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*An Evaluation of the Vigil System*

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# VIGIL Final Report

**Project Title:** An Evaluation of the VIGIL System.

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## **Section I: Goals, Objectives, Research Questions, Hypotheses**

This project assessed the extent to which modern technology can augment, and/or substitute for direct staff intervention in non-acute late evening and night-time situations in the nursing home setting. The impacts associated with the presence of such technology on the quality of care provided to, and quality of life experienced by, nursing home residents with dementing illness are the topics central to this project. A service (VIGIL) was implemented for residents of a Special Care Unit (SCU) maintained by the lead nursing home for persons with dementing illness; an SCU matched for cognition was used as a comparison unit on which the service (VIGIL) was not implemented.

There were three clusters of hypotheses. These related to primary resident and staff outcomes. (The alpha level for each variable within the cluster was prespecified at 0.05 for a two-tailed test.) The study hypotheses were:

1. The presence of an automated sensing system (VIGIL) will reduce the number of times that nurses and Certified Nurses' Aides (CNAs) have to check residents' nocturnal status.
2. Due to the presence of VIGIL, the absence of excess noise and light associated with otherwise mandated routine rounds will enhance sleep quality and permit/promote sleep consolidation, thus reducing the occurrence of deviant behaviors and improving the affect of residents.
3. Through the use of the intervention aspect of the VIGIL system, its presence will contribute to the reduction of falls and accidents and injuries, thus improving quality of life for the residents.

## **Section II: Background and Rationale**

Day and colleagues<sup>1</sup> provide a conceptual orientation to the study of the environment, discussing the need to consider individual characteristics in the design of environments. This is reminiscent of the concept of person-environment fit introduced 30 years ago by Kahana<sup>2</sup>, which provided a context for the study of human factors that examines the relationship between task demands and personal components. The environment is important because it is closely linked to quality of life, defined by Lawton as “the multidimensional evaluation by both intra-personal and social-normative criteria, of the person-environment system of the individual” (p.6)<sup>3</sup>.

As reviewed in Holmes, Teresi and Ory<sup>4</sup>, despite decades of research regarding person-environment fit, it is still unclear how best to individualize care environments, given the constraints implicit in the need to serve many individuals, with varying needs, in a single congregate setting.

Day and colleagues<sup>1</sup> emphasize that targeting and tailoring to stage of dementing illness is an important aspect of environmental design. They show that some environmental modifications work best for people at moderate stages of impairment, while others work better for people at later stages. This point cannot be over-emphasized, as the prevalence of cognitive impairment in chronic care settings is high. For example, the National Institute on Ageing collaborative studies found that almost 90% of nursing home residents were cognitively impaired, about half severely so (see Teresi, Morris, Mattis and Reisberg<sup>5</sup>).

Confusion and disorientation can alternatively be exacerbated or helped by environmental interventions. An example of both the importance of considering the environment in the context of the people (residents and staff) and the difficulty associated with attempted remediation is a study by Schnelle and colleagues<sup>6</sup> of the impact of an intervention to reduce noise and light at

night, which they have shown to be associated with awakenings. Staff members were so resistant to the intervention that they never achieved a noise reduction characterized by episodes below 50db. These findings, showing the difficulty in implementing the most basic of interventions, highlight the need for sharpened awareness on the part of administrators and regulators regarding the importance of the environment. Sloane, Mitchell, Calkins and Zimmerman<sup>7</sup> document the lower than recommended levels of lighting found in both activity areas and in resident's rooms in SCUs, along with uneven lighting and glare. Additionally, decibel levels in the 60s were found in the dining room during lunch and outside the nurses' station, a level equivalent to loud talking. Given the association of low lighting, circadian rhythms, sleep disorder and agitation observed in several studies, and the relationship between noise and negative outcomes observed in others, this situation is less than ideal and deserves attention. It can be posited that the reduction of the need for night rounding could reduce noise and result in sleep enhancement and improved behavior and affect.

Many facilities are understaffed: nursing shortages have become endemic and public reimbursement for institutional care has been reduced. Further, great emphasis has been placed on reducing or eliminating the use of physical and/or chemical restraints as a form of behavior management. There has also been a focus on eliminating the use of bedrails for residents, as it has been shown that they can increase the number of falls and other injuries as residents attempt to get out of their beds during the night<sup>8</sup>. Indeed, a decrease in bed rail use did not result in increased serious injuries for nursing home residents<sup>9</sup>.

