Developing predictive models for return to work using the Military Power, Performance and Prevention (MP3) musculoskeletal injury risk algorithm: a study protocol for an injury risk assessment programme

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ABSTRACT

Background Musculoskeletal injuries are a primary source of disability in the US Military, and low back pain and lower extremity injuries account for over 44% of limited work days annually. History of prior musculoskeletal injury increases the risk for future injury. This study aims to determine the risk of injury after returning to work from a previous injury. The objective is to identify criteria that can help predict likelihood for future injury or re-injury.

Methods There will be 480 active duty soldiers recruited from across four medical centres. These will be patients who have sustained a musculoskeletal injury in the lower extremity or lumbar/thoracic spine, and have now been cleared to return back to work without any limitations. Subjects will undergo a battery of physical performance tests and fill out sociodemographic surveys. They will be followed for a year to identify any musculoskeletal injuries that occur. Prediction algorithms will be derived using regression analysis from performance and sociodemographic variables found to be significantly different between injured and non-injured subjects.

Discussion Due to the high rates of injuries, injury prevention and prediction initiatives are growing. This is the first study looking at predicting re-injury rates after an initial musculoskeletal injury. In addition, multivariate prediction models appear to have move value than models based on only one variable. This approach aims to validate a multivariate model used in healthy non-injured individuals to help improve variables that best predict the ability to return to work with lower risk of injury, after a recent musculoskeletal injury.

Trial registration number NCT02776930.

BACKGROUND

Musculoskeletal injuries are a primary source of disability in the US Military.[1–3] In the US Army, musculoskeletal injuries accounted for 73% of all disability cases from 1997 to 2002, and have been identified as the single most common (53%) reason for discharge from service.[1–3] Disability from musculoskeletal injury is a significant deterrent to US Soldiers being ready to deploy in support of military operations.[2–5]

In 2007, musculoskeletal injuries resulted in approximately 2.4 million medical visits to military treatment facilities and accounted for US$548 million dollars in direct patient care costs.[6] The cumulative incidence of injuries requiring an outpatient visit in the US Army entry-level training has reported at about 25% for men and 55% for women.[7–9] Lower extremity injuries are the leading cause of limited work days, accounting for over 4.8 million of the 11 million limited work days annually related to injury, and accounting for 80% of all ambulatory care visits related to musculoskeletal injuries.[10 11]

One of the most consistent risk factors described in the literature for sustaining musculoskeletal injuries is a history of prior injury.[12–17] Reoccurrence of musculoskeletal injuries is prevalent in athletes, with re-injury rates ranging between 17.8%, 24% and 33% for ankle sprains, anterior cruciate ligament (ACL) reconstruction and hamstrings strains, respectively.[18–20] The same is true in a military population. Prior injury was one of the strongest predictors of sustaining an injury in a cohort of the US Army Rangers.[21] Failure to completely recover from a prior injury is associated with delayed graduation from training or complete separation from military service.[22] History of a prior lower extremity injury or low back pain (LBP) is also identified with increased injury rates during predeployment training in soldiers.[17] This highlights the need for an improved understanding of musculoskeletal injury risk after an initial injury, and when soldiers can return to work after injury, with minimal risk of future injury.

Some research suggests that while traditional measures of strength and joint range of motion may normalise after injury, movement asymmetries and neuromuscular control deficits may persist, leading to a higher risk of injury.[23 24] This may be a recurrence of a previous injury, or as a result of persistent deficits in movement and motor control from a previous injury, a different injury can occur. Screening functional movement and biomechanics to identify injury risk has been used before,[25] but most research has been done in healthy populations in order to identify risk of injury in a healthy individual.[24] The predictive value of these tests have been assessed in healthy soldiers.[21] However, the predictive validity of many of these measures is limited, and they have not been specifically studied in a heterogeneous military population after an

injury has occurred. Critical analysis of these measures in military service members cleared to return to work without limitations after a musculoskeletal injury would help identify factors that are predictive of re-injury. This would help optimise return to work planning and interventions that help minimise the risk of recurrence. These findings can ultimately help guide injury prevention efforts in order to ensure appropriate, safe and rapid return to work without limitations.

