

Immersive Virtual Reality to  
Improve Outcomes in Patients with  
Stroke: A Pilot Study

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## Specific Aims

Over the last decade, virtual reality (VR) has emerged as a cutting-edge technology in stroke rehabilitation. VR is defined as a type of user-computer interface that implements real-time simulation of an activity or environment allowing user interaction via multiple sensory modalities. VR interventions in a stroke population have been shown to be equivalent to usual care therapies and to enhance motor, cognitive, and psychological recovery when utilized as an adjunct. The proposed feasibility pilot project will address the RR&D goal of maximizing functional recovery by pilot testing an immersive VR intervention designed to increase exercise dosage for the upper limb and decrease pain for inpatient Veterans post stroke without increasing therapist time [1]. **The VR intervention will use a head mounted display, more commonly known as goggles, to which selected APPs can be uploaded. APPs and goggles are commercially available and have been selected based on the following criteria: (1) address the treatment goals of overall upper extremity neurologic recovery, hand dexterity, and pain reduction, (2) utilized while patient lying in bed, (3) provide no stimulation to move legs or reach outside of bed area, (4) simple to use (require no technological expertise), (5) involve graded head, neck, upper extremity movement and distraction to reduce pain, and (6) cognitive burden ranges from minimal to moderate. The VR intervention will be administered bedside for two 30-minute therapy sessions per day for four weeks. Our long-term goal is to provide Veterans with an exercise and pain reduction modality that can serve as an adjunct to scheduled therapy and assist with the clinic to home transition. Our short-term goal is to determine the feasibility of conducting a randomized controlled trial to determine the effectiveness of using VR as an adjunct to usual care therapy to enhance upper extremity neurologic recovery and hand dexterity and to decrease pain.** Our proposal is innovative in four distinct ways. First, we will use immersive 3-dimensional rather than the more typically used 2-dimensional VR. Immersion and the resulting 'presence' within the virtual environment are thought to be the principal mechanisms of positive change [2]. **Second, we will assess pain reduction after stroke using VR APPs, which is not well represented in the literature.** Third, we are using VR as an adjunct therapy - adding additional therapy time with less burden on clinicians than is required in traditional therapy. Finally, VR, when used in patients' rooms, presents an opportunity similar to home-based practice exercises. Our targeted enrollment is 10 clinical staff (Research Question (RQ) 1.1) and 10 inpatient Veterans being treated for stroke (Aim 2).

### Specific Aim 1: Determine the feasibility and tolerability of using a therapeutic VR platform in an inpatient comprehensive stroke rehabilitation program.

RQ 1.1: What is the feasibility of using the VR platform from the clinician perspective?

RQ 1.2: What is the tolerability for inpatients post-stroke using the VR platform?

### Specific Aim 2: Estimate the initial clinical efficacy, or effect size, associated with the VR platform using APPS for distraction and upper extremity exercise for Veterans post-stroke.

RQ 2.1: What are the estimated effect sizes and degree of precision for the outcomes of **upper extremity neurologic recovery, hand dexterity, and pain?**

RQ 2.2: **How clinically responsive are dexterity and upper extremity neurologic recovery (primary) outcomes to early stroke rehabilitation using a therapeutic VR platform?**

**Impact.** Veterans and clinicians will gain experience using a portable VR platform that increases access to care by making additional therapeutic activities available outside of usual scheduled therapy time. This unique experience offers the potential for seamless transition from inpatient rehabilitation to the home. Moreover, policy makers can observe firsthand the potential benefits and limitations of using therapeutic VR in comprehensive stroke care. The results of this study will inform a subsequent larger trial, which will focus on the effectiveness of immersive VR for patients in both the subacute and chronic stages post-stroke and will begin inpatient and continue post discharge into the patient's home.



Figure 1 VR intervention

## Research Plan

### Background and Significance

Over the last decade, virtual reality (VR) has emerged as a cutting-edge technology in stroke rehabilitation. VR is defined as a type of user-computer interface that implements real-time simulation of an activity or environment allowing user interaction via multiple sensory modalities [3]. VR interventions can be characterized as immersive or non-immersive. Immersion refers to the sensation of being inside a particular environment or world, for example, a three-dimensional world [4]. Non-immersive VR typically uses commercial video game systems developed by the entertainment industry for home use, although some researchers have developed rehabilitation specific non-immersive VR applications [5-7]. Non-immersive VR uses 2D interfaces such as Nintendo Wii, Microsoft Xbox, and Sony PlayStation [8-10]. Immersive VR uses a 3D virtual environment with the intention of making the user feel a part of, inside, or immersed in the environment to the extent that they become unaware of their physical surroundings [4]. Immersive VR experiences typically involve the use of a Head Mounted Display (HMD) which creates a three-dimensional image in all fields of view. We will use the most current VR technology, which at this time is a wireless immersive HMD application with hand controllers such as the Oculus Quest.

