

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 and Karen J. Nolan, PhD

CONTRACTING ORGANIZATION: Kessler Foundation

REPORT DATE: AUGUST 2020

TYPE OF REPORT: Final

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

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE AUGUST 2020		2. REPORT TYPE Final		3. DATES COVERED 30 Sep 2014 – 29 May 2020	
4. TITLE AND SUBTITLE Improving Balance in TBI Using a Low-Cost Customized Virtual Reality Rehabilitation Tool				5a. CONTRACT NUMBER W81XWH-14-2-0150	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Denise Krch, PhD and Karen J. Nolan, PhD ~~E-Mail:dkrch@kesslerfoundation.org; knolan@kesslerfoundation.org~~				5d. PROJECT NUMBER 0010557682-0001	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Kessler Foundation, 0705 120 Eagle Rock Ave., Suite 100 East Hanover, NJ 07936-3147				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The proposed study will implement and evaluate a novel, low-cost, Virtual Reality (VR) rehabilitation tool (Island Quest; IQ) 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) IQ; 3) IQ 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 IQ 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 IQ as a customizable balance treatment in TBI, and to evaluate the impact of this remediation program on overall functioning.					
15. SUBJECT TERMS Virtual reality, balance dysfunction, dual task, traumatic brain injury, multisensory, cognitive, motor					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	37	19b. TELEPHONE NUMBER (include area code)

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1. INTRODUCTION:

The proposed study will implement and evaluate a novel, low-cost, Virtual Reality (VR) rehabilitation tool (Island Quest; IQ (recently renamed from Mystic Isle) 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) IQ; 3) IQ 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 IQ 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 IQ 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?**

Project Milestones & Deliverables	Timeline	
Phase I - Project Kick-off	9/30/14 - 3/30/15	% Complete
Subtasks Phase I:		
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	100%
2. Coordinate with CRM RP, USC ICT, NICOE ISO (Fort Belvoir) and VANJHCS.	09/30/14 - 03/30/15	100%
3. Purchase study equipment and supplies, configure for study methods, and set up at study sites.	09/30/14 - 03/30/15	100%
4. Advertise for, interview, and hire study personnel.	09/30/14 - 03/30/15	100%
5. Prepare study assessment and outcome measures, organize participant folders (e.g., case report forms) and paperwork.	09/30/14 - 03/30/15	100%
6. Train study personnel in study methods, including evaluation of balance, global functioning, and cognition.	12/31/14 - 03/30/15	100%
7. Train study personnel in double-blind RCT procedures.	12/31/14 - 03/30/15	100%
8. Train study personnel in administering study treatment conditions.	12/31/14 - 03/30/15	100%
9. Set up study database.	01/31/15 - 03/30/15	100%

10. Finalize project-related modifications to the balance treatment protocols.	01/31/15 - 03/30/15	100%
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Phase II - Clinical Trial (Years .5 to 3.5)	3/31/15 - 09/29/19	% Complete
Subtasks Phase II:		
1. Conduct telephone and in-person screening to evaluate for inclusion/exclusion criteria.	03/31/15 - 09/29/19	100%
2. Begin Clinical Trial Recruitment and Enrollment.	03/31/15 - 09/29/19	100%
3. Randomize participants into Standard of Care Balance (control), Island Quest (IQ; experimental), or IQ Dual Task (experimental) treatment.	03/31/15 - 09/29/19	100%
4. Conduct Balance, Global Functioning, and Cognition baseline assessments.	04/30/15 - 09/29/19	100%
5. Review sessions to evaluate treatment fidelity.	03/31/15 - 09/29/19	100%
6. Conduct immediate follow-up Balance, Global Functioning, and Cognition assessments.	07/31/15 - 09/29/19	100%
7. After completion of the treatment protocol, randomize single task IQ group participants into Maintenance or Non-Maintenance group.	07/31/15 - 09/29/19	100%
8. Conduct Maintenance sessions.	07/31/15 - 09/29/19	100%
9. Conduct long-term follow-up Balance, Global Functioning, and Cognition assessments.	07/31/15 - 09/29/19	100%
Phase III: Project Completion (Final 12 Months)	09/30/15 - 09/29/19	% Complete
Subtasks Phase III:		
1. Conclude data collection.	09/30/17 - 09/29/19	100%
2. Conduct data analysis.	03/31/18 - 09/29/19	48%
3. Prepare final report and manuscripts for publication, and other dissemination efforts to military and civilian consumers and professionals.	03/31/18 - 09/29/19	30%
Phase I, II, and III Outcomes, Products and Deliverables:	09/30/14 - 5/29/19	% Complete
• Personnel hired and trained.	09/30/14 - 03/30/15	100%
• Equipment and methods set up and implemented at study sites.	09/30/14 - 03/30/15	100%
• Full IRB approval and DoD Human Research Protection Office.	09/30/14 - 09/29/15	100%
• Subjects run according to the methodological plan.	03/31/15 - 09/29/19	100%
• Data entered, analyzed, interpreted and presented (progress reports, manuscripts).	03/31/18 - 05/29/20	38%

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

Phase I - Project Kick-off Major Activities	% Complete	Specific Objectives Achieved
1. Submit Administrative Approval requests - regulatory review and approval processes to include local Institutional	100%	• Kessler's initial IRB application submitted to Kessler Foundation (KF) IRB (05/5/2014); Approval received (6/13/14).

Review Board (IRB) and DoD Human Research Protection Office.		• 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). • IRB amendment submitted with minor clarification changes (9/11/14); Approval Received (9/18/14). • IRB amendment submitted with changes to be in compliance with the requirements of the U. S. Army Medical Research and Material Command (USAMRMC) (9/24/14); Approval received (9/29/14). • 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). • Established IRB Agreement with USC ICT, with USC ICT acting under Kessler's FWA (04/01/15). • Submitted recruitment flyer to local IRB (4/7/15); Received approval from local IRB for flyer (4/8/15) • Submitted flyer to VANJHCS IRB contact person to seek guidance on steps to gain approval to post flyer for Veteran recruitment on VANJHCS campus. • Submitted yearly review/continuation application to local IRB (5/1/15); Received continuation approval (5/5/15). • Submitted amendment with HRPO changes to local IRB (6/19/15); Received approval of changes from local IRB (6/23/15). • Submitted amendment to add required VANJHCS language to flyers to local IRB (7/16/15). Received approval (7/17/15). • Ft. Belvoir site specific amendment (SSA) submitted to Ft. Belvoir IRB Manager for initial review (7/30/15) and forwarded for administrative review on 7/31/15. • Teleconference between the Defense Health Agency (DHA), Ft. Belvoir Research Staff, and Dr. Zhang in order to discuss the need for a Data Sharing Agreement (DSA) between the DHA and Kessler
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		Foundation/System Security Verification (SSV) for data capture system (8/6/15). It was later established that neither a DSA or an SSV would be required. • Scientific Review completed by the Scientific Review Chair at Ft. Belvoir (8/25/15). • 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). • 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. • IRB manager compiled a list of suggested revisions and additional documentation required for the new project submission and sent it to the Fort Belvoir (FB) Research Coordinator for review and editing (9/9/15). • Received draft marketing project (study advertisement to be displayed in hospital/TBI NICOE ISO clinic and on electronic display board in hospital), (9/18/15). FB RC made final edits to this document and received final version on 9/22/15. • DRP Administrative Review is completed for NICOE ISO (9/25/15). • The Office of the Undersecretary of Defense for Personnel and Readiness Research Regulatory Oversight Office (R2O2) delegated that the Component Level Administrative Review (CLAR) be performed by Sarah Rule, Acting Chief Department of Research Programs, Human Protections Administrator, and Research Oversight & Compliance Officer at Fort Belvoir Community Hospital (FBCH) (10/8/15). • A request was submitted from the Fort Belvoir Department of Research Programs to the Kessler IRB for clarification regarding the risk determination of the protocol and Fort Belvoir study staff was subsequently notified that the protocol was determined to be greater than minimal risk and as a result of this determination a DoD Research Monitor (RM) would need to be assigned to oversee the protocol (10/23/15). • A research monitor was identified by the PI and study coordinator at Fort Belvoir and following completion of human subjects training (CITI) was added to the protocol. The updated SSA and supporting documentation were then submitted to the Fort Belvoir IRB Manager for review (12/3/15). • The CLAR was completed by Sarah Rule at Fort Belvoir (12/7/2015) and then forwarded to R2O2 for review
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		(12/8/2015). • Submitted amendment adding alternate test (Bilingual Aphasia Test: Verbal Comprehension) to Token Test for individuals with color vision impairment (12/9/15). Received approval (12/15/15). • Fort Belvoir forwarded IRB documents to KF IRB for review (12/22/15). • Fort Belvoir SSA was approved by the Kessler IRB on 12/24/2015 and approval documents were sent to Fort Belvoir (1/15/2016). • Face-to-face PI Responsibilities meeting between Sarah Rule and Dr. Purohit, FB RC also in attendance (1/29/2016). • Sarah Rule sent email to Kessler PI, Karen Nolan, requesting clarification on the risk determination on 2/2, and received clarification from Dr. Greene regarding the risk determination. The Kessler IRB determined the risk of the research protocol to be no greater than minimal risk (2/8/16). • IRB amendment submitted correcting medical therapy section of the protocol (2/9/16); Approval Received (2/11/16). • Submitted protocol amendment (Amendment #1) after receiving clarification in risk from Kessler; updated SSA to reflect this change from greater than minimal risk to minimal risk and to remove DoD Research Monitor. Also, updated Dr. Chae's status from Collaborator to Associate Investigator (2/11/16). • Received required revisions back from FB IRB Manager along with notification that adding Dr. Chae as an AI on the protocol would require the leadership signature to go up a level to LTC Waits, the Director of Behavioral Health and Dr. Chae's supervisor at FBCH (2/17/16). • LTC Waits signed off on the protocol and all required revisions and documentation were submitted to the Fort Belvoir IRB (2/26/16). • Amendment #1 and all supporting documents sent to Kessler IRB for review (3/3/16). • Amendment #1 was approved by the Kessler IRB on 3/3/2016 and the approval letter was forwarded to Ft. Belvoir investigators (3/8/16). • Fort Belvoir's protocol package submitted to USAMRMC HRPO (3/9/16). • Deferral of Headquarters-Level Review and Oversight to the Fort Belvoir Community Hospital, Department of Research Programs for the protocol (3/23/16). • Fort Belvoir study staff received notification that the Headquarters-Level Review had been completed and the NICoE ISO site was granted approval by FBCH to initiate the research protocol (3/29/16). • Annual IRB review submitted (4/11/16). Approval
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		pending minor revisions received (4/12/16). Revisions submitted and final approval received (4/14/16). - Continuation submitted to HRPO (5/3/16). HRPO approval received (5/4/16). - Amendment submitted to IRB to allow questionnaires to be administered via telephone (5/13/16). Approval received (5/14/16). - Annual IRB review submitted (3/6/2017). Reviewed 3/29/17. Approval pending minor revisions received (4/3/2017). Revisions submitted (4/6/2017) and final approval received (4/10/2017). Continuation submitted to HRPO (4/20/17). HRPO approval received (5/22/17). - Annual IRB review submitted (2/2/2018). Reviewed 2/28/2018. Approval pending minor revisions received (3/13/2018). Revisions submitted (3/15/2018) and final approval received (3/16/2018).
2. Coordinate with CRM RP, ICT, NICOE ISO and VANJHCS.	100%	- Established communication with DoD Science Officer (07/29/2014). - Contract negotiations completed; award date established by DoD Contracting Officer (09/17/2014). - A subcontract was established with the University of Southern California, Institute for Creative Technologies (USC ICT; agreement executed 11/19/2014). - A subcontract was initiated with Geneva for collaboration with NICOE ISO (signed by Geneva on 12/1/2014). - Conducted first site visit (3/11/2015) at Fort Belvoir (Karen Nolan and Denise Krch, Co-PIs; Irene Ward, Treatment Intervention Liaison). - Established communication with VANJHCS regarding recruitment through consultant Glenn Wylie - 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. - Began recruiting veterans in coordination with KF's dedicated recruitment coordinator, Justin Stanley, who has previous experience recruiting veterans with TBI for KF. - Supported IRB application preparation activities at NICOE ISO through regular communication with NICOE ISO's research coordinator (RC). - Conducted site visit (3/10/2017) at FBCH (Karen Nolan and Denise Krch, Co-PIs; Irene Ward, Treatment Intervention Liaison) to evaluate treatment fidelity and to ensure successful transition of Site PI from Maulik Purohit to Melissa Guerra. - New recruitment coordinator, Samantha Schmidt hired to replace Justin Stanley. Will work with Ms. Schmidt to continue recruitment efforts targeted at veterans.

