



A pre-training conditioning program to increase physical fitness and reduce attrition due to injuries in Dutch Airmobile recruits: Study protocol for a randomised controlled trial



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ABSTRACT

Background: Low baseline fitness of recruits entering basic military training is shown to be associated with an increased risk of musculoskeletal injuries (MSIs) and attrition of military training. This in turn leads to an increased demand for health care, increased health care costs and decreased personnel occupancy rate of military units.

Design: Study protocol for a randomised controlled trial.

Objective: To determine the effects of a pre-training conditioning program on cardiovascular endurance, incidence of overuse injuries, and attrition rates in Dutch Airmobile recruits undertaking initial military training.

Setting: Royal Netherlands Army, Air Assault Brigade military training course.

Participants: Recruits are considered eligible for this study when they are 'low-fit' at the start of the initial military training. Time to complete a 2700 m run test in $\geq 12'23''$ is used as selection criteria.

Interventions: We use a complex system approach to cover multiple domains of MSI prevention and optimise intervention circumstance; a pre-training conditioning program, training staff support, process-focused culture and health accountability. The pre-training conditioning program contains functional training to improve mobility, power, agility, lower and upper body strength and cardiovascular endurance. Cardiovascular endurance will be targeted both by endurance training and high intensity interval training.

Main outcome measurements: Outcome measures include cardiovascular endurance, injury incidence, attrition rates, lost training days due to injuries, and implementation fidelity of the PCP.

Trial status: Recruitment of participants commenced April 18, 2018 and final results are expected in August 2019.

Trial registration: Dutch trial register www.trialregister.nl/ = trial/6791.

1. Introduction

Poor physical fitness has shown to be strongly associated with an increased risk of training-related musculoskeletal injuries (MSIs) in military trainees [1–5]. In particular, there is strong evidence that poor performance on a timed run test with a fixed distance is a predictor for such injuries [6].

In the Royal Netherlands Army (RNLA), pre-enlistment fitness tests are used to select eligible recruits for the Airmobile basic military training course (BMT). However, recruits who initially pass the fitness tests regularly decline in fitness between the date of testing and the first

day of BMT. Internal data shows that in Airmobile BMT platoons ($n = 734$), 18% did not meet physical fitness criteria in week one of initial military training, in the period 2015–2017. In addition, we found that attrition due to MSI risk was 4.3 times higher in recruits with a time ≥ 12 min on a set distance run (2700 m) versus those who finished the run in < 12 min (26% vs 6%). Overall, 53% of recruits starting Airmobile initial training completed the training successfully in 2016–2017. Twenty percent of drop-outs reported an injury as the main reason for terminating training.

In a study performed in the British Army, 58% of 1810 recruits sustained at least one injury during initial military training. Overuse

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MSIs were more common than acute injuries, representing 65% and 35% of injuries, respectively. MSIs resulted in 122 training days lost per 1000 person-days [2]. An observational retrospective study in 2016/2017, in the same population, suggested that integrated injury prevention strategies—Project OMEGA—contributed to both reduced MSIs and medical discharge in British infantry recruits [7]. Also, a study performed in the US Army explored the effects of a preconditioning program for low-fit recruits [8]. The authors found promising results in their population in terms of reduced attrition and reduced injury risk. Randomised controlled studies of such an approach have, however, not been performed to date.

To improve outcome of military training, we introduced a pre-training conditioning program (PCP) for low-fit recruits in the Airmobile BMT. The PCP employs a complex system approach similar to that used in Project OMEGA. The following study questions will be addressed: 1) Do low-fit recruits who followed the PCP show more improvement in cardiovascular endurance post intervention and at mid-term BMT than recruits following the regular procedure? 2) Is the risk of attrition due to overuse injuries in low-fit recruits who followed the PCP lower than in those who followed the regular procedure? 3) What barriers and facilitators are identified by training staff for structural implementation of a PCP for low-fit recruits at the start of the BMT? Here, we report the design of the study and the content of the intervention program in detail.