**Upper Limb VR Research.** Upper limb deficits occur in up to 85% of stroke survivors and significantly affect performance of activities of daily living (ADLs) [11]. The literature on the use of VR in stroke rehabilitation is fairly extensive, but is characterized by small, lesser quality studies with widely varying definitions of what constitutes a VR intervention. The stroke VR literature base has been criticized for lack of a control group, making it difficult to discern if positive effects were the result of the VR intervention itself or simply the result of extra therapy time, for example, when VR is used as an adjunct [12]. Studies on the use of VR for post-stroke upper limb dysfunction have shown mixed results [4-10, 13-17]. A Cochrane Review published in 2017 [18] concluded that overall effects of VR on upper extremity function were not significantly different when compared with conventional therapy (including both specialized VR systems designed for rehabilitation or commercial gaming consoles). However, when VR was utilized as an adjunct to standard care compared with no additional intervention (increased overall therapy time), the VR group experienced statistically significant benefits in upper limb function (Standardized Mean Difference (SMD) = 0.49, 95% confidence interval (CI) 0.21 to 0.77). The overall quality of the trials included for upper limb function outcomes was low. The Cochrane Review also found a small, yet statistically significant effect of VR on ADLs (SMD = 0.25, CI 0.06-0.43). Because of the heterogeneity in outcomes used in studies investigating the effect of VR on upper limb function post-stroke, two systematic reviews and meta-analyses (SR/MA) [3, 19] grouped outcomes by the International Classification of Function domains. For studies that used a virtual world environment approach to VR, medium effect sizes (ES) were found: Body Structure/Function ES = 0.43 [3] to 0.54 [19], Activity ES = 0.54 [3] to 0.62 [19], and Participation ES = 0.38 [19] to 0.56 [3]. Gains post intervention were preserved at follow up [19]. A limitation of both SR/MAs was the variability in how VR was delivered in terms of intensity and duration [3, 19] and lack of clarity regarding control group therapy.

Three recent randomized controlled trials (RCTs) [12, 20, 21] of non-immersive VR interventions (using 2D interfaces) that included control groups dose matched for therapy time found mixed results. A single-center study [21] that compared 10 sessions of a self-administered upper extremity rehabilitation program including four game applications on a smart phone and tablet with control therapy of one hour of conventional OT per day found a significant difference on the Fugl-Meyer Assessment-Upper Extremity (FMA-UE) at one-month follow-up in favor of the intervention group. In contrast, neither the EVREST trial [12] that compared 10 sessions of commercial gaming with control recreational activities or the VIRTUES multi-center trial [20] that compared 16 sessions of VR designed for rehabilitation with conventional therapy found significant differences. The authors of the EVREST study did, however, speculate that utilizing an immersive VR system might have led to significant results. As VR becomes more immersive, more interactive, and less expensive, and because of its flexibility, studies of the use of VR in the inpatient environment [22] suggest that VR is efficacious, easy to use, safe, and contributes to high patient satisfaction.

**VR and Pain.** A recent multi-site study ( $N = 546$ ) found a 30% prevalence of pain across the acute, subacute, and chronic post-stroke stages [23]. Cognitive factors (e.g., attention) are important to pain perceptions, even when people are not engaged in specific tasks [24]. Theory suggests that VR directly or indirectly affects cognitive and attentional processes to attenuate pain. VR can be a distraction

mechanism that consumes cognitive and attentional resources to limit pain processing capabilities [25]. A randomized crossover study found a 56% reduction in time thinking about pain when using VR versus self-selected distraction (e.g., meditation, smartphone;  $p < .001$ ) [26]. VR may also create neurobiological interactions in the brain by regulating sensory stimulation to produce an analgesic effect [27]. Sense of immersion and presence are important to distraction and analgesia because distraction therapy is the most commonly used intervention in VR pain research [28]. A rapid evidence assessment of VR (20 studies,  $N = 337$ ) found strong evidence for short-term reduction in pain intensity and moderate evidence for pain analgesia [29]. A meta-analysis (14 studies,  $N = 581$ ) estimated a large standardized effect (0.90, 95% CI = .72 to 1.08) for VR pain distraction studies using between-group and mixed-model designs [30]. Thus, integration of VR during rehabilitation may have promising implications for post-stroke pain.

