

AWARD NUMBER: W81XWH-14-2-0150

TITLE: Improving Balance in TBI Using a Low-Cost Customized Virtual Reality Rehabilitation Tool

PRINCIPAL INVESTIGATOR(S): Denise Krch, PhD

CONTRACTING ORGANIZATION: Kessler Foundation  
West Orange, NJ 07052

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

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# REPORT DOCUMENTATION PAGE

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<b>6. AUTHOR(S)</b> Denise Krch, PhD and Karen J. Nolan, PhD  email: dkrch@kesslerfoundation.org				<b>5d. PROJECT NUMBER</b>	
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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> <p>The proposed study will implement and evaluate a novel, low-cost, Virtual Reality (VR) rehabilitation tool (Mystic Isle; MI) targeting somatosensory, vestibular, and vision systems through a double-blind RCT. Given the importance of dual-task skills for real-world functioning, we will also evaluate the relative effectiveness of dual task (balance and cognitive) VR training to improve balance.</p> <p>A total of 180 participants (Service Members, Veterans, civilians) with mild to severe TBI and documented balance impairments will be randomly assigned into one of three balance treatment groups: 1) Standard of care (control condition); 2) MI; 3) MI dual task (balance plus cognitive). All groups will undergo 2 treatment sessions/week x 6 weeks. Following completion of the treatment protocol, participants in the MI training group will be randomly assigned to a maintenance training group (2 sessions/month x 4 months) or a non-maintenance group. All participants will undergo baseline, immediate (6 weeks), and long-term (4 months) follow-up assessments of: 1) static and dynamic balance and 2) community integration, self-efficacy, quality of life, and cognitive function. This design will allow us to assess the efficacy of MI as a customizable balance treatment in TBI, and to evaluate the impact of this remediation program on overall functioning.</p>					
<b>15. SUBJECT TERMS</b> Virtual reality, balance dysfunction, dual task, traumatic brain injury, multisensory, cognitive, motor					
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1. **INTRODUCTION:**

The proposed study will implement and evaluate a novel, low-cost, Virtual Reality (VR) rehabilitation tool (Mystic Isle; MI) targeting somatosensory, vestibular, and vision systems through a double-blind RCT. Given the importance of dual-task skills for real-world functioning, we will also evaluate the relative effectiveness of dual task (balance and cognitive) VR training to improve balance. A total of 180 participants (Service Members, Veterans, civilians) with mild to severe TBI and documented balance impairments will be randomly assigned into one of three balance treatment groups: 1) Standard of care (control condition); 2) MI; 3) MI dual task (balance plus cognitive). All groups will undergo 2 treatment sessions/week x 6 weeks. Following completion of the treatment protocol, participants in the MI training group will be randomly assigned to a maintenance training group (2 sessions/month x 4 months) or a non-maintenance group. All participants will undergo baseline, immediate (6 weeks), and long-term (4 months) follow-up assessments of: 1) static and dynamic balance and 2) community integration, self-efficacy, quality of life, and cognitive function. This design will allow us to assess the efficacy of MI as a customizable balance treatment in TBI, and to evaluate the impact of this remediation program on overall functioning.

2. **KEYWORDS:** *Virtual reality, balance dysfunction, dual task, traumatic brain injury, multisensory, cognitive, motor*

