Evaluating the Feasibility of an Automated Bidet Intervention to Decrease Caregiver Burden (NCT04283123)

Study Protocol

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World Health Organization Data Set

Primary Registry and Trial Identifying Number	ClinicalTrials.gov: NCT04283123
Date of Registration	February 14, 2020
Secondary Identifying Numbers	IRB ID#: 201610044
Source(s) of Monetary Support	TOTO USA, Inc
Primary Sponsor	Washington University School of Medicine
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Public Title	Feasibility of an Automated Bidet Intervention to Decrease Caregiver Burden
Scientific Title	Evaluating the Feasibility of an Automated Bidet Intervention to Decrease Caregiver Burden
Countries of Recruitment	United States
Health Condition(s) or Problem(s)	Caregiver Burnout

Intervention(s)	Study arm 1: Treatment • Participants assigned to this group will receive an automated bidet (TOTO Washlet S300e with remote control) and an occupational therapy intervention over 2-3 in-home visits. • During the first intervention visit, a licensed contractor will install the bidets in participants' homes. The OT will then educate and train the caregiver and care recipient to successfully use the bidet, and make any modifications to the remote as needed. Throughout the intervention, the OT will use motivational enhancement strategies. The OT will make minor modifications to the remote as needed. A second intervention visit will occur 1-2 weeks post-installation to address any new difficulties. Check-in phone calls will be offered to the caregiver and care recipient if needed. Study arm 2: Waitlist Control • Caregivers will wait for 30 days and then will be offered the intervention. • No intervention.
Key Inclusion and Exclusion Criteria	Inclusion criteria: (1) provided unpaid care and lived with a care recipient aged 55 years or older (2) assisted with toileting for at least 6 months (3) did not have an automated bidet (4) had a working toilet and bathroom outlet, and (5) their care recipient was willing to participate Exclusion criteria: (1) Caregivers scoring 10 or above on the Short Blessed Test, indicating possible cognitive impairment
Study Type	Randomized waitlist control feasibility study
Date of First Enrollment	December 20, 2016
Target Sample Size	10
Recruitment Status	Complete
Primary Outcome(s)	1. Number of participants recruited 2. Number of caregivers retained 3. Ability to install the automated bidets, including any modifications needed 4. Caregivers' or care recipients' ability to operate the bidet 5. Acceptability 6. Preliminary efficacy: reduction of physical barriers to toileting 7. Preliminary efficacy: Performance 8. Preliminary efficacy: Satisfaction 9. Preliminary efficacy: Self-efficacy 10. Adverse events

Organizational Structure and Responsibilities

Susan Stark, Ph.D., OTR/L FAOTA is the principal investigator and will manage and oversee all aspects of this project. She will ensure compliance with quality-assurance requirements as stipulated by human subjects, and submit appropriate materials as needed throughout the study.

Rebecca Bollinger, OTD/S will coordinate this study by developing study materials, reporting adverse and serious events for all participants, recruiting, screening, and enrolling participants, as well as implementing quality control procedures, and assisting in data management and analysis. She will also develop materials for regulating bodies with assistance from study staff.

Emily Somerville, MS, OTR/L will supervise and train staff during this study.

Marian Keglovits, OTD, MSCI, OTR/L will train staff and assist with assessments and statistical analysis performed for this project.

Yi-Ling Hu, MS will assist with data analysis for this study and maintain randomization codes.

Study Objectives

The objective of this feasibility study is to assess the acceptability and preliminary efficacy of a toileting intervention using an automated bidet system and training by an occupational therapy practitioner (OT) to reduce the amount of physical assistance required from caregivers.