2. Methods

2.1. Design

The ‘Pre-training Conditioning Program (PCP) Airmobile BMT-study’ is a randomised controlled trial conducted in the context of the Airmobile basic military training course in the RNLA. Eligible recruits will be randomised to one of two groups; the control group (CON: regular procedure Airmobile BMT) or the intervention group (PCP). Participants will be enrolled at the start of their initial military training and monitored until completion of the BMT, or until attrition. Five successive cohorts consisting of 80–100 recruits start a BMT period each year. The following cohorts are included in this study: April/2018, June/2018, August/2018, November/2018. For the vast majority is this BMT the start of their military career, a few originate from other units of the NAF.

The trial has been registered in The Netherlands National Trial Register (<http://www.trialregister.nl/NTR-TC-6977>). The findings of our trial will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement [9].

2.2. Ethical approval

The Medical Research Ethical Committee of the UMC Utrecht, The Netherlands confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study (protocol number: 17–631/C) and waived the study from formal approval. Ethical standards will adhere to the World Medical Association's Declaration of Helsinki [10].

2.3. Setting and participants

The source population for the study is formed by Airmobile recruits of the Airmobile Brigade of the RNLA. The trial will be conducted at the Airmobile Training Centre, Schaarsbergen, The Netherlands. For the NAF, the minimum age of employment is 17 years with a maximum age of 27 years and 11 months. Both men and women can sign up. Prior to—sometimes months before—participating in initial military training, all applicants must pass a three-day functional physical and mental test and a centralized medical screening. Fitness requirements include a 2700 m run in ≤ 12 min, carry loads 25 times across 25 m (10*20 kg

(kg), 10*30 kg, 5*40 kg), and loaded marching (2000 m*25 kg, 2000 m*35 kg, 800 m*45 kg). Recruits are considered eligible for this study when they are ‘low-fit’ at the start of the initial military training (week 1). Recruits are considered low-fit when they complete the 2700 m run test in $\geq 12'23''$ which is one standard deviation above the average of recruits in 2017. Recruits who complete the 2700 m run test $< 12'23''$ will be admitted to the regular training course.

2.4. PRE-randomisation procedure

This study will employ a Zelen's design—using a double consent procedure—to enhance recruitment, limit bias due to crossover, and to limit resentful demoralisation [11]. After the Airmobile physical fitness test in week one of the BMT, but prior to being informed about the study and signing informed consent, eligible recruits will be randomised. Because we expect relatively small numbers of eligible participants per cohort, we will use stratified randomisation based on 2700 m run completion time ($12'23'' \leq x \leq 13'47''$, vs $x > 13'47''$) to ensure that the distribution of baseline physical fitness is comparable between groups. For feasibility reasons, a maximum of 16 recruits can be included in the intervention group per cohort. Thus, a maximum of 32 recruits can be randomised per cohort. If more than 32 recruits are eligible for the study we will first make a random selection of 32 recruits who will subsequently be randomised 1:1 to CON or PCP. The remaining recruits will receive the regular procedure. After randomisation, both groups will be informed verbally and by information letter. Recruits signing informed consent will be monitored for all outcomes. To ensure the randomisation procedure and allocation concealment, an independent study assistant of the Field Lab¹ office will perform the online (<https://www.randomlists.com/team-generator>) 1:1 stratified randomisation and will ensure correct group assignment of the participants, which will be communicated to the recruits by military staff.

2.5. Sample size calculation

A priori sample size calculation indicated that a total of 37 participants (i.e. approximately 19 per group), derived from the four successive BMT cohorts, is required to provide 80% power to detect a clinically meaningful difference of 35 s (standard deviation 30 s) on the 2700 m run test mid-term BMT, alpha set at 5% and taking a 40% dropout rate into account [2,6].

