Award Number: W81XWH-14-1-0173

TITLE: “Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members”

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CONTRACTING ORGANIZATION: The Geneva Foundation
Tacoma, WA 98402

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Tacoma, WA 98402

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**14. ABSTRACT**  
This study’s objective is to determine to what extent the King-Devick Test results discriminate healthy individuals from both their pre-Combatives baseline and their post-Combatives assessment, to determine to what extent individuals diagnosed as having an mTBI event differ from their King-Devick Test pre-Combatives baseline, and to determine to what extent individuals who report a history of concussion during their pre-Combatives baseline differ from those who have not reported a prior concussive event.

**15. SUBJECT TERMS**  
Nothing listed

**16. SECURITY CLASSIFICATION OF:**

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USAMRMC

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**Introduction:**

The primary study objective is to determine the concurrent validity, sensitivity, and specificity of the King-Devick Test to cognitive impairment of attentional processes associated with acute mild traumatic brain injury (mTBI) in service members. The secondary objective is to explore the neurophysiological and neurostructural changes in the brain associated with both combatives training and acute concussion.

**Keywords:**

MTBI, concussion, neurocognitive

**Accomplishments:**

**What were the major goals of the project?**

1) Initiate, Plan and Design Study [Months 2-3]

2) Execute Study (collect and analyze data) [Months 3-9]

3) Conclude Study [Month 10]

**What was accomplished under these goals?**

Two protocols were approved.

1) (A-18002) Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members.

2) (A-18002.2) Imaging Assessment of Neurological Changes Associated with Subconcussive and Concussive Events in US Soldiers.

In addition we -

1) Hired and trained a new technician to assist with data collection.

2) Major renovations to data collection RV.

3) Attained Fort Benning command approval to park RV outside Combatives school house.

4) Received approval of an amendment to the protocol with respect to the addition of our new team member.

5) Approved for a one-year no-cost extension in order to complete the study.

6) Commenced recruitment and data collection (11 participants enrolled as of 25 July 16).

**What opportunities for training and professional development has the project provided?**

Nothing to Report

**How were the results disseminated to communities of interest?**

Updates have been briefed to the quarterly Noninvasive Neuro-Assessment Devices In progress Review Meetings (USAMRMC CCCRP).

**What do you plan to do during the next reporting period to accomplish the goals?**

Complete data collection. Analyze data and provide findings.

**Impact**

The findings from this project has the potential to impact policy for screening concussion during training in CONUS. The secondary and tertiary effects may result in continued research within other military populations and operational environments. This policy change would come through dissemination of findings to USAMRMC, MEDCOM, OTSG, and DVBIC. The results of the second protocol aimed at exploring the neuroanatomical and physiologic changes associated with combatives training (both subconcussive and concussive events) will inform the community of the sensitivity and specificity of various brain imaging techniques compared to neurocognitive measures of interest.
What was the impact on the development of the principal discipline(s) of the project?
Nothing to Report

What was the impact on other disciplines?
Nothing to Report

What was the impact on other disciplines?
Nothing to Report

What was the impact on technology transfer?
Nothing to Report

What was the impact on society beyond science and technology?
Nothing to Report

Changes/Problems:

Changes in approach and reasons for change
Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them
Unexpected administrative and procedural changes at the IRB of record and repairs to the RV resulted in a delay in data collection. To mitigate this delay, a one-year no-cost extension was attained. Data collection has commenced (25 July 2016).

Changes that had a significant impact on expenditures
Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to Report

Products:
Nothing to Report

Participants & Other Collaborating Organizations

What individuals have worked on the project?

<table>
<thead>
<tr>
<th>Name</th>
<th>Contribution to Project</th>
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<tbody>
<tr>
<td>Dr. Michael Dretsch</td>
<td>Dr. Dretsch serves as the overall study PI on this research project.</td>
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<tr>
<td>Nearest person month worked: 3.6</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Contribution to Project</th>
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</thead>
<tbody>
<tr>
<td>Jenifer Fauth</td>
<td>Jenifer Fauth serves as the Project Director and on-site lead for this research project.</td>
</tr>
<tr>
<td>Nearest person month worked: 12</td>
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</tbody>
</table>
Additional key personnel hired and added to protocol

**What other organizations were involved as partners?**
Auburn University MRI Research Center will be providing structural brain scans under a second protocol in order to assess changes in the brain associated with both combatives training and concussion.

**Organization Name:**
Auburn University

**Location of Organization:** (if foreign location list country)

**Partner’s contribution to the project (identify one or more)**
- [ ] Financial support;
- [ ] In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);
- [ ] Facilities (e.g., project staff use the partner’s facilities for project activities);
- X Collaboration (e.g., project staff work with project staff on the project);
- [ ] Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and
- [ ] Other

**Special Reporting Requirements:**
None

**Collaborative Awards**
Nothing to Report

**Quad Charts**
The Quad Chart (available on [https://www.usamraa.army.mil](https://www.usamraa.army.mil)) shall be updated and submitted as an appendix.

**Appendices:**
Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members

Log Number 12089007
W81XWH-14-1-0173

PI: Dr. Michael Dretsch  Org: The Geneva Foundation  Award Amount: $403,671

Study/Product Aim(s)

- Main Study Aim is to evaluate the ability of the King-Devick test to accurately detect concussions in Soldiers; Does the Post Incident K-D Test vary from the individual’s pre-combatives baseline assessment?
- Additional Aims:
  b. Does the pre-combatives baseline K-D Test assessment of individuals who report a history of concussion on their baseline questionnaires vary from the pre-combatives baseline K-D Test assessment of individuals who have not reported a prior concussion event?
  c. Does the post-combatives K-D Test assessment vary from the pre-combatives baseline assessment in healthy individuals who do not suffer a concussive event?

Approach

- Subjects will be recruited at the Fort Benning Combatives School, and other Combatives training
- Recruitment will occur on the first day of training during Soldiers’ in-processing
- Any Soldier that volunteers to participate will be given the informed consent and HIPAA documents
- Any volunteers that agrees to the consent process will be given a pre-combatives questionnaire and K-D test before training begins
- Volunteers who suffer a concussive event during training will be given a post-incident questionnaire (which includes the MACE and GCS) and K-D test within 24 hours after the event occurs
- Volunteers who do not have a concussive event during training will be given a post-combatives questionnaire and K-D test on the last day of their training
- Recruitment and testing will be conducted until 100 concussed Soldiers have been tested
- A brain imaging arm of the study will recruit from enrolled subjects, but will occur at Auburn University

Timeline and Cost

<table>
<thead>
<tr>
<th>Activities</th>
<th>CY</th>
<th>14</th>
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<tbody>
<tr>
<td>Finalizing protocol documents, training employees, meeting with post personnel, and awaiting IRB approval</td>
<td></td>
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<tr>
<td>Approved protocol. Hire additional study personnel, complete training.</td>
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<td>Data collection; data analysis</td>
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<tr>
<td>Complete data analysis, and publish findings</td>
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Estimated Budget ($403,671) $99,540 $201,835 $102,295

Goals/Milestones

CY16 Goals –
- Begin data collection
- Conduct analysis and provide preliminary results

CY17 Goals –
- Finish data collection and analysis by second quarter
- Preparation of reports by third quarter

Comments/Challenges/Issues/Concerns
- Major delays in IRB process.
- Unexpected repairs on RV.

Budget Expenditure as of 6.30.16

Projected Expenditure: $403,671
Actual Expenditure: $181,534

Updated: 19 JULY 2016