

Military-Civilian Collaborations for mTBI Rehabilitation Research in an Active Duty Population: Lessons Learned From the Assessment of Military Multitasking Performance Project

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Abstract:

This article describes lessons learned in the planning, development, and administration of a collaborative military-civilian research project, the Assessment of Military Multitasking Performance, which was designed to address a gap in clinical assessment for active duty service members with mild traumatic brain injury who wish to return to active duty. Our team worked over the course of multiple years to develop an assessment for military therapists to address this need. Insights gained through trial and error are shared to provide guidance for civilian researchers who may wish to collaborate with active duty researchers.

Keywords:

active duty military; mTBI; project administration; research planning

With the recent conflicts in Iraq and Afghanistan, traumatic brain injury (TBI) entered the American consciousness as a prevalent and significant injury that occurs in military service.¹ While severe brain injuries sustained in combat made headlines and mobilized public support to offer rehabilitation for injured service members (SMs), a less recognized fact is that the majority of SM brain injuries are not sustained in combat.² An estimated 80% of these injuries occur (or are diagnosed) in nondeployed settings, typically as a result of training or the active lifestyle of those in military service.³ Some injuries diagnosed following deployment may have occurred during combat, so exact location of incidence is not always clear.³ Nevertheless, the large majority (82.4%) of brain injuries are mild, with 352 619 mild traumatic brain injuries (mTBIs) sustained by active duty (AD) and reserve SMs across all branches of the military since 2000.³ As the Department of Defense (DoD) improves methods of identifying, tracking, and treating TBI, collaborative partnerships between military and civilian professionals are addressing the ramifications of these injuries in clinical and research contexts. These collaborations have the potential to close knowledge gaps related to TBI identification, assessment, and rehabilitation. Civilian and AD clinicians in military medical centers bring clinical expertise and contextual knowledge of the medical system, stakeholders, and infrastructure, whereas civilian researchers contribute knowledge of research processes and methods.

The Veteran's Administration (VA)/DoD handbook is an excellent starting point for anyone considering research with veterans or AD military populations.⁴ The main focus of this handbook is to provide guidance for collaborations between VA and DoD investigators. The purpose of this article was to describe lessons learned through ongoing collaborations between non-VA civilian occupational and physical therapists with AD military therapists, researchers, and administrators. Our group shares a common goal of developing military-specific assessment tools and interventions that target the demands of AD, in particular for those who have sustained mTBI. Insights gained by our team may be beneficial to civilian rehabilitation researchers considering mTBI research projects with an AD population. We have organized our recommendations and reflections into 2 categories of considerations including preparing a research proposal and conducting a study.

Preparing Your Research Proposal

The process of developing a research concept, establishing funding, administering the project, and disseminating results is typically a multiple-year process. An implementable and fundable proposal requires that civilian researchers understand military culture, the role and capacity of military rehabilitation clinicians, and DOD research priorities. Civilian researchers must build relationships with potential military partners and identify possible funding mechanisms, which can take some time to develop.

To successfully work with AD and veteran populations, an understanding of military culture is important. There are several resources available to provide insight into and knowledge of military customs, courtesies, rank structures, and language, including modules created by the VA that can be accessed at no charge.^{5,6} Those who join the military become a part of a cohesive

group that upholds clear values of honor, courage, integrity, commitment, restraint, and obedience, respecting the hierarchy inherent in the system.

Military SMs commonly make sacrifices, often of life-threatening significance, for the benefit of their mission or fellow SMs. This mind-set of accepting sacrifice as a part of the military role may influence response to injury or impairment such that difficulties are denied or managed with stoicism in order to remain “in the fight” and in support of one's unit. Awareness of these important elements of military culture aids the researcher in understanding the hierarchy, common behaviors, and motivations of potential collaborators and research participants.^{2, 8} Those who serve are often more likely to volunteer as research recruits in projects that have clear benefits to fellow SMs. On the contrary, volunteering time to participate in a research study may be a lower priority if that commitment competes with unit mission or family priorities.