2.6. Interventions

2.6.1. Pre-training conditioning program (PCP)

The PCP will be conducted by military staff of the Airmobile Training Centre, physical training (PT) instructors and other military experts (i.e. Field Lab, medical staff). A complex system approach was applied to cover multiple domains of MSI prevention and optimise intervention circumstances [7,12,13]. The PCP fills the gap between two successive cohorts, whereby the period varies between 7 and 12 weeks. The first author (ID), Field Lab and PT instructors jointly created a PT-supervised program. The program was designed in such a way that it maximized training load while still providing sufficient variation and recovery to minimize the risk of overuse MSI [14]. The PT program aims to prepare recruits for the regular BMT, and contains functional training to improve mobility, power, agility, lower and upper body strength and cardiovascular endurance [15]. Cardiovascular endurance will be targeted both by endurance training and high intensity interval training (HIIT) [16,17]. Training intensity will be individually adapted for heart rate (HR) zones. Endurance training aims at intensity 4

¹ Field Lab office of the Airmobile Brigade is responsible for monitoring physical and mental wellbeing of military trainees and personnel, in order to advice commanders in adapting trainings load for their unit.

Table 1
Physical training program PCP.

Week	Monday	Tuesday	Wednesday	Thursday	Friday	Weekend
1 – Baseline, test #1						REST
2	Introduction heart rate training, Max HR test	Running – Extensive interval training, 600 m x4	MFT – including 2700 m run	HIIT 2 x 4 x 60" bike	Introduction meeting PT, PCP, measurement resting HR Holiday - REST	REST
3	Running – Extensive interval training, 800 m x4	Running – endurance training + calisthenics	Weight training – strength endurance	HIIT 3 x 3 x 60" running	REST	REST
4	Running – Extensive interval training, 800 m x4	Weight training – strength endurance	HIIT 3 x 4 x 60" strength	Holiday - REST	Holiday - REST	REST
5	Running – Extensive interval training, 800 m x5	Running – endurance training + calisthenics	Weight training – strength endurance	HIIT 2 x 3 x 80" running	REST	REST
6	Holiday - REST	Extensive interval training, 1000 m x4	Running – endurance training	Weight training – strength endurance	HIIT 3 x 5 x 60" military self defence	REST
7	Running – Extensive interval training, 1000 m x4	Running – endurance training + calisthenics	Weight training – strength endurance	REST	HIIT 2 x 5 x 60" bike	REST
8(-12)	Running – Extensive interval training, 1000 m x6	Running – endurance training + calisthenics	Weight training – strength endurance	HIIT 2 x 3 x 90" running	REST	REST
Post-intervention, test #2	Taper period, preparation AMF		MFT – including 2700 m run			

Airmobile basic military training 12 weeks Mid-term test #3.
 PT = Physical Training; PCP = Pre-training conditioning program, HR = Heart Rate, HIIT = High Intensity Interval Training, MFT = Military physical fitness test.

(80%–90% of maximum HR) and HIIT aims at intensity 5 (90–100% of maximum HR) [18]. Training load will be increased by increasing the distance per block, and blocks per session. Heart rate will be monitored by Polar H10. See Table 1 and Table 2 for detailed description of the PT content.

In accordance with the complex system approach, we additionally targeted the following contextual factors:

2.6.1.1. Training staff support. Previous research showed that the training methods and qualification of PT instructors are relevant for recruits' fitness development in initial military training [19]. Therefore, qualified PT instructors received additional education by the first author (ID) and Field Lab on MSI prevention enhancement during the PCP and initial military training. Learning goals for these educational sessions were understanding the basic principles of the balance between injury prevention and high performance, determining target fitness domains for functional training of this population, and understanding the physiological framework used to achieve the primary objectives of the PCP [14,20].

2.6.1.2. Process-focused culture. We considered adoption of a “growth mindset”—believing that individual abilities can be developed—to be fundamental for both training staff and recruits [21]. The first author (ID) and Field Lab provided training sessions for the military staff of the PCP platoon (i.e. platoons commander, senior instructor, and two non-commissioned officers—group instructors) to support a process-focused culture. Goals of these sessions were familiarizing with the growth mindset concept, introducing strategies to reflect personal behaviour, and determining rewarding strategies.

