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Comparison of the Effectiveness of Two Protocols for Treating Nursing Home Residents with Advanced Dementia

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Abstract

The Serial Trial Intervention (STI) is a decision support tool to address the problem of under assessment and treatment of pain and other unmet needs of people with dementia. This study compared the effectiveness of the 5-step and 9-step versions of the STI using a two-group repeated measures quasi-experimental design with randomization of 12 matched nursing homes. The sample consisted of 125 residents with moderate to severe dementia. Both the 5 and 9-step STIs significantly decreased discomfort and agitation from pre to posttest (effect sizes .45 to .90). The 9-step version was more effective for comorbid burden and increased cortisol slope (effect sizes .5 and .49). Process variables were all statistically significantly improved using the 9-step STI. Nurse time was not different between the two groups. The clinical decision support rules embedded in the STI, particularly the 9-step version, helped nurses change practice and improved resident outcomes.

Keywords

Dementia; Randomized clinical trial; pain; agitation; cortisol

Assessing and treating unmet needs of nursing home residents with dementia is challenging. Factors contributing to these challenges include multiple coexisting illnesses, atypical

symptom presentation, and staff knowledge. Clinically, 93% of people with Alzheimer's disease have at least one additional chronic illness, and approximately 61% have three or more (Fillit, 2000). Symptom presentation is often vague and atypical (Ham, Sloane, Warshaw, Bernard, & Flaherty, 2006). People with advanced dementia are often unable to verbally report symptoms, but may display increased agitation and other changes in behavior during acute illness and exacerbations of chronic illness (Feldt, 2000; Kovach, Cashin, & Sauer, 2006; Zwakhalen, Hamers, & Berger, 2006). Complicating matters further, the behavioral changes that are evident when there is a physical change in condition, may also be exhibited when there is a psychosocial unmet need (Cummings, 2005; Gotell, Brown, & Ekman, 2003). Nursing homes are heavily staffed with licensed practical nurses and associate degree registered nurses, who, when confronted with the complexity of caring for those with advanced dementia, may lack adequate training to make decisions regarding appropriate care (Seblega et al., 2010).

BACKGROUND

Clinical decision support tools have been developed to assist health care professionals in standardizing the assessment and interventions for patients with specific problems. These systems guide or direct the flow of action steps and may be useful in addressing complex practice problems, inconsistencies in practice, or practice inefficiencies (McGinn et al., 2000; Shapiro, 2006). There are several types of decision support tools but the terms used to refer to these different tools are not used or defined consistently; algorithms, protocols, evidence-based decisions support, clinical prediction rules, clinical information systems and clinical decision rules (Bakken et al., 2008; Ersek, Turner, Cain, & Kemp, 2008; Kim et al., 2007; Laupacis, Sekar, & Stiell, 1997; Shapiro, 2006). Decision support tools vary in format, the methodological rigor of development and testing, the degree to which the tool mandates versus suggests a possible course of action, the quality of evidence that informs the initial development of the tool, and the degree to which the system does or does not utilize computerized technology.

With the number of individuals with dementia residing in nursing homes continuing to grow (US Administration on Aging, 2008) and those with dementia experiencing more complicated health conditions (Feng, Grabowski, Intrator, & Mor, 2006), the use of decision support tools may improve resident care and outcomes. According to the Consequences of Need-Driven Behavior (C-NDB) model, shown in Figure 1, needs of people with dementia may be left unmet because communication via non-normative behaviors makes it difficult for caregivers to know that the person has a need and the extent of such need (Kovach, Noonan, Schlidt, & Wells, 2005). Not meeting needs of people with dementia affects the person with dementia, care factors, and contextual factors. When needs are left unmet, cascading effects can occur resulting in new problems and behavioral symptoms. This framework suggests that caregiver actions can mediate the sequence of events that lead to many unresolved needs.

The Serial Trial Intervention (STI) is a decision support tool to address the problem of under assessment and treatment of pain and other physical problems of nursing home residents with advanced dementia that are unable to clearly or consistently verbally report symptoms. Because changes in behavior are often evident when people with more advanced dementia have an unmet need or change in condition, the STI is initiated when there is a behavior change that is not ameliorated through basic care provided by the ancillary staff. The Serial Trial Intervention (STI) was initially developed as a 5-step assessment and treatment process, as described in the first five steps in Table 1. If an assessment is negative, or if interventions fail to decrease symptoms, the nurse moves to the next step.