3. Purchase study equipment and supplies, configure for study methods, and set up at study sites.	100%	• Purchase orders for KF neuropsychological tests submitted end of December, 2014. • Created neuropsychological testing administration binder. • Created data collection worksheets, sample subject binder, clinical trial regulatory binder, and IRB communication binder. • Conducted ongoing meetings with KF, Kessler Institute for Rehabilitation (KIR), and USC ICT regarding study methodology. • Completed POs for balance intervention equipment. • Received office supplies, computer equipment (including monitor and Microsoft Kinect), patient hi-low table, and Mini Mental Status Examination to determine capacity to consent. • Balance intervention equipment ordered for KF. All equipment received.
4. Advertise for, interview, and hire study personnel.	100%	• Kathleen Goworek Chervin was assigned as the Research Coordinator (RC) at KF. • Lea Frank, Research Assistant (RA), was hired at KF. • NICoE ISO placed ad for RA. • Fort Belvoir hired Caitlin Jones, RC (start date 3/30/15). • Kelli Sullivan was assigned the RA at NICoE ISO. • Advertised for Physical Therapist position at KF. • Hired PTs Adam Kesten and Christina Cording at KF. • Lea Frank, RA, left KF for graduate school. • Hired Rebecca Spero to replace Lea Frank as RA at KF. • Hired second RA for KF, Sharon Gute. • Fort Belvoir hired Sara Salkind and Haymanot Yalewayker. Cross-trained staff on study protocol. • Sara Salkind left her position with Fort Belvoir. Dr. Guerra is actively looking for a replacement.
5. Prepare study assessment and outcome measures, organize participant folders (e.g., case report forms) and paperwork.	100%	• Created scoring algorithm spreadsheet and hard copy summary sheet for patient testing. • Study statistician completed first version of electronic case report form system. • Study statistician optimized electronic case report form system for data collection and randomization.
6. Train study personnel in study methods, including evaluation of balance, global functioning, and cognition.	100%	• All KF and KIR personnel completed CITI training. • Kessler RC and RA trained to use Mystic Isle. • KF RC completed training the RA and engineer on balance and mobility assessments. • KF RA completed training on administration of cognitive and global functioning evaluation tools. • NICoE ISO Site PI and RC completed CITI training. • KF PTs completed CITI training. • NICoE ISO RC completed training on administration of cognitive and global functioning evaluation tools.

		• KF RAs (Spero and Gute) completed training on administration of cognitive and global functioning evaluation tools, as well as mobility assessment.
7. Train study personnel in double-blind RCT procedures.	100%	• Reviewed RCT procedures with Kessler study staff; briefed Fort Belvoir on double-blind procedures during site visit. • Finalized RCT procedures with KF study staff.
8. Train study personnel in administering study treatment conditions.	100%	• Kessler study staff was briefed on administration of treatment conditions. • Continued progress in treatment protocol manual to be provided to all study staff to ensure standardization of treatment administration across personnel and sites. • Finalized implementation of treatment conditions using IQ with USC ICT. • Finalized manualization of Standard of Care treatment. • KF PTs were trained to use IQ. Clinical review of SOC and IQ treatment conditions resulted in additional required software refinements. Coordinated with USC ICT to begin implementing these refinements. • Completed software refinements. • Finalized manualization of IQ treatment conditions. • NICoE ISO PT completed onsite training at KF to review SOC and IQ treatment conditions. • Coordinated with NICoE ISO study staff to prepare for enrollment and data collection launch at NICoE ISO.
9. Set up study database.	100%	• Study statistician completed first version of electronic case report form system. • Study statistician optimized electronic case report form system for data collection and randomization. • Neuropsychological data entry sheets were added to the electronic data capture system. • Secondary randomization time point was implemented. • KF RC and RA implemented procedures for data entry and randomization of subjects.
10. Finalize project-related modifications to the balance treatment protocols.	100%	• Finalizing implementation of treatments conditions using Mystic Isle with USC ICT. • Finalized manualization of Standard of Care treatment. • Continued progress in treatment protocol manual to be provided to all study staff to ensure standardization of treatment administration across personnel and sites. • Initial delivery of the updated Island Quest (previously 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. • All treatment conditions finalized and implemented.

Phase II - Clinical Trial Major Activities	% Complete	Specific Objectives Achieved
1. Conduct telephone and in-person screening to evaluate for inclusion/exclusion criteria.	100%	• Ongoing telephone and in-person screening
2. Begin Clinical Trial recruitment and enrollment.	100%	• 99 participants have been enrolled to date.
3. Randomize participants into Standard of Care Balance (control), Island Quest (IQ; experimental), or IQ Dual Task (experimental) treatment.	100%	• 73 participants have been randomized into treatment
4. Conduct Balance, Global Functioning, and Cognition baseline assessments.	100%	• 73 participants have completed baseline assessments
5. Review sessions to evaluate treatment fidelity.	100%	• KF PT is completing clinical documentation after each treatment session to allow the PIs to monitor treatment fidelity and ensure systematic treatment delivery
6. Conduct immediate follow-up Balance, Global Functioning, and Cognition assessments.	100%	• 55 participant have completed immediate follow-up assessments
7. After completion of the treatment protocol, randomize single task IQ group participants into Maintenance or Non-Maintenance group.	100%	• 55 participants, who have completed follow-up assessment, have been potentially randomized. Participants will always be randomized (if relevant to treatment arm) or sham randomized (when not relevant to treatment arm) – in order to maintain blinding.
8. Conduct Maintenance sessions.	100%	• Where appropriate, maintenance sessions were conducted.
9. Conduct long-term follow-up Balance, Global Functioning, and Cognition assessments.	100%	• 46 participants have completed long-term follow-up assessments.

