated in any of the previous data collections please raise your hand now so I can help you with additional forms.

I want to thank everyone again for participating. This is the last data collection for this platoon. I will not be back here again. I want to remind you that Deniz is the principal investigator for this study (write email on board) and you can contact her at any time if you have any questions about the study. Once again, thank you so much for participating. You are helping to shape the R2MR program and your contributions are greatly appreciated.

List of Symbols/Abbreviations/Acronyms/Initialisms

BMQ	Basic Military Qualification
CAF	Canadian Armed Forces
CAF-MHSUQ	Canadian Armed Forces Mental Health Service Use Questionnaire
CD-RISC	Connor-Davidson Resilience Scale
CFAT	Canadian Forces Aptitude Test
CFLRS	Canadian Forces Leadership and Recruit School
CMP	Chief of Military personnel
DRDC	Defence Research and Development Canada
FORCE	Fitness for Operational Requirements of Canadian Armed Forces Employment
FY	Fiscal Year
GAD7	Generalized Anxiety Disorder Scale
GRCT	Group Randomized Control Trial
ICC	Intra-class Correlation Coefficient
K10	Kessler Psychological Distress Scale
MHSU	Mental Health Service Use
NCM	Non-Commissioned Member
OMR	Optical Mark Recognition
PDF	Portable Document Format
PHQ9	Patient Health Questionnaire
PIN	Personal Identification Number
R2MR	Road to Mental Readiness
RCT	Randomized Control Trial
RHQ	Recruit Health Questionnaire
SN	Service Number
SUDS	Subjective Units of Distress Scale
T1	Time 1
T2	Time 2
T3	Time 3
TSD	Trait Self Descriptive Inventory

DOCUMENT CONTROL DATA

(Security markings for the title, abstract and indexing annotation must be entered when the document is Classified or Designated)

1. ORIGINATOR (The name and address of the organization preparing the document. Organizations for whom the document was prepared, e.g., Centre sponsoring a contractor's report, or tasking agency, are entered in Section 8.)

DRDC – Toronto Research Centre
Defence Research and Development Canada
1133 Sheppard Avenue West
P.O. Box 2000
Toronto, Ontario M3M 3B9
Canada

2a. SECURITY MARKING (Overall security marking of the document including special supplemental markings if applicable.)

CAN UNCLASSIFIED

2b. CONTROLLED GOODS

NON-CONTROLLED GOODS
DMC A

3. TITLE (The complete document title as indicated on the title page. Its classification should be indicated by the appropriate abbreviation (S, C or U) in parentheses after the title.)

Feasibility Findings from a Pilot Group Randomized Control Trial on the Road to Mental Readiness (R2MR) Program

4. AUTHORS (last name, followed by initials – ranks, titles, etc., not to be used)

Blackler, K.; Fikretoglu, D.; Liu, A.

5. DATE OF PUBLICATION (Month and year of publication of document.)

February 2018

6a. NO. OF PAGES (Total containing information, including Annexes, Appendices, etc.)

48

6b. NO. OF REFS (Total cited in document.)

32

7. DESCRIPTIVE NOTES (The category of the document, e.g., technical report, technical note or memorandum. If appropriate, enter the type of report, e.g., interim, progress, summary, annual or final. Give the inclusive dates when a specific reporting period is covered.)

Scientific Report

8. SPONSORING ACTIVITY (The name of the department project office or laboratory sponsoring the research and development – include address.)

DRDC – Toronto Research Centre
Defence Research and Development Canada
1133 Sheppard Avenue West
P.O. Box 2000
Toronto, Ontario M3M 3B9
Canada

9a. PROJECT OR GRANT NO. (If appropriate, the applicable research and development project or grant number under which the document was written. Please specify whether project or grant.)

Road to Mental Readiness

9b. CONTRACT NO. (If appropriate, the applicable number under which the document was written.)

10a. ORIGINATOR'S DOCUMENT NUMBER (The official document number by which the document is identified by the originating activity. This number must be unique to this document.)

DRDC-RDDC-2018-R003

10b. OTHER DOCUMENT NO(s). (Any other numbers which may be assigned this document either by the originator or by the sponsor.)

11a. FUTURE DISTRIBUTION (Any limitations on further dissemination of the document, other than those imposed by security classification.)

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Background: Conducting Randomized Control Trials (RCTs) in military operational and training settings poses special challenges. Thus, it is important to assess the feasibility of RCTs in pilot studies.

Objective: A pilot study was completed to assess the feasibility of two related studies: a Group RCT (GRCT) to test the efficacy of the Road to Mental Readiness (R2MR) mental health education and training program among Anglophone Non-Commissioned Member (NCM) recruits and a parallel non-randomized, uncontrolled pre-post-post study among Francophone NCM recruits.

Methods: Eight Anglophone platoons and two Francophone platoons were recruited for the pilot with a total of 536 potential participants. Three data collection sessions took place in week 2, 5, and 9 of Basic Military Qualification (BMQ). At each data collection session participants completed questionnaires assessing their psychological health and resilience as well as their attitudes towards mental health service use. In the efficacy arm of the pilot with Anglophone participants, platoons randomized to the intervention condition received R2MR in week 2 of their BMQ (after the first data collection session); platoons randomized to the control condition received R2MR in week 9 of their BMQ (after the last data collection session). In the effectiveness arm of the pilot with Francophone participants, both platoons received R2MR in week 2 of their BMQ (after the first data collection session). Feasibility issues examined included participation rates, attrition rates, participant demographics, missing data, problems with randomization, scheduling, blinding, contracting, data collection, data linkage and management, as well as possible threats to data validity.