The 5-step STI was tested using a double-blinded randomized experiment in 14 nursing homes with 114 participants. The treatment group had significantly less discomfort than the control group at posttesting (effect size .89) and more frequently had behavioral symptoms return to baseline ($p = .002$) (Kovach, Logan, et al., 2006). Though effective, specific problems with nursing care were identified after the STI was initiated. Nurses' responses to behavior change were dismissive (i.e. no treatment initiated), static (i.e. continued use of the same ineffective treatments), and reactive (treatment without assessment) (Kovach, Kelber, Simpson, & Wells, 2006). After initial treatment of a problem, thoughtful follow through was often lacking as evidenced by failure to get effective treatments scheduled for regular use and failure to add adjunctive and preventive therapies to the therapeutic regimen (Kovach, Cashin, et al., 2006).

A number of nursing home studies have identified that communication challenges exist between nurses and other caregivers and impede treatment (Adams-Wendling, Pimple, Adams, & Titler, 2008; Castle, 2007; Scott-Cawiezell et al., 2004). For example, Kruse et al. (2005) found that failure to communicate effective interventions decreased nursing home residents' comfort and quality of life, while increasing the cost of treating illnesses due to delays in problem identification and increased illness severity. A Swedish study found that quality of drug use in nursing homes was positively associated with the quality of nurse-physician communication and with regular communication among multidisciplinary team members (Schmid & Svarstad, 2002).

To correct identified problems with the 5-step version, the 9-step STI added steps 6 to 9 as described in Table 1. The additional four steps are designed to shift the nurse from focusing solely on short-term comfort, to longer-term resolution of the problem that is believed to be causing behavioral symptoms and negatively impacting quality of life. Hence, the purpose of this study is to compare the effectiveness of two versions of a protocol that guides nurses' assessment and treatment of nursing home residents with dementia. Dose response and differences in nurse time spent on resident unmet needs were also compared between groups.

HYPOTHESES

1. Residents treated using the 9-step STI will receive more assessment-driven treatment (i.e. treatment preceded by assessment, new problems identified and treated) and evaluation-driven follow through (i.e. scheduled dosing of effective treatments, adjunctive/preventive treatments added) and less static and dismissive care than residents treated using the 5-step STI.
2. Residents treated using either the 5 or 9-step STI will decrease their discomfort, stress, agitation and comorbid burden from pre to posttest.
3. Residents treated using the 9-step STI will have less discomfort, stress, agitation, and comorbid burden than residents treated with the 5-step STI.

METHODS

Design

This study used a double-blinded two-group repeated measures quasi-experimental design with no control group. Nursing homes were matched based on percentage of residents receiving Medicaid funding, urban or suburban location, and number of beds, and randomized to the two conditions; 5-step STI and 9-step STI. Random assignment was executed using a coin toss by a researcher not directly involved in the project. One baseline measure and three posttest measures were obtained at 2, 4, and 6 weeks following

intervention. Resident treatment variables included measures of assessment driven treatment, evaluation driven follow through, static, and dismissive care as well as nurse time. Resident outcome measures were discomfort, stress, agitation, and comorbid burden. We determined that a sample size of 61 patients per group (122 total) would have at least 80% power to detect an effect size of 0.63 between arms for each outcome. Other resident characteristics were measured for possible inclusion as covariates, and chronic illness, functional status, and nursing home working characteristics were tested for moderating effects.

Setting and Participants

Twelve not-for-profit nursing homes in the upper Midwest were chosen by convenience of proximity to the university to obtain a convenience sample of 125 residents. Inclusion criteria for residents were: Mini-Mental State Examination (MMSE) score 15 or below (Crum, Anthony, Bassett, & Folstein, 1993); no chronic psychiatric diagnosis other than dementia; no known pituitary or adrenal diseases; not taking corticosteroids; a length of stay of at least 4 weeks to control for relocation stress; and no acute illness. Residents were dropped from the study if the medication protocol was refused by a family member or physician, or if the resident was transferred to acute care prior to completion of the first posttest. In addition, since the STI is initiated when there is a behavior change that is not ameliorated through basic care provided by the ancillary staff, those residents that did not exhibit such behavior change over the study period never had the STI initiated and were dropped from the study.