An aspect of military culture where specific training is necessary involves learning the language, terminology, and common acronyms used to describe units, activities, and roles. Successful efforts are enhanced when civilians who interact with AD SMs learn this unique language. When attempting to negotiate access for a project, an understanding of the rank structure within the military is critical. Contact with a lower-ranking officer about possible collaboration must be worked up the hierarchy to engage individuals who have the authority to commit to collaboration. This process may be time-consuming, and commitment to project involvement may come with caveats related to other mission critical activities. Respect for the established command hierarchy is also important when seeking access to SMs, as commanders must prioritize the project for its potential benefits as well as allow SM participation, taking time away from the duty day.

Determining a research focus and identifying funding

As with any research endeavor, identifying a funding source, writing a proposal in line with research priorities, assembling a team of collaborators, and developing a plan so that submission deadlines can be met are critical. Military research priorities are shared annually with requests for proposals, and information about various DoD and veteran funding streams is extensively documented in the VA/DoD handbook.⁴ Priorities can also be identified through existing projects that focus on mTBI described on the US Army Medical Research and Materiel Command (USAMRMC) Web site.⁹ The Clinical and Rehabilitative Medicine Research Program (CRM RP) may prove the most relevant for mTBI-related studies, with numerous funding links provided on the CRM RP page.¹⁰ In addition, there are funding opportunities related to mTBI annually through the Congressionally Directed Medical Research Program (CDMRP).¹¹ Many rehabilitation-oriented conferences have special interest groups or sections that address priorities of federal healthcare providers or military rehabilitation and routinely have presentations and papers that are focused on military mTBI where potential collaborators may be identified.

Military-Oriented Special Interest Groups:

- American Physical Therapy Association—Federal Section¹²
- American Congress of Rehabilitation Medicine—Military & Veterans Affairs Networking Group¹³

- American Psychological Association—Division 19, Military Psychology¹⁴

Military and TBI Educational Conferences:

- Defense and Veterans Brain Injury Center (DVBIC)/Defense Center of Excellence¹⁵
(often held virtually with participating centers)
- Military Health System Research Symposium¹⁶
- North American Brain Injury Society¹⁷
- International Brain Injury Association¹⁸
- Federal Interagency Conference on TBI (held infrequently)

The DoD primarily funds rehabilitation research through specific calls for proposals with clear priorities (CDMRP or CRMRP) and the Broad Agency Announcement (BAA), which allows field-initiated proposals not addressed in specific program-oriented calls. Both require development of a letter of intent or preproposal of several pages, which is an ideal way to conduct preliminary planning and establish a team of collaborators. Requests for full proposals are processed relatively quickly for a specific line of research, with a short turnaround time for the full proposal to be submitted. If USAMRMC is interested in a BAA preproposal, a full proposal is requested. It is important to note that funds may not be available for unsolicited submissions. However, proposals with high programmatic relevance and scientific rigor are kept on file for funding as it becomes available.

In our case, the focus for a research program took shape during consultation regarding concussion care management for the Army Office of the Surgeon General TBI Program in 2007. This program administers critical TBI policy recommendations and efforts to prevent injury, identify injury, and encourage appropriate treatment and tracking of injury in the US Army.¹⁹ A review of current practices in the management of military concussion/mTBI was conducted with collaboration among civilian academic, as well as civilian and military, clinical and research partners, resulting in clinical recommendations for occupational²⁰ and physical therapy practice.²¹ Further work to describe best practice culminated in the creation of a toolkit for use in military practice by occupational, physical, and speech therapists.²²

A gap was identified between existing approaches for “return-to-play” decision making, used in athletic populations, and an urgent need to make return-to-duty decisions after mTBI sustained in military service. The ability to reliably document a performance problem in a way that would make sense to an SM and his or her command was a critical goal and was deemed a necessary first step to improve rehabilitation for injured SMs with mTBI.²³ Emerging evidence for the importance of challenging both physical and cognitive abilities simultaneously in a performance-based assessment guided our development of several novel assessments to inform return-to-duty decisions,²⁴ resulting in development of the Assessment of Military Multitasking Performance (AMMP).²⁵ The AMMP was created with a participatory approach to understand specific therapist needs in rehabilitation. We solicited input from end users to learn about strategies military therapists were using to inform return-to-duty decisions after mTBI. End users indicated a need for reliable, valid, and feasible methods for clinical practice that could be used in a range of environments, potentially in austere settings. This drove test development with minimal need for “laboratory” equipment and a battery of tests that use complex multitask or dual-task

approaches. The process and rationale for development of the AMMP have been described previously,²³ and preliminary reliability of AMMP elements has been examined.²⁵