METHODS/DESIGN

The proposed study is a prospective observational cohort, and has been registered (clinicaltrials.gov: NCT02776930). Ethics review and approval has been provided by the Madigan Army Medical Center Institutional Review Board.

Participants

We plan to enrol 480 active duty service members who have recently sustained a musculoskeletal injury, but have recovered to the point where they have been cleared to return to full work duties without any limitations (figure 1).

With an expected injury rate of 20%–50% and a study completion rate of 75%, we plan to have 180 subjects (360 total) that successfully complete the study for each of the two target conditions (lower extremity and lumbar/thoracic spine injuries) at 1 year. This will allow for enough subjects to be enrolled to account for any problems with baseline data collection and over-sampling/undersampling based on the unit-based data collection procedures used in this study. Based on recruitment from previous work, we anticipate a 75%–85% recruitment rate and a 75% 1-year completion rate (75% in Prevention of Low Back Pain in the Military trial[26] and 85% in Military Power, Performance, Prevention trial.[21] Estimates from a healthy population estimate that approximately 20% of male and 40%–50%

Figure 1 Proposed study flow of subjects through the study. MDR, Military Health System Data Repository; SMS, Short Message Service.

of female service members will sustain at least one time loss musculoskeletal injury over a 1-year period.[7–9] As a history of prior injury is one of the strongest predictors for re-injury, and all of our subjects will already have this variable present, we have moved our conservative male injury rate from 20% to 30% and expect to have successful completion of 135 subjects per specific cohort. We further estimate based on these numbers, that approximately 40 service members per cohort will sustain a time loss injury, thus providing the potential for a robust 5–10 variable regression model per cohort.[27] At the same time, in order to test our hypothesis based on sex, we will keep enrolment open to female subjects until we reach a minimum target of 100.

Inclusion criteria

1. The US active duty military service member.
2. Age 18–45 years (or emancipated minor).
3. A lower extremity or lumbar/thoracic spine injury was the primary reason the patient was seeking care.
4. Patient has been deemed ready to return to work without any limitations by their medical provider.

Exclusion criteria

1. Service members who plan on leaving the military in the following 12 months after enrolment in the study (separation or retirement from the military, or medical board), which will be the full period of injury surveillance.
2. A concomitant injury for which the patient is already seeking or planning to seek medical care.
3. Any type of restricted or modified work programme due to a musculoskeletal injury; must be returning to work without any limitations.
4. Service members pending a Medical Evaluation Board.
5. Trauma or polytrauma that results in amputation of any limbs or appendages.
6. Injuries from high velocity incidents, such as motor vehicle injury, etc.
7. Pregnancy, or recently pregnant within the last 6 months—subjects who become pregnant during the course of the study will be withdrawn based on the different injury risk factors that may be associated with musculoskeletal injury during pregnancy.

TRAINING

Great effort was taken to standardise the training and ensure testing is being conducted the same at all sites. All testers were required to complete online courses offered by Functional Movement (functionalmovement.com) and by Medbridge (medbridge.com) related to this material, and then attended a 2-day training course to review everything in person with subject matter experts in the content (study authors, etc). They were required to show independence and appropriateness with administering every single test, and had to be checked off on every test by one of the content experts.

STUDY FLOW

Entry into study

Patients will be managed by their medical provider according to usual practice. Once the episode of care is complete for that injury and at the point when medical provider would normally discharge a soldier back to full duty, the soldier will be referred for a physical performance discharge testing. This will include the methodologies listed in the next section, which have all been identified to help predict injury in various military and
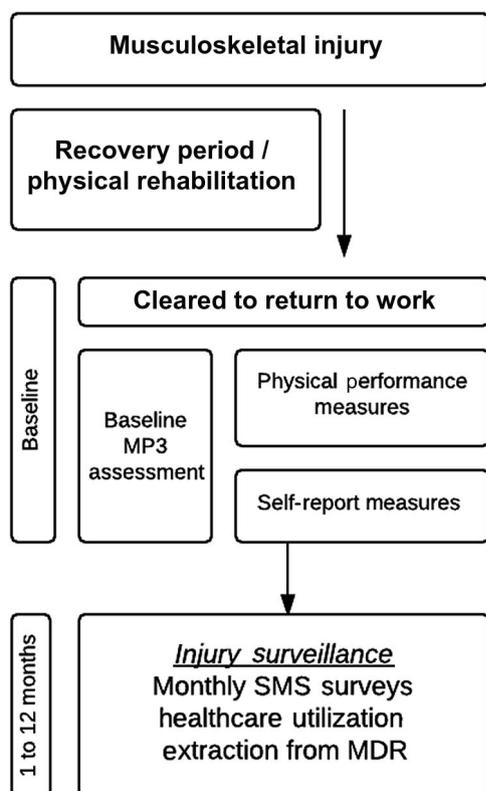
athlete populations. These were also used in the recent prospective cohort our team conducted to derive an injury prediction algorithm across various healthy military occupational specialties in the US Army.