One solution to the need to attend better to resident safety, while maintaining independence has been the introduction of resident monitoring systems. At the annual meeting of the American Association of Homes and Services for the Ageing (AAHSA) in 2004, there was a

session focused on “Solutions to the Aging Services Crisis,” in which presentations from universities and private corporations demonstrated new technologies that have been developed to enable caregivers to provide services more efficiently, particularly in nursing homes. Experts at the conference asserted that Skilled Nursing Facilities (SNFs) and assisted living will be the primary focus of technologic innovation during the next several years, so as to reduce costs and improve staff efficiency. Fall-monitoring equipment is not currently considered a routine aspect of nursing care, and knowledge about the value of such devices is poor;<sup>10</sup> more evidence is needed on both the benefits and shortfalls of using monitoring equipment.

A major theme of the 2005 International Association of Homes and Services for the Ageing Conference (IAHSA) was technology and its uses in aged care, including both the monitoring of older people in residential care or in their homes, and the use of technologies to enhance the role of the aged care workers. Glascock and Kutzik<sup>11</sup> presented the Automated Behavioural Monitoring System (ABMS), which has been in use for 10 years. This system uses off the shelf components. Based on use by 30 home care clients, the developers claim that alterations in care was achieved for 26 clients, and that the relationship between the nurses and the clients was enhanced because the clients felt an increase in their ‘peace of mind’. Such anecdotal evidence underscores the need for more vigorous evaluation of monitoring systems.

## **Section III: Methods**

### **Description of the Intervention**

The VIGIL monitoring system, evaluated in this study, is comprised of a bed exit sensor, which is positioned under each resident's bed sheet, and bathroom and bedroom exit monitors. An incontinence sensor is also available. VIGIL alerts caregivers via a silent pager when a high risk resident exits their bed, bedroom, or bathroom according to rules that are established for each resident. This allows caregivers to aid the resident and potentially reduce falls. In addition VIGIL records caregiver response times. For this study, the incontinence sensor was not used because nursing staff felt that the diapers used were sufficiently absorbent that the monitor would not be able to detect moisture.

### **Study Design**

The study was a quasi-experimental design that compared the residents from a unit in which the VIGIL system was installed (the intervention unit) with residents from a unit in which there was no such installation (the comparison unit). The VIGIL system was installed in one of the facilities larger special care units (SCU)(50 beds), which serves residents with moderate to severe levels of dementia; another 50 bed SCU – in a separate building – matched for case mix index and cognitive impairment was the comparison unit.

### **Procedures**

In addition to examining the case mix index for the units, the MMSE data used routinely for placement decisions were considered in the selection of the two units that appeared to be the best matches among the 17 candidate units.

All residents who lived on the two units were approached to participate in the study. For those who were not able to give consent, their families were approached to give consent on behalf of the resident; one family refused to allow contact with the resident.

A computer was installed in the nursing unit and rooms were wired to receive VIGIL. Additionally, bed pads were ordered. The system was installed free of charge. Nursing staff were trained in its use; additional retraining was later required. VIGIL staff performed this training on-site, in addition to ongoing remote monitoring. Research staff showed CNAs how to use the pagers, and nurses how to set rules for egress. For example, rules could be set so that the CNA would be paged only after prespecified time in the bathroom. The time would be determined by the nursing staff, based on previous patterns of behavior. The research assistant helped the nursing staff set rules, and monitored carefully the behavior of the staff and kept daily logs regarding implementation (e.g., rules set and bed pad operations); performance feedback was provided to staff.

### **Sample**

At baseline, on both units, residents were primarily female, white, widowed; 44% of them had worked in clerical or sales positions. The average age on both units was 87 ( $\pm 7.5$  years). There were no significant demographic differences between the two groups. A total of 118 residents were eligible for baseline, in-person data collection. As new residents replaced those who had left the unit, they were entered into the study. A total of 92 residents completed the baseline assessments. Ten residents partially completed the instruments and 16 refused or were unable to participate due to hospitalization or illnesses.



## **Data Collection**

Data were collected at 3 points: baseline, 12-month follow-up and 15-month follow-up. A total of 78 residents (38 on the intervention unit and 40 on the comparison unit) completed a baseline and one additional follow-up, and constituted the analytic sample. Sixty-six residents completed all three waves of data collection.