Phase III - Project Completion Major Activities	% Complete	Specific Objectives Achieved
1. Conclude data collection.	100%	
2. Conduct data analysis.	48%	
3. Prepare final report and manuscripts for publication, and other dissemination efforts to military and civilian consumers and professionals.	30%	• Abstract submitted and accepted for poster presentation at the American Congress of Rehabilitation Medicine annual conference in October, 2016: Krch, D., Ward, I., Lange, B., Kesten, A. G., Cording, C. M., Frank, L. E., Mejia, M., Chervin, K., König, S., Chang, C., Rizzo, A., Jasey, N. J., & Nolan, K. J. (2016). A Systematic Delivery for Multisensory Balance Impairment using Virtual Reality in TBI. <i>Archives of Physical Medicine and Rehabilitation - ACRM Annual Conference 2016</i>, 97(10). • Nolan, K. J., Krch, D. (June, 2018). <i>Treating Common Symptoms following TBI: Treating Balance Dysfunction</i>

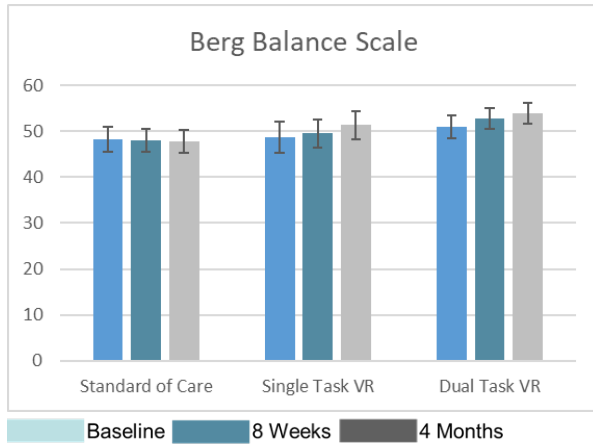
		via Dual Task Methodology in TBI. In Chiaravallotti, N. D. <i>New Research in Treating Common Symptoms Following TBI</i>. Symposium conducted at the 4th Federal Interagency Conference on TBI, Washington, DC. • Pilkar, R., Nolan, K.J., Saleh, S., Barrance, P., Forrest, G.F. (March 2020). Advanced Rehabilitation Approaches to Improve Static and Dynamic Balance in Neurologically Impaired Populations, Symposium presented at the International Society of Physical & Rehabilitation Medicine (ISPRM) World Congress and AAP Annual Meeting 2020 • See Products section below for additional dissemination.
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- ***Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative).***

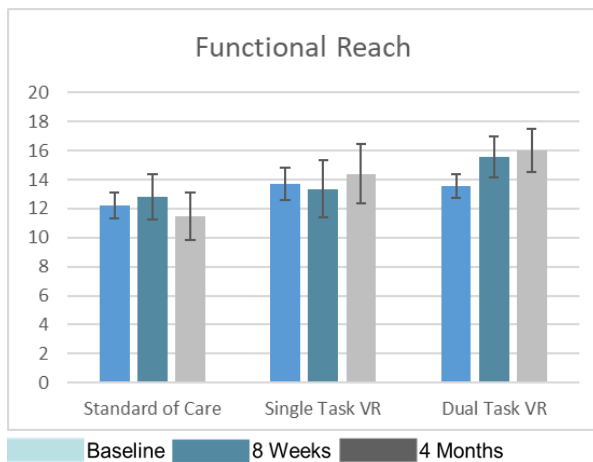
	Kessler Foundation	Fort Belvoir	Total
Recruited	188	97	285
Screened	114	48	162
Enrolled	67	43	110
Baseline	62	34	96
Short Term F/U (8wk)	55	22	77
Long Term F/U (4mo)	52	17	69
Completed	52	17	69

	Kessler Foundation	Fort Belvoir	Total
Gender	Male 46 Female 21	Male 36 Female 7	Male 82 Female 28
Age	47.36	44.56	46.26
Time since Injury	9.41	8.41	9.02
Severity of Injury	Mild 10 Moderate 16 Severe 41	Mild 36 Moderate 5 Severe 2	Mild 46 Moderate 21 Severe 43

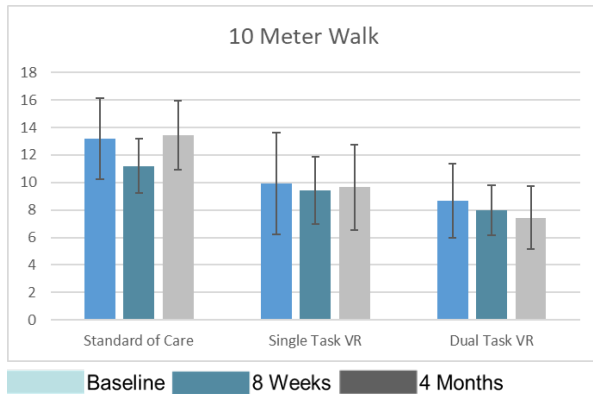
Preliminary Data Analysis (n=35)
September, 2018



The Berg Balance Scale is a 14-item scale designed to measure balance activities, including sitting, standing, single leg standing, and postural transitions with eyes open and closed. The total score ranges from 0 to 56, with higher scores indicating independence. Scores less than 42 are associated with an increased risk of falls. There were no significant differences between the three treatment groups (standard of care, single task VR and dual task VR) at post-treatment or at 4-months long-term follow-up.



The Functional Reach Test assesses stability by measuring the maximum distance an individual can reach forward while standing in a fixed position. Results demonstrated significant increases in the VR dual task group's functional reach ability relative to the other two groups. This differences was noted both at post-treatment and at 4-months long-term follow-up.



The 10 Meter Walk Test is a measure of functional ambulation. A decrease in time indicates an improved walking speed. Results showed that the Standard of Care group was slower overall relative to both VR groups, with the most gains achieved by the VR Dual task group.

Data Analysis Update (n=55)
September, 2019

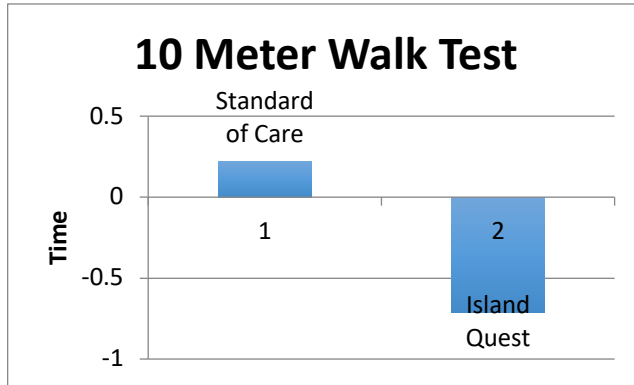
Data Screening and Cleaning. The following tasks are ongoing on the full (completed) data set in order to prepare for data analysis and dissemination:

- Evaluated incomplete participants and dropouts at both data collection sites for missing or incomplete follow-up data.
- Ran Mahalanobis distance across all used variables to find extreme response patterns and exclude these outliers at $p < 0.001$ – no exclusions were made (28df).
- Computed scaled Median Average Distance (as available in MATLAB) to identify univariate outliers. Outliers that existed at baseline or 8-week follow-up were either consistent (or consistently extreme) and thus were not considered errors due to data entry and appropriate for exclusion.
- Ran Mahalanobis distance prior to each analysis for baseline and 8-week follow-up variables (2df, $p < 0.001$). This excluded a number of participants, but no more than 5 participants per variable-pair/analysis.
- Replaced outliers and individual missing data points that, to the best of our knowledge, are missing at random with mean substitution. Given the small number of data points that were replaced, mean substitution was an appropriate approach.

Preliminary Findings. As per the primary aims and planned analyses, 3 ANCOVAs have been conducted: functional mobility (10 Meter Walk), physical impairment (Functional Independence Measure, FIM), and static balance (Berg Balance Scale, BBS). Dynamic balance (Sensory Organization Test, SOT) analyses are still being compiled and further analysis is ongoing. In all cases, baseline values are used as covariate and post-treatment scores as the dependent variable.

- The 10 Meter Walk Test is a measure of functional mobility. Shorter times indicate faster walking speed. From pre- to post-treatment, the VR groups showed a decrease in

walking speed (0.67" faster) relative to the Standard of Care group (who actually increased in speed; 0.22"), a statistically significant group difference, $F(1, 66) = 4.090$, $p = .047$. It is notable that these findings are consistent with the analysis conducted one year ago on a smaller sample, providing promising preliminary support for a treatment effect in the Island Quest treatment conditions.



- There were no group differences found on the FIM and BBS outcomes. We are currently evaluating for potential moderators variables (baseline factors that define subgroups of responders and non-responders) and mediator variables (factors occurring during treatment that explain how or why the intervention is exerting its effects) that may have impacted the lack of an overall treatment effect.