Results: Out of a possible 536 recruits, a total of 452 (354 Anglophone) participated in the initial week 2 baseline data collection session (84.33%). Of those 452 participants, 332 (261 Anglophone) completed all three data collection sessions (73.45%). In the efficacy arm with Anglophone platoons, there was not a significant difference in attrition between the intervention and the control group. There were a few issues around randomization and scheduling where the assessment sessions did not respect the randomization scheme, or sessions had to be rescheduled and the data collection team was not informed. These issues were resolved quickly and procedures were implemented for communicating changes. There was an instance of possible unblinding of participants, which led to additional training for study staff in charge of data collection. Some potential threats to data validity were noted, for instance the late evening timing of assessment sessions, participants' difficulty understanding and/or complying with the instructions of some of the study measures, participants' decreasing motivation to complete repeated measures over the course of the study, and concerns around data entry. A number of adjustments were made to the study procedures to minimize the effects of these threats.

Conclusions: As the Canadian Armed Forces (CAF) moves towards testing mental health interventions such as the R2MR in RCTs, it will be important to increase awareness of and capture lessons learned about feasibility. This pilot study is the first GRCT on a mental health intervention in the CAF and provides novel information about feasibility issues that may be of use to future researchers.

Contexte : Effectuer des essais contrôlés randomisés (ECR) dans le cadre d'une formation et d'opérations militaires représente une difficulté particulière. Il est donc important d'évaluer la faisabilité des ECR lors d'études pilotes.

Objectif : On a mené une étude pilote pour évaluer la faisabilité de deux études connexes : un ECR par grappes pour évaluer l'efficacité du programme d'éducation et de formation en santé mentale d'En route vers la préparation mentale (RVPM) auprès des recrues militaires du rang (MR) anglophones et une étude avant-après non contrôlée et non randomisée menée en parallèle auprès des recrues MR francophones.

Méthodes : Huit pelotons anglophones et deux francophones ont été choisis pour l'étude pilote, soit un total de 536 participants potentiels. Trois séances de collecte de données ont eu lieu durant les semaines 2, 5 et 9 de la Qualification militaire de base (QMB). Au cours de chaque séance, les participants ont rempli un questionnaire d'évaluation de leur santé psychologique, de leur résilience, ainsi que de leur attitude face à l'utilisation des services en santé mentale. Dans le volet efficacité de l'étude pilote menée auprès des participants anglophones, les pelotons randomisés du groupe d'intervention ont reçu la formation sur RVPM durant la semaine 2 de leur QMB (après la première séance de collecte de données), les pelotons randomisés du groupe témoin ont reçu la formation sur RVPM durant la semaine 9 de leur QMB (après la dernière séance de collecte de données). Dans le volet efficacité de l'étude pilote menée auprès des participants francophones, les deux pelotons ont reçu la formation sur RVPM durant la semaine 2 de leur QMB (après la première séance de collecte de données). Les problèmes de faisabilité examinés incluaient le taux de participation, le taux d'attrition, les renseignements démographiques sur les participants, les données manquantes, les problèmes de randomisation, l'établissement du calendrier, le recours à l'insu, la passation de marché, la collecte, le couplage et la gestion des données, ainsi que les menaces potentielles à leur validité.

Résultats : Parmi les 536 participants potentiels, un total de 452 (354 anglophones) ont pris part à la séance initiale de collecte de données de la semaine 2 (84,33 %). Sur ces 452 participants, 332 (dont 261 anglophones) ont participé aux trois séances de collecte de données (73,45 %). Dans le volet efficacité parmi les pelotons anglophones, il n'y avait pas de différence significative dans l'attrition entre le groupe d'intervention et le groupe témoin Quelques problèmes relatifs à la randomisation et à la planification sont survenus parce que les séances d'évaluation ne respectaient pas le schéma de randomisation, ou bien parce que les séances devaient être reportées et que l'équipe de collecte des données n'en avait pas été informée. Les problèmes ont été résolus rapidement et des procédures ont été mises en œuvre afin de communiquer les changements. Une possible levée de l'insu a donné lieu à une formation supplémentaire du personnel de l'étude responsable de la collecte des données. On a noté certaines menaces potentielles à la validité des données, par exemple, les séances d'évaluation tenues en fin de soirée, les participants qui avaient de la difficulté à comprendre les instructions de certaines mesures de l'étude ou à s'y conformer, la diminution de la motivation des participants à exécuter des mesures répétées pendant la durée de l'étude et les préoccupations entourant la saisie des données. Un certain nombre de corrections ont été apportées aux procédures de l'étude pour minimiser les répercussions de ces menaces.

Conclusions : Tandis que les Forces armées canadiennes (FAC) se préparent à évaluer les interventions en santé mentale telles que le RVPM dans les ECR, il importe d'accroître la sensibilisation aux leçons retenues concernant la faisabilité et leur consignation. Cette étude pilote, le premier ECR par grappes d'une intervention en santé mentale dans les FAC, fournit de nouveaux renseignements sur les problèmes de faisabilité qui pourraient s'avérer utiles aux futurs chercheurs.

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Road to Mental Readiness; mental health education