**Neuroplasticity.** Decades of animal research and recent research in human subjects provides compelling evidence that the adult brain affected by stroke can reorganize itself in response to experience and training, with sufficient repetition playing a critical role [31-35]. In patients with subacute stroke, gains in the upper limb and hand dexterity (strength, ROM, speed of movement) require more intensive repetitive task practice than gains in lower limb and mobility [1, 36, 37]. In addition, task motivation is essential for learning [31-35]. Immersive VR exposure is hypothesized to deliver the crucial impetus to drive lasting neural changes by providing a motivating environment for post-stroke patients to retrain movement, ROM, movement speed, fractionation (use of individual fingers), and force production [38]. In the proposed study, immersive VR will be utilized as adjunct therapy, allowing patients to increase their therapy dose and thereby engage in the repetition essential for motor learning.

**Immersive VR.** Non-immersive VR environments are projected on 2D screens (e.g., laptop). Non-immersive VR can facilitate stroke symptom improvement [12, 20, 21], but it is lower on the immersion spectrum and less efficacious than immersive 3D VR [28, 39]. Immersion and presence are theoretical mechanisms of change which may facilitate greater learning within virtual environments [25, 40]. Immersive VR interventions may be cost-effective and less resource intensive than many traditional interventions with comparable efficacy [41].

**Significance.** According to the VA Informatics and Computing Infrastructure, in Fiscal Year (FY) 2018 there were more than 10,000 unique Veteran inpatient admissions for stroke. The proposed study is an innovative treatment paradigm utilizing sophisticated immersive VR technology available at the bedside to increase therapy dosage. This cutting-edge technology has the potential to not only drive neurologic recovery by augmenting the brain's own intrinsic repair capacity in response to a stroke insult (neuroplasticity), but also improve Veterans' quality of life by diminishing pain and enhancing self-efficacy. Immersive VR could ultimately become a new standard of care in acute inpatient rehabilitation, allowing unlimited rehabilitation experiences for patients with stroke. In addition, there is strong potential for seamless transition to home, as immersive VR technology rapidly becomes more sophisticated and less costly. Finally, the proposed research supports modernization of the Veterans' Health Administration by incorporating technology-assisted rehabilitation, addresses the RR&D goal of maximizing functional recovery, and focuses on VA Office of Research and Development priorities including access to care, mental health, health care value, and pain.

## Preliminary Studies

**Virtual Reality Pilot for Fear of Movement for Veterans with Chronic Pain.** In a pilot study [42, 43] in the James A. Haley Veterans' Hospital (JAHVH) inpatient Chronic Pain Rehabilitation Program, Dr. Winkler and Fellow, Dr. Chris Fowler, found evidence for the feasibility of VR within the chronic pain population as well as a decrease in fear of movement, pain interference with mobility, pain intensity, and pain catastrophizing. Veteran attendance (91%) and completion of attended 20-minute VR sessions was high (97%). Veterans typically rated 20-minute VR sessions as 'too short'.

## Research Design and Methods

**Design.** Our methodological framework is based on the work by Virtual Reality Clinical Outcomes Research Experts (VR-CORE) committee [39]; we will use their VR2 clinical study design: conducting early prospective testing with a focus on feasibility and tolerability (**Aim 1**), and initial efficacy (**Aim 2**). Per VR-CORE guidelines, we will use a single group so that we may optimize recruitment to represent the breadth and depth of our target patients.

**Population.** There are two populations for the proposed project. The first is Veterans ( $N=10$ ) who have been diagnosed with an acute ischemic or hemorrhagic stroke and post-stroke are admitted to JAHVH inpatient rehabilitation. Inclusion criteria are: (1) Age 18-80, (2) Stroke diagnosis verified by brain imaging. Exclusion criteria are: (1) Unable to follow instructions or participate in immersive VR therapy due to significant cognitive impairment, (2) History of seizures. The second population includes the occupational therapists (OT) and the rehabilitation nurses (clinician champions) working in the Comprehensive Interdisciplinary Inpatient Rehabilitation Program, who will provide data on the feasibility of using VR in an inpatient environment (**Research Question (RQ) 1.1**).