## **Instruments**

Prior to in-person data collection, demographic data were obtained during reviews of residents' charts. Information regarding date of birth, age, place of birth, gender, marital status, education level, past occupation, and father's first name were gathered from charts, to be used when assessing residents' memory and orientation.

**Resident Interview:** In-person assessments were conducted with residents during approximately an hour long session, in which interviewers administered the following assessments: the Institutional Comprehensive Assessment Referral Evaluation (INCARE)<sup>12-20</sup> and the INCARE Cognitive Screening measures (including Mattis Attention Subscales<sup>21</sup>, the Range of Motion Scale, the Feeling Tone Questionnaire<sup>22</sup>, the Cornell Scale for Depression in Dementia<sup>23</sup>, and the Performance Activities of Daily Living (PADL)<sup>24</sup>. Interviews were conducted in a private setting, in either the resident's room or a quiet sitting area located on each unit.

**Observed Behavior & Affect:** Interviewers performed five minute behavioral observations at ten different times: morning, afternoon and evening, over a three day period, in order to capture residents in normal, everyday settings. Observations of resident affect were examined through the Behavioral Observation Checklist<sup>25</sup> and the Observed Emotional Scale<sup>26</sup>.

**Functional Capacity:** CNAs were interviewed by research staff member to complete the Functional Assessment Staging (FAST)<sup>27</sup> and the Personal Activities of Daily Living

Questionnaire<sup>25</sup>. These interviews were conducted on three separate days and followed-up every three months. They occurred in private, at the nurses' station located on each unit, and with consideration to the activities of daily activity schedules for each CNA.

**Staff Informant Questionnaire, Behavior & Activities:** Social workers familiar with each resident were asked to report on residents' affect and sleep patterns and activity participation using the Multidimensional Observation Scale for Elderly subjects (MOSES)<sup>28</sup>. Also, therapeutic activity workers most familiar with each resident were asked to report on residents' social contracts and activities.

**Sleep Logs: Staff Burden & Direct Care:** Facility nursing staff were periodically asked to fill out weekly log sheets describing sleep behaviors for each resident. Night shift CNAs logged the amount of time spent caring for residents, and answered questions about resident nighttime behaviors and sleep interruptions and staff burden. Log sheets were completed one night per week (approximately) for each resident. At each wave of data, on average, 12 to 30 weeks of data were collected for each participant.

**Falls and Injuries:** A Quality Assurance Audit summary was completed by the nursing department throughout the three waves of data collection, which detailed accidents and incidents, including falls and internal and external risk factors for falls.

**Chart & Medical Record Data on Behavior:** The Patient Review Instrument (PRI) contains four items that reflect resident behaviors: physically abusive, verbally abusive, wandering and socially inappropriate behavior. These data were used primarily to examine any long-term changes, which may have occurred accompanying extended exposure to the intervention.

## **Analytic Variables**

### **Covariates**

Covariates were selected based on variables which were significantly different at baseline between intervention and comparison groups. Although the units were matched initially on case mix index and cognition, it was not possible to control completely for differences in resident characteristics.

1. Cognition: The Mini-Mental State Examination (MMSE) was used in these analyses. The twenty item scale (alpha of 0.75 for this sample) measures the degree of cognitive impairment, and is scored in the disordered direction.
2. Activity: The social contacts/activities scale from the Helmes and Csapo's Multidimensional Observation Scale for Elderly subjects (MOSES)<sup>28</sup> (alpha of 0.74 for this sample) consists of six items that measure how frequently in the past week residents were "initiating interactions with day shift staff members or residents", "helping other residents" or "responding to social contacts". This scale is scored in the positive direction.
3. Activities of Daily Living: The Performance Activities of Daily Living (PADL) (alpha of 0.93 for this sample) is a 27-item scale that measures an individual's lack of ability to perform certain activities of daily living independently. This scale is scored in the deviant direction.
4. Age: Age was considered as a covariate because of its theoretical relationship to outcomes such as falls. As shown below, there were no differences between the units on average.
5. Walking Outside: The walking outside scale consists of 5 items (alpha of 0.81 for this sample) that measures an individual's ability to walk outside of the building. This scale is scored in the deviant direction.