Data Analysis Update (n=110) ***August, 2020***

We are actively preparing 3 papers for publication. Below is a brief summary of the findings from each.

1. **Methodology Paper.** This first paper presents a practical example of how a virtual reality balance treatment was developed and evaluated and how this process compares to the principles of Birkhead and colleagues' three-phase VR framework. Methodology, tools, barriers and solutions will be discussed.

Abstract: Virtual reality (VR) applications have long been suggested as innovative and motivating clinical tools in neurorehabilitation. Literature reviews of the past twenty years have consistently reported the strong potential of these applications to rehabilitate cognitive and motor functions of individuals with acquired brain injuries beyond what traditional rehabilitation tools can accomplish. However, these same literature reviews have also concluded that due to vast differences in development and research methodology and the lack of statistical and methodological rigor, no conclusions about the efficacy of the investigated VR applications' efficacy are warranted (e.g. Ogourtsova et. al., 2015; Pietrzak et. al., 2014; Rizzo & Koenig, 2017). In 2019, an international working group with VR clinical trial experience was formed to discuss and disseminate methodology and best practices regarding VR development and evaluation in a clinical context (Birkhead et al 2019). A three-phase framework of clinical studies was proposed that can serve as a guideline for human-centered design of

clinical VR applications. This paper presents a practical example of how a virtual reality balance treatment was developed and evaluated and how this process compares to the principles of Birkhead and colleagues' three-phase VR framework. Methodology, tools, barriers and solutions will be discussed. To be submitted for publication by 9/30/20.

2. **Paper addressing Objective 1:** Evaluate the effectiveness of Island Quest to improve balance in individuals with TBI. Goal is to submit for publication by 12/31/20.

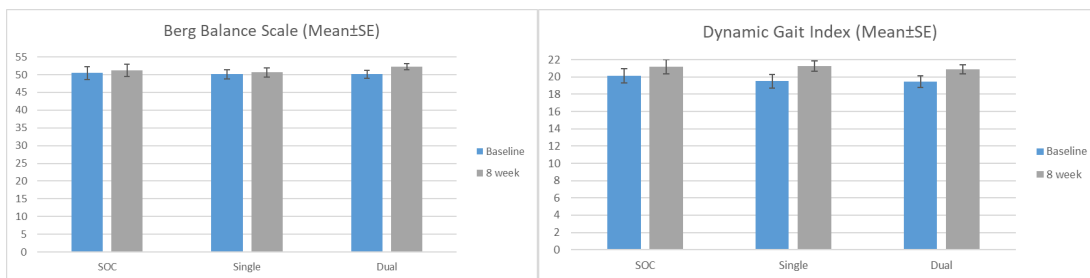
Data Screening and Cleaning. The following tasks are ongoing on the full (completed) data set in order to prepare for data analysis and dissemination:

- We have evaluated incomplete participants and dropouts at both data collection sites (n=105) for missing or incomplete follow-up data. Below is a sample of 75 participants that will be considered for further analysis for evaluating changes in balance function.

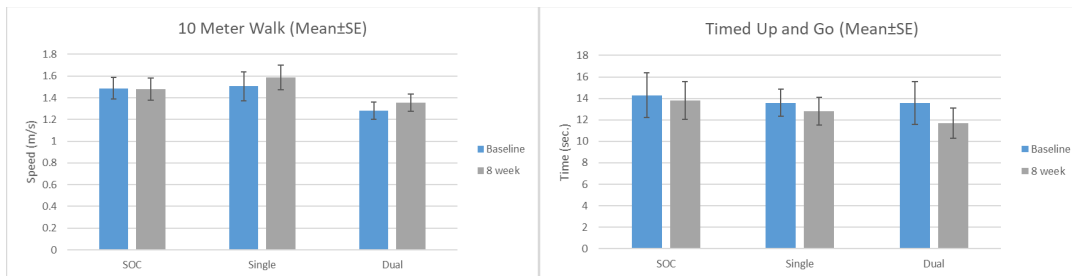
Group	N	Gender	Age (yrs.)	Time Since Injury (yrs.)	Height (in.)	Weight (lb.)	Severity
SOC	26	12 F, 14 M	51.42 ± 11.10	12.69 ± 12.21	67.04 ± 4.67	172.15 ± 50.26	7 Mi, 5 Mo, 14 S
Single	26	4 F, 22 M	43.85 ± 12.52	7.87 ± 9.05	68.25 ± 3.69	190.50 ± 40.54	8 Mi, 3 Mo, 15 S
Dual	23	7 F, 16 M	46.87 ± 10.31	9.21 ± 7.33	68.07 ± 4.74	192.04 ± 44.50	11 Mi, 2 Mo, 10 S

- We have evaluated the data across sites as well as the combined sample for data fidelity. Below is a demographic table for Kessler Foundation (KF) and Ft Belvoir (FB)
- The objective is evaluate the effectiveness of a Virtual Reality based balance (single task and dual task) training to improve balance in individuals with TBI through a randomized clinical trial as compared to traditional balance therapy. Systematically addresses multisensory balance impairment:
 - Multisensory approach
 - Systematic progression
 - Within a clinical block of time
 - Customized to patient impairment level
- Preliminary results indicate that a multisensory balance intervention can be administered in a clinical block of time. Balance may be improved using VR as a delivery system and Standard of Care and VR (single and dual task) can improve balance post TBI.

Site	Group	N	Gender	Age (yrs.)	Time Since Injury (yrs.)	Height (in.)	Weight (in.)	Severity
FB	SOC	5	2 F, 3 M	47.20 ± 12.81	6.68 ± 5.61	68.60 ± 5.13	172.00 ± 41.32	2 Mi, 3 Mo
FB	Single	7	1 F, 6 M	47.57 ± 8.85	9.60 ± 14.18	66.29 ± 5.85	194.00 ± 35.75	7 Mild
FB	Dual	8	1 F, 7 M	44.88 ± 5.06	10.31 ± 6.38	68.38 ± 4.87	196.75 ± 25.80	8 Mild
KF	SOC	21	10 F, 11 M	52.43 ± 10.75	14.07 ± 13.03	66.67 ± 4.61	172.19 ± 53.06	5 Mi, 2 Mo, 14 S
KF	Single	19	3 F, 16 M	42.47 ± 13.58	7.24 ± 6.73	68.97 ± 2.32	189.21 ± 43.01	1 Mi, 3 Mo, 15 S
KF	Dual	15	6 F, 9 M	47.93 ± 12.27	8.77 ± 7.84	67.90 ± 4.83	189.53 ± 52.54	3 Mi, 2 Mo, 10 S



- Berg Balance Assessment: >45 is associated with an increased risk of falling. There were no significant differences baseline to 8 weeks.
- Dynamic Gait Index demonstrated improvements for all three groups.



- The 10 meter walk and timed up and go (TUG) tests provide measures of functional ambulation. Participants with a speed over .8 meters per second are classified as full community ambulators. The 10 meter walk test is a measure of fastest walking speed so faster speeds provide an ability to modulate speed which would impact participation and quality of life in the community. Only the VR and Dual tasks groups demonstrated improvements in speed post intervention. For the TUG individuals reduced their time to completed the test also indicating improvements in speed and balance.

3. **Paper addressing Objective 2:** Evaluate the effectiveness of Island Quest to improve community integration, self-efficacy, and quality of life. Goal is to finish secondary analysis and submit for publication by early Spring 2021.

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

- *KF PT, Adam Kesten, conducted vestibular rehabilitation and technology inservice to Kessler Institute for Rehabilitation Brain Injury PTs July, 2016.*
- *Co-PI Krch presented Virtual Reality didactic lecture for Rutgers, KF, and Children's Specalized Hospital post-doctoral fellows April, 2016.*
- *KF PT, Adam Kesten, pursued and obtained a neuroclinical specialist certification in March, 2017 was directly related to experience gained in association with this project.*

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

- We are actively disseminating information about the project and creating increased awareness about balance deficits and the use of virtual reality in rehabilitation in TBI to various communities of interest. Please see the Products section below for a details regarding publications, conference papers and presentations to Kessler Foundation Stakeholders, industry collaborators, clinical and academic audiences, scientific venues, and the general public.

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

- Conduct data analysis and prepare findings for presentations and publications.
- Continue to transfer the VR treatment to a mobile, immersive VR environment using the HTC Vive for later deployment in telerehabilitation applications.

- **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 IQ 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 IQ, 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 IQ’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. Further adoption/transition of this system will be facilitated by efforts to transfer the VR treatment to a mobile, immersive VR environment using the HTC Vive for later deployment in telerehabilitation applications.*
- **What was the impact on society beyond science and technology?**
 - *Island Quest 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. In order this impact, we are*

actively taking steps transfer Island Quest to a telerehabilitation application.

-
- **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. None foreseeable in the data analysis phase.

- **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.*

- **PRODUCTS:**

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

- **Journal publications.**

- Larkin, M. (2017). Exploring virtual environments for cognitive and physical rehabilitation. *The Journal on Active Aging*. 16(5): 44-51.]