There were two convenience nurse samples; staff nurses who were surveyed and interventionists. Staff nurses aged 21 and over, employed at least three months, and working 20 or more hours per week were asked to complete a survey about working conditions. Interventionists were fulltime dayshift nurses with a minimum of six months experience caring for people with dementia. If a Registered Nurse was not available to serve as the interventionist, a Licensed Practical Nurse (LPN) was used. Surveys were completed by 199 nurses and 44 nurses served as interventionists (15 RNs, 29 LPNs). The majority of interventionists stated their age as over 45 and the interventionists had been working in nursing for an average of 20 years ($SD = 14.1$). There were no significant differences in the age range, years of nursing experience or ratio of RNs to LPNs between the two study conditions.

This study was approved by the designated Institutional Review Board (IRB) for each site. For resident participants, consent was solicited from the durable power of attorney and verbal assent was solicited from the resident. Interventionists provided written informed consent and return by mail of completed questionnaires signaled survey consent.

Intervention Training and Fidelity

Interventionists received 7 hours of instruction from two APNs regarding: a) their assigned intervention condition; b) data collection; c) fidelity checks; and d) obtaining needed prn analgesic orders and order changes. Information provided during training included common behaviors associated with unmet needs, physical and affective assessment procedures, analgesic use, and non-pharmacological comfort interventions. Categories of psychotropic drugs were reviewed with information on side effects, overuse and misuse of specific drugs. There were no instances in which interventionists missed training sessions. Nursing homes were reimbursed for training time. Four case study booklets were used to train and test the accuracy of applying the 5 and 9-step STI. Further training and retesting were done when accuracy was less than 80%.

Following education of the interventionists, the STI was initiated when a participant exhibited behavior change or verbal symptoms. The STI was used for six weeks. A research staff advanced practice nurse (APN) met with the nurse twice a week to answer interventionists' questions. The APNs were also contacted by phone several times by interventionists when particularly challenging treatment questions arose. Fidelity checks were completed twice a week by the APN. When fidelity was less than 80%, the APN halted data collection, reeducated the interventionist until agreement on treatment was above .80, and then resumed data collection.

Measurement of Resident Treatments and Nurse Time

Resident treatment measures were extracted from daily tracking forms completed by the interventionist during the six week posttest period. The tracking forms included areas for recording behaviors, assessments, treatment changes, communication with others on the health care team, and any order changes. Interventionists were taught to complete data collection using digitally produced case examples until interrater reliability was .85 or greater. In order to assure valid and complete tracking of information, a research staff advanced practice nurse (APN) met with the nurse twice a week and cross-checked the tracking forms with the interventionists report and resident charts to investigate and resolve discrepancies.

Based on percentages of care calculated from our earlier trial, we targeted that having at least 85% of *treatment preceded by assessment* would constitute a clinically meaningful change in assessment driven treatment. In the earlier study, nurses using the 5-step STI failed to assess before treatment 34% of the time. Another measure of assessment driven treatment was *new physical problems identified and treated*.

To assess evaluation driven follow through, we measured whether actions were taken to ensure *scheduled dosing of effective treatments* and whether or not *adjunctive or preventive treatments* were *added* to the treatment plan for new problems. To begin to understand the process of evaluation driven follow through, we also measured whether new orders were obtained or if there was written or verbal documentation indicating that a change in plans was communicated to other staff.

In our earlier study, of those who had their behavior change dismissed, behavior changes were dismissed 30% of the time and static care was evident for 33% of those receiving the STI (Kovach, Kelber, et al., 2006). *Static* and *dismissive* care scores were calculated by counting the number of days each type of care was given and converting this to a percentage based on the number of days behavioral symptoms were present in the posttest period. Based on our earlier trial, we targeted that having less than 15% of responses to behavior change characterized as dismissive or static would constitute clinically meaningful changes. *Treatments stopped*, because of ineffectiveness, side effects, or because the treatment was not needed was measured as another indication of reduction in static care. Interrater reliability of coding for these variables ranged from .80–.98.

To calculate *nurse time* spent on resident unmet needs, a count of the number of distinct times the nurse documented contact with the resident or others regarding new resident problems was counted and converted to a percentage based on the number of days behavioral symptoms were present in the posttest period.