Procedures for referral for discharge assessment

The appointment for Physical Performance Discharge Assessment (PPDA) will be an appointment booked in the physical therapy clinic. The patient's managing medical provider (either physical therapist or primary care) will deem when it is appropriate to book that appointment for each patient based on their individual plan of care. This will be done at the normal point in time in which the clinician would typically discharge the patient. At that time the patient will be booked into that appointment via normal standard-of-care procedures for booking appointments in each physical therapy clinic.

Discharge assessment procedures

Upon arrival at the PPDA medical appointment, the service member will begin the discharge testing with self-report questionnaires that consist of a global rating of change, Fear Avoidance Belief Questionnaire (FABQ), Pain Catastrophising Scale (PCS), body region-specific disability, Patient Health Questionnaire 9 (PHQ-9) and perceived injury recovery status. These are all standard of care tools that are commonly used in standard physical therapy care for these patients.

Upon completion of these steps, the patient will be informed about the details of the study, be consented by approved study personnel and then enrolled in the study. At that point, the following additional tools will be filled out by the subject: Pittsburgh Sleep Quality Index (PSQI), injury surveillance contact information and study-specific demographic information.

Patients who do not wish to enrol or do not meet the inclusion criteria will be discharged with instructions to continue with the original discharge plan of care outlined by their specific medical provider.

Subjects who are enrolled in the study will also be provided instructions to continue with the original plan of care outlined

by their provider upon discharge from medical care (physical therapist or primary care provider). Each service member will then also be contacted monthly for the following year to identify information about additional injury or profile that they may have sustained during the prior period of time. Information about injury will also be calculated from patient chart reviews and Department of Defence (DoD) healthcare utilisation database, as outlined further below.

ASSESSMENTS

The following assessments will be provided to every subject, and a proposed flow of testing has been outlined in figure 2. Specific details of how every physical performance test will be setup, executed and scored are outlined in online supplementary appendix A.

Physical performance measures

The functional movement screen

The functional movement screen (FMS) is a comprehensive exam that rates quality of fundamental movement patterns to identify an individual's limitations or asymmetries (see online supplementary appendix A1).[28 29] It is an objective measure of seven individual movement tasks (push up, in-line lunge, hurdle step, rotary stability, shoulder mobility, active straight leg raise and deep squat) that is scored on a 0–3 ordinal scale. The scores from the seven movement patterns are summed, a composite score is obtained and any asymmetries are recorded. The inter-rater reliability of the FMS has been evaluated by the research team as well as other researchers and exhibited substantial to excellent agreement (κ values=0.74–1.00) in an athletic population.