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

- Nothing to report.*

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

- Industry Collaborators:

- Nolan, K.J., Krch, D. (2016). *Multisensory Balance Treatment Using a Virtual Environment*, Presentation to MotekForce Link, West Orange, NJ. January, 2016.
 - Rizzo, A.A. (2017). Clinical Virtual Reality: A Brief Review of the Future! Keynote Invited Address to the Dell Corporate Group. Austin, TX. March, 2017.
 - Nolan, K.J., (2016). *Brain Injury Mobility Research*, Presentation to Parker Hannifin, West Orange, NJ. April, 2016.
 - Rizzo, A.A. (2016). Clinical Virtual Reality: A Brief Review of the Future! Invited Featured Speaker at the Annual VR Days Europe Conference. Amsterdam, NL. November, 2016.
 - Nolan, K.J., Krch, D. (2017). Demonstration of new VR technology. Presentation to VRHealth. September, 2017

- Clinical Dissemination:

- Kesten, A., Vestibular rehabilitation and technology inservice presented to to Kessler Institute for Rehabilitation Brain Injury Physical Therapists. July, 2016.

- Krch, D., Virtual Reality. Presentation to Rutgers, KF, and Children's Specialized Hospital postdoctoral fellows, April, 2016.
- Krch, D. (2017). Using VR in Rehab. Panelist presentation at Health 2.0 NYC – The New York Healthcare Innovation Group Shades of Reality: Virtual, augmented & mixed reality in healthcare. May, 2017 (Link to YouTube video of presentation: <http://bit.ly/2vazNHk>)
- Rizzo, A.A. (2017). Advances in Virtual Reality and New Technologies for Childhood Health Conditions, Children's Specialized Hospital Grand Rounds, Mountainside, NJ. January, 2017.
- Academic:
 - Rizzo, A.A. (2017). Virtual Reality for advancing the assessment of brain function and psychological health. Brain Research Symposium. University of Auckland, Auckland New Zealand, April, 2017.
- Scientific Collaborators:
 - Krch, D., Ward, I., Lange, B., Kesten, A. G., Cording, C. M., Frank, L. E., Mejia, M., Chervin, K., König, S., Chang, C., Rizzo, A., Jasey, N. J., & Nolan, K. J. (2016). A Systematic Delivery for Multisensory Balance Impairment using Virtual Reality in TBI. Archives of Physical Medicine and Rehabilitation - ACRM Annual Conference 2016, 97(10), e139-e140.
 - Rizzo, A.A. (2017). Clinical Virtual Reality: A Brief Review of the Future! *American Psychiatric Association* Convention, San Diego, CA. May, 2017.
 - Rizzo, A.A. (2017). Virtual Reality, Memory, and Immersion and PTSD! Keynote Address at the Annual Conference of the *Institute for Functional Medicine*. Los Angeles, California, June, 2017.
 - Krch, D., Nolan, K.J. "Treating Balance Dysfunction via Dual Task Methodology in TBI". In Symposium: Chiaravallotti, N.D. "New Research in Treating Common Symptoms Following TBI." Abstract submitted for presentation at the 4th Federal Interagency Conference on TBI in June, 2018.
 - Nolan, K. J., Krch, D. (June, 2018). *Treating Common Symptoms following TBI: Treating Balance Dysfunction via Dual Task Methodology in TBI*. In Chiaravallotti, N. D. *New Research in Treating Common Symptoms Following TBI*. Symposium conducted at the 4th Federal Interagency Conference on TBI, Washington, DC.
 - Pilkar, R., Nolan, K.J., Saleh, S., Barrance, P., Forrest, G.F. (March 2020). Advanced Rehabilitation Approaches to Improve Static and Dynamic Balance in Neurologically Impaired Populations, Symposium presented at the International Society of Physical & Rehabilitation Medicine (ISPRM) World Congress and AAP Annual Meeting 2020
- Kessler Foundation Stakeholders
 - Nolan, K.J., Krch, D. (2014). Improving Balance in TBI using a Low-Cost, Customized, Virtual Reality Rehabilitation Tool. Presentation to Kessler Foundation's Scientific Advisory Board.
 - Krch, D., Nolan, K.J. (2014). Improving Balance in TBI using a Low-Cost, Customized, Virtual Reality Rehabilitation Tool. Presented to the Kessler Foundation's Board of Directors Meeting.
- General Public
 - Social media and press releases by KF's Communications Department.
 - Krch Invited to present at the 22nd Annual Government Video Expo, Washington, DC. Presenting "VR: Changing the Game in Rehabilitation".
- **Website(s) or other Internet site(s)**
 - 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).

Article published in Streaming Media Magazine [Dreier, T. (2017). *Virtual Reality, Real Medicine: Treating Brain Injuries with VR*. Streaming Media Magazine.] September.

<http://www.streamingmedia.com/Articles/Editorial/Featured-Articles/Virtual-Reality-Real-Medicine-Treating-Brain-Injuries-With-VR-120738.aspx>

Health 2.0 NYC – The New York Healthcare Innovation Group. Krch presented at Shades of Reality: Virtual, augmented & mixed reality in healthcare, May, 2017 (Link to YouTube video of presentation: <http://bit.ly/2vazNHk>)

- **Technologies or techniques**

Nothing to report.

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

Nothing to report.

- **Other Products**

- *Software:* For the purpose of this project, Island Quest (previously known as 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.

- **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

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

Kessler Foundation

<i>Name:</i>	<i>Denise Krch, PhD</i>
<i>Project Role:</i>	<i>Co-Principal Investigator</i>
<i>Researcher Identifier:</i>	<i>N/A</i>
<i>Nearest person month worked:</i>	<i>3.6</i>
<i>Contribution to Project:</i>	<i>Dr. Krch contributed to personnel hiring and training, study organization and set-up, and acted as a liaison between personnel across study sites. Dr. Krch provided guidance and oversight to treatment study software refinements. Dr. Krch facilitated training study staff on administration of the cognitive testing protocol. Dr. Krch is responsible for determining cognitive dual task difficulty level for participants.</i>
<i>Name:</i>	<i>Karen J. Nolan, PhD</i>
<i>Project Role:</i>	<i>Co-Principal Investigator</i>
<i>Researcher Identifier:</i>	<i>orcid.org/0000-0002-4667-0873</i>
<i>Nearest person month worked:</i>	<i>3.6</i>

<i>Contribution to Project:</i>	<i>Dr. Nolan contributed to personnel hiring and training, study organization and set-up, and acted as a liaison between personnel across study sites. Dr. Nolan provided guidance and oversight to treatment study software refinements. Dr. Nolan (unblinded) oversees treatment intervention sessions.</i>
<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. Ms. Chervin trained RAs and engineers on the mobility outcome measures. Ms. Chervin provides guidance for all study activities at NICOE ISO. She also manages the electronic capture system.</i>
<i>Name:</i>	<i>Rebecca Spero, BA</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. Spero assisted Ms. Chervin in administrative activities and ordering study supplies. She became proficient in administering the study balance assessments. Ms. Spero conducts screening and study balance and cognitive assessments. She is responsible for entering data into the data capture system.</i>
<i>Name:</i>	<i>Christina Cording, 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>4.5</i>
<i>Contribution to Project:</i>	<i>Christina Cording is responsible for administering all balance treatment sessions at KF.</i>
<i>Name:</i>	<i>Melvin Mejia, B.S.</i>
<i>Project Role:</i>	<i>Biomedical Engineer</i>
<i>Researcher Identifier:</i>	<i>N/A</i>
<i>Nearest person month worked:</i>	<i>4.8</i>
<i>Contribution to Project:</i>	<i>Melvin Mejia conducts balance assessments and assists the PT with treatment administration. His technological expertise is utilized in various aspects of this technology-based research study.</i>
<i>Name:</i>	<i>Sharon Gute, B.S.</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. Gute became proficient in administering the study balance assessments. She conducts screening and study balance and cognitive assessments and is responsible for entering data into the data capture system.</i>

NiCoE ISO

Name:	Melissa Guerra, MD,
Project Role:	Principal Investigator
Research Identifier:	N/A
Nearest person month worked:	0.6
Contribution to Project:	Dr. Guerra assists with personnel hiring, study organization and manages all study activities at NiCoE ISO. She also liaises with Drs. Krch and Nolan between personnel across study sites.
Name:	Caitlin Jones
Project Role:	Research Coordinator
Researcher Identifier:	N/A
Nearest person month worked:	12
Contribution to Project:	Ms. Jones manages all administrative and IRB tasks at NiCoE ISO. She administers the mobility outcome measures and as well as the cognitive outcome measures. Ms. Jones works closely with the KF RC, Kate Chervin to ensure standardization across sites.
Name:	Lara Chase
Project Role:	Physical Therapist
Research Identifier:	N/A
Nearest person month worked:	3
Contribution to Project:	Lara Chase is responsible for administrating all balance treatment sessions at NiCoE ISO.

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
 - No.
- **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 Island Quest software from a game-based exercise/rehabilitation tool to a multisensory balance treatment*
 - *Will provide software support and assistance with data extraction from the Island Quest 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*
- **SPECIAL REPORTING REQUIREMENTS.**
 - **QUAD CHARTS:** *See below in Appendices.*
- **APPENDICES:**
 - Media coverage of Island Quest study; The Journal on Active Aging, July/August 2017.
 - Quad Chart.

