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University of Pittsburgh
US Department of Veterans Affairs
Human Engineering Research Laboratories

Development and Evaluation of PPAL Bedside Commode for Safe Independent Toileting Transfers

STUDY25010091: PPAL Field Trial

PPAL Protocol and Statistical Analysis Plan

10/3/25

Field In Home Testing. Once participants are screened for eligibility by the research team, they will be scheduled for a home visit. The Study Research Assistant will visit the home and administer informed consent with the end-user and their caregivers. They will be provided with an orientation to study procedures. At this visit, questions will be answered, the presence of at least one caregiver will be verified, and the home will be screened for the ability to accommodate the PPAL in the intended use space. A home evaluation checklist will be used. The RA will ask and record information about their current toileting habits and recollection of toilet related falls and near falls such as loss of balance while transferring to toilet or commode in the past 6 months. The RA will also observe the participant's transfer methods to their customary toilet or commode to ensure that they are an appropriate candidate for the PPAL. The RA will provide the participant with a log book to track information. They will note the number of times they use the toilet or commode each day. They will note the level of difficulty on a scale that starts at 1 or not at all difficult and goes to 10 for extreme difficulty. They will also note the difficulty they have in transferring to the customary toilet or commode, any toileting related falls or near falls, and toileting mishaps such as not being able to make it to the toilet fast enough. Participants can opt to receive a text message to an online survey using Qualtrics that will ask them to record this information if they prefer. A delivery date for the PPAL will be scheduled a minimum of 3 weeks later to allow time to gather baseline data. On the arranged date of delivery, a moving service will pick up the PPAL and accompanying supplies at the Pitt HERL and deliver it to the participant's home. The RA will help

determine the appropriate placement of the device in the designated area. The RA will observe the participant's transfer to their customary commode and score the transfer per OASIS Section GG Toilet Transfers. The RA will demonstrate the PPAL device use, storage and waste management. At present, the PPAL uses a disposable odor suppressing commode receptacle liner placed into the commode bucket. The absorbent pad within the liner turns waste into gel in a few seconds. The receptacle has a lid, as does the receptacle compartment of the PPAL, both of which can be closed until the caregiver is able to change and dispose of the receptacle liner. The RA will request a return demonstration by the end user and caregiver to ensure understanding of proper device use. If safe transfers and ability to appropriately manage waste cannot be adequately demonstrated after training, the dyad will be disqualified from the trial. Once participants are able to demonstrate safe transfers to and from the PPAL and can demonstrate appropriate waste management, cleaning and storage, the RA will score the transfer to and from the PPAL using the OASIS Section GG Toilet Transfer. Baseline surveys will be administered at this visit via a tablet using Qualtrics. The RA will collect the baseline paper logbook and leave a new one to use for tracking both customary toilet or commode and PPAL use. They will do this by noting the number of times per day they use either, along with other measures including difficulty with transfer, falls or near falls and mishaps. The study team will telephone the participants the day after delivery, 3 days later, and weekly thereafter to identify concerns, answer questions, and identify adverse events such as accidental falls or device malfunction or breakage. The participant and their caregivers will also be provided with a number that they can call for technical support if they experience any problems or issues with the device. The device will remain in the participant's home for 6 weeks. At the end of the 6 week trial, the study team will arrange a final study visit date. At that visit, the moving service will retrieve the PPAL and return it to HERL for cleaning, preventive maintenance and repair or refurbishment as needed. The RA will administer the exit surveys and will observe the participant performing a toilet transfer using the PPAL and their customary commode, scoring both using the OASIS GG score. Outcome measures using Qualtrics will be administered and a semi-structured interview will be conducted to ascertain acceptability and satisfaction with the PPAL.

Stats Plan

Field (in home) Trial:

Usability and Performance: The SUS and NASA-TLX scales post-trial will be analyzed descriptively to determine if the real-world use of the device has acceptable usability (SUS

scores > 68) and level of performance (NASA-TLX < 50). In addition, device satisfaction using the QUEST 2.0 (total device subscale score) will be determined.

Utility: Graphical methods commonly used for data analysis in single-subject designs will be used to examine changes and trends over time in the personal logged daily number of customary and PPAL toilet transfers. These metrics will also be averaged over the first three weeks (baseline period-no PPAL use) and compared to the same measures averaged over the first 3 weeks and last 3 weeks of PPAL use using a repeated measures ANOVA or non-parametric test equivalent.

Health Outcomes: Near falls and separately fall incidence will be determined as a rate of occurrence per week averaged over the baseline period (3 weeks) and compared to the intervention period (6 weeks) using a Wilcoxon signed-rank test (given the small sample size). Similarly, the CATOM and SCI-FCS scores will be compared pre-post PPAL use using the Wilcoxon signed-rank test. A Wilcoxon signed rank test will be used to compare the pre-post OASIS Section GG scores.

Our projected sample size for Aim 2 is based on a comparative usability study design wherein we aim to show that using the PPAL is better than the conventional methods of toileting. Research in the usability community recommends to engage between 8 and 25 participants when statistically significant findings are being sought with 10-12 participants being considered a good baseline range. Factoring in a 20% attrition rate we aim to recruit 16 end-users (and their caregivers) resulting in 12 participant completers. We will interview participants that complete study as well as those who do not complete to gain insight into the characteristics of individuals who may be more likely to adopt or use a PPAL longer term.