**Recruitment.** All patients admitted to the Comprehensive Interdisciplinary Inpatient Rehabilitation Program at JAHVH (a designated Primary Stroke Center) with a diagnosis of acute ischemic or hemorrhagic stroke will be considered for inclusion in the study. A minimum of five beds will be designated for study participants. The Comprehensive Interdisciplinary Inpatient Rehabilitation Program admits 3.5 stroke patients per month, 42 per year. We feel this is a sufficient subject pool from which to enroll the target sample size of **10** patients (**16%** of the patients admitted over the 18-month enrollment period). We have found that the technology is motivating to patients which will help retention.

#### Procedure and Data Collection.

**VR Intervention.** The VR intervention uses off the shelf technology: Oculus Quest Head Mounted Display and commercially available APPs specifically developed or adapted for Oculus Quest. APP selection for individual patients will be guided by motor difficulty of the APPs. See Table 1. For example, patients will begin with the green coded APPs, the easiest activity level in the toolkit. These APPs primarily address pain via distraction with minimal head and neck movement, but no hand movement, required. As tolerated, patients will advance to more difficult APPs which require hand and finger movement, with the high-level APPs requiring controlled movement.

Table 1 APPs in VR Toolkit for the Oculus Quest					Hand Controller Use				
Outcome			APP Name	Source	Description		None	Min	Mod
R	D	P							
			Ocean Rift	Oculus	Distraction (nature, music)		X		
			Within	With.in	Distraction (cinematic vr)		X		
			Nature Treks	Sidequestvr	Distraction (nature)			X*	
			National Geographic Explore	Oculus	Distraction (nature)				X*
			Mr. Scribbles	Oculus	Hand, finger movement		X		
			Virtual Piano	Sidequestvr	Play piano by moving hands up and down		X		
			Cubism	Sidequestvr	Grab shapes with hand and put in container		X		
			VR Fishing	Oculus	Holding fishing rod, coordination				X

R=neurologic recovery, D=hand dexterity, P=pain

Level of difficulty: Green=passive, minimal movement, Blue=moderate movement, Pink=controlled movement

\* hand controller used to select view, intact extremity can be used

**APPs are commercially available and have been selected based on the following criteria:** (1) address the treatment goals of overall upper extremity neurologic recovery, hand dexterity, and pain reduction, (2) can be utilized while patient lying in bed, (3) provide no stimulation to move legs or reach outside of bed area, (4) are simple to use (require no technological expertise), (5) involve graded head, neck, upper extremity movement and distraction to reduce pain, (6) cognitive burden ranges from minimal to moderate. Because hand tracking APP technology is developing/improving at a rapid pace, upon notice of funding, it is likely that we will need to update the VR Toolkit (**Appendix 4**).

**Prior to beginning the intervention, clinician champions (OT and nursing) and project manager OT Delikat will be instructed in the use of the head mounted display and VR APPs by technology expert Kaplan. Staff will have the opportunity to practice with the**

## **head mounted display and APPs for two weeks prior to using the APPs with patients.**

Following IRB approval and funding on site, potential subjects will be identified by the admitting physician, PI Tran, and/or the project manager in Dr. Tran's absence. The project manager will use a HIPAA waiver to check inclusion and exclusion criteria.

**Week 1 Baseline and Pre-intervention Data Collection.** Once patients are enrolled, the project manager (an OT) will collect baseline data and administer the pre-intervention outcome measures. See **Table 2**. Also, PI/physician Tran, OTs Co-I Winkler and project manager Delikat, and technology expert Co-I Kaplan will select APPs from the VR Toolkit (Appendix 4) that best address the individual patient's treatment goals, based on his/her current functional level.

**Weeks 2-4 VR Intervention.** Patients will be instructed in the use of the head mounted display with VR APPs by project manager OT Delikat. It is anticipated that subjects may need 1-3 sessions of instruction. VR dosage will be two one-half hour sessions per therapy day, facilitated by OT project manager Delikat and clinician champions, overseen by PI Tran. The timing of VR sessions will vary based on the patient's therapy schedule. During the VR session, the patient will be reclining or seated in bed with both bed rails raised. The clinician champion will bring the VR Headset to the bedside and assist the patient with donning the device. Once the patient is comfortable using the head mounted display with VR APPs, the clinician champion will begin each session by setting the patient up and making sure that they are successfully engaging with the APP. The clinician champion will return 30 minutes later to remove the VR head mounted display from the room. This process will be repeated a second time each therapy day. Patients can initiate use of a more challenging APP (blue category) that gradually includes hand/arm movement. Some patients may progress to the pink category in which hand/arm coordination is required.