3. **ACCOMPLISHMENTS:**

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

<b>Project Milestones &amp; Deliverables</b>	<b>Timeline</b>	
<i>Phase I - Project Kick-off</i>	<i>9/30/14 - 3/30/15</i>	<i>% Complete</i>
<b>Subtasks Phase I:</b>		
1. Submit Administrative Approval requests - regulatory review and approval processes to include local Institutional Review Board (IRB) and DoD Human Research Protection Office.	09/30/14 - 03/30/15	80%
2. Coordinate with CRMRP, USC ICT, NICoE ISO (Fort Belvoir) and VANJHCS.	09/30/14 - 03/30/15	95%
3. Purchase study equipment and supplies, configure for study methods, and set up at study sites.	09/30/14 - 03/30/15	75%
4. Advertise for, interview, and hire study personnel.	09/30/14 - 03/30/15	90%
5. Prepare study assessment and outcome measures, organize participant folders (e.g., case report forms) and paperwork.	09/30/14 - 03/30/15	95%
6. Train study personnel in study methods, including evaluation of balance, global functioning, and cognition.	12/31/14 - 03/30/15	65%
7. Train study personnel in double-blind RCT procedures.	12/31/14 - 03/30/15	75%
8. Train study personnel in administering study treatment conditions.	12/31/14 - 03/30/15	65%
9. Set up study database.	01/31/15 - 03/30/15	95%
10. Finalize project-related modifications to the balance treatment protocols.	01/31/15 - 03/30/15	90%
<i>Phase II - Clinical Trial (Years .5 to 3.5)</i>	<i>3/31/15 - 03/30/18</i>	<i>% Complete</i>
<b>Subtasks Phase II:</b>		

1. Conduct telephone and in-person screening to evaluate for inclusion/exclusion criteria.	03/31/15 - 09/29/17	0%
2. Begin Clinical Trial Recruitment and Enrollment.	03/31/15 - 11/29/17	0%
3. Randomize participants into Standard of Care Balance (control), Mystic Isle (experimental), or Mystic Isle Dual Task (experimental) treatment.	03/31/15 - 11/29/17	0%
4. Conduct Balance, Global Functioning, and Cognition baseline assessments.	04/30/15 - 03/30/18	0%
5. Review sessions to evaluate treatment fidelity.	03/31/15 - 03/30/18	0%
6. Conduct immediate follow-up Balance, Global Functioning, and Cognition assessments.	07/31/15 - 03/30/18	0%
7. After completion of the treatment protocol, randomize single task MI group participants into Maintenance or Non-Maintenance group.	07/31/15 - 01/30/18	0%
8. Conduct Maintenance sessions.	07/31/15 - 03/30/18	0%
9. Conduct long-term follow-up Balance, Global Functioning, and Cognition assessments.	07/31/15 - 03/30/18	0%
<b>Phase III: Project Completion (Final 12 Months)</b>	<b>09/30/15 - 09/29/18</b>	<b>% Complete</b>
<b>Subtasks Phase III:</b>		
1. Conclude data collection.	09/30/17 - 03/30/18	0%
2. Conduct data analysis.	03/31/18 - 09/29/18	0%
3. Prepare final report and manuscripts for publication, and other dissemination efforts to military and civilian consumers and professionals.	03/31/18 - 09/29/18	0%
<b>Phase I, II, and II Outcomes, Products and Deliverables:</b>	<b>09/30/14 - 9/29/18</b>	<b>% Complete</b>
• Personnel hired and trained.	09/30/14 - 03/30/15	90%
• Equipment and methods set up and implemented at study sites.	09/30/14 - 03/30/15	30%
• Full IRB approval and DoD Human Research Protection Office.	09/30/14 - 09/29/15	60%
• Subjects run according to the methodological plan.	03/31/15 - 03/30/17	0%
• Data entered, analyzed, interpreted and presented (progress reports, manuscripts).	03/31/18 - 09/29/18	0%

▪ **What was accomplished under these goals?**

Major Activities	% Complete	Specific Objectives Achieved
1. Submit Administrative Approval requests - regulatory review and approval processes to include local Institutional Review Board (IRB) and DoD Human Research Protection Office.	80%	<ul style="list-style-type: none"> <li>• Kessler's initial IRB application submitted to Kessler Foundation (KF) IRB (05/5/2014); Approval received (6/13/14).</li> <li>• IRB amendment submitted to reflect changes in protocol consistent with DoD grant application methodology (08/26/2014); e.g., addition of veteran and military personnel to protocol; Approval received (9/3/14).</li> <li>• IRB amendment submitted with minor clarification changes (9/11/14); Approval Received (9/18/15).</li> <li>• IRB amendment submitted with changes to be in compliance with the requirements of the U. S. Army Medical Research and Material Command</li> </ul>