## Outcomes

Prespecified outcomes were:

- 1) Resident falls and injuries received as an outcome of those falls.
- 2) Affect: The Feeling Tone Questionnaire (FTQ)<sup>22</sup>: The FTQ Affect scale contains 16 questions asked of the resident; typical items are: “Are you feeling well?”; “Are you feeling happy today?”; “Do you feel lonely?”; “Do you have a good appetite?”; “Do you sleep well?”. Answers to these questions are scored, and additional ratings on affect, based on the responses are recorded. Resident affect was rated on a 5-point scale which describes affect as being: “extremely positive,” “moderately positive,” “neutral,” “moderately negative,” “extremely negative.” The FTQ is collected three times per administration and an average score is computed from these. The alpha coefficient for the affect scale for this sample was 0.80. This scale is scored in the deviant direction.
- 3) Observed Behavior: The Behavior Observation Checklist<sup>25</sup> measure is a 37-item behavioral observation checklist completed by trained raters. Typical items include: “Argumentative”; “Asking for help”; “Noisy”; and “Uncooperative.” The individual was rated with respect to each behavior as to whether the behavior occurred “Not at all, ” “Very little (1x or 2x during observation period), ” “With some frequency (several times), ” “With moderate frequency (many times but not continuous), ” or “With great frequency (continuous). ” Residents were observed ten times per administration and an average score from these observations is computed. The alpha coefficient for this sample was 0.68 for observed behavior. This scale is scored in the deviant direction.
- 4) Staff Direct Care, Intervention and Burden: Direct Care was measured using one item, “Time spent with resident,” (recorded in minutes) from the nurse reported Sleep Logs;

Staff Burden was measured using a scale developed from seven items in the nurse reported Sleep Logs. Items were scored on either a three or five point Likert scale. Typical items are: “How well did resident sleep tonight?” (“Very well,” “Well,” “OK,” “Not very well,” and “Not well at all”); “Did you have to check on resident?”; “Was resident night-time behavior a bother to you?” (“Not at all,” “Somewhat,” and “A great deal”); “How cooperative would you say the resident was tonight?”; “Night-time care for resident is getting?” (“Much harder,” “A little harder,” “About the same,” and “Much easier”); and “Do you think resident night-time behavior is?” The other items had similar response categories. Individual items were averaged over a month period, and then the seven items were summed to create a score for the month. The Cronbach’s alpha for this measure was 0.92. This scale was scored in the burdened direction.

**Rationale for Selection of Outcomes:** The most effective fall prevention strategies are multifactorial, with multiple associated outcomes. It was thus hypothesized that the outcomes would be multifactorial.

**Cluster 1:** It was hypothesized that falls, accidents, and injuries would be reduced in the intervention group.

**Cluster 2:** Affect was selected as an outcome because residents who have nighttime interruptions are more likely to feel worse the following day, exacerbated by having to wait for attention or care. Additionally, falls are related to decreased affect. Thus it was posited that the intervention group would experience, on average, decreased negative affect. Observed Behavior was selected as an outcome because it has been shown that disturbed nocturnal sleep was related to agitation<sup>29</sup>. It was hypothesized that a decrease in behavior disorder would be observed.

**Cluster 3:** Direct Care was selected as an outcome as it was expected that the time the nurses spent with the residents during the night would decrease, if rounding decreased. Staff Burden was selected as an outcome as it was expected that the use of the VIGIL system would decrease staff burden. Additionally, it was posited that the residents who were exhibiting disturbing behaviors during the night would be attended to quickly and cause less interruptions and therefore less burden for the nurses.

### **Analytic Procedures**

A repeated measures mixed model analysis was performed. The mixed (random and fixed effects) model is used to adjust for design effects associated with residents clustered within units. The correlation within the unit can be modeled through consideration of an appropriate covariance structure (in this case, unstructured). The model holds even with unbalanced and missing data, so long as the missing data are random. The SAS PROC MIXED software constructs an objective function associated with Maximum Likelihood (ML) or Restricted/residual maximum likelihood (REML), and maximizes it over all unknown parameters.

Generalized linear mixed models have been specially developed for outcomes that are not normally distributed (in this case, the falls and injuries). It resembles generalized least squares, the fixed effects component of the mixed model procedure. SAS GLIMMIX was used to model falls or injuries each month. Further, the robustness of the model was checked with the SAS GEE procedure, a quasi-likelihood formulation useful in accounting for missing observations and handling continuous covariates that may be time dependent.