Background & Study Rationale

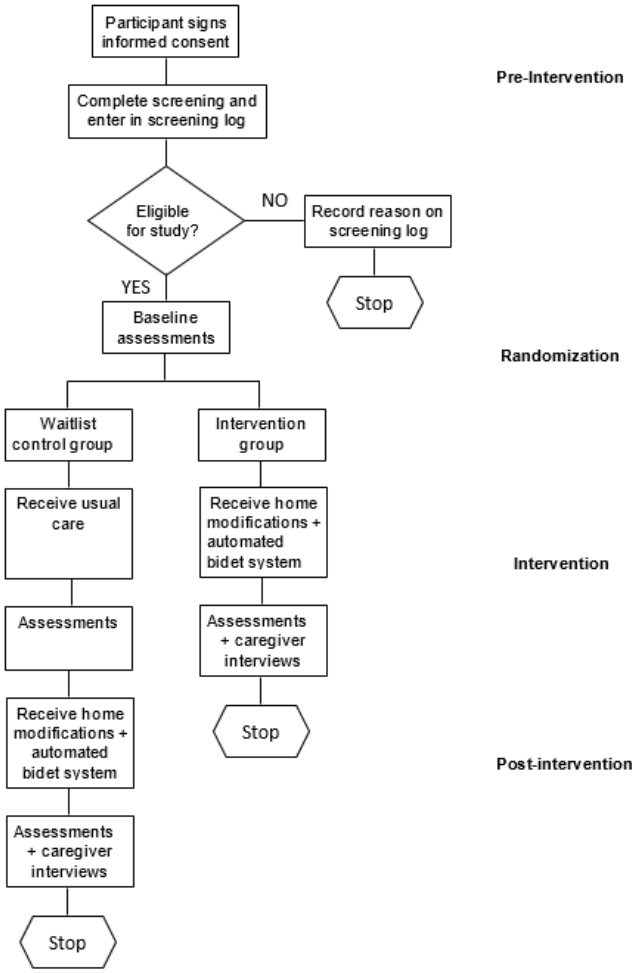
Informal caregivers are unpaid family members or friends that provide over 30 billion hours of care annually for older adults (Chari, Engberg, Ray, & Mehrotra, 2015). They assist with activities of daily living (ADLs) and instrumental activities of daily living (IADLs), enabling their loved one to remain at home (Darragh et al., 2015; National Alliance for Caregiving and AARP Public Policy Institute, 2015). However, they often receive little to no training, especially for assisting with toileting, and are at an increased risk for physical injury, stress, and burnout (Darragh et al., 2015; National Alliance for Caregiving and AARP Public Policy Institute, 2015). This jeopardizes their loved ones' ability to age in place. Care recipients are more likely to be placed in a nursing home if they have difficulties completing ADLs such as toileting (Luppa et al., 2010).

Informal caregivers report that assisting with toileting and managing incontinence are some of the most difficult ADLs (Darragh et al., 2015; King, Holliday, & Andrews, 2018; National Alliance for Caregiving and AARP Public Policy Institute, 2015). Informal caregivers with low self-efficacy or beliefs about their ability to assist with toileting tasks are at risk of experiencing depression or burnout (Bandura, 1982; Gilliam & Steffen, 2006; Grano, Lucidi, & Violani, 2017). Thus, a potential solution is an automated bidet system, a toilet seat with built-in cleaning features, to replace physical support provided by a caregiver for toileting. Automated bidet systems have been shown to reduce caregivers' use of non-neutral postures by 15% and severe trunk flexion by 32% (King et al., 2019). In another study, participants reported an increase in competence, adaptability, and self-esteem after using an automated bidet system compared to their regular toileting routine (Yachnin, Gharib, Jutai, & Finestone, 2017). Automated bidet systems have the potential to increase caregivers' self-efficacy, increase caregivers' satisfaction, reduce the amount of physical assistance needed for toileting, and decrease caregivers' risk for injury when assisting with toileting.

Study Design

In this randomized waitlist control feasibility study, ten informal caregivers and care recipient dyads will be recruited to the study and randomly assigned to either the treatment group or the waitlist control group. The treatment group will participate in the intervention immediately, receiving the automated bidet system and training, while the control group waits to receive the automated bidet. After completion of this phase, control participants will be provided with the automated bidet system and subsequent training. Outcome measures will be collected at pretest and posttest (30 days post-intervention for the treatment group or 30 days post-enrollment for the control group), and at follow-up for the waitlist control group (30 days post-installation). Assessments will be used to evaluate the feasibility of the feasibility, acceptability, and preliminary efficacy of this OT intervention to reduce the amount of assistance needed from caregivers. Overview of the study's major steps is shown in Figure 1.

Figure 1: Study Flow Diagram



Participants

Ten informal caregivers will be recruited to participate in this study from a study registry, clinicians, exercise groups, and word of mouth in St. Louis, Missouri.

Informal caregivers will be contacted by phone and screened for eligibility. Caregivers will be eligible for this study if they: (1) provide unpaid care and lived with a care recipient aged 55

years or older; (2) have assisted with toileting for at least 6 months; (3) do not have an automated bidet; (4) have a working toilet and bathroom outlet; and (5) their care recipient is willing to participate. Participants will be excluded if they score a 10 or above on the Short Blessed Test, indicating a possible cognitive impairment.