Selective functional movement assessment

The selective functional movement assessment (SFMA) is a short inventory of the quality of 10 basic musculoskeletal movements to identify incomplete movements as well as the presence of painful patterns (see online supplementary appendix A2). The SFMA targets a more basic level of movement in comparison with the FMS and complements the information provided
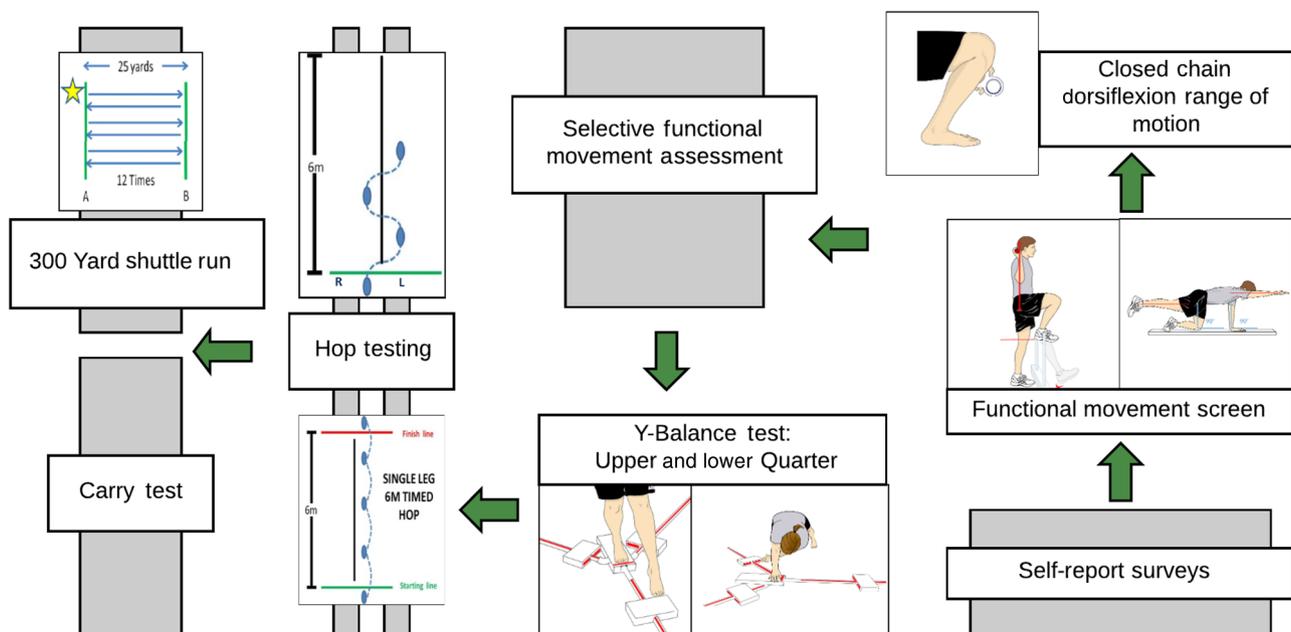

Figure 2 Proposed flow of testing stations.

by the FMS in an abbreviated time frame (3 min). Each movement of the SFMA is scored as either functional or non-functional and as painful or non-painful. How performance on the SFMA changes over the course of rehabilitation is also being evaluated by others.[30]

Lower quarter Y-balance

The lower quarter Y-balance (YBT-LQ) is a test of dynamic balance that examines single limb reach in three different directions to examine an individual's limitations and asymmetries of this metric (see online supplementary appenidx A3).[31 32] Dynamic balance performance is examined independently using the right and left leg as the stance leg while reaching in the anterior, posteromedial and posterolateral directions. Reach distances are normalised to leg length in order to minimise the effect of anthropometric measures on the testing. Previous research has established the YBT-LQ as a reliable measure across raters and days, as well reach asymmetries and low performance on the test has previously been observed in the literature to predict non-contact injuries in athlete populations.[32–34]

Upper quarter Y-balance

The upper quarter Y-balance (YBT-UQ) is a test of upper quarter function that examines how far an individual can reach in three directions (medial, inferolateral and superolateral) while maintaining a plank position with one hand and two feet in contact with the ground (see online supplementary appendix A4). Performance on the test examines overall reach performance, normalised to arm length, as well as asymmetries between sides. Previous research on the YBT-UQ has suggested moderate correlations exist between YBT-UQ test performance and traditional functional tests of the shoulder and core musculature.[35] There appear to be no apparent differences between extremity sides or genders in an active adult population.[35]

Hop testing

Standardised hop testing will be completed to assess lower extremity strength and power (see online supplementary appendix A5). The protocol for the current study will examine single leg hopping for a single jump, triple jump and triple crossover jump. Hop data will be collected for left and right sides and the data will be analysed using a limb symmetry index. Previous research on this hop testing protocol has been established to be reliable as well as being effective in distinguishing patients who have recently been discharged from ACL rehabilitation.[36–38]

300 m shuttle run

In order to identify functional endurance limitations, a 300 m shuttle run will be included in the discharge protocol (see online supplementary appendix A6). This protocol will be completed using a weighted condition (weighted vest (normalised to soldier weight) and a simulated weapon) and a non-weighted condition. Subjects will be instructed to run facing forward as fast as they can between cones that are 25 m apart. This will be completed for 12 total repetitions for a total of 300 m. The time to completion will be recorded as a biomarker of functional endurance during the discharge testing.