2.6.1.3. Health accountability. To make recruits aware of their own accountability for their health, and of the influences of personal health behaviour and lifestyle on the chance of successfully completing the Airmobile BMT, classroom lessons on sleep, exercise preparation, recovery techniques, nutrition and mindset were incorporated in the daily program of the PCP. These lessons are provided by military instructors, PT instructors and a military physician. In addition recruits keep a journal about personal goals, strategies, rating of perceived exertion (RPE) of PT-sessions and their own progress in physical, mental and social domains [14]. They evaluate their progression with their group instructors and PT instructors weekly.

2.6.2. Control group

The CON will receive the standard physical training program, supervised by designated sports instructors, during the whole BMT. This program includes running, calisthenics, obstacle course, strength circuits, military self-defence, wall climbing, and rope climbing. Recruits in the CON will be briefly informed regarding nutrition and recovery, conform usual practice.

2.7. Blinding

Due to the nature of the intervention, participants and training staff cannot be blinded for group assignment. To reduce the risk of detection bias, medical staff assessing injury outcomes and statisticians will be blinded to group assignment until study completion.

2.8. Outcome measures

The primary outcome measure will be the time to complete the 2700 m run mid-term BMT—physical fitness. Secondary outcomes include MSI incidence, lost training days, attrition rates, and implementation fidelity.

Table 2
Content training components PCP.

Running – Extensive interval training	Running – Endurance training + calisthenics
15 min (°) Dynamic Warming up: Technique, Dynamic running drills 25' Training	15' Warming up 25' Training: 3–8 km low intensity running (active recovery) short sets of bodyweight exercises: push ups, sit ups, pull ups, plank. 15' Cooling down Log scores in journal
15' Cooling down: Low intensity 2 × 400 m, calf raises, lunge knee drives, hip thrusts Log scores in journal	Log scores in journal
Weight training – Strength endurance	High Intensity Interval Training: HIIT
5' Introduction training 20' Warming up: Mobility exercises, based on seven core movements (i.e. bend, pull, push, twist, squat, lunge, gait) 25' Training 2 sets 15 reps (exercises: para, chest press, planking, pull up, overhead press, squat, superman, TRX supinated curl, shoulder press, row). Exercises will be intensified through the PCP 8' Cooling down Log scores in journal	20' Warming up 15' High Intensity Intervals at HR. Increasing the work load over time, numbers of reps/sets vary starting with 1' and 4 reps, working up to 4 × 3 set of 80" 20' Cooling down Log Session-Rating of Perceived Exertion in journal

2.9. Data collection

2.9.1. Physical fitness

Physical fitness measures will be obtained during three military physical fitness test sessions at baseline (week 1 of the Airmobile BMT, T_0), post-intervention (T_1), and mid-term Airmobile BMT (T_2) (Fig. 1). The regular Military physical Fitness Test (MFT) for this Brigade includes anthropometric measures (height, weight, body fat% (Bioimpedance: Tanita MC-780 MA)), general warm up, change-of-direction speed (pro-agility test [22]) strength (shoulder press, squat, pull up; 1 min maximum repetitions * weight), core stability (time in plank position, hand and feet alternated lifted), running endurance (2700 m run for time), and hand grip strength (LODE HDM-915), in that particular order. A team of experienced PT instructors are responsible for the MFT. They share their data with Field Lab who create an individual dashboard to determine fitness and monitor individual progression. For this study, Field Lab adds research variables in the research database on a regular basis during follow up.