Identifying and collaborating with military (active duty) clinicians

Once you have identified military research priorities that align with your area of expertise, the success of a potential study will depend upon having collaborators (civilian or AD) within military medical centers and/or research institutions. In our search for individuals interested in mTBI rehabilitation research, there were a number of challenges. The majority of military rehabilitation is musculoskeletal in nature given the long-term physical demands of military service, so expertise in treatment of mTBI is not the norm. Over the past decade, vestibular rehabilitation following blast injury and mTBI emerged as an important area of care. One of our team members (M.R.S.) was in a doctoral program, studying vestibular dysfunction as a consequence of military mTBI, as we laid the groundwork for the AMMP study. Our research team enlisted his involvement with our project, which was critical to our success. We also tapped collaborators who were part of the TBI Polytrauma system, US Public Health Service therapists assigned to military treatment facilities, collaborators engaged in ongoing projects through DVBIC, and TBI experts within the Army Office of the Surgeon General's TBI Program (Rehabilitation and Reintegration Division or R2D)¹⁹ for guidance. In collaboration with DVBIC, the development of clinical recommendations^{26,27} and presentations about TBI initiatives in the US Army were also part of our team activities.

We collaborated with researchers assigned to the US Army Research Institute of Environmental Medicine (USARIEM) and US Army Aeromedical Research Laboratory (USAARL). The laboratory scientists offered additional insights into how our efforts might be used in a military context, facilitated pilot testing with SMs, advised on military institutional review board (IRB) processes, aided in test development and subject recruitment, and provided guidance in seeking other military collaborators. At USARIEM, a group of SMs serve as human research volunteers, with the primary duty of voluntary participation in research projects. Neurosensory injury experts at USAARL offered assistance in the development of AMMP tasks that targeted hearing and vestibular function.

Military laboratory investigators may collaborate on external projects if a project aligns with the laboratory's established research lines and effort is approved by his or her Division Chief. A percentage of AD SM time may be negotiated without requiring funds from an external source. In fact, investigators writing a grant proposal are not allowed to pay an AD collaborator. While this arrangement is a benefit to the overall bottom line of a grant budget, it presents timing and availability challenges.

Another approach that may prove efficacious for civilian researchers is to identify civilian therapists who work in a Military Treatment Facility (MTF) and have interest in a research project. Engaging “insiders” whether AD (of any branch, including US Public Health Service) or civilian helps in gaining support for a project with administration or decision makers, informs project feasibility, and ensures that the focus of the project is one that is perceived as an important one for clinical practice.

While a great deal of the Army Medical Command's research initiatives is performed at dedicated laboratories under USAMRMC, clinical research may be best conducted in military medical facilities where patients obtain care. If a military site does not have a dedicated research infrastructure, including an IRB and clinical research support networks, civilian academic or research experts must link with military clinicians.

An additional factor that underscores the need for collaboration with nonmilitary clinicians and researchers is that military personnel frequently move between assignments and locations. This continuous cycle of relocation impacts the ability of AD investigators to participate in a program of research. Civilian and academic partners who have the stability to manage multiple-year research projects are a valuable resource to facilitate military research. Such collaborations allow teams to take advantage of military expertise and participation in research initiatives while benefiting from civilian researcher expertise and interest in establishing a research program. This teamwork leverages military clinician deployment and stateside experiences that lead to insights into critical knowledge gaps so that meaningful projects can be planned. In addition, AD team members can facilitate access to the military base, military treatment facilities, and AD personnel, all valuable benefits that are often inaccessible for civilian investigators.