Carry test

Carrying and lifting heavy objects is a common task in the military (see online supplementary appendix A7). The ability to quickly lift and carry heavy loads has been the focus of efforts to measure physical performance and predict injury in various studies.[39–42] Many soldiers are required to lift and carry objects as part of their occupation (load ammunition, lift and carry heavy backpacks, place gear into vehicles, etc).

Closed kinetic chain dorsiflexion range of motion

Ankle dorsiflexion range of motion will be measured with the subjects in a half kneeling position (see online supplementary appendix A8). This measurement will provide an estimate as to the mobility of the ankle when it is loaded with the body weight of the individual. The measurement will be taken bilaterally in order to assess the presence of any asymmetries. Reliability of a test similar to the ankle dorsiflexion measurement proposed that was performed in bilateral stance reported intraclass correlation coefficient (ICC) values of 0.92.[43] This test was shown to be predictive of injury in a cohort of the US Army Rangers.[21]

Self-report measures

Self-perception on physical health and ability to return to full duty

This consists of a total of nine questions, five of them modified from the 36-item Short Form survey. They ask questions related to the subject's perception of their physical health. The first five questions are related to the subject's perception of ability to return to full duty, need for additional healthcare for their current condition and function at the level that they feel is expected of them. The final four questions ask about their perception of general physical health.

Oswestry Disability Index

The Oswestry Disability Index (OSW) Questionnaire, originally described by Fairbank et al[44] as a condition-specific measure of functional status for patients with LBP. The OSW is a 10-item scale with higher numbers indicating greater disability. We will use the modified version that replaces the sex life item with an employment/homemaking item due to poor compliance with the former.[45 46] The OSW is widely used in research on non-operative management of patients with LBP.[47] Previous research has found the modified OSW to have high levels of test-retest reliability among stable patients (ICC=0.90), good construct validity and responsiveness to change for patients with acute LBP, with a minimum clinically important difference of six points for patients with acute LBP receiving physical therapy.[45]

Lower Extremity Functional Scale

The Lower Extremity Functional Scale, originally described by Binkley et al,[48] provides global assessment of function related specifically to the lower extremities. It is one self-report outcome measure that can capture adverse impact on function from multiple injuries or specific locations in the lower extremity. It consists of total 20 questions related to functional activities, each with a possible score ranging from 0 to 4, where 0 indicates that the activity cannot be performed at all and 4 indicates that the activity be performed with no limitations. The total maximum score is 80 points, indicating no limitations with any of the functional tasks. It has been shown to be valid, reliable and responsive to change in various patient populations and in different body regions in the lower extremity (ankle, knee and hip).[48–50]

Global rating of change

The global rating of change is a 15-point scale, which will be used as described by Jaeschke et al to measure the patient's perception of change in symptoms.[51] The survey asks the patient to rate the degree of change in his or her condition from the beginning of treatment to the present. The midpoint of the scale is

no change (0). Ratings from −1 to −7 represent varying degrees of a worsening of the patient's condition, while rating from +1 to +7 represent varying degrees of improvement.

Pittsburgh Sleep Quality Index

The PSQI is a 19-item self-report questionnaire that yields 7 component scores: subjective sleep quality, sleep latency, duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication and daytime dysfunction. There are five additional questions that are completed by a bed partner if there is one. Although it has not specifically looked at a population with lumbar spine and lower extremity disorders, psychometric properties of the PSQI demonstrated appropriate internal consistency,[52] concurrent validity[53 54] and discriminative validity[53 54] in healthy and ill populations. This may have a significant role in affecting outcomes of patients with LBP as several preliminary studies have shown a correlation between chronic back pain and quality of sleep. Sleep deprivation is commonly seen in the active duty population with a high operational tempo.