		<p>(USAMRMC) (9/24/14); Approval received (9/29/14).</p> <ul style="list-style-type: none"> <li>• Kessler’s initial IRB application submitted to HRPO (11/4/2014); Received request for clarification from HRPO (1/13/15); Responded to HRPO’s requests for clarification (1/30/15) and submitted memo to local IRB to request risk determination (1/30/15) in reference to HRPO’s 1/13/15 email correspondence; IRB determined non-significant risk (3/2/15); Submitted IRB non-significant risk determination to HRPO (3/2/15); Received additional requests for clarification from HRPO (3/4/15); Responded to HRPO’s requests for clarification (4/8/15); Received additional requests for clarification from HRPO (5/14/15); Responded to HRPO’s requests for clarification (6/4/2015); Received permission from HRPO to submit changes to local IRB (6/15/15); Submitted local IRB approval of changes to HRPO (6/23/15); Received request for clarification of protocol version number from HRPO (6/30/15).</li> <li>• Established IRB Agreement with USC ICT, with USC ICT acting under Kessler’s FWA (04/01/15).</li> <li>• Submitted recruitment flyer to local IRB (4/7/15); Received approval from local IRB for flyer (4/8/15)</li> <li>• Submitted flyer to VANJHCS IRB contact person to seek guidance on steps to gain approval to post flyer for Veteran recruitment on VANJHCS campus.</li> <li>• Submitted yearly review/continuation application to local IRB (5/1/15); Received continuation approval (5/5/15).</li> <li>• Submitted amendment with HRPO changes to local IRB (6/19/15); Received approval of changes from local IRB (6/23/15).</li> <li>• Submitted amendment to add required VANJHCS language to flyers to local IRB (7/16/15). Received approval (7/17/15).</li> <li>• Submitted amendment adding names of recently hired physical therapists and personnel from collaborating sites to local IRB (9/3/15). Received approval (9/4/15).</li> <li>• Sarah Rule, NICoE ISO Fort Belvoir Community Hospital’s (FBCH) Research Compliance Officer agreed to rely on Kessler’s IRB review for NICoE ISO approval (9/25/15). The IRB reliance agreement (IAIR) is currently being routed for signature at the FBCH Command Suite level.</li> <li>• DRP Administrative Review is completed for NICoE ISO.</li> <li>• A Component Level Administration Review (CLAR) has been initiated. Once completed, documents will be forwarded to KF IRB for review.</li> </ul>
2. Coordinate with CRM RP, ICT, NICoE ISO and VANJHCS.	95%	<ul style="list-style-type: none"> <li>• Established communication with DoD Science Officer (07/29/2014).</li> <li>• Contract negotiations completed; award date established by DoD Contracting Officer (09/17/2014).</li> </ul>