The process of administering a research project on a military installation is multifaceted and requires considerable time. A local principal investigator (PI), often someone on AD, must be willing to take responsibility for the project as a requirement for IRB approval, although the PI may have limited time to manage the administrative requirements of a study. Given that AD assignments may shift, project planning and administration may require coordination with more than 1 local PI. Therefore, a plan to transition responsibilities on a project from 1 AD investigator to his or her replacement is critical to ensure seamless transitions, continuity, and consistent completion of study aims over the phases of a multiple-year project.

Members of our team made a trip to Fort Bragg with an AD researcher from USARIEM to develop a collaborator network during the process of planning our proposal. His clinical networks allowed us to meet with a range of therapists with interest in our project, to determine feasible recruitment methods, and to develop leads for locating testing space. A uniformed military investigator on our team added a level of credibility, trust, and “insider” status. Study design questions were clarified in discussion with AD collaborators, allowing us to drill down to legitimate research gap areas and to verify face validity of planned testing approaches. Access to subjects, negotiation of military IRBs, and facilitation of communications related to approvals were all positively influenced by the presence of a uniformed investigator on the research team. Our local PI facilitated patient and healthy control recruitment, guided us toward improved project feasibility and access to space, and secured attention of other high-ranking officers or individuals in decision-making roles to complete the project.

Conducting a Study

Access and training

Physical access to military installations requires vehicle inspection and an access pass obtained through security offices at the main installation gate or by local PI sponsorship. Two of our team

members completed training and background review to obtain credentials for access to military facilities and MTF records prior to work on the project. The project manager took responsibility for completion of administrative tasks and perhaps, more importantly, offloaded tasks from the local PI. Familiarity with the military installation and culture, the operational tempo of units, and general processes for working on a military base facilitated efficient project management.

An alternative to engaging local project staff directly is to work with a contract agency (General Dynamics, Henry M. Jackson Foundation, Geneva Foundation, etc) whose mission is to support military research on military installations through all phases of a project. They have the ability to hire local project staff, coordinate training and credentialing, manage regulatory requirements, and manage many of the day-to-day challenges inherent in a research project on a military installation. The involvement of such an agency has the significant benefit of further reducing administrative time required of a local PI.

IRB considerations

MTFs that have a local IRB typically have a greater research infrastructure and ongoing projects with dedicated staff who offer guidance to ensure that military IRB processes are followed appropriately. The Clinical Investigative Services Office at Womack Army Medical Center provided suggestions to minimize the need for revisions and to expedite IRB approval. Access to the electronic IRB system by project staff facilitated project administration and management of regulatory issues. If a site does not have a local IRB, a national-level IRB fulfills the role of review and approval. Whenever possible, a university or research center IRB should rely on the military IRB to reduce competing requirements for IRB protocols, as military regulatory requirements are often inflexible. Alternatively, specific protocol components relating directly to SM participation can be the focus for military oversight, with the oversight of data handling and analysis deferred to a civilian institution IRB.

Once local IRB approval was obtained, an additional level of review for the military was required, with the Human Research Protection Office (HRPO). This second level of review was not only more administrative but also required time (up to 3 weeks) before data collection could begin.²⁸ Project managers are advised to develop a collaborative relationship with the HRPO personnel. This allowed anticipation of turnaround times for HRPO approval, so study logistics were timed to coincide with final approvals. In addition, HRPO personnel advised regarding tasks that could be completed as a protocol was being reviewed within the MTF IRB. There are multiple requirements that may not be specifically relevant to your protocol but are still mandatory to obtain HRPO approval.

If protocol deviations occur, even those that do not affect the health or safety of participants, specific reporting of those deviations is required. Therefore, careful consideration of the level of detail described in the protocol is critical to minimize the need for deviation reports to 1 or more IRBs. All project personnel must be appropriately trained, often to higher standards than civilian IRBs, with specific requirements determined by the IRB. Military IRB approval can be slow. Our research team included AD collaborators who were familiar with military IRB requirements and local IRB staff who provided advice prior to protocol submission, enabling us to expedite reviews and approvals within the military IRB. Whenever possible, civilian PIs should identify which elements of the military or civilian IRB requirements are “nonnegotiable” before

submitting the protocol for approval to avoid having to rewrite and resubmit a modified protocol at a later time.