Measurement of Resident Outcomes

Observational visual analog scales were used to measure discomfort (Discomfort-DAT) (Hurley, Volicer, Hanrahan, Houde, & Volicer, 1992) and agitation (Wisconsin Agitation Inventory (WAI) (Kovach et al., 2004). The Discomfort-DAT, with a possible range of 0 to

75, requires a 5-minute observation period to measure overall level of discomfort and the WAI, with a possible range of 0 to 100, measures the number, duration and intensity of 29 behaviors through multiple 3 minute observations. Items in the Discomfort-DAT assess facial expression, body tension, fidgeting and negative vocalization. Examples of agitated behaviors included in the WAI are hitting, pacing, repetitive questioning, and verbal combativeness. Internal consistency alpha coefficients ranged between .77 and .82 for the Discomfort-DAT morning measurements and between .63 and .67 for the evening measurements. Interrater reliability was achieved for both the Discomfort-DAT and WAI (kappa .85 and .87 respectively), and retested every eight weeks to prevent drift. Both the Discomfort-DAT and WAI have been responsive to change in previous intervention studies (Kovach, Logan, et al., 2006; Kovach et al., 2004).

Raters, blinded to study conditions, waited 30 minutes past the time of any potentially discomfort- or stress-producing event before collecting observational data. Time sampling schedules with random sequencing were used to obtain 2 measures of discomfort (midmorning and after dinner) and 8 measures of agitation (2 during breakfast, midmorning, before and after dinner), which were averaged.

Assays of salivary cortisol were used as a marker of stress. Dysregulation in the hypothalamic-pituitary-adrenal (HPA axis), and more specifically, glucocorticoids, have been linked to stress responses (Lovallo & Thomas, 2002). Salivary cortisol has been extensively validated as a measure of endogenous cortisol production and is now an accepted approach to assess circulating biologically active (i.e., unbound) cortisol and long-term stress (Raff, 2000; Weibel, 2003). A normal diurnal rhythm of cortisol is characterized by a negative slope created by a peak in cortisol after waking followed by a decline in levels throughout the day (Edwards, Evans, Hucklebridge, & Clow, 2001). Flatter cortisol slopes were recently linked to increased mortality in a sample of 4,047 men and women with an average age of 61. This increased mortality risk was mainly driven by an increased risk of cardiovascular death (Kumari, Shipley, Stafford, & Kivimaki, 2011).

Saliva samples were collected from under the tongue using three hydrocellulose microsponges (Granger et al., 2007) 30 minutes after awakening, 45 minutes after breakfast, and 45 minutes before and after dinner (± 15 minutes). Following collection, samples were centrifuged and frozen at -40 degrees Celsius. Salivary cortisol was measured using an ELISA (Salimetrics, LLC, State College, PA), according to the manufacturer's protocol (Gibson et al., 1999). All samples from the same participant were run in the same batch to avoid between batch variability. The intra-assay coefficients of variation (CV) were 5.2% at 3.1 (SD, 0.2) nmol/L ($n = 10$) and 2.6% at 10.4 (0.3) nmol/L ($n = 10$). Inter-assay (total) CVs were 11% at 2.8 (0.3) nmol/L ($n = 10$), 11% at 10.1 (1.1) nmol/L ($n = 10$), and 6.9% at 25.0 (1.7) nmol/L ($n = 10$) (Raff, Homar, & Skoner, 2003).

Comorbid burden was measured through direct physical assessment. Thirty two items that measure potentially painful physical signs that are either modifiable or the discomfort associated with the item is modifiable were chosen by seven experts from a list of 84 for inclusion in the Comorbid Burden Scale (CBS). Examples of items assessed in the CBS include swollen joint, dyspnea, and skin excoriation. The CBS is a four point scale from no abnormality present to severe abnormality present. Scores are summed to yield a possible range of scores from 32 to 128. The Content Validity Index for both items and the scale was .84 and inter-rater reliability between two APNs was .93 (Polit & Beck, 2004; Waltz, Strickland, & Lenz, 2005). The CBS assessment was completed by an APN blinded to study condition.

Pretest data for all outcome measures were collected on the same weekday, chosen by convenience. Using the same procedural guidelines as in the pretesting phase, the discomfort, agitation and salivary outcome data were collected during Weeks 2, 4, and 6 and the CBS was completed in Weeks 2 and 6 after the STI was initiated.