		<ul style="list-style-type: none"> <li>• A subcontract was established with the University of Southern California, Institute for Creative Technologies (USC ICT; agreement executed 11/19/2014).</li> <li>• A subcontract was initiated with Geneva for collaboration with NICoE ISO (signed by Geneva on 12/1/2014).</li> <li>• Conducted first site visit (3/11/2015) at Fort Belvoir (Karen Nolan and Denise Krch, Co-PIs; Irene Ward, Treatment Intervention Liaison).</li> <li>• Established communication with VANJHCS regarding recruitment through consultant Glenn Wylie</li> <li>• Began discussing steps required to obtain IRB approval to post Veteran recruitment flyer on VANJHCS campus as well as those steps required to submit an IRB application to gain access to the VANJHCS subject recruitment database.</li> <li>• Supporting IRB application preparation activities at NICoE ISO through regular communication with NICoE ISO's research coordinator (RC).</li> </ul>
3. Purchase study equipment and supplies, configure for study methods, and set up at study sites.	75%	<ul style="list-style-type: none"> <li>• Purchase orders for KF neuropsychological tests submitted end of December, 2014.</li> <li>• Created neuropsychological testing administration binder.</li> <li>• Created data collection worksheets, sample subject binder, clinical trial regulatory binder, and IRB communication binder.</li> <li>• Conducted ongoing meetings with KF, Kessler Institute for Rehabilitation (KIR), and USC ICT regarding study methodology.</li> <li>• Completed POs for balance intervention equipment.</li> <li>• Received office supplies, computer equipment (including monitor and Microsoft Kinect), patient hi-low table, and Mini Mental Status Examination to determine capacity to consent.</li> <li>• Balance intervention equipment ordered for KF. Most equipment has been received.</li> </ul>
4. Advertise for, interview, and hire study personnel.	90%	<ul style="list-style-type: none"> <li>• Kathleen Goworek Chervin was assigned as the Research Coordinator (RC) at KF.</li> <li>• Lea Frank, Research Assistant (RA), was hired at KF.</li> <li>• NICoE ISO placed ad for RA.</li> <li>• Fort Belvoir hired Caitlin Jones, RC (start date 3/30/15).</li> <li>• Kelli Sullivan was assigned the RA at NICoE ISO.</li> <li>• Advertised for Physical Therapist position at KF.</li> <li>• Hired PTs Adam Kesten and Christina Cording at KF.</li> </ul>
5. Prepare study assessment and outcome measures, organize participant folders (e.g., case report forms) and paperwork.	95%	<ul style="list-style-type: none"> <li>• Created scoring algorithm spreadsheet and hard copy summary sheet for patient testing.</li> <li>• Study statistician completed first version of electronic case report form system.</li> <li>• Study statistician optimized electronic case report form system for data collection and randomization.</li> </ul>
6. Train study personnel in study methods, including evaluation	65%	<ul style="list-style-type: none"> <li>• All KF and KIR personnel completed CITI training.</li> <li>• Kessler RC and RA trained to use Mystic Isle.</li> </ul>

of balance, global functioning, and cognition.		<ul style="list-style-type: none"> <li>• KF RC completed training the RA and engineer on balance and mobility assessments.</li> <li>• KF RA completed training on administration of cognitive and global functioning evaluation tools.</li> <li>• NICOE ISO Site PI and RC completed CITI training.</li> <li>• KF PTs completed CITI training.</li> </ul>
7. Train study personnel in double-blind RCT procedures.	75%	<ul style="list-style-type: none"> <li>• Reviewed RCT procedures with Kessler study staff; briefed Fort Belvoir on double-blind procedures during site visit.</li> <li>• Finalized RCT procedures with KF study staff.</li> </ul>
8. Train study personnel in administering study treatment conditions.	65%	<ul style="list-style-type: none"> <li>• Kessler study staff was briefed on administration of treatment conditions.</li> <li>• Continued progress in treatment protocol manual to be provided to all study staff to ensure standardization of treatment administration across personnel and sites.</li> <li>• Finalizing implementation of treatments conditions using Mystic Isle with USC ICT.</li> <li>• Finalized manualization of Standard of Care treatment.</li> <li>• KF PTs were trained to use Mystic Isle. Clinical review of SOC and Mystic Isle treatment conditions resulted in additional required software refinements. Coordinated with USC ICT to begin implementing these refinements.</li> </ul>
9. Set up study database.	95%	<ul style="list-style-type: none"> <li>• Study statistician completed first version of electronic case report form system.</li> <li>• Study statistician optimized electronic case report form system for data collection and randomization.</li> <li>• Neuropsychological data entry sheets were added to the electronic data capture system.</li> <li>• Secondary randomization time point was implemented.</li> <li>• KF RC and RA completed initial beta testing of data entry and randomization of subjects.</li> </ul>
10. Finalize project-related modifications to the balance treatment protocols.	90%	<ul style="list-style-type: none"> <li>• Finalizing implementation of treatments conditions using Mystic Isle with USC ICT.</li> <li>• Finalized manualization of Standard of Care treatment.</li> <li>• Continued progress in treatment protocol manual to be provided to all study staff to ensure standardization of treatment administration across personnel and sites.</li> <li>• Initial delivery of the updated Mystic Isle software from USC was delayed. Upon delivery, KF's study team conducted a thorough review of the software and identified areas in need of refinement. Since then, we have been working diligently with USC to implement these refinements to bring the software in line with the SOC treatment.</li> </ul>

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

*Nothing to report.*

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

Although we do not yet have results to disseminate, we have disseminated information about the project and created increased awareness about balance deficitis in TBI to several communities of interest, including Kessler Foundation’s Scientific Advisory Board, Kessler Foundation’s Board of Directors, as well to the public through social media and press releases by Kessler Foundation’s Communications Department.