Patient Health Questionnaire

The PHQ-9 will be assessed to help determine the impact of symptoms of depression[55–58] on future injury risk. The PHQ-9 has demonstrated reliability and validity in different settings and among culturally diverse populations.[57 59] The nine items on this questionnaire comes directly from signs and symptoms of major depression. Each item is rated from 0 (not at all) to 3 (nearly every day), giving the scale a potential range of 0–27.[56] A score ≥10 had a sensitivity of 88% and a specificity of 88% for major depression.[56]

Fear Avoidance Belief Questionnaire

The FABQ[60] will be used to measure patients' beliefs about how physical activity and work may affect their pain and perceived risk for re-injury. The FABQ contains two subscales: a 7-item work subscale and a 4-item physical activity subscale. Test-retest reliability of the FABQ subscales is high,[60 61] and validity is supported by associations with disability and work loss in patients with acute and chronic LBP.[62 63] Heightened fear-avoidance beliefs have been shown to be a risk factor for the development of chronic LBP following an acute episode.[64 65] Other research suggests it may be appropriate for other body regions, specifically evaluating its use in lower extremity injuries within a physical therapy setting.[66]

The Tampa Scale of Kinesiophobia

The Tampa Scale of Kinesiophobia (TSK) is a self-report measure of fear of movement or re-injury.[67] It consists of 17 statements about the subject's condition that they rate on a 4-point Likert scale (1=strongly disagree to 4=strongly agree). The scores of items 4, 8, 12 and 16 are inverted and then a total score is calculated. The total score will range from 17 to 68 with higher scores indicating a higher degree of kinesiophobia ("an irrational and debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or (re) injury"). The statements on the TSK relate to fear of pain or movement having an influence on disability, rather than the pain itself lending to the disability.[68]

Pain Catastrophising Scale

The PCS is a 13-item patient-report scale developed to measure the extent to which people catastrophise in response to pain.[69] Each item is scored from 0 ('not at all') to 4 ('all the time'). The

PCS is reported as a total score, with higher scores indicating greater catastrophising, and is composed of three subscales: Rumination (four items; eg, "When I am in pain, I keep thinking about how badly I want the pain to stop"), Magnification (three items; eg, "When I am in pain, I become afraid that the pain will get worse") and Helplessness (six items; eg, "When I am in pain, I feel I can't go on"). The PCS has been shown to have high levels of internal consistency and construct validity.[69 70] Pain catastrophising has also been found to play a role in the transition from acute to chronic back pain.[64]

Patient satisfaction

Patient satisfaction with the care received in physical therapy will be measured using a 10-item instrument that has been validated and found capable of distinguishing among three different dimensions of satisfaction (caring, information and treatment effectiveness) among patients with LBP attending primary care.[71] It has been modified for this study to include lower extremity and thoracic spine.

Injury surveillance

An injury will be defined as an event or condition that results in restricted occupational and/or physical participation in unit activities. Injury data will be collected using three sources of injury tracking: monthly individual injury surveys completed using text messaging, healthcare utilisation data according to medical record reviews and healthcare utilisation according to the Military Health System Data Repository (MDR) database. Once the 1-year injury surveillance data have been collected, the specific injury risk algorithms will be developed. Furthermore, it is hypothesised that algorithms will require adjustment to match the injury risk of the specific soldier populations (sex and body region location of injury) tested. These procedures will allow for algorithms to be developed that assist in identifying service members at risk for musculoskeletal injuries. After the algorithms are developed, the future goal of this project is to provide both service members and the rehabilitation professionals who manage these patients, with this information. Specifically, in the future, service members and rehabilitation professionals will receive an individual report identifying their injury risk factors prior to discharge to full duty after physical rehabilitation.

Healthcare utilisation

Finally, healthcare utilisation data will be collected at the end of the year, and used to determine those injuries that required medical utilisation as well as the economic impact of those injuries. The data will be abstracted from the MDR, serves as the centralised data repository for all Defence Health Agency corporate healthcare data. The MDR is a worldwide network of more than 260 DoD healthcare facilities and a few non-DoD entities that feed into its database. This includes record of every single person-level interaction for healthcare where the Tricare Health Plan is the payer, both inpatient and outpatient, and either in a civilian network or DoD healthcare facility. Further details are available regarding how data are abstracted to capture injuries and associated healthcare resources.

