A Pilot Clinical Trial of TENA Identifi in the Nursing Home Setting

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Objective

The purpose of this pilot study is to prospectively compare a standard of care manual toileting protocol (e.g., "check and change" strategy) to toileting patterns recorded by the TENA Identifi system in identifying incontinence patterns and events, and, secondarily, whether such data differentially improve a care planning strategy, nursing effort, product use, and wet-time for UI.

Primary Outcome:

1. Comparison of number of wet events per 24 hours, as recorded by TENA Identifi, intervention versus control

Secondary Outcomes:

1. Comparison of amount of time wet per 24 hours, intervention versus control
2. Comparison of number of disposable briefs per 24 hours, intervention versus control
3. Nursing staff (e.g., assistants, care planners) satisfaction with using TENA Identifi
4. Nursing staff assessment of ease of use of TENA Identifi for recording and care planning compared to their current check and change care standard(s)
5. Value of TENA Identifi system to nursing staff in developing care plans

Study Design

This quasi-experimental study compares treatment plans of NH residents in two different groups—those informed by data from the TENA Identifi system to those informed by standards of care already in practice within nursing homes. The TENA Identifi system consists of a sensor integrated with a disposable brief that provides a digital time stamp of each wet event when a resident is changed, how long a resident has been exposed to urinary moisture without being changed (i.e., damp segments), and volume of urinary output from each wet event. These data are captured in a TENA Identifi Report that the nursing home staff can use fore care planning.

The study staff will consent 32 long-stay residents (or their legally authorized representative) for inclusion in our study from different nursing homes that meet our inclusion criteria. The study will be approved by all relevant Institutional Review Boards prior to beginning study activities.

Eligibility Criteria

Inclusion Criteria for Residents:

1. Males or females 55 years of age or older with stable clinical status
2. Long-stay status (more than 90 days)
3. Ambulatory and able to use a toilet either independently or with assistance
4. Minimum Data Set (MDS) Level 1 (occasionally), Level 2 (frequently) or 3 (always) rating of incontinence
5. Currently wearing disposable briefs for urinary incontinence

Exclusion Criteria for Residents:

1. Chronically bed-bound (MDS G0110A rating 8)
2. MDS self-performance rating of 4 (total dependence) for toilet use
3. Fecal incontinence (MDS H0400 rating 0)
4. Use of urinary appliance such as catheters or ostomies (MDS H0100 Z)
5. Private duty nurse care
6. Residents who tear at clothing or disposable undergarments
7. Current urinary tract infection receiving treatment
8. Current diarrhea receiving treatment
9. Residents who are not likely to benefit from a toileting plan based on assessment of nursing staff

Inclusion Criteria for Nursing Homes:

1. Medicare or Medicaid certified nursing facilities in the U.S.
2. Use of a nursing aide care tracking device (e.g., CareTracker™, HealthMEDX), electronic health record, and/or paper voiding diaries
3. Provides care for residents 55 years of age and older

Exclusion Criteria for Nursing Homes:

1. Nursing homes that do not report MDS data to CMS
2. Unwilling to participate in TENA Identifi training and use

Each NH will have a control and intervention group. Control and intervention groups will be randomized and consist of 16 residents each. Nursing staff will receive TENA Identifi training on how to use the device prior to beginning Observation 1 assessment. Both groups will receive an assessment of the NH's current standard of care procedure for UI assessment and care planning between observational periods.

Both groups will wear disposable briefs with the TENA Identifi sensor for 72 consecutive hours. Nursing staff in both groups will follow standard of care check and change procedures during this time period. After the 72-hour period with parallel check and change assessment, data collected by the TENA Identifi sensor will be assessed in the intervention group and used to create new treatment plans.

Nursing staff for the control group will be blinded to sensor data and will create new treatment plans based on usual care planning processes. Modified treatment plans will be implemented in both groups and observed for a final 72 consecutive hours using TENA Identifi in both groups. TENA Identifi sensor data will be collected from both groups during this period (sensor data from the control group will be used as control data), and the data will be compared. Nursing staff will be surveyed to obtain data on ease of use with TENA Identifi and interpreting its data, as well as how it compares to other standard of care recording methods.

Statistical Analysis Plan

The study design is a two group, two timepoint, four site, randomized, longitudinal clinical trial. Descriptive statistics were computed for demographic data from the MDS, medications from the medication administration record, and TENA Identifi sensor data (i.e., number of wet events per 24 hours, the amount of time the resident was wet per 24 hours, and the number of brief changes). The means for number of wet events and number of brief changes were generated by averaging the 3 daily counts in each assessment period. The first assessment period was pre-intervention and the second assessment was post-intervention. A mixed-effects linear model was used to compare the intervention vs. control. Fixed effects included group (intervention vs. control), time and the group by time interaction. Random effects included site and participant. A random effect for the site by group interaction was planned but not estimable due the fact that only the intervention group was tested at the first site. For this model, the group by time interaction was a test of the intervention. Least square (or adjusted means) along with their standard errors were reported from the mixed-effects model. Significance was set at a p-value of 0.05.

These data will be collected using four data sources and recorded on a study-specific case report form:

A. TENA Identifi sensor data. This electronic monitoring system provides real-time data of residents' voiding patterns including time at which a wet event occurred (i.e., minimum of 2 sensor segments on TENA Identifi Report), how long a resident was wet after voiding (i.e., damp segments), and urinary output (i.e., void volume). These data are collected over a consecutive three-day period through a sensor worn in a disposable brief and automatically transmitted to a secure online web portal where it is converted into a detailed voiding report. It is anticipated that data collection will begin on a Tuesday at 8 AM and be completed at 8AM on Friday for a total collection period of 72 hours. The TENA Identifi logger and sensor briefs are not provided to facilities after completion of the study.

B. CareTracker™, HealthMEDX, other electronic or paper tracking data, which contains manually recorded voiding information including when residents are checked and changed and number and time of wet events.

C. Minimum Data Set (MDS), which contains health information on each resident, including residents' functional status and capabilities, as well as any health problems.

D. Medication administration record, which contains information on medications administered to NH residents.

Data for some secondary outcomes will be collected using a survey given post-study to nursing staff.