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

- Finalize IRB Reliance Agreement for KF IRB to serve as FBCH’s acting IRB. Submit FBCH’s IRB application for approval.
- Continue to communicate with VANJHCS to recruit at VANJHCS.
- Finalize organizing and setting up the balance treatment space at KF.
- Geneva will complete making purchases for NICoE ISO.
- Geneva on behalf of NICoE ISO will post advertisement for physical therapist.
- Continue training NICoE ISO study team on study methods and evaluation of global functioning and cognition.
- Continue training NICoE ISO study personnel in administering study treatment conditions.
- Finalize study database in coordination with study statistician.
- Continue collaboration between KF, KIR and USC ICT.
- Align local study subject database with FITBIR.
- KF study team to travel to NICoE ISO to train their study team on cognitive and balance study assessments and treatment protocols.
- Finalize Mystic Isle software refinements.
- Begin patient recruitment and telephone and in-person screening for inclusion/exclusion criteria.
- Begin enrollment and randomization of qualifying participants.

4. **IMPACT:**

▪ **What was the impact on the development of the principal discipline(s) of the project?**

- *For the purposes of this project, we utilized existing balance treatment strategies and synthesized them into a multisensory treatment protocol to be delivered systematically through a virtual environment approach. Balance dysfunction is the result of damage or deficits to multiple systems, however, these integrated systems are often not treated systematically. Our experimental protocols treat the various components of balance dysfunction individually, and then as integrated system, thus enabling us to target impairments in their individual domains as well as holistically. The systematic delivery of this approach is accomplished through the use of virtual reality technology. These features are what elevates the treatment protocol to have greater potential than existing treatments for balance dysfunction.*

- **What was the impact on other disciplines?**
  - *The additional utilization of a dual task treatment protocol will enable us to extend the research question to the field of neuropsychology. Implementing a dual task condition will enable us to better understand whether challenging the brain to attend to cognitive and motor demands will effect a significantly greater change in the target system of interest (i.e., balance) relative to treatment of that system alone.*
  
- **What was the impact on technology transfer?**
  - *We believe the prototype system that we now have would be considered to be at DOD Technology Readiness Level (TRL) 7: “System prototype demonstration in an operational environment”. We anticipate that the results from this investigation will produce evidence for the MI system at TRL 9 through empirical clinical and objective support for its widespread application as a standard efficacious clinical and research tool. A customizable tool, such as MI, could be offered as a rehabilitation treatment to clinics or health care providers. A number of health care providers and small businesses have demonstrated interest in the existing VR-based prototype tool. We expect MI’s greater efficacy and cost effectiveness, decreased lab space requirement, and decreased requirement for sophisticated equipment and skilled technicians, to further adoption/transition of our system as a standard treatment tool for balance.*
  
- **What was the impact on society beyond science and technology?**
  - *Mystic Isle has implications as a telerehabilitation application, which would enable Service Members and Veterans in distant locations to independently use the training system with remote clinical supervision. This would also represent a great benefit to rural patients as well as patients with transportation barriers. The ability to reach far more patients than would ordinarily be able to present themselves to a rehabilitation facility translates into significantly improved overall quality of care and health care outcomes, and thus, is beneficial in reducing healthcare costs and burden to the healthcare system.*

**5. 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**

1. FBCH's IRB application has been delayed due to internal processing decisions (i.e., who will act as the IRB of record). As of September, 2015, FBCH has decided to use KF IRB as the IRB of record and is currently awaiting signatures on the IRB Reliance Agreement. Caitlin Jones, the RC at NICoE ISO, has been in communication with Pat Shank, our HRPO liaison, and is preparing to submit HRPO documentation once FBCH receives local IRB approval. We anticipate no further delays once submission has been made.
2. There was an initial delay in the delivery of updated Mystic Isle software from USC. Upon receipt, KF's study team conducted a thorough review of the software and identified areas in need of refinement. Since then, we have been working diligently with USC to implement these refinements to bring the software in line with the SOC treatment. We have made significant progress and are nearing completion.