2.9.2. MSI registration

The occurrence of an MSI is routinely registered in the Defence electronic patient record system, according to a registration protocol, when recruits visit a military physician. An MSI is defined as musculoskeletal pain or complaint during military training or the PCP, for which the recruit sought military medical care, and is classified with a Locomotor ICPC-2 code [23] (Internal Classification of Primary Care). Acute injuries are defined as those caused by a single abrupt overload of the tissue or joint with sudden onset and a known cause [2,24]. Overuse injuries are defined as those resulting from long-term energy exchanges resulting in cumulative micro-trauma over time [24].

To enhance careful registration of MSIs—and thus limit information bias—we instructed the involved physicians of the Health Care Centre on correct and complete MSI registration. Also, posters were issued and put on display to remind the physicians of the ongoing study.

In addition, self-reported (free from-) injury state is measured using the recruit monitoring questionnaire. The questionnaire is routinely used on a weekly basis in the Airmobile BMT. It contains 9 statements concerning physical and mental wellbeing rated on a 5-point Likert scale. For this study we use one of those statements: “I feel free from injuries”, to evaluate self-reported injury state throughout the intervention period.

2.9.3. Lost training days

Lost training days are defined as days on which recruits were, by physicians order, restricted to participate in physical training, marching or other military specific training aspects. Number of days are counted based on physicians patient record registration. After the training

period, a trained military physician blinded to group allocation will import the data from the Defence electronic patient record system into the research database.

2.9.4. Attrition rates

Attrition rates will be collected from the recruit management office. This office routinely registers the start and end date of training, success rates and, wherever applicable, date of attrition and reasons for attrition. In regards to implementation of our intervention, dropout related to the content of the PCP will explicitly be noted.

2.9.4.1. Post-intervention selection. After testing physical fitness at T_1 , recruits in both PCP as well as CON will be either selected to proceed the Airmobile BMT (2700 m run < 12'23") or be withdrawn from Airmobile initial military training (2700 m run \geq 12'23").