Bibliography of Products

Publications, conference papers, and presentations

2016 Archives of Physical Medicine and Rehabilitation Annual Conference Abstract

Research Poster 836

A Systematic Delivery for Multisensory Balance Impairment using Virtual Reality in TBI



Denise Krch, PhD , Irene Ward, Belinda Lange, Adam G. Kesten, Christina M. Cording, Lea E. Frank, Melvin Mejia, Kathleen Chervin, Sebastian König, Chien-Yen Chang, Albert Rizzo, Neil J. Jasey, Karen J. Nolan

Research Objectives: Treatment for balance dysfunction is challenging because balance impairments are complex and may involve multiple systems. The purpose of this investigation is to present a treatment delivery system that systematically addresses multisensory balance impairment using two environments: 1) Virtual reality and 2) Traditional standard of care for individuals with TBI.

Design: Development a systematic clinical intervention.

Setting: Movement Analysis Laboratory and Traumatic Brain Injury Laboratory within a Rehabilitation Research Center.

Participants: Individuals (Civilians, Veterans and Military personnel) with traumatic brain injury and impaired balance.

Interventions: Systematic multisensory balance intervention using virtual reality (Microsoft Kinect™) and traditional standard of care delivered in 12, one-hour treatment sessions.

Main Outcome Measure(s): Time to administer treatment, task progression, therapy equipment utilization, and feasibility.

Results: Two discrete balance interventions (virtual reality and traditional standard of care) were developed in parallel and adapted from clinical multisensory treatments for balance impairment. Each treatment included innovative progression in order to deliver a systematic intervention within a one hour treatment time, targeting 5 balance domains: 1) Cardiovascular; 2) Somatosensory; 3) Visual-oculomotor; 4) Vestibular; and 5) Multisensory static and dynamic balance activities.

Conclusions: Further research applying these interventions in individuals (Civilians, Veterans and Military personnel) with traumatic brain injury with various level of balance impairment is needed to determine the

potential utility of these multisensory balance treatments using a virtual reality environment as an alternative to traditional balance training.

Key Words: Rehabilitation, balance, traumatic brain injury, virtual reality

Disclosures: None disclosed.

2016 Federal Interagency Conference on TBI Symposium Abstract

TBI is a major public health issue, with 2.8 million TBIs occurring in the US in 2013 and 3.2-5.3 million people in the US currently living with long-term disabilities resulting from TBI. There are number concomitants of TBI that exert of significant impact on daily life functioning and overall quality of life. The identification of effective treatment for these post-TBI symptoms could result in substantial improvement in a person's ability to interact effectively with his / her environment. Such symptoms include cognitive deficits, difficulties with balance, emotional processing deficits, fatigue and sleep disturbance. Numerous ongoing and completed studies at Kessler Foundation seek to address these symptoms. Technological advances provide new, innovative options for treatment development in an increasingly engaging and interactive format. Several investigators at Kessler Foundation are applying virtual reality technology (VR) to the rehabilitation of post-TBI symptomatology. This symposium will discuss recent applications of such technology to both cognitive and physical deficits. Cognitive deficits are common following TBI with multiple realms of cognition impacted including attention, processing speed, executive functions and memory. Ongoing VR work at Kessler Foundation applies this technology to cognitive rehabilitation of executive dysfunction in an effort to improve executive functioning and overall daily life functioning of persons with TBI. Similar work is being conducting to address balance deficits, which will be the focus of our 2nd presentation within this symposium. Emotional processing deficits have a similar negative impact on social integration, participation and overall quality of life. A growing body of work at Kessler Foundation seeks to identify the source of this deficits via neuroimaging and is working toward the validation of effective treatment for these deficits, which will be discussed in our third presentation. Fatigue and sleep are similarly disruptive and require new treatment options. Such ongoing work, utilizing advances in neuroimaging and pharmacology, will be the focus of the 4th and 5th presentation in this symposium.

2020 International Society of Physical & Rehabilitation Medicine World Congress and AAP Annual Meeting Symposium Abstract

The proposed session will highlight novel approaches aimed at assessing and improving static and dynamic aspects of balance in neurologically impaired populations, including individuals with traumatic brain injury, spinal cord injury and cerebral palsy. We will discuss the underlying biomechanical, electrophysiological, and neurophysiological mechanisms of balance function and how a neurological impairment affects these mechanisms and the overall function. We will also present innovative rehabilitation approaches that employ technologies such as computerized biofeedback, virtual/augmented reality, and neuromodulation to improve the static and dynamic balance of neurologically impaired populations. These research findings will be supported using clinical assessments (Berg Balance Scale, Timed-Up and Go and walking speed), and novel outcomes derived from biomechanical (center of pressure, center of mass, joint angles, torque), electrophysiological (electromyograms (EMG), electroencephalograms (EEG)), neuroimaging (brain structural and functional connectivity measures), and psychophysical (perception of perturbation threshold) measures. In summary, the proposed session will highlight recent advances in the assessment of balance dysfunction and

rehabilitation approaches that use novel technologies to specifically improve static and dynamic aspects of balance in neurologically impaired populations.

Media and Press Releases

Denise Krch, and Karen Nolan, Kessler Foundation (IMAGE)

KESSLER FOUNDATION



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CAPTION

Drs. Krch and Nolan are research scientists at Kessler Foundation.

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Media Contact

Carolann Murphy
cmurphy@kesslerfoundation.org
973-324-8382

@KesslerFdn

<http://www.KesslerFoundation.org>

More on this News Release

Kessler Foundation wins DOD grant to test virtual reality in balance dysfunction after TBI
KESSLER FOUNDATION

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KEYWORDS

COLLABORATION COMPUTER SCIENCE

DISABLED PERSONS GRANTS/FUNDING

MEDICINE/HEALTH NEUROBIOLOGY

REHABILITATION/PROSTHETICS/PLASTIC SURGERY

RESEARCHERS/SCIENTISTS/AWARDS

SOFTWARE ENGINEERING

TRAUMATISM/INJURY

MULTIMEDIA

Denise Krch, and Karen Nolan, Kessler Foundation (IMAGE)

ORIGINAL SOURCE

<http://kesslerfoundation.org/media/displaynews.php?id=584>

Agenda – Shades of Reality, Health 2.0 NYC 2017

- 6:00 Meet, Tweet & Greet with healthy snacks and beverages #H2NYC
- 6:15 Welcome & Introduction
- 6:30 Presentation by Mike Marett of Confideo Labs & Josh John of Boehringer Ingelheim
- 7:00 Presentation by Dr. McAleavy of Weill Cornell
- 7:20 Introduction to Bliss by Tami Rich of L'Effet Papillon
- 7:25 Networking Break & AR/VR Demos
- 7:55 Presentation by Dr. Denise Krch of the Kessler Foundation
- 8:15 Presentation by Kevin Hallock of Pfizer Innovation Laboratory
- 8:30 Presentation by Oshamah Chandhry of MedaVis
- 8:45 Panel Discussion Moderated by Kimberley Overs, Esq.
- 9:00 Wrap Up and After Event

Tonight's Speakers



Dr. Osamah Choudhry is co-founder and CEO of **MediVis**, the mixed-reality medical company. He also works as a senior resident in neurosurgery at NYU Langone Medical Center.



Kevin Hallock, Ph.D. is Senior Manager of **Pfizer Innovation Laboratory** and is currently the Modeling and Visualization lead who manages Pfizer's visualization center.



Josh John is Associate Director of Customer Engagement Strategy at **Boehringer Ingelheim**. Josh spearheads commercialization of disruptive engagement technology tools and deployed the industry's first VRDetail.



Dr. Denise Krch, PhD, is a Research Scientist at the **Kessler Foundation**. She offers expertise in developing and evaluating VR applications that help patients recover from traumatic brain injuries.



Mike Marett is Founder & CEO of **Confideo Labs**, a digital media firm advancing technology to engage healthcare stakeholders. Mike helps pioneer immersive multimedia across the pharmaceutical industry.



Dr. Andrew McAleavy, Ph.D. is an Instructor of Psychology at **Weill Cornell**. His work focuses on technologically innovative improvements to psychological practice including treatment of trauma and pain.



Tami Rich is a patient advocate at Boston Children's Hospital and a spokesperson (aka Hype Girl) for **L'Effet Papillon's Bliss** product which is designed to help patients cope with anxiety and pain.



Kimberley Danzi Overs, Esq. is a healthcare technology lawyer who helps her clients launch products and services and leverage data. She will be moderating the panel.

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Exploring virtual environments

for cognitive and physical rehabilitation



Kessler Foundation research scientist Denise Krch, PhD, is investigating how virtual reality (VR) can help treat individuals with traumatic brain injury. The findings also have important implications for older adults, many of whom cope with similar impairments, she reveals in this exclusive interview

by Marilyn Larkin, MA

The word is out: Virtual reality is emerging as a key technology for helping older adults. In a 2017 Consumer Technology Association blog post ("Seniors: the next

frontier of virtual reality"),¹ Coordinator of Partnerships Marketing Michael Williams states, "Because seniors are the fastest-growing population segment in the United States—and this population will continue to grow significantly in the future—technology must cater to this demographic for both entertainment and healthcare."