Despite delays in these areas, we have continued to move forward on other major project goals and have begun to look toward clinical trial milestones. For example, we have begun the process of identifying potential participants to be contacted for recruitment.

- **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.*

- **Significant changes in use or care of human subjects**

- *Nothing to report.*

- **Significant changes in use or care of vertebrate animals.**

- *Nothing to report.*

- **Significant changes in use of biohazards and/or select agents**

- *Nothing to report.*

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

- **Journal publications.**

- *Nothing to report.*

- **Books or other non-periodical, one-time publications.**

- *Nothing to report.*

- **Other publications, conference papers, and presentations**

Krch, D., Nolan, N. (2014). Improving Balance in TBI using a Low-Cost, Customized, Virtual Reality Rehabilitation Tool. Presented to the Kessler Foundation’s Board of Directors Meeting.

- **Website(s) or other Internet site(s)**

[www.kesslerfoundation.org](http://www.kesslerfoundation.org) - Official website of Kessler Foundation, a non-profit research organization dedicated to improving the lives of persons with disabilities. This website provides information about current research (with links to related press releases), publications and presentations, and community outreach. (Kessler Foundation is the primary research site).

- **Technologies or techniques**

*Nothing to report.*

- **Inventions, patent applications, and/or licenses**

*Nothing to report.*

- **Other Products**

- *Software: For the purpose of this project, Mystic Isle software was modified from a game-based exercise/rehabilitation tool to a multisensory balance treatment software that can be systematically delivered to individuals with neurological conditions.*
- *Clinical interventions: For the purposes of this project, a Standard of Care multisensory balance treatment protocol was synthesized and manualized.*

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

<b><u>Kessler Foundation</u></b>	
Name:	Denise Krch, PhD
Project Role:	Co-Principal Investigator
Researcher Identifier:	N/A
Nearest person month worked:	3.6
Contribution to Project:	Dr. Krch contributed to personnel hiring and training, study organization and set-up, and acted as a liaison between personnel across study sites.
Name:	Karen J. Nolan, PhD
Project Role:	Co-Principal Investigator
Researcher Identifier:	orcid.org/0000-0002-4667-0873
Nearest person month worked:	3.6
Contribution to Project:	Dr. Nolan contributed to personnel hiring and training, study organization and set-up, and acted as a liaison between personnel across study sites.

<i>Name:</i>	<i>Kathleen Goworek Chervin, PhD</i>
<i>Project Role:</i>	<i>Research Coordinator</i>
<i>Researcher Identifier:</i>	<i>N/A</i>
<i>Nearest person month worked:</i>	<i>10.2</i>
<i>Contribution to Project:</i>	<i>Ms. Chervin managed administrative and IRB tasks as well as organized the regulatory and IRB documentation for KF and HRPO.</i>
<i>Name:</i>	<i>Lea Frank, BS</i>
<i>Project Role:</i>	<i>Research Assistant</i>
<i>Researcher Identifier:</i>	<i>N/A</i>
<i>Nearest person month worked:</i>	<i>6</i>
<i>Contribution to Project:</i>	<i>Ms. Frank assisted Ms. Chervin in administrative activities and ordering study supplies. She also created the neuropsychological testing binder and learned study balance assessments.</i>
<i>Name:</i>	<i>Adam Kesten, DPT</i>
<i>Project Role:</i>	<i>Physical Therapist</i>
<i>Researcher Identifier:</i>	<i>N/A</i>
<i>Nearest person month worked:</i>	<i>1.2</i>
<i>Contribution to Project:</i>	<i>Adam Kesten worked with the study team to refine the treatment protocols. He contributed to creation of the treatment protocol manual.</i>