Other Measures

Variables that were measured for moderating effects were baseline chronic illnesses (The Cumulative Illness Rating Scale-Geriatric) (Leon, Cheng, & Neumann, 1998) functional status (Functional Assessment Staging Tool) (Reisberg, Ferris, & Franssen, 1985), staff perceptions of nursing home working conditions (baseline Nursing Home Working Conditions survey) (Scott-Cawiezell, Jones, Moore, & Vojir, 2005); staff and nurse turnover, and staffing level. Staff surveys were distributed at the start of the study and returned by mail. Turnover was calculated based on both voluntary and involuntary dayshift turnover on each unit involved in the study one month prior to the training date and three months following that date (Castle & Engberg, 2006). Unit staffing level was calculated as the proportion of nurses to residents and CNAs to residents on the unit calculated one month prior to the training date and three months following that date.

Because cortisol levels are influenced by multiple non-HPA axis factors, data were collected on multiple variables (i.e. diagnosis of depression, diabetes, use or withdrawal of benzodiazepines, estrogen use, opioids, ketoconazole, gender, obesity) for possible inclusion as covariates. Psychotropic and analgesic medication changes were counted for possible inclusion as covariates with all outcome measures. Dose of the intervention was measured as a percentage of days in which steps of the STI were used in response to behavioral symptoms.

Data Analysis

To test hypothesis 1, differences in resident care between the 5-Step and 9-Step STI were described using frequencies and percentages and compared using Fisher's exact test for binary outcomes. Ordinal process variables were collapsed to a binary outcome because most of the responses for one of the groups were either on the top or bottom of the range.

To address the second hypothesis of whether there were changes over time, separately in each treatment group, a mixed model for repeated measures data with a time effect was used. Log transformations of the cortisol slope were used to correct for skewness. Adjustments for covariates and for clustering within nursing homes were tested and were not significantly associated with outcomes. To test hypothesis 3, we fit a model including both groups with a time effect, a group effect, and a time by group interaction. This time by group interaction tests for whether the mean changes from baseline were different in the two groups. We also used contrasts to compare baseline values between the two groups, as well as changes from baseline to each subsequent time point. Finally we computed an estimate of the effect size based on the change from baseline to 6 week posttest (difference in change scores between treatment and control, divided by SD of difference).

We also tested whether the effectiveness of the intervention was moderated by resident or facility characteristics. Moderating effects between treatment and resident characteristics were tested using regression models for the 6 week posttest, adjusting for the baseline measurement as a covariate. Moderating effects between treatment and facility characteristics were tested using mixed models for the 6 week posttest outcome, adjusting for the baseline measurement as a covariate and treating facility as a random effect. Because of the large number of moderating effects being tested, a significance level of 0.01 was used to identify statistical significance.

We also investigated the effect of dose of the intervention on the outcomes, after adjusting for baseline measurement, using linear regression techniques. To account for confounding by number of new problems, we adjusted the CBS model. Differences between groups in nurse time were analyzed with a t-test.

RESULTS

Figure 2 describes participants' flow through the study. The consent rates were close to 33% in both groups, though more consenting residents in the 5-step group (25%) did not meet eligibility criteria than in the 9-step group (12%). More people in the 9-step condition ($n = 35$; 34%) did not receive the allocated intervention than in the 5-step group ($n = 14$; 19%), with the biggest difference being fewer residents having a behavioral change identified in the 9-step group. Also, in the 9-step group, 4 participants were dropped because either the family member or prescribing physician refused to have a medication administered that was consistent with the STI protocol. One interventionist in each group had to take an emergency medical leave, which led to 2 participants in the 5-step and 4 participants in the 9-step not receiving the allocated intervention. Table 2 describes sample characteristics and shows that the groups were not statistically significantly different in measured characteristics.

Results in Table 3 show that hypothesis 1 was supported. Residents treated using the 9-step STI more frequently had treatment preceded by assessment, new physical problems identified and treated, scheduled dosing of effective treatments and adjunctive and preventive treatments added. There were more written orders and more communication with staff regarding the plans for scheduled dosing and adding treatments. Static and dismissive responses to resident behavior change were less in the 9-step STI group, and this group had more treatments stopped because of ineffectiveness, side effects, or because the treatment was not needed.

As seen in Table 4, hypotheses 2 and 3 were partially supported. Residents treated with both the 5 and 9-step versions of the STI had statistically significant decreases from pre to posttest in discomfort and agitation, with effect sizes ranging from .45 to .90. The decrease from pre to posttest in comorbid burden was only seen in the group receiving the 9-step STI (effect size .47).