The resident constituted the unit of analysis for the resident outcomes, and there was clustering within the units. (Our previous analyses of these types of data, and the fact that only

one facility is sampled indicate that the facility design effect can be ignored, but that the unit effect is important.) Therefore, sample sizes had to be larger to account for unreliability of measures and for the design features of clustering. Despite the attempt to match units, some inter-unit differences were observed. For example, the intervention group was more cognitively impaired than was the comparison group.

Extensive psychometric analyses have accompanied development and cross validation of the CARE scales as well as most other data collected. CARE scales have retained high reliability (coefficients in the 80's and 90's) for most samples. Validities, depending on the method for assessment, remain adequate to good. Psychometric analyses were conducted to check the properties of the scales for this sample.

Preparatory to final bivariate or multivariate analyses, extensive initial analyses were performed. In the case of nominal/ordinal data, various forms of dummy coding were used. When appropriate, bivariate data plots and residual plots e.g. box plots, scatter plots, histograms and normal probability plots were examined in order to detect possible departures from linearity, heteroscedasticity and outliers. Diagnostic statistics (Cook's D values, studentized residuals) were used to assess the influence of individual data points, detection of outliers and examination of model fit preparatory to analyses; formal collinearity diagnostics were performed.

Adequacy of group matching was assessed with a low threshold ( $p$ -values  $< 0.15$ ) for detecting deviations from equality of means, variances and proportions in demographics and baseline variables within the two groups.

The covariates described above were included. Binomial tests were conducted on dichotomous and Poisson tests were carried out on non-binomial (e.g., count) data. Analysis of falls and injuries data was performed using up to 15 months of data. If a resident had any fall or

injury in a month, regardless of number, they were coded as having a fall or injury for that month. The number of falls or injuries per month were not taken into account because there were few multiple falls or injuries per month. The analyses were first run including age as a covariate; however, because age was not different between the groups, and was also not significantly related to the outcomes in the multivariate context, it was removed in the final analysis.



## Section IV: Results

### Bivariate Analyses of Group Differences in Potential Covariates

Examination of the cognitive scales contained within the INCARE<sup>12-25, 30-34</sup> revealed that at baseline residents exhibited moderate to severe levels of cognitive impairment, including several non-testable residents. Non-response was due to residents' lack of alertness or arousability, displayed inability to respond to simple commands, and responses offered that were primarily rambling and/or tangential. Residents of the intervention unit evidenced more cognitive deficit than their counterparts on the comparison unit. (See Table 1.) Direct resident assessments indicated that the intervention group displayed more physical limitation in their range of motion and performance of ADL's. Additionally, therapeutic activities workers reported that this group was more likely to attend or participate in social activities and functions.

Table 1: Baseline descriptive statistics for the covariates.

| Covariate                               | UNIT             |           |                    |           | t-test p-value |
|---|------------------|-----------|--------------------|-----------|----------------|
|   | SP3 (Comparison) |           | MG1 (Intervention) |           |                |
|   | Mean             | Std. Dev. | Mean               | Std. Dev. |                |
| Age                                     | 87.55            | 7.49      | 87.43              | 7.00      | 0.930          |
| Cognition (MMSE)                        | 16.23            | 5.01      | 19.84              | 7.20      | 0.005          |
| Activities of Daily Living (PADL)       | 3.39             | 6.62      | 8.20               | 9.65      | 0.010          |
| Activity (Activity Participation Scale) | 16.45            | 4.26      | 19.10              | 5.58      | 0.004          |
| Walking Outside                         | 2.84             | 1.17      | 3.62               | 0.85      | 0.001          |

### Bivariate Analysis of Group Differences in Outcome Variables

#### Accident/Incident Information

As indicated by the Accident/Incident Reports, a total of 192 accidents occurred through the duration of our study. The majority of these accidents did not occur during resident transfer

(88.5%), but 46.4 % of all accidents reported occurred in residents' rooms. Data indicated that 75.5% of accidents were the result of a fall, with 49.0% of those falls the result of an unknown origin and involved residents being found on the floor. The least number of accidents (1.0%) occurred at the nurses' station. Among those who experienced an accident, 53.7% sustained an injury. Injuries other than lacerations, hematomas, abrasions, etc. were the most common (37.9%). Lacerations or cuts were the second most noted injury (30.1%). There were no occurrences of concussions, sprain, strain, or viscera injury reported, and only one reported occurrence of a burn or scald caused by spilled food or drink (0.5%). The two groups did not differ significantly in terms of number of falls at baseline; however, there was a significant group difference in falls at baseline with respect to the final analytic sample, in the context of the multivariate analyses.