Kiplinger's Retirement Report featured the article "Tech revolution benefits aging"² in its June 2017 issue. Author Sally Abrahms notes, "While still in its infancy, VR for seniors is gaining fans among physicians, long-term care staff,

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Kessler Foundation's Dr. Denise Krch and colleagues examine the use of virtual reality to treat balance. Photo: Joan Banks-Smith, Kessler Foundation

Exploring virtual environments for cognitive and physical rehabilitation

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Simulating 'the complexity of occupational scenarios,' the Wonderkin Wonderworks program creates cognitive tasks that train task switching and multitasking, says research scientist Dr. Denise Krch. Photo: Dr. Sebastian T. König, Katana Simulations Pty Ltd

researchers, physical therapists and family members ... For older adults with mobility issues or cabin fever, VR breaks up day-to-day monotony and loneliness, letting seniors 'travel' ... without leaving home."

As part of this "revolution," companies are beginning to offer VR programming to support the concept of aging in place. *Bett+r with Age* is a series of VR films aimed at allowing homebound older adults to revisit favorite sites that they can no longer access physically—Russell Square in London, England, and Broadway in New York, for example.

Boston-based Rendeavor is an "armchair travel system" targeted to assisted living. The VR start-up won a USD\$25,000 Massachusetts Institute of Technology (MIT) Healthcare Innovations prize, and took second place in the 2016–2017 Stanford Center on Longevity Design Challenge. The program is being tested under the supervision of MIT AgeLab Director Dr. Joseph Coughlin and Research Scientist Dr. Chaiwoo Lee.

On a related front, One Caring Team in San Carlos, California, has produced the Aloha VR program. This relaxation program seeks to improve quality of life for assisted-living residents who feel anxious or depressed, and who may be living with dementia. [Ed. Marilyn Larkin will look at VR programming in a future installment of her new "TechTalk" column for the *Journal on Active Aging* (JAA).]

The emergence of such programs does not surprise Denise Krch, PhD, a research scientist in Traumatic Brain Injury Research at Kessler Foundation in East Hanover, New Jersey. In 2013, Krch received a three-year, USD\$600,000 grant from the National Institute on Disability and Rehabilitation Research (now the National Institute on Disability, Independent Living and Rehabilitation Research, part of the United States Department of Health and Human Services' Administration for Community Living) to develop a VR-based program to treat executive-function impairments such as distractibility, poor task-persistence and difficulty multitasking.

The funding enabled Krch, who is also an assistant professor in the Department of Physical Medicine and Rehabilitation at the Rutgers New Jersey Medical School, in Newark, and a licensed psychologist in New York State, to extend the collaboration between Kessler Foundation, Katana Simulations Pty Ltd., and the University of Southern California (USC) Institute for Creative Technologies. The research team has completed the development of the VR-based program, which is now undergoing evaluation for preliminary efficacy.

Krch tells the *JAA* that although her work has focused on traumatic brain injury, "most of what we've been learning is applicable to aging populations as well—particularly those with cognitive impairment and balance issues." Such studies are needed, she says, because there is still a dearth of published research on VR therapy.

"In the rehabilitation area, we mainly have assessment programs such as the Virtual Reality Functional Capacity Assessment Tool (VRFCAT)," Krch explains. This computer-based test simulates instrumental activities of daily living in a realistic and interactive virtual environment. It is used primarily to assess functional capacity in clinical trials of schizophrenia treatments.³

VR programs aimed at actually improving function are scarce, however, according to Krch's research for a review chapter on the subject. "When it comes to treatment, there's our program, which is not commercially available yet," she states. "The Laboratory of Computational Psychology at Lufõsona University in Lisbon, Portugal, offers a portfolio of behavior modification and rehabilitation games online, but they're in Portuguese. A French product, AGATHE, was also in development as of a few years ago, but it's not clear what its status is now."

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Appendix 1.

Exploring virtual environments for cognitive and physical rehabilitation

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Moving his hand to direct his avatar's movements, a man interacts with a virtual environment being used to treat balance issues as part of a study by Kessler Foundation's Dr. Denise Krch and colleagues. Photo: Joan Banks-Smith, Kessler Foundation

Krch continues, "While we are now seeing applications being deployed for older adults, we don't yet see studies demonstrating or validating their efficacy. A number are being investigated, as ours was and will continue to be. The VR treatment field is still young," she adds, "but its potential is great."

JAA talked with Krch about her work, which includes VR programs to improve balance as well as executive function, and the promise of VR for improving activities of daily living and quality of life for older adults across settings.

ML: *I understand there are different types of VR. What are the differences, and which system is best for older adults?*

DK: There are three main categories. Most people are familiar with **immersive VR**, which is where an individual puts

on a headset and navigates through an artificial environment that convincingly replaces the real-world surroundings. Individuals can relatively easily suspend disbelief and fully engage with the created environment. Although some rehabilitation applications are being developed for head-mounted displays, those devices can cause "simulator sickness," which is essentially dizziness and nausea. We want to be careful using this technology with patient populations, who may already be dizzy or nauseated either from an injury, medications or illness, and then have the device exacerbate symptoms.

Recently, we've been exploring newer headsets, like the Oculus Rift and the HTC Vive, which have significantly improved the "lag" time in the displays that can trigger those symptoms. These may be more appropriate for patients, and we're beginning to experiment with them.

Semi-immersive VR generally involves the use of a large screen, a projection system and high-end computer graphics. This VR experience is similar to what you might see in an IMAX movie.

But most applications for rehabilitation currently are **nonimmersive VR**. That means the virtual environment is viewed on a desktop system or a tablet computer, using a standard high-resolution monitor. Users can interact with the environment using a keyboard, mouse, trackball, joystick or other interaction device—or they can sit passively as the software explores the environment for them.

Even within the nonimmersive category, we've seen that both patients and healthy controls have more dizziness and nausea when using a joystick or mouse. If the software navigates the environment for individuals, and they don't have to touch or click anything to move around in it, then it works well. Users can concentrate on their specific tasks while the environment takes care of itself.

Our experience with brain injury patients would likely be similar for older adults, so if organizations are considering purchasing VR systems or devices, I suggest they do a trial run first to see what works best for their specific populations.

ML: *Do you create your own software for your studies or use off-the-shelf products?*

DK: We create our own software. Off-the-shelf games or activities are not rehabilitation products, though certainly some organizations might use them for this purpose. We simply don't know if they're efficacious yet. We do know that they're not designed to target the "sweet spot" of appropriately raising the level of challenge without becoming frustrating for patients who might have limitations.

ML: Tell us more about your work with executive function.

DK: We know that impairments in executive functions negatively impact capacity for independent living and adversely affect quality of life. We have found that virtual environments offer a way to evaluate a person's ability to carry out tasks that depend on executive function, and potentially to improve performance.

Our three-year development study led to the completion of a virtual environment that simulates the complexity of occupational scenarios and the creation of a set of cognitive tasks that specifically train task switching and multitasking. We created and fine-tuned the program, called Wonderkin Wonderworks, during that time. This program, which has eight modules, is designed with "adaptive difficulty," meaning that if someone is really struggling, the program automatically decreases the amount of distractions that could interfere with the completion of a task. And if a person is doing well, we can make the program more difficult by adding distractions.

Each module lasts about half an hour. We start by educating the participants, explaining what we're targeting, why that task is important, and what it might look like in daily life. For example, we explain what task switching is—being able to switch from one task to another and back again. And we explain what practice means in the context of rehabilitation—that is, the more we do a task, the more the brain "wires" that connection and the stronger that connection gets, enabling us to be better able to perform a particular cognitive skill.

We also educate participants about transference, or the generalizability of what they're doing in the clinical scenario, and how that is relevant to their activities of daily living. This provides

context. It explains why they should care, and how playing the game will help them.

Then we launch into some tasks in the virtual environment, which in our software is an office setting. But it's not just a typical office. The software is video-game-like in that we have a fun storyline that involves animated animals.

We know the program needs to be game-like to be motivational. The more fun it is, the less people will perceive it as a boring, traditional, repetitive rehab task, and the harder they're probably going to try. Compliance will be better. Individuals will be more invested in completing the tasks. And we hypothesize that therefore outcomes will be better. Our pilot trial will begin to sort out whether our hypothesis is upheld.

ML: Can you give an example of the kinds of scenarios participants encounter?

DK: Sure. Participants sit at a desk in a cubicle in a virtual office environment that includes other desks in other cubicles. Their desk has a computer monitor, keyboard and mouse, a telephone and a tablet. In that setting they need to look through incoming emails to find those that contain an order placed for an animated animal. Participants also receive plenty of spam messages, so they have to pay attention to the type of email content and delete the spam. Once they find the order, they have to click on it, and then send it to a tablet on their desk. That means switching from the primary task, which is the email task, and picking up the tablet to process the order.