Finding and keeping space for research

Space within an MTF is at a premium. Space requirements are dictated by individual protocols, requiring consideration for whether dedicated space is required for administration of the project and storage of equipment or whether testing occurs intermittently, a process for securing and storing equipment when not in use. Identification of space on Fort Bragg was guided by the goal of ensuring ease of access to potential volunteers for the study. Finding space that could be used during the duty day was necessary for administration of our project. Given the time and space requirements for our project (3-hour test sessions), evening and weekend data collection was deemed not feasible; therefore, use of recreational space or clinical space was not a viable option.

Our project began with the use of shared space with a tenant unit where we stored testing equipment but had to move furniture and equipment before and after each testing session. The mission needs of the unit sharing the space with us took priority, so test times occasionally had to be rescheduled. Our local PI was able to communicate our needs to installation personnel who had management responsibility for physical space across Fort Bragg. They identified an unused space that met our requirements for size, setup, and storage, and we became the sole tenants of that space for the remainder of the study. Access to the space and the assignment of keys required the signature and responsibility of an AD SM. This final arrangement was ideal but required significant engagement by our local PI and project staff.

Recruiting participants

While SMs can be identified through military treatment facilities, recruiting them for participation in research can be a slow and challenging process. One strategy to minimize project delays presented by working with AD participants is to plan synergistic components that address similar questions in an easier to access civilian population. In our case, we conducted pilot testing with Reserve Officers' Training Corps cadets accessible in a university environment or National Guard and Reserve units for the development of test battery components. Another strategy is to identify and recruit similar study populations, such as student athletes with concussion, to collect preliminary data, for establishing procedures, or for “proof-of-concept” confirmation, prior to application of similar methods in the potentially less accessible military population. This approach also facilitates the process of obtaining military IRB approval. Common military-civilian rehabilitation research goals facilitate collaboration, as the broader application of developed methods beyond a single setting is appealing and allows work to proceed on multiple fronts at once.

Recruitment of AD research participants requires persistent and diverse efforts. Over the course of a 2-year recruitment period at Fort Bragg, North Carolina, we recruited 229 individuals willing to participate; of those, 108 participants completed the testing protocol (54 in each group: mTBI and healthy controls). Our project required one 3-hour test session, which was one

of the main reasons for dropout after recruitment—SMs, especially lower enlisted, often had difficulty committing time for such a large portion of their duty day. In addition, SMs are required to follow command policies and obtain permission from their command before participating in research studies. Participation in research studies that offer compensation incentives is typically restricted in amount and form (gift card vs cash) and must be approved by the IRB of record and included in the project budget and proposal.

Using a recruitment index described by Blanton et al,²² it took 6.7 days to recruit a participant throughout the course of the project. Of potential healthy controls briefed about the project ($n = 818$), 13% of them volunteered to participate ($n = 110$), and 49% of those actually completed testing (overall 6.6% of those briefed). Of those with mTBI who indicated interest in participating ($n = 119$), 45% completed testing.

Overall, we had a 26% cancellation rate ($n = 60$) of scheduled test sessions for those who had agreed to participate. The reasons for cancellation were typically duty related and often at the last minute. This was true in particular for enlisted SMs who often were not informed of duty assignments more than a few days in advance or their supervisor (sergeant, team leader, squad leader) assigned a work-related duty that was deemed more critical than participation in a research project. We believe that if our test protocol was shorter, volunteer rates would have been higher, so careful consideration of the length of testing is critical.

While higher-level command may endorse a study and allow recruitment within their ranks, the immediate unit commander for an SM ultimately has to grant permission to participate. Ultimately, SMs must be free to decide to participate (or not) in research without feeling coerced and also be granted the time to participate during the duty day, especially if the protocol requires longer time commitments.

Therapists who interacted with individuals with mTBI provided information about our study by using a self-screener that listed inclusion and exclusion criteria. If individuals were interested in participating, they could provide their contact information via the screening form or could make contact with our research assistant directly to schedule a time to participate if willing.