**Week 4 Post-Intervention Data Collection.** The average length of stay on the acute inpatient rehabilitation unit at JAHVH is 4-6 weeks. Accordingly, post-intervention data will be collected in week 5 or at the end of week 4 if the Veteran is being discharged. **RQ 1.2** tolerability data will be collected throughout the subjects' participation in the study.

**End of Data Collection.** Once all Veterans have completed the study, **RQ 1.1** feasibility data will be collected from clinician champions.

### **Outcomes**

**Aim 1.** Feasibility is the degree to which the VR treatment can be successfully integrated within the flow of usual care [15]. Feasibility will be measured with a six item survey (**Appendix 5**), based on the Consolidated Implementation Framework [44], that will be administered to 10 clinical staff using REDCap®. Tolerability refers to the prevalence of patient-reported physical (e.g., vertigo, nausea = "cybersickness") and emotional (e.g., fear and anxiety) adverse effects of the VR treatment, along with any discomfort or inconvenience related to the VR equipment (e.g., ill-fitting headset, facial discomfort, inability to explore the three-dimensional environment fully due to limited mobility, etc.) [2, 39]. Tolerability data (complaints and adverse events frequencies) will be extracted from detailed meeting minutes where such events are reported and discussed.

**Aim 2.** See **Table 2**.

**Table 2** Aim 2 Outcome variables and covariates

Variable	Definition	Source
<b>Outcomes</b>		
Hand dexterity Appendix 6	Action Research Arm Test (MCID*: chronic=5.7, acute=12) [45, 46] <b>Primary</b>	Clinical assessment and Self-report
Neurologic recovery Appendix 7	Fugl-Meyer Assessment of Motor Recovery after Stroke-UE MCID*=4-7 [47] <b>Primary</b>	
Pain Appendices 8 and 9	Pain Outcomes Questionnaire-VA, Initial, item 12 and Discharge, item 2 (Pain Numeric Rating Scale) (ES*= 0.85, medium effect, SEM*=0.79) [48] <b>Secondary</b>	
<b>Demographic and Clinical</b>		
Age	Age on date of baseline data collection	CPRS
Sex	Male, female	
Race/ethnicity	Caucasian, African American, Hispanic, other	
Time since index stroke	In days: index event - baseline data collection	
Type stroke	Ischemic =0, hemorrhagic =1	

\* MCID=Minimal Clinically Important Difference, ES=Effect Size, SEM=Standard Error of Measurement, CPRS=Computerized Patient Record System

**Analyses.** With the proposed pilot study design, the overall analytic goals are to: (1) determine the feasibility and tolerability of using a therapeutic VR platform in an inpatient comprehensive stroke rehabilitation program and to (2) estimate, with reasonable precision, the effect sizes of **upper extremity neurologic recovery, hand dexterity, and pain reduction outcomes**.

**Aim 1.** Qualitative descriptive analyses [49] will be used to address **RQ 1.1** (feasibility) and **RQ 1.2** (tolerability). For **RQ 1.1**, responses will be downloaded from REDCap®. The six survey items address three feasibility constructs: adaptability, patient need, and staff comments. Responses for each construct will be pasted into an excel spreadsheet, one tab for each construct. Responses will then be grouped by similar content. Results will be reported as themes and subthemes. Similarly, for **RQ 1.2**, patient concerns, complaints, and adverse events associated with use of the VR platform will be abstracted from the research team meeting notes and will be tabulated. Responses will then be grouped by similar content. Results will be reported as themes and subthemes. Note that all adverse events will be immediately reported per VA and IRB policy. The analyses described here are for dissemination purposes.

**Aim 2.** For **RQ 2.1**, the primary outcomes will consist of pre- to post-intervention changes on two physical measures of stroke recovery: the Action Research Arm Test (ARAT) [45] (Appendix 6) and the Fugl-Meyer Assessment of Motor Recovery after Stroke-Upper Extremity [47] (Appendix 7). Both of these measures are scored on a continuous scale, as is the outcome of pain, as listed in **Table 2**. Therefore, the initial step will be to examine distributions of each outcome measure, including distribution of change scores from pre- to post-intervention. To estimate effect sizes over 4 weeks with the use of the VR platform, standardized effect sizes and 95% confidence intervals will be calculated using the within-group pre-test/post-test design described by Morris and DeShon (2002) [50] and Kadel and Kip (2012) [51]. Recognizing the pilot study design, yet concern over potential type I error due to multiple outcomes evaluated, the confidence intervals for the two co-equal primary outcomes will be evaluated with a type I error rate of 0.025 (i.e. to determine if the confidence interval for the outcome difference scores includes the null effect size value of 0); secondary outcome will be evaluated with a type I error rate of 0.01. The above confidence interval approach parallels use of the paired *t*-test to determine statistical significance. For **RQ 2.1**, since the effect sizes to be calculated are standardized measures, corresponding results across these outcomes will be directly comparable. However, these metrics do not necessarily translate to meaningful clinical differences (improvements). Therefore, for those outcome measures with published metrics for minimal clinically important difference (MCID) [52], results of the VR platform will be compared across outcomes. As listed in **Table 2**, the measures of dexterity and neurologic recovery have published references for MCID, whereas we are unaware of a published MCID for the Pain Outcomes Questionnaire VA (POQ-VA). Therefore, for the POQ-VA, we will first determine the change (pre versus post scores) in