Informed Consent

Written informed consent to participate in the study will be obtained before any assessments are conducted. If eligible, an occupational therapist (OT) will schedule a time to obtain consent at the potential participant's home. All elements of consent will be reviewed with caregivers prior to enrolling in the study, including the purpose of the study, risks, benefits, alternatives to the study, how confidentiality will be maintained, the PI's contact information, no consequences to withdrawal, and how study results will be shared. Participants will be given a copy of the signed consent for their records.

A written waiver of consent/exempt information sheet will be presented in person to all care recipients at the initial interview prior to administering the IHOPE-Assist. The OT will review the exempt information sheet with the care recipient during the consent visit in a private setting, including the purpose of the study, study procedures, and how confidentiality will be maintained. If the care recipient does not want to participate in the performance-based component of the evaluation, which includes toileting activities normally done in the home with the assistance of a caregiver, then the caregiver and care recipient will not be enrolled in the research study.

All study staff have undergone IRB training. In addition, all staff members have participated in cultural competence training and are trained to interview older adults. All study documents will be available in multiple formats, are developed in 12-point Arial font, and are written in plain language. If a participant needs to be re-consented at any point during the study, the study staff will visit the person in home and repeat the consent process. All signed consents will be stored in the office of the PI under double locks.

Study Intervention

After randomization, the OT will contact all participants to inform them of their group allocation (Treatment or Control). A home visit will be scheduled as soon as possible for the participants in the treatment group. The waitlist control group will wait 30 days before receiving the automated bidet system and subsequent training.

Intervention Procedures. A visit will be scheduled after the pretest visit for installation and training on the automated bidet system (TOTO Washlet S300e with remote control). During the first intervention visit, the licensed contractor will install the automated bidet. After installation, the OT will provide training to the caregiver and care recipient on using the automated bidet system and will make modifications to the remote as needed. A second intervention visit will be completed 1-2 weeks post-installation to address any new difficulties with using the automated bidet system. During the intervention visits, the OT will utilize motivational enhancement and active practice, and provide education on programming the remote control for the care recipient's desired temperature, water pressure, and wand position to increase independence with toilet hygiene. The caregiver will be instructed to contact the OT if they have any questions.

Control Group Procedures. The procedures for the waitlist control group will be the same as above. During the initial 30 days, participants randomized to the control group will wait to receive the automated bidet. After completing assessments after the first 30 days, they will receive the automated bidet and follow the same intervention procedures described above.

Randomization

Caregivers will be randomized using a 1:1 ratio by gender with a web-based randomization tool, Research Electronic Data Capture system (REDCap) after signing the consent (Harris et al., 2009). Randomization sequence concealment will be achieved by the Research Electronic Data Capture (REDCap) system (Harris et al., 2009).

Data Collection

Data will be collected at pretest and posttest (30 days post-intervention for the treatment group or 30 days post-enrollment for the control group), for the caregiver and care recipient in the participants' homes. Caregivers in the waitlist control group will also complete assessments at follow-up (30 days post-installation).

Covariate Assessments to be collected during the initial screening from the caregiver:

Demographics. Caregivers will be asked basic demographic information that includes birthdate, gender, marital status, ethnicity, income, years of education, years of caregiving, relation to care recipient, diagnosis of care recipient, and hours of caregiving provided per week.

Short Blessed Test (SBT). The SBT is a six-item measure that will be used to assess the caregiver's cognition, memory, and orientation as a screening tool prior to enrolling in the study (Katzman et al., 1983). The SBT has good validity. The score for each item is calculated based on the number of errors and a weighting factor; these scores are combined to calculate the total score. Total scores range from 0-28; higher scores indicate more cognitive impairment. Informal caregivers who score 10 or above will not be eligible for the study as that indicates impairments consistent with dementia.

Primary endpoint assessments to be completed by the caregiver throughout the study:

In-Home Occupational Performance Evaluation for Providing Assistance (I-HOPE Assist). The I-HOPE Assist is a reliable and valid assessment which measures caregivers' self-reported satisfaction and performance, impact of environmental barriers, and self-efficacy for assistance with 43 specific daily activities (Keglovits, Somerville, & Stark, 2015). Caregivers use activity cards to identify the top 10 caregiving activities which are difficult or worrisome for them, one of which must be toileting. Next, they provide self-ratings of their performance, satisfaction with performance and self-efficacy for those activities on a scale of 0 to 5, with higher scores indicating better performance, satisfaction, and self-efficacy. For self-care and transfers for toileting, the OT will also record barriers to performance and rate the impact of the barrier on the caregiver's performance, yielding scores of barrier severity. This assessment will be used to measure changes in caregiver performance, satisfaction, and self-efficacy for providing assistance with toileting to evaluate the effects of the automated bidet system intervention on caregiver outcomes.