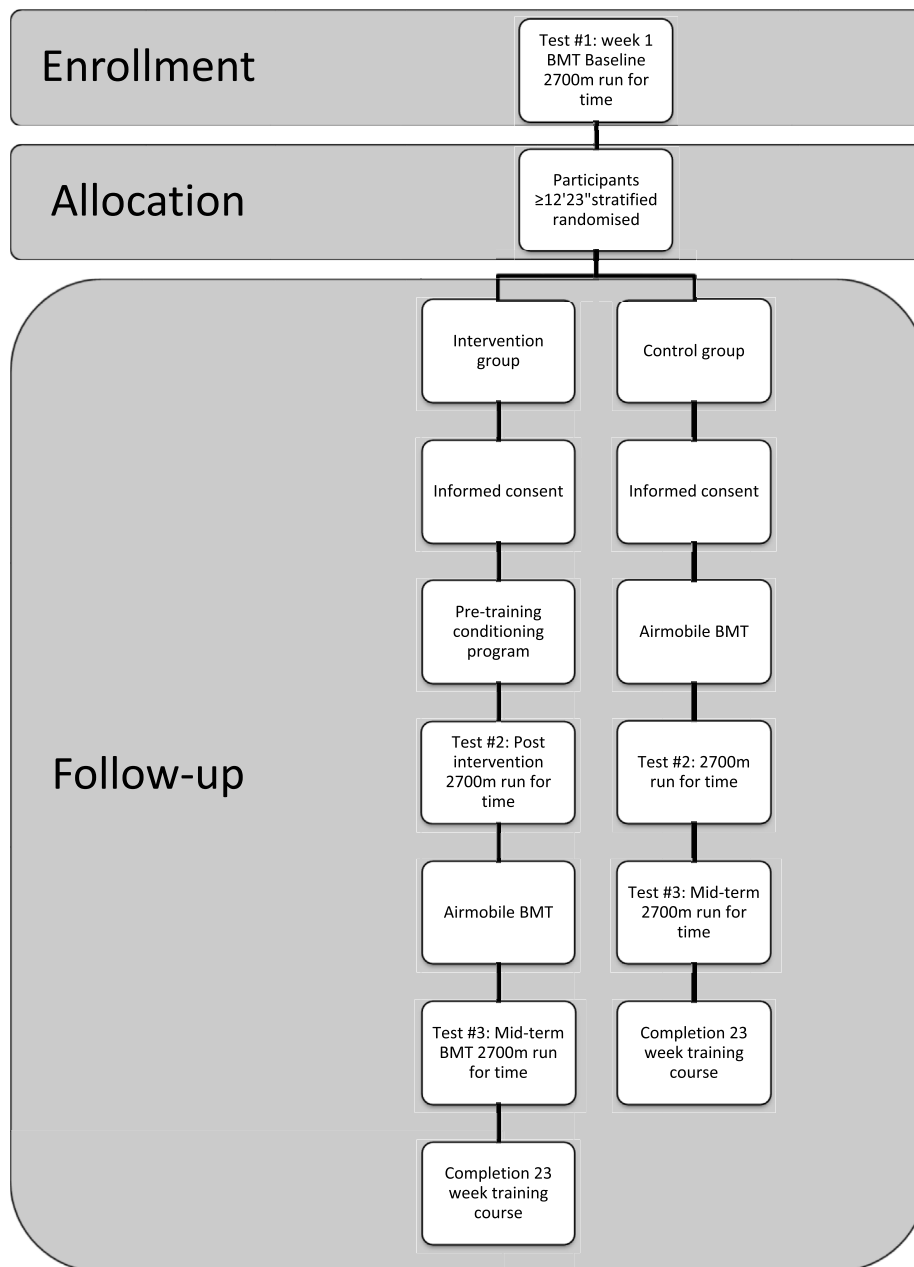
2.9.5. Satisfaction

Process evaluation will be done during structured transfer meetings with a note taker, after each successive cohort [25]. Also, we will use surveys to query perceived effects of the program, as well as envisioned barriers to and actions needed for its structural implementation. A separate survey will be used for participants and training staff.

2.10. Statistical analysis

Statistical analysis will be performed using R version 3.1.3 or later. We will use the intention-to-treat principle, where all randomised participants will be included in the final analysis in the group to which they were allocated. In addition, we will perform per protocol analysis based on received treatment, in case of crossover.

Participant characteristics and baseline data will be summarised using descriptive statistics. Baseline comparability of clinical and sociodemographic characteristics will be checked. A linear mixed effect model with a random intercept, a random slope and group-by-time effect coefficient will be used to test the primary outcome. Linear mixed effects models take between person and within person variability into account, and can adequately handle missing data. However, in case of non-ignorable dropout, data may be missing not at random. We will consider the use pattern mixture models to correct the models accordingly if needed [26]. Mean difference in change of time to complete the 2700 m run will be expressed using a standardized effect size, Cohen's d (0.2 = small effect, 0.5 = medium effect, 0.8 = large effect) [27]. Clinical reported MSI incidence, attrition rates and lost training days will be expressed as relative risks with a 95% Confidence Interval, and will be tested for statistical significance using the Fisher exact test. In case of relevant baseline differences, Poisson models with a log link and robust standard errors will be used to calculate adjusted relative risks.



BMT: Basic military training course Air Assault Brigade

Fig. 1. Flow of participants through the trial
BMT: Basic military training course Air Assault Brigade.

Statistical significance is considered at $p < 0.05$.

Self-reported (free from-)injury state scores will be reported as percentages throughout the intervention period, and will be displayed for the CON and PCP separately in a graph. Satisfaction will be evaluated through summarizing survey outcomes of recruits and training staff in contingency tables (Likert scale percentages per statement). Noted barriers and solutions to those barriers will be summarised descriptively.

3. Discussion

This randomised controlled study will evaluate the effectiveness of a pre-training conditioning program on physical fitness, and secondary on the incidence of musculoskeletal overuse injuries and attrition of

initial military training due to those injuries during Airmobile initial military training.