standard deviation units (from the baseline value) that denotes MCID for the measures of dexterity and neurologic recovery. We will then average these two calculations of standard deviation units to estimate the magnitude of change in pre-to-post scores on the POQ that may approximate MCID on this measure. Thus, in addition to comparison of standardized effect sizes across the three outcomes measures, all three measures will be compared in terms of proportion of subjects who experience MCID.

**Potential Limitations and Strategies.** As this pilot study will employ a within-subject design to evaluate magnitude of stroke rehabilitation over 3 weeks with the use of VR technology, there will be no control condition to judge rehabilitation results to that which might be expected from time alone and natural history of stroke recovery. Therefore, as described for **RQ 2.1**, we will place a premium on evaluating rehabilitation results using MCID, which are highly relevant to patients and generally would not be expected to be achieved simply from time alone (4 weeks).

**Project Management Plan. Personnel.** **Dr. Tran** will lead the administrative and scientific aspects of the project and will be responsible for recruitment and collection of medical data. **Dr. Kip** will oversee data management, analysis, and assist with interpretation of data. **Project Manager Delikat**, an Occupational Therapist (OT), will obtain informed consent, perform pre and post data collection, **instruct study subjects in use of VR technology**, and enter data into the study dataset. **Mr. Kaplan and PI Tran** will perform initial technical assessment, instruct clinicians in use of VR technology, and update APPs weekly to meet individual patient needs. **Dr. Winkler** will serve as a Research Mentor and can provide OT expertise. **Joel Scholten, MD** will serve as our Program Partner from the Physical Medicine and Rehabilitation Office.

**PI Tran will meet with research mentor Winkler and Project Manager Delikat (Occupational Therapist [OT]) daily initially and then twice weekly to monitor participant clinical progress, APP intervention progression, and data collection. Technology expert Kaplan will be onsite weekly to check equipment and update APPs. Mr. Kaplan will be available as needed between weekly visits. While the primary strategy for team coordination will be twice-monthly research team VA Skype meetings led by PI Tran, problems will be addressed immediately by the team via Skype meeting.** Scheduled twice-monthly research team meetings will bring clinical and research team members together to review and interpret deidentified findings, discuss and resolve expected and unexpected issues that may arise, and to reinforce the project timelines.

**Data Management.** **Dr. Kip** will create a dataset during the first month of the study using Excel software as Excel is easily imported into SAS for analysis. We have chosen to use Excel on our local research server rather than VA Informatics and Computing Infrastructure (VINCI) because this is a prospective cohort of new admissions and a relatively small sample. Data will be collected and entered into the database by **Project Manager Delikat**. Data entry will be verified by **PI Tran**. Data will be stored on the secure JAHVH Research Service R-drive.

**Dissemination.** Dissemination will be led by **Dr. Tran (PI)**. Channels for dissemination include: (1) annual progress and final summary reports to VA RR&D service; (2) bulleted briefings to our Program Partner; (3) presenting findings at national and local research meetings/conferences and VA Cyberseminars and Military Health System Speaker series; and (4) submitting manuscripts to relevant peer-reviewed journals.

**Timeline.** See **Table 3** for timeline.

Task	Person(s) Responsible	Year 1				Year 2			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
IRB, R&D	T, PM								
Train staff	T, PM, K2								
Enroll subjects	T, PM								
Train patients	PM								
Data Collection/Intervention	T, PM								
Analyze Data	K1								
Disseminate findings	T, W, RT								

T=Dr. Tran, W=Dr. Winkler, K1=Dr. Kip, K2=Mr. Kaplan, PM=Project Manager, RT=Research Team