On the tablet, participants might see lots of animated horses and goats, cats and dogs on the screen wearing hats, flowers and scuba gear—and they're tasked with looking for and selecting only goats wearing scuba gear. There might be



The Kessler Foundation's Dr. Denise Krch investigates the use of virtual reality therapy. Photo: Christopher Wood

eight goats that aren't wearing anything scuba-related, and there are flowers and other graphical figures affixed to the animals. The user has to sift through all that and pick the relevant stimuli.

Distractions are attached to every task. In this scenario, an office coworker carrying a heavy box keeps coming by, asking if the shipment belongs to the participant. So individuals constantly have to stop the email and tablet tasks to tend to this staff person, otherwise the heavy box becomes too much and he falls.

These modules really challenge people to use and improve skills that are meaningful in real life. But they get to use those skills in an environment that's not so serious and therapy-like. Because our feasibility work showed that participants enjoyed and could navigate the program and complete the tasks, we recently embarked on a small clinical trial to gain some preliminary data on how individuals with traumatic brain injury handle these tasks compared with controls.

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Exploring virtual environments for cognitive and physical rehabilitation *Continued from page 49*

ML: *What about your balance study?*

DK: The balance study emerged from a partnership between Kessler Foundation and our collaborators at the USC Institute for Creative Technologies, under the direction of Dr. Albert "Skip" Rizzo, director for Medical Virtual Reality. Dr. Rizzo, Dr. Belinda Lange and colleagues developed VR software called Jewel Mine, which runs on Microsoft Kinect. This software was designed as an upper-body mobility treatment for people with orthopedic and neurologic problems, as well as balance issues associated with aging.

In the Jewel Mine game, the user takes on the role of a miner who has to gather jewels from a mine shaft by reaching and

touching each jewel individually. The scenario can be changed instantly to, for example, a meadow in which the user has to reach out and gather flowers; or to a library, where he or she has to reach for books. As with Wonderkin Wonderworks, the level of challenge can be tailored to the individual's level of ability and progress.

Several years ago, we deployed Jewel Mine with our clinical population at the Kessler Institute for Rehabilitation in New Jersey. We had a mixed sample from the neurorehabilitation unit—patients with strokes and brain tumors as well as traumatic brain injury. They were all ages, from 20 to 98, and everyone used the software. We didn't collect outcomes data at that point, but the

feedback was very positive and participants felt it was challenging and fun.

Building on that experience, we refined the Jewel Mine software to be a balance-specific treatment, now called Island Quest. Island Quest also uses Microsoft Kinect technology—in other words, it uses infrared light to project the person's avatar onto the screen. The game takes place on an island. As users explore the island, they have to do different things, such as reaching for virtual fruit off a tree while performing sit-to-stand and other traditional rehab exercises.

We have a multisite clinical trial underway to look at whether our gamified treatment will be more efficacious than the standard-of-care treatment. This study, funded by the US Department of Defense, is being carried out in civilian, veteran and active duty military populations at Kessler Foundation and Fort Belvoir Community Hospital National Intrepid Center of Excellence Intrepid Spirit One in Virginia. A second treatment arm in the study involves participants doing all the reaching and other physical exercises on the island while simultaneously being challenged with cognitive tasks. For example, in cone tipping, participants must calculate the sum of two numbers in order to determine how many times to tap the cone with their foot. Our hypothesis is that if you challenge your system overall, brain and body, your balance will improve because you're forced to do more in a given moment. We've also started experimenting with the feasibility of running Island Quest in a Vive head-mounted display.

ML: *What about the fear factor? Are participants or therapists reluctant to participate in the studies because they feel uncomfortable with the technology?*

DK: The setup for both the cognitive and balance software is simple. For the cognitive software, you click the program on, you choose the session and you

VR as a therapeutic tool

Kessler Foundation research scientist Denise Krch, PhD, presented at an event, "Shades of Reality: Augmented, Virtual and Mixed Realities in Healthcare," on May 31, 2017, in New York City. In addition to talking about her own research, Krch highlighted the advantages and limitations of VR as an intervention for individuals with a range of cognitive and physical challenges.

Advantages of VR

- Potential to simulate real-life situations
- Enhanced ecological validity—that is, skills gained during VR game play are generalizable to real-life settings
- Ability to control stimuli consistently, providing opportunities for repetition/practice for a specific sensory mode
- Ability to provide real-time feedback to participants, and exact replays of behavior

- Program can be tailored to level of impairment (complexity)
- Safe environment
- Enhanced motivation with fun interface

Limitations of VR

- Cost
- Clinician needs knowledge of the technology
- Novel, emerging approach, so few established protocols/best practices
- Complexity in data extraction and interpretation
- Potential side effects

Krch's presentation, along with those of the other speakers, is available on YouTube at <http://bit.ly/2vazNHk> (Krch's talk begins about an hour into the video).

click run. Yes, there's a lot of high-tech stuff that happens in the background, so the more savvy person can, for example, send a large amount of data to a printer that can then be looked at and analyzed. But, for the most part, it's a very simple user interface—just like going into an email program.

The balance software is only slightly more complicated because you can change a task's level of difficulty on the fly using a toggle button on the treatment screen. Other than that, the software is similar to the cognitive program: You see a main menu, you pick your desired module and you pick the task you want. Trained physical therapists do this every day, so there's nothing confusing about it. As noted earlier, we've seen patients of all ages and ability levels enjoy the games and navigate them, albeit with varying degrees of difficulty.

Overall, I think that something positioned as a game is less likely to provoke fear than something more "serious." Though again, all of what we do is really accessible.

ML: *What do you envision for VR with rehab going forward?*

DK: The field is wide open. VR is a hot area of study and development globally, although the treatment field, in particular, is still young. But again, the potential is so great.

For example, within my domain as a neuropsychologist, there's really little out there to rehabilitate such complex executive functions as organizing and planning. Those functions can't easily be broken down into simple enough tasks to deliver by paper and pencil; the tasks simply won't mimic real world. The only way to really help rehabilitate these functions, which are used in all kinds of daily activities, is to expose individuals to similar situations. And there are only two ways to do that: Take them out into

the real world, which is not always feasible or cost- or time-effective—or use a virtual environment.

We can mimic any environment virtually in the safety of a clinic, or an outpatient or inpatient facility, and have complete control over the amount of stimulation someone receives. So we're able to target cognitive areas that we previously could not, and we can tailor the treatment to the individual.

I envision that this capability will only get stronger over time. With the right equipment and validated programs, VR therapy will make a difference in people's lives—and not only in cognition and balance, but in a whole array of domains that can be modified through practice. 

Marilynn Larkin, MA, is an award-winning medical writer and editor, an ACE-certified personal trainer and group fitness instructor, and a contributing editor and technology columnist for the Journal on Active Aging.*

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2. Abrahms, S. (2017). Tech revolution benefits the aging. *Kiplinger Retirement Reports*, June 2017 issue. Retrieved on August 24, 2017, from <http://bit.ly/2xg4N6j>.
3. Ruse, S. A., Harvey, P. D., Davis, V. G., et al. (2014). Virtual reality functional capacity assessment in schizophrenia: Preliminary data regarding feasibility and correlations with cognitive and functional capacity performance. *Schizophrenia Research: Cognition*, 1(1), e21–e26; doi: 10.1016/j.scog.2014.01.004.

Resources

Internet

Bett>r with Age
<http://bettvrwithage.com>

COPELABS, University of Lusófona: Systemic Lisbon Battery
<http://bit.ly/2g8HUgQ>

Kessler Foundation
<https://kesslerfoundation.org>

One Caring Team: Aloha VR
<https://onecaringteam.com>

Rendever
<http://rendever.com>

University of Southern California (USC) Institute for Creative Technologies: Jewel Mine
<http://ict.usc.edu/prototypes/jewel-mine>

USC Institute for Creative Technologies: Medical VR
<http://medvr.ict.usc.edu>

Multimedia

"AGATHE: a tool for personalized rehabilitation of cognitive functions"
<http://bit.ly/2wJT6Hl>

"Bett>r with Age"
<https://vimeo.com/215876073>

Virtual Healthcare 2017: "Shades of Reality: Augmented, Virtual and Mixed Realities in Healthcare"
<http://bit.ly/2vazNHk>

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 Island Quest (IQ) 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) IQ; 3) IQ + dual task (balance and cognitive).



Service member using Island Quest, 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	15/16	16/17	17-20
IRB submittal and study prep					
Study staff training					
Recruitment and Data collection					
Data analysis					
Estimated Budget (\$K)		\$647k	\$804k	\$796k	\$741k

Updated: August 27, 2020

Goals/Milestones

CY14 Goal – Study preparation

- ☒ IRB submittal
- ☒ Preparation of study materials
- ☒ Clinician Training with Island Quest system

CY15 Goal – Study preparation and staff training

- ☒ Refine software to be aligned with initial treatment conceptualization
- ☒ HRPO submittal; Initiate participant recruitment
- ☒ Training study staff in testing and intervention procedures

ICY 2016-2020 Goals – Data collection

- ☒ Recruit and enroll participants from KF/KIR and NICoE ISO
- ☒ Apply for EWO

☐ Data analysis and Dissemination

Comments/Challenges/Issues/Concerns

- Phases 1 and 2 of the Project completed.