The interaction between treatment and time was statistically significant for comorbid burden and cortisol slope (effect sizes .5 and .49). Residents treated with the 9-step STI had less comorbid burden and an increase in cortisol slope at 6 weeks posttest. The increase in the cortisol slope was due to a decrease in cortisol level at the last measure of the day. While residents treated using the 9-step STI had less discomfort (effect size .18), and agitation (effect size .26) than residents treated with the 5-step STI, the differences were not statistically significant. There were no significant moderating effects for any of the facility or resident characteristics.

After adjusting for new problems identified, there was a significant negative association between dose of the intervention and comorbid burden ($p = .026$). The regression coefficient of -3.01 indicates that a one unit increase in dose was associated with a 3 unit decrease in average comorbid burden. There were no significant effects of dose on discomfort, agitation or cortisol slope. Results comparing nurse time showed that interventionists averaged less than 1 contact per day ($M = .82$, $SD = .55$) regarding a residents change in condition in the 9-step STI group and averaged 1 contact per day ($SD = .63$) in the 5-step STI group. This difference was not statistically significant ($t = 1.65$, $p = .102$).

DISCUSSION

Prior studies demonstrated that assessment and problem identification are two critical and distinct steps in managing the care of nursing home residents (Longo, Young, Mehr, Lindbloom, & Salerno, 2004). However, there is inconsistency in the use of these steps (Barry et al., 2002; Bates-Jensen et al., 2003; Wipke-Tevis et al., 2004). The 9-step version of the STI contained four additional decision rules than the 5-step STI. The 9-step STI led to improved care with less static and dismissive responses to resident behavior change. Residents receiving care from nurses using the 9-step STI had significantly more treatments preceded by an assessment and more new physical problems identified and treated. In addition, nurses who used the 9-step STI more frequently obtained new nurse or physician orders, got effective treatments scheduled for regular use, added more adjunctive and preventive therapies to the care plan, and more frequently communicated with staff regarding the plan of care.

Of critical importance, the time it took to assess and treat instances of behavior change over the 6 week posttest period was not significantly different between the 9-step and 5-step versions of the STI. While the time it takes to respond to behavior change using the 9-step version of the STI may be longer while completing the additional steps, this study suggests that over time the need to complete assessment and treatment in response to behavior change will not be greater than while using the 5-step version. One possible explanation for this lack of difference may be that the lower comorbid burden and stress in residents treated with the 9-step STI decreased instances of behavior change and/or care needs. This is a question for future research.

Previous research (Kovach, Logan, et al., 2006) demonstrated effectiveness of the 5-step STI for the outcomes of discomfort and behavioral symptoms. In this study both versions of the STI significantly decreased discomfort and agitation, but only the 9-step version was effective at decreasing comorbid burden and increasing cortisol slope. The increases in cortisol slope found in this study represent improvement as participants moved from a flatter slope to a more normal slope. The increased slope may indicate a decrease in physiological stress later in the day or better sensitivity of the HPA axis to negative feedback (Stone et al., 2001; Wilkinson, Peskind, & Raskind, 1997).

Nurses working in nursing homes with residents who have compromised verbal communication are faced with the difficult task of identifying and meeting the residents' needs. Adding to the complexity of care, are the multiple comorbid conditions and vague and atypical symptom presentation so often seen in the older adult population. Findings from this study suggest that the nurse's critical thinking, communication and actions when a resident with advanced dementia experiences behavior change are critically important to quality of care and quality of life. Comprehensive assessment and pursuit of treatment and new treatment orders for newly identified problems are steps in the STI that were associated with positive resident outcomes. Frequent communication with physicians and other staff regarding care needs and the plan of care is an important aspect of providing quality care. The use of a systematic decision support tool such as the STI can assist nurses in the flow of action steps needed to resolve a change in condition or unmet need. It is encouraging that findings suggest that when nurses invest the time into providing thorough assessment driven treatment and follow through, future nursing care needs of the resident may decrease.

LIMITATIONS

Limitations of the study include convenience sampling and a potential difference between the two groups in those that did not receive the allocated intervention. A larger number of eligible participants in the 9 step STI group were reported by nurses to exhibit no changes in

behavior. Further, errors in measurement could have occurred. Consistent procedures were used for observations and to collect saliva samples in the same manner and from the same location in the mouth. Cortisol levels, agitation and discomfort can be impacted by multiple factors. Though we tested for confounding influences, it is possible that other factors in the nursing home or within the individual, such as environmental stressors, caregiver demeanor, or other medications, could have acted as confounds. While procedures were used to ensure accurate and complete information on daily tracking forms, missing information could have occurred. The STI is a multi-component intervention, and this study does not allow conclusions about which parts of the STI, either separately or in combination, affected outcomes. Finally, use of an additional no-treatment control group would have strengthened the design.