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  - *Nothing to report.*
- **What other organizations were involved as partners?**
  - *Kessler Institute for Rehabilitation, West Orange, NJ, USA*
    - *Significant contribution to the manualization of the Standard of Care and the Mystic Isle treatment protocols.*
    - *Training clinical staff and refining and standardizing treatment delivery across treatment sites*
  - *University of Southern California, Institute for Creative Technologies, Los Angeles, CA, USA*
    - *Modification of the Mystic Isle software from a game-based exercise/rehabilitation tool to a multisensory balance treatment*
    - *Will provide software support and assistance with data extraction from the Mystic Isle system.*
  - *National Intrepid Center of Excellence, Intrepid Spirit One, Fort Belvoir Community Hospital, Fort Belvoir, VA, USA*
    - *Study data collection site for active duty military population*
    - *Provided input on refining treatment protocols for military populations*

## 8. SPECIAL REPORTING REQUIREMENTS.

- **QUAD CHARTS:** *See below in Appendices.*

## 9. APPENDICES:

- Quad Chart.

# Improving Balance in TBI using a Low-Cost Customized Virtual Reality Tool

MR130466

W81XWH-14-2-0150



**PI:** Denise Krch, PhD and Karen J Nolan, PhD

**Org:** Kessler Foundation

**Award Amount:** \$2,987,537

## Study/Product Aim(s)

- Objective 1:** Evaluate the effectiveness of Virtual Reality (VR)-based balance training using Mystic Isle (MI) to improve balance in individuals with TBI.
- Objective 2:** Evaluate the improvement on measures of global functioning following the VR balance training customized for a rehabilitation setting.
- Objective 3:** Evaluate the effectiveness of VR-based dual task (balance and cognitive) training to improve balance in individuals with TBI.
- Objective 4:** Evaluate the long-term efficacy of VR-based balance training through the inclusion of a 4-month, follow-up assessment examining balance and functional gains.
- Objective 5:** Evaluate utility of maintenance training.

## Approach

Participants (n=180) will be enrolled into a double-blind RCT at Kessler Foundation/Kessler Institute for Rehabilitation and the National Intrepid Center of Excellence: Intrepid Spirit One (NICoE ISO) Fort Belvoir Community Hospital. Individuals with TBI will be randomly assigned into 1 of 3 balance interventions (2 sessions/week x 6 weeks): 1) Standard of Care; 2) MI; 3) MI + dual task (balance and cognitive).



Service member using Mystic Isle, the customized, low-cost virtual reality rehabilitation tool. This tool has been developed with input from military and civilian clinicians and patients with neurological injury and will undergo evaluation in the proposed study.

## Timeline and Cost

Activities	CY	14	15	16	17
IRB submittal and study prep		■			
Clinician training		■			
Data collection			■		
Data analysis					■
<b>Estimated Budget (\$K)</b>		<b>\$647</b>	<b>\$804</b>	<b>\$796</b>	<b>\$741</b>

**Updated:** October 14, 2015

## Goals/Milestones

**CY14 Goal** – Study preparation

- IRB submittal
- Preparation of study materials
- USC ICT Clinician Training with Mystic Isle system

**CY15 Goal** – Data collection

- Initiate participant recruitment
- Recruit and test 35 participants from Kessler Foundation (KF)/Kessler Institute for Rehabilitation (KIR) 10 participants from Veterans Administration New Jersey Health Care System (VANJHCS) and 15 participants from NICoE ISO Fort Belvoir Community Hospital

**CY16 Goal** – Data collection

- Recruit and test 35 participants from KF/KIR, 10 participants from VANJHCS and 15 participants from NICoE ISO

**CY17 Goal** – Data collection

- Recruit and test 35 participants from KF/KIR, 10 participants from VANJHCS and 15 participants from NICoE ISO
- Data analysis and Dissemination