ACADEMY OF SPINAL CORD INJURY PROFESSIONALS

Digital Avatars for Psychosocial and Integrative Health Support of Veterans with Spinal Cord Injury

Marinella Galea, MD [1,2,3] ; April Jones, RN, CRRN, MSN-Ed[1], Johane Simelane, MPH[1]; Vincent Galea, PhD[3]; Victor Wang, MS[4]
[1]The James J Peters VAMC, Bronx, NY; [2] The Icahn School of Medicine at Mount Sinai, New York, NY; [3] New York Medical College, Valhalla, NY, Department of Medicine; [4]care.coach corporation

Background

The Spinal Cord Injury Disease Management Protocol (SCI DMP) was developed by the Veterans Health Administration (VHA/VA) to address the unique needs of individuals living with SCI. It has proven effective in decreasing the severity of comorbidities and improving health-related quality of life (HRQoL). However, there were practical limitations to its wide-spread adoption: patients' engagement was low as a result of the tedious and repetitive nature of the content items (mean enrollment duration was only 116 days) and individuals with hand impairments secondary to SCI had difficulties completing the extensive questionnaire daily. To resolve these issues and facilitate the effective administration of the SCI DMP, our team partnered with a health technology company (care.coach) to apply a relational agent "avatar," a technological artifact capable of building social relationships with patients by conversing verbally with them day-to-day. This poster will present the preparatory work and methods for a future clinical trial.

Objectives

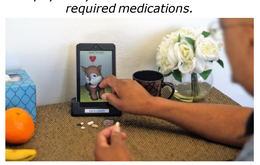
1. The primary aim of this study is to assess whether this avatar-enabled, comprehensive SCI intervention improves quality of life, as measured by the SCI-QOL, a patient-reported outcome measure (PROM) that quantifies physical-medical health, emotional health, social participation, and physical functioning, when compared to the standard of care.
2. The secondary aim is to assess whether the avatar improves mental health in patients with SCI by comparing the mental health PROM scores of patients treated with a version of the avatar including the SCI DMP, with a socialization-only version of the avatar, and with the standard of care.
3. The tertiary aim is to assess whether the avatar-administered SCI DMP yields a reduced incidence of emergency department visits, urinary tract infections and pressure ulcers, and improved self-management of common co-morbid conditions

Preparatory Work

As part of Department of Defense award W81XWH-18-1-0634, our team developed a complete research plan, laid the administrative and funding groundwork to execute the plan, and adapted and improved upon the necessary components of the VA's SCI, diabetes, hypertension, and depression DMPs. We integrated into our proposed avatar-enabled platform the DMPs, alongside adaptations of common musculoskeletal health, rehabilitation, and integrative medicine-based interventions

Above: a patient has difficulty engaging with the SCI DMP as originally delivered by a data messaging device.

Below: a patient engages verbally and physically with an avatar to take required medications.



Adaptive Design

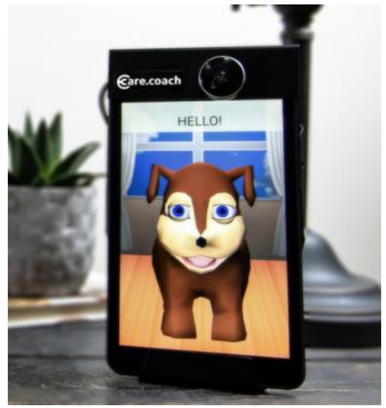
If a significant difference in the outcomes is observed at the 6-, 12-, or 18-month visits, for example if we observe that the protocol-enabled avatar intervention significantly increases SCI-QoL over usual care, we will adaptively drop from the study any group that significantly underperforms, by escalating those study participants to a hypothetically more effective intervention. For example, usual care patients may receive a socialization-only avatar, and socialization-only avatars may be remotely upgraded to start delivering health-related protocols.

Thus, we aim to (1) deliver the most benefit to as many veterans as possible, (2) gain scientific knowledge of the effects across all three groups and distinguish the impact of the care protocols versus the psychosocial support provided by the avatar, and (3) pragmatically focus on the most effective group(s) and gather as much longitudinal data as possible with the most effective intervention, to validate long-term engagement and potential as a standard of care. We aim through the adaptive design to transition all subjects to the protocol-enabled avatar intervention after the 12-month study visits (or failing that, after the 18-month visits), so that the final months of the study can focus on iterative improvements to the avatar and avatar-delivered protocols.

Power Analysis

The study will be sized to detect a clinically significant difference between the study groups in the primary outcome, the SCI-QoL. In the absence of prior literature establishing the minimum clinically significant difference, we defined the clinically significant difference as one half of the standard deviation, a commonly used distribution-based approach. Power analysis determined that 63 patients in each of two simultaneous study groups are needed to detect a clinically significance difference of 5 points (power = 80%; $\alpha = 0.05$).

Allowing for a 15% loss to follow-up, we size the study to 75 patients per simultaneously active study group, for a total of 150 patients. Given the available patient population per VA SCI center, we expect each center to be able to reliably enroll 50 patients. Therefore, patients will be recruited across 3 VA SCI centers.