RECOMMENDATIONS FOR FUTURE RESEARCH

Future research should examine the influence of components of the STI on outcomes and the short and long-term consequences of meeting needs of those with advanced dementia. For example, decreasing comorbid conditions may decrease health service use and costs. Decreasing agitated behavior may decrease environmental stress and improve other residents' quality of life as well as staff satisfaction. There is a need for further research to understand the mechanisms of action that affect changes in cortisol slope. The 9-step STI changed nursing care practices. Translational research is needed to examine structured approaches to widespread implementation of the STI in for making changes in the performance of nurses working in nursing homes.

CONCLUSION

In conclusion, results from this study support that the 9-Step STI changes nursing practice and resident outcomes. Nurses are faced with complex resident situations and are challenged with making judgments through integrating different aspects of information about the resident. The STI offers an organized method for providing consistency and follow through of nursing care. As the number of people with dementia residing in nursing homes continues to grow and the complexity of care needs increases, the use of empirically tested decision support tools such as the STI should be considered for adoption.

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Figure 1.
Consequences of the Need-Driven Behavior Model

Figure 2.
Study Participants Progress in Study

Table 1**Description of Steps of the Serial Trial Intervention (STI)***

Identify behavioral symptoms by using an explicit schedule and procedures for the nurse and ancillary staff. When a resident exhibits changes in behavior that are not effectively treated through basic care provided by the ancillary staff, the STI is initiated by the nurse.

The STI process is stopped when behavioral symptoms decrease by 50% or more. Continued movement through steps of the STI is based on results of assessments and decreases in symptoms by less than 50% in time frames that have been established for specified treatments. If the behavioral symptom continues after completing these 5 steps, the process is repeated.

STI Step 1: Perform physical needs assessment that focuses on conditions associated with discomfort. If assessment is positive, a targeted intervention is implemented or the appropriate discipline is consulted to begin treatment. If the assessment is negative, or if treatment fails to decrease symptoms by at least 50%, the nurse moves to the next step.

STI Step 2: Perform affective needs assessment that focuses on needs of people with dementia: (1) environmental stress threshold not exceeded, (2) balance between sensory-stimulating and sensory-calming activity throughout the day, and (3) receipt of meaningful human interaction each day. If assessment is positive, a targeted intervention is implemented or the appropriate discipline is consulted to begin treatment. If the assessment is negative, or if treatment fails to decrease symptoms by at least 50%, the nurse moves to the next step.

STI Step 3: Administer a trial of nonpharmacological comfort treatment(s). Treatments used are tailored to the person and the situation and are based on a list of psychosocial and environmental treatments that have been associated with decreasing agitated behaviors. If a trial of nonpharmacological comfort treatment(s) does not ameliorate behaviors in a time frame likely to show outcomes, the nurse should move to step 4.

STI Step 4: Administer a trial of analgesics by either administering the prescribed “as needed” (i.e., pro re nata [prn]) analgesic or obtaining orders to escalate a current analgesic. If there is not a response to a trial course of analgesics, consider consultation regarding further escalation or proceed to the next step.

STI Step 5: Consult with other disciplines or practitioners (i.e., the nurse practitioner, physician, hospice, geropsychiatry). A trial of a prescribed psychotropic drug may be administered in this step if the behavior continues and the nurse carefully considers alternatives and weighs the potential for side effects against the comfort needs of the resident.

STI Step 6: Schedule dosing of effective treatments for continued use. If a one-time treatment is effective and continued use is desirable, take actions needed to ensure continued treatment (e.g. get a written order for continued use; communicate new order to other staff). For treatments ordered by the nurse (e.g. hand massage, walking activity), write the order on care cards with prescribed times of administration.

STI Step 7: Stop ineffective treatments. Using the daily tracking forms, look for patterns of continued use of the same treatments, even though the resident’s problems or behavioral symptom are not resolved or recur. For these treatments, determine if the treatment may be ineffective, not needed, or associated with side effects. Take measures to stop these treatments (e.g. discontinue use or consult with prescriber to get order stopped).