With the overall aim to help soldiers develop their physical and mental fitness, we developed a PCP with the primary objective to improve cardiovascular endurance. Training programs with adequate training loads are suggested to decrease injury risk and produce high fitness [14]. Theoretically we aim to increase recruits' work capacity with conditioning exercises intended to increase the storage and delivery of energy plus increasing maximal oxygen uptake [28]. In addition, we aim to induce neuromuscular adaptations such as increased motor unit recruitment and firing frequency, and bone mineral density by adding calisthenics and resistance training to the program [29,30]. The duration of the intervention—7 to 12 weeks—is chosen to facilitate implementation in existing time frames between successive cohorts.

Also, we expect that this period is sufficient to achieve relevant improvement in aerobic capacity [16,31]. HIIT is suggested to induce metabolic adaptations in as little as six sessions in 2 weeks [32].

Notably, the Netherlands Armed Forces (NAF) take part in a research task group of the North Atlantic Treaty Organization (NATO) that aims to identify incidence rates of MSIs, injury mechanisms, and existing and novel strategies which may reduce the injury burden in military populations in NATO countries. To contribute to the objectives of the task group, we follow “The Translating Research into Injury Prevention Practice (TRIPP) framework” proposed by Finch in 2006 [33]. This sports injury prevention framework is an addition to the work of Van Mechelen et al., in 1992 [34]. The stages of the TRIPP framework are; injury surveillance; establish aetiology; develop preventive measures; scientific evaluation; implementation strategies; and evaluation in implementation context. Our current study aims to scientifically evaluate an experimental intervention but also evaluate implementation strategies.

Although cardiovascular endurance is believed to be a key factor, MSI prevention is of course more complex [33]. This is why the PCP was designed using a complex system approach; the PCP not only uses a renewed PT approach of physical training, but also explicitly tries to optimise contextual factors that are fundamental to intervention fidelity, or that could moderate the effect of the training intervention on improved fitness and reduced risk of MSI. These factors include training staff support, mindset and health behaviour of recruits [21]. Since other factors of attrition include lack of motivation, deflecting career ambitions, not fitting in the military culture, and lagging personal competences, we believe that these contextual factors are crucial in such intervention programs [35].

There are some uncontrollable factors that could influence the results of this RCT. In particular, the risk of contamination due to crossover after randomisation. Because the intervention cannot be blinded, performance bias may also occur. On one hand, so-called Pygmalion and Hawthorne effects may occur related to the novelty of the intervention and the fact it is closely monitored in a randomised controlled study. This might lead to an overestimation of the effect of the intervention. On the other hand, due to the pragmatic character of the study, training staff rotates through the study period—and thus instructors can be involved in a CON after being instructor of a PCP group—which could dilute the effect.

Second, compliance (i.e. effort and focus) during PT is essential—but obviously we can only manage this to a certain degree. Third, being included in the PCP means an extended military training period. This can be perceived by the recruits as a setback or disappointment. It requires a certain level of resilience and accountability of recruits to see the PCP as an opportunity to grow and learn and to become a physically and mentally stronger soldier. Of course, we cannot foresee how the program will be received by the recruits.

Despite these insecurities, we believe that this pragmatic prospective randomised controlled study, which is designed with future implementation in mind, will be of value for military training staff nationally and internationally. We extend the work of colleagues of the British- and US Army and provide additional knowledge to the NATO workgroup. Also, we expect that the findings of our study and experiences during the trial will affect the policy of the Airmobile training Centre. If successful, the PCP will be of value in terms of enhancing training completion, reduced demand for health care and decreased health care costs associated with MSIs.

In conclusion, the results of this randomised controlled trial will help provide insight in the effectiveness and implementation fidelity of a pre-training conditioning program in Dutch Airmobile recruits on physical fitness, MSI incidence, and attrition due to overuse MSIs.

Trial status

The trial started April 18, 2018 and will continue until target

inclusion has been reached or until four consecutive Airmobile basic military training cohorts of the Airmobile Brigade have started their training. Final results are expected in August 2019.

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