QLP 41-017

Automated Step-Count Feedback and Disease-Specific Tailoring to Promote Physical Activity

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RESEARCH PLAN

Participants will include those with coronary artery disease, type 2 diabetes, BMI 25 or above, and those with chronic pain conditions (primarily low back, knee, and hip pain). All participants will wear enhanced pedometers all day, during the 7 week baseline/intervention period. Each day, participants will connect their enhanced pedometers to the USB port of a computer and connected to a secure study website on the Internet. Participants will receive software that will allow them to upload time-stamped, step-count data to a secure central computer server. Participants will then be able to log into the website, see graphical and written representations of their daily step counts, and find informational and behavioral tailored messages. Participants will receive daily informational messages, weekly behavioral messages, updated step-count feedback at each upload, and a new step goal each week. At the end of the intervention participants will be asked to complete an online post-intervention survey, weight and blood pressure measurement, and a follow-up interview.

METHODS

As this is a usability test on a small number of participants, much of the analysis will be qualitative. Quantitative baseline descriptive statistics describing the population will include gender, race, co-morbidity data, comfort with computers, self-efficacy for success in a walking program, and age and body mass index. Quantitative outcome summary statistics will include user satisfaction ratings, number of minutes to upload data, and number of minutes spent reviewing content on the website. We will provide summary statistics of baseline blinded step counts, post-intervention step counts, and change between baseline blinded and post-intervention steps. Qualitative themes will be identified via the semi-structured usability interview forms. Themes will be reported with particular attention to themes that suggest a need for modification to the website to improve usability, interest, retention or motivation for the user.

STATUS

Patient participation in the pilot study was completed in December 2007. Out of nine patients recruited for this pilot study, seven participants completed the study while two patients withdrew due to personal conflicts that made it difficult to complete enrollment criteria. Quantitative analyses revealed the average participant increased steps by over 1,000 steps yet, participants averaged 1.2 lbs in weight gain. Family Medicine provided HSR&D with all de-identified data in December 2007 and subsequently destroyed all electronic records for the pilot study. Due to confounding influences (i.e., server breach) and mixed results in this small sample, the investigators will not use the quantitative data in this pilot study for grant proposals. However, qualitative findings were more encouraging. Qualitative data was summarized in brief written summaries by project staff. All seven participants who completed the study reported coping with a chronic pain condition, including 3 with chronic back pain. Despite ubiquitous nature of chronic pain in our sample, all participants who met enrollment requirements also completed the six-week intervention including participating in post-intervention interviews. Given this was primarily a feasibility assessment, the interviews were the main focus of our data collection. In general, none of the participants indicated having significant problems with downloading the study software or uploading steps from the pedometer. They also had no trouble with completing the health surveys or getting on the study website. The participants also liked the pedometers because they were accurate and could be worn anywhere, including in a pocket. All of the participants indicated that the intervention helped to make them more physically active and none of the patients with chronic pain indicated having difficulty with walking because of their pain. The participants all thought this could be good program for their fellow veterans and one of the more frequent suggestions

for how to improve the intervention involved adding a social component or more human contact. This feasibility data was incorporated into an IIR proposal that that was submitted in June 2008 and which reflects pilot study feedback by proposing to incorporate an e-community and more human contact to address patient desires for social support. Subsequently, the IIR proposal was funded for Co-PI's Richardson and Krein. All data is now de-identified and will be saved on the Austin I-Drive. All study records are currently locked in file cabinet in A201 and all paper data records will be shredded upon confirmation of end-of-study report by the VA IRB. Participant consent forms will be stored in an official VA storage box in A626 of the Ann Arbor VAMC and will be scheduled for destruction (shredding) on 12/31/2012. All de-identified electronic data has also been moved to a Closed Projects folder on the Austin drive, where it will be burned to a back-up tape and moved to a locked and secure offsite storage facility maintained by OI&T. Project data will be removed from the Closed Projects folder on November 30, 2008 per request of D. Goodrich to the HSR&D OI&T representative.