STI Step 8: Add adjunctive and preventive treatments. For each new problem, determine if anticipatory care, preventive treatments or additional treatments may help to manage the problem or the discomfort associated with the problem. Take measures to add these treatments (e.g. obtain written order, communicate new order or approach to other staff).

STI Step 9: Monitor for recurrence and new problems. Conduct regular comprehensive assessment. Establish clear criteria for evaluation of problems, and treatment effectiveness, need for treatments and possible side effects.

* The 5-step version of the STI uses steps 1–5 and the 9-step version uses steps 1–9.

Table 2

Description of Participants in the 5 and 9-Step STI groups.

Variable	5-Step Group (n=61)	9-Step Group (n=64)	Probability
Gender	Male = 13 Female = 48	Male = 15 Female = 49	p=.776
Race/Ethnicity	White,-non-Hispanic = 0 Black, non-Hispanic = 61 Hispanic = 0 Unknown or Not Reported = 0	White,-non-Hispanic = 1 Black, non-Hispanic = 61 Hispanic = 1 Unknown or Not Reported = 1	p = .374
FAST-function	Stage 5 = 1 Stage 6 = 37 Stage 7 = 23	Stage 5 = 0 Stage 6 = 31 Stage 7 = 32	p=.298
Age	Mean = 87.64 SD = 5.44	Mean = 86.02 SD= 8.84	p=.222
MMSE-cognition	Mean = 7.77 SD = 5.92	Mean = 5.78 SD = 6.04	p=.066
Length of Stay (in months)	Mean = 29.72 SD = 24.48	Mean = 36.14 SD = 35.39	p=.243

Table 3
Differences in Resident Care Between the 5-Step and 9-Step STI Conditions

Resident care variable	5-Step STI (n=61)		9-Step STI (n=64)		p
	f	%	f	%	
ASSESSMENT DRIVEN TREATMENT					
Treatment preceded by assessment: 85% of care	10	16	43	63	<.001
New physical problems identified and treated: 3	17	28	35	52	<.001
EVALUATION DRIVEN FOLLOW THROUGH					
Scheduled dosing of effective treatments	31	48	61	90	<.001
➤ New nurse or MD order obtained	30	47	60	88	<.001
➤ Communication with staff re: plan	31	48	61	90	<.001
Adjunctive/preventive treatments added	27	42	64	94	<.001
➤ New nurse or MD order obtained	41	64	64	94	<.001
➤ Communication with staff re: plan	40	63	64	94	<.001
STATIC AND DISMISSIVE CARE					
Static care: 15% of care	34	53	63	93	<.001
➤ Treatments stopped	12	20	39	61	<.001
Dismissive care: 15% of care	46	72	65	96	<.001

Table 4
Means, Standard Deviations, and Repeated-Measures Analysis of Variance Comparing Resident

Outcome variable	Pretest	2 Week Posttest	4 Week Posttest	6 Week Posttest	Pre to 6 Week Post			Time × Group Interaction		
					F	p	Effect Size	F	p	Effect Size
Comorbid Burden										
5 Step STI	45.8 (5.3)	45.4 (5.0)	-----	46.5 (6.9)	1.04	.357	.10	3.33	.037	.5
9 Step STI	47.2 (7.2)	45.5 (7.3)		45.7 (6.2)	4.98	.008	.47			
Discomfort										
5 Step STI	38.1 (17.6)	31.9 (18.9)	29.3 (18.7)	27.2 (14.9)	7.43	<.001	.56	.69	.557	.18
9 Step STI	43.0 (15.9)	32.8 (14.3)	31.2 (15.7)	28.6 (14.9)	20.46	<.001	.90			
Agitation										
5 Step STI	62.4 (25.3)	52.1 (25.9)	49.4 (25.1)	50.6 (20.6)	6.96	<.001	.45	1.01	.386	.26
9 Step STI	69.1 (22.1)	58.9 (19.9)	54.4 (23.5)	51.3 (21.0)	15.76	<.001	.78			
Cortisol slope										
5 Step STI	.046 (.060)	.052 (.067)	.060 (.053)	.040 (.056)	1.73	.165	.18	2.67	.048	.49
9 Step STI	.044 (.079)	.051 (.056)	.044 (.047)	.064 (.066)	1.32	.272	.30			