Hypothesis

The SCI DMP delivered by the avatar will yield similar benefits to HRQoL as the original SCI DMP, while overcoming practical limitations and improving mental health in veterans with SCI.

Primary Outcome

The primary outcome will be the SCI-QoL. The SCI-QoL comprises 22 subdomains across the four broad domains of physical-medical health, emotional health, social participation, and physical functioning. Computer adaptive testing (CAT) allows individual participants to complete only a small subset of the items and have their scores be directly comparable to full item bank scores. Each subdomain is scored via the use of a standardized T metric, which yields a mean of 50 and a standard deviation of 10.

Secondary Outcomes

Secondary outcomes will be incidence of emergency department (ED) visits, urinary tract infections (UTIs) and pressure ulcers (PUs), self-management of common co-morbid conditions, and loneliness. ED visits and UTIs will be identified by retrospective chart review at each study visit. PUs will be evaluated by an independent observer, who will be granted access to anonymized digital pictures of the PUs, using a validated grading system. The degree of self-management of common comorbid conditions will be assessed by the SDSCA diabetes diet and medication adherence subscales and the HBP SCP hypertension self-care profile. Loneliness will be evaluated by the UCLA Loneliness Scale, a 20-item scale designed to measure one's subjective feelings of loneliness as well as feelings of social isolation.

Methods

Design: prospective, randomized, multi-center study

Patients: 150 veterans with SCI across 3 VA SCI centers in the United States

Randomization: each patient at each center will be randomized into one of 3 groups such that each center will have equal representation of each study group

Groups: (1) usual care control, (2) socialization-only avatar (no health-related protocols), (3) protocol-enabled avatar intervention

Visits: 5 in-person study visits (enrollment, 6-month, 12-month, 18-month, and 2-year) across a 2-year period. Primary and secondary outcomes will be assessed at each visit.

Consent: informed consent will be obtained from each patient at the enrollment visit

Data: anonymized by each center and uploaded to the coordinating center via a secure, web-based portal for independent analysis

Analysis Plan

After each study interval's set of in-person visits across all subjects, preliminary, crude analysis each of the outcomes will be conducted via univariate tests. The chi-squared test will be used to assess variation in the prevalence of the dichotomous outcomes between the groups. Continuous outcomes will be evaluated with either the Kruskal-Wallis or ANOVA methods, depending on their normality distribution.

In addition, at the 1- and 2-year visits, the SCI-QoL subdomains will be assessed in piece-wise linear mixed effect models with repeated measures (spline models). This approach allows for the linear modeling of longitudinal datasets in which the outcome's rate of change is expected to vary over time. The points at which the linear segments change in slope are called "knots". We expect the rate of SCI-QoL improvement to vary between the study intervals, such that the most significant improvement will be seen between the enrollment and 6-month visit, followed by either modest improvements or no change. For each model, the observations will be clustered by patient nested within study site, which will be tested as a random effect, in order to control for the potential variations in care between the centers. This approach is also well-suited to account for patient loss-to-follow-up. Linear mixed-effects models account for all available data, thus allowing for missing data; therefore, all participants will be included in each model regardless of follow-up visit completion.

Statistical analysis will be conducted by an independent statistician, who will be unaware of the study group assignments to reduce the risk of bias.

References

1. Woo C, Guihan M, Frick C, Gill CM, Ho CH.*Increasing specialty care access through use of an innovative home telehealth-based spinal cord injury disease management protocol (SCI DMP)*. J Spinal Cord Med. 2011;34(3):322-31. doi: 10.1179/2045772311Y.0000000003. Review. Erratum in: J Spinal Cord Med. 2011 Jul;34(4):437. PMID: 21756573
2. Dorstyn D, Mathias J, Denson D. *Applications of telecounselling in spinal cord injury rehabilitation: a systematic review with effect sizes*. Clinical Rehabilitation 27(12) 1072-1083, Jul 2013, DOI: 10.1177/0269215513488001
3. Tulsky D, Kisala P, Victorson D, et al. *Overview of the Spinal Cord Injury-Quality of Life (SCI-QOL) measurement system.* The Journal of Spinal Cord Injury Medicine, 38:3, 257-269, May 2015, DOI: 10.1179/2045772315Y.0000000023
4. Woo C, Seton JM, Washington M, Tomlinson SC, Phrasavath D, Farrell KR, Goldstein B. *What's happening now! Telehealth management of spinal cord injury/disorders. J Spinal Cord Med.* 2016;39(1):3-12. doi: 10.1179/2045772314Y.0000000202. Epub 2014 Mar 12. PMID: 24617497
5. Wang V, Galea VP, Galea M. Digital Avatars for Psychosocial and Integrative Health Support of Veterans with Spinal Cord Injury. *1st International Conference on Teleneurorehabilitation*. May 2019. Crotone, Italy.
6. Bott N, Wexler S, Drury L, Pollak C, Wang V, Scher K, Narducci S.*A Protocol-Driven, Bedside Digital Conversational Agent to Support Nurse Teams and Mitigate Risks of Hospitalization in Older Adults: Case Control Pre-Post Study*. J Med Internet Res. 2019 Oct 17;21(10):e13440. doi: 10.2196/13440. PMID:31625949