Process Evaluation. During the final study visit, caregivers will complete an 8-item process evaluation to assess the feasibility of the toileting intervention using an automated bidet system. Caregivers will rate how much they thought the automated bidet: (1) made assisting with toileting easier, (2) improved their confidence, and (3) addressed their concerns for assisting the care recipient with toileting. Caregivers will rate agreement with statements about the appearance, ease of use, and training and whether they will continue to use the automated bidet after the study on a scale of 0 (strongly disagree) to 4 (strongly agree), with higher scores indicating greater acceptance of the intervention. Caregivers will also complete a qualitative

interview to determine whether the number and length of visits were sufficient.

Statistical Analyses

Descriptive statistics will be used to examine demographic characteristics and feasibility outcomes. A Wilcoxon-signed rank test will be used to examine secondary outcomes to compare groups. Qualitative interviews will be analyzed using a grounded theory approach and constant comparative analysis.

Potential Benefits, Risks, and Alternatives

Benefits. Participants may or may not benefit from being in this study. The information from this study may help researchers to better understand and address the needs of caregivers in the future.

Risks. Visits may result in feeling tired or disrupted. In addition, some questions, or demonstrations performing activities caregivers assist with, may touch on emotionally sensitive issues that could cause anxiety, embarrassment, or other forms of emotional stress. Participants will be told that their involvement in this research study is voluntary and that they may choose not to participate or to withdraw their consent at any time. Participants who undergo the study visits will be given the option to take a break or reschedule the visit at any time. All research-related information will be kept confidential and accessible only to authorized members of the research team.

Minimization of Risks and Confidentiality

To protect against and minimize potential risks, participants will be carefully screened and evaluated for eligibility by the research coordinator. To avoid or minimize symptoms of fatigue or emotional distress during visits, participants will be instructed to notify the rater or interventionist if they experience any discomfort. They will also be periodically questioned about their tolerance for the tests/intervention. Testing and interviews will be terminated if participants develop fatigue or emotional distress.

To help protect participants' confidentiality, an ID number will be assigned to each participant. All data collected from a participant will be labeled with that ID number. All participant electronic and hard-copy data will be kept under double-lock protection. All hard-copy forms that contain personal identifiers (e.g., name, address, phone number) will be stored in a separate, locked file drawer under double-lock protection. No publication or presentation of the study data will uniquely identify or provide sufficient information to uniquely identify participants.

To guard against unauthorized data access, all shared-use computer systems at Washington University School of Medicine are protected with passwords, which are changed at 4-month intervals. Only individuals with a particular "need to know" status are given access, and system privileges are carefully restricted. All personal computers to be used in the Administrative Unit are located within a secure area, and the system is locked when not in use. SAS and SPSS software packages will be used for data management and analysis. Datasets generated from these programs will be password protected, which will make accessing study data difficult even in the event that unauthorized computer access occurs.

Adverse Event Reporting and Safety Monitoring

All SAEs will be reported to the Human Research Protection Office in the following time frames: (a) death–immediately, (b) life-threatening–within 7 calendar days, (c) all other SAEs–within 15

calendar days using the Electronic Serious Adverse Event Reporting System. Should an SAE occur that increases the risk to the participants, the study will be stopped, an investigation will be conducted, and a findings report will be generated before the study is resumed.

Dr. Stark will be responsible for reviewing study progress and outcomes including recruitment, data quality, safety, and efficacy. Quarterly reports will be reviewed by the principal investigator. Because risk in the proposed study is considered minimal, the data monitoring plan will include continuous, close monitoring by the study investigator with prompt reporting of any AEs. Ms. Bollinger will monitor the study for AEs, adherence to the protocol, and safety.

Premature Study Termination

Preliminary study data will be monitored by the data management team for any potentially harmful outcomes. If interim data raise significant safety concerns, the trial will be ended early.

Indemnity

Washington University School of Medicine is responsible for any non-negligent damage incurred as a result of participating in this study. The indemnity is renewed on an annual basis. Washington University School of Medicine assures that it will continue renewal of the indemnity for the duration of the trial.

Ethics and Dissemination

The informed consent forms will be reviewed and approved by the Washington University IRB with respect to scientific content and compliance with applicable research and human subjects regulations. All study personnel involved in the conduct of this research will receive the required education on the protection of human participant rights.

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