The goal of the MDR databases will be to determine which of these subjects sought healthcare for an injury in the 1-year period after data collection, and cross-reference this with patient self-report of injury that occurs with each monthly survey. This injury data (type, location, number of clinic visits, types of specialty clinic visits, imaging and associated medication) will allow us to determine how these predictive variables

are associated with the incidence and severity of musculoskeletal injury. A similar approach was used in the predictive model for injuries in healthy soldiers within this same setting.[21]

DISCUSSION

There are many efforts in place to mitigate injury by predicting future risk, although the concept is not without controversy.[72] While some methodological flaws have been pointed out regarding the validity of movement screening for the predicting injury risk,[72] we still believe the potential benefits are worth the risk. First of all, we agree that single tests alone may lack the required strength to be of value in predicting injury risk. Injuries are complex and many different factors can be contributory. Several studies looking at movement screens alone found very weak associations between performance and injury risk,[73–76] making it difficult to recommend in isolation. However, the multifactorial nature of injuries highlights the need for multifactorial assessment. Predictive models that have looked at a variety of risk factors in combination have found more promising results. One study suggested that the FMS and Y-balance focused on different risk factors, and therefore should be used together with a thorough history of injury.[77] Lisman *et al* observed that marine trainees who exhibited low performance on the FMS and low performance on the 3 mile run were 4.2 times more likely to sustain a musculoskeletal injury during basic training.[78] The combined model significantly improved from the independent variables alone. Similarly, another multivariate model found that athletes who exhibited poor scores and asymmetries on the FMS and YBT-LQ had pain during testing, and a history of injury was 3.4 times more likely to sustain a non-contact lower extremity injury.[79] A combined multivariate model has also been used in the military already, for predicting future risk of injury in healthy individuals.[21]

WHO published criteria for appraising the value of screening programmes.[80] The proposed criteria includes the following questions: (1) is the condition being screened an important and common health issue, (2) is there a detectable early stage, (3) will early treatment be of greater benefit than delayed treatment and (4) is there a suitable assessment to detect the condition in the early stage?

Certainly numbers 1 and 3 are well justified in this population. Numbers 2 and 4 align with the purpose and aims of the proposed study. History of a prior injury is a very strong predictor for future injury, and in this particular cohort 100% of the subjects have this variable. Therefore, they already are at risk for injury. However, this relationship is temporal, and as time passes, the risk decreases. For example, re-injury rates for ankle sprains in athletes can be as high as 50% within the first 6 months of returning to sport, but after about 2 years, revert to the same level of risk as those without a history of prior injury.[81] Similar associations have been reported for ACL injuries.[82] Capturing them immediately after being cleared to return to work from an injury allows us to assess this relationship at what is likely the most critical point.

Identification of an injury is critical to deriving accurate injury prediction models. However, surveillance to detect injuries can be a challenge. For athletes on a collegiate or professional team, these injuries are likely monitored with much greater detail than in other populations. The injury documentation and medical care is likely to stay relatively confined to a smaller system and/or group of medical providers. In the military, there is a lot more heterogeneity as military service members have many different occupations, and are often relocated to different geographical assignments. This adds to the challenge of accurately identifying an injury occurrence. Fortunately, we have employed multiple approaches to capture these data. First, patients will be sent a brief injury survey text message every month via Short Message Service to their mobile phone. This survey can be answered quickly and directly from their cellular phone, and all responses are logged in an online database (Mosio, Seattle, Washington, USA). Second, every medical visit with the healthcare system, regardless of location worldwide, is logged and tracked by the MDR. This allows for data capture and identification of an injury, based on billing and diagnosis International Classification of Diagnosis, 10th edition. Stratification of injuries, based on management costs and/or type of injury are also possible.

We feel that our approach is unique and different in many ways. We are the first to look at injury prediction models exclusively in patients with a prior injury. We are using a multivariate approach, including many different physical and sociodemographic self-report variables. Finally, our method for identifying injuries will provide additional information beyond the traditional dichotomous nature of injury occurrences common in most studies to date.

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