Our strategies to recruit healthy controls began with unit briefings and word-of-mouth contacts. Securing time in these briefings was difficult to arrange related to identifying units at a time in training cycles and interested commanders who would allow for participation in research. These requests may be more feasible if transmitted through AD personnel who are part of a particular unit and can strategize about competing priorities to determine realistic opportunities for recruitment. Group briefings also required ombudsman attendance (appointed by the IRB) to ensure that there was no implied coercion to participate by a unit's chain of command, which created an additional level of scheduling. Advertisement through posters in public areas that soldiers frequent (wellness center, gyms) resulted in very few volunteers.

Eventually, we shifted our healthy control recruitment efforts to a briefing required of all personnel newly arriving at Fort Bragg. These briefings occurred several times throughout the week and covered many installation-specific topics. DVBIC staff conduct a section of the overall brief that included education about prevention, identification, and treatment of mTBI. Research assistants for several projects were on hand to provide a 2-minute study description and provide a self-screening tool that SMs could review to ensure they met inclusion criteria and, if willing, offer to participate. This method did not require coordination with the ombudsman or

identification of willing unit commanders and avoided the potential for coercion since SMs attended the briefing as individuals rather than in a unit meeting. A benefit of recruiting in this manner was that often SMs had more time flexibility upon first arriving at Fort Bragg before they signed in with their units. Through this method, we yielded the greatest number of healthy control volunteers and the percentage of those who were able to follow through with participation also increased. Therefore, identifying the location where newly arriving soldiers to an installation are briefed on various programs and topics is ideal for research recruitment. Often trial-and-error strategies must be employed until the best option is determined. Again, having a local AD collaborator can facilitate this process.

Military guidance for project administration

Each grant or contract is assigned a military representative who provides the PI advisement on technical aspects of the award, monitors the progress of a project, and answers questions throughout the timeline of the award. The procedures used in grant administration are described in an Award Guide.²⁸ A Science Officer (SO) and/or a Grant (Contract) Officer's Representative (GOR or COR) is assigned to work with and support the PI, providing guidance on a range of issues including military culture and research processes, reporting requirements and timelines, and acting as a liaison between the PI and the Grant Officer (GO). The SO and the GOR may be the same person.

The GOR/SO interfaces with the GO on behalf of the PI for the award, as the PI is not permitted to interact with the GO directly. Representatives from the PI's institutional Sponsored Projects Administration Office can interact directly with the GO, related to specific financial questions, such as requesting a no-cost extension. The GOR is typically invited to participate in strategic military meetings that are conducted relative to related research areas. The GOR may also share project progress with military decision makers, possibly improving future funding opportunities or identifying future collaborations within the military research system. The GOR/SO is present during annual reporting meetings such as the In Process Review and can provide critical guidance regarding the scope of reporting that is expected in such meetings.

Conclusion

The process of identifying and carrying out research that addresses the needs of mTBI in the military is complex; however, obstacles to project completion may be reduced by adopting practices employed by our group (see Table 1).

Identifying AD military therapists who had similar research interests was a significant boost to our project success. As our civilian team members increased their knowledge and awareness of military culture, we approached the project planning process with patience and persistence. Research performed with AD SMs with data collection on military installations carries a higher administrative burden than a comparable project in a civilian environment. We were successful in navigating the IRB process, obtaining dedicated testing space, and recruiting AD participants with and without mTBI in addition to completing our project aims. We benefitted from tremendous support from our local PI and the GOR who worked with our team to derive solutions to obstacles. Our military-civilian collaboration offered the diverse skills and

perspectives necessary to bring the project to completion, offering a reliable testing approach that we hope will prove useful in return-to-duty decision making for individuals serving in the military. Although additional work is necessary to validate the AMMP components, the approaches described in this article will be used by members of our team in future collaborations to move our project and related efforts forward.

The synergies that develop with the collaboration of AD and civilian researchers offer significant benefits to all involved and address important clinical issues that stand to improve the healthcare of individuals serving in the military. Application of findings in military research also informs projects with civilian populations who are facing similar injuries and rehabilitation needs. Innovations in either civilian or military sectors may benefit others by clarifying groups' similarities and differences. It is our hope that this article will encourage researchers who are considering military collaborations, offering practical guidance to pursue research to meet the needs of those who serve our country.

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