### **Behavior and Affect**

As indicated by nurse informants, the intervention group more prominently displayed the occurrence of sleep disturbance and disturbing behaviors. Overall, this group was more prone to exhibiting agitated behaviors, specifically aggressive and physically agitated behaviors. The two groups did not differ significantly in the occurrence of verbally agitated behaviors. Psychotic behaviors were also more evident in the intervention group, with an especially higher occurrence of hallucinations. The intervention group also demonstrated greater baseline affective disorder, according to observed measures and direct assessment (FTQ) of affect. However, this difference was not significant in the multivariate analyses. A slightly higher occurrence of anxiety/fear and sadness was observed from the AARS scores for this group.

### **Staff Direct Care & Burden**

Staff for the intervention group reported a greater amount of direct care at baseline than did the comparison group staff; however, this difference was not significant in the multivariate analyses. A significantly greater degree of staff burden was reported by intervention group staff than by staff in the comparison group.

### **Examination of the Bivariate Associations Among Variables**

As was expected, older residents were significantly more cognitively impaired, participated in few activities, and had more impairment in walking outside.

### **Longitudinal Analyses and Tests of Hypotheses**

Mixed models analyses were performed in order to examine the outcomes, controlling for the four designated covariates. Terms for group effect, time, and the group by time interaction were entered into the model. A significant group term indicates that the groups were different at baseline. A significant time effect indicates a worsening over time of the outcome, and a significant interaction term indicates that the intervention group (relative to the comparison group) improved (declined less) than the comparison group.

The intervention group experienced fewer falls initially (estimate = -1.61,  $p = 0.017$ ), and received a significantly higher Staff Burden score from the nurses at baseline, than did the comparison group (estimate = 3.29,  $p < 0.001$ ).

Examination of the time effects, from baseline to 15 months indicated that there was no significant change in the number of falls over the project period (estimate = -0.07,  $p = 0.148$ ), and no significant change in the rates of injuries (estimate = -0.03,  $p = 0.645$ ). The amount of direct care decreased significantly overall (across comparison and intervention groups) over the project period (estimate = -0.31,  $p < 0.001$ ).

A test of the hypotheses that the intervention group, as contrasted with the comparison group, would evidence a reduction in disturbing behavior, affect, and falls and injuries over time was accomplished through examination of the interaction of group\*time.

The odds of falling over the 15 month period was not significantly different (estimate = 0.09,  $p = 0.180$ ) between the intervention group and the comparison groups.

Table 2: Results for primary outcomes of the VIGIL system study.

| Effect     | FALLS <sup>a</sup><br>(n = 76) |            |        | INJURIES <sup>a</sup><br>(n = 76) |            |        | AFFECT <sup>b</sup><br>(n = 73) |            |         | BEHAVIOR <sup>b</sup><br>(n = 73) |            |         | DIRECT CARE <sup>c</sup><br>(n = 124) |            |         | STAFF BURDEN <sup>c</sup><br>(n = 124) |            |         |
|------------|--------------------------------|------------|--------|-----------------------------------|------------|--------|---------------------------------|------------|---------|-----------------------------------|------------|---------|---------------------------------------|------------|---------|--|------------|---------|
|            | Estimate                       | Std. Error | Sig.   | Estimate                          | Std. Error | Sig.   | Estimate                        | Std. Error | Sig.    | Estimate                          | Std. Error | Sig.    | Estimate                              | Std. Error | Sig.    | Estimate                               | Std. Error | Sig.    |
| Intercept  | -3.5422                        | 1.1877     | 0.0053 | -4.2151                           | 1.5947     | 0.0125 | 36.8558                         | 5.1729     | <0.0001 | 5.8599                            | 1.3850     | <0.0001 | 2.9700                                | 4.8631     | 0.5440  | 13.3349                                | 1.2483     | <0.0001 |
| MMSEPRO    | 0.0088                         | 0.0287     | 0.7598 | -0.0015                           | 0.0427     | 0.9721 | -0.1669                         | 0.1507     | 0.2721  | 0.0286                            | 0.0398     | 0.4750  | 0.3072                                | 0.1322     | 0.0205  | 0.0233                                 | 0.0338     | 0.4920  |
| PTOTALPR   | 0.0373                         | 0.0208     | 0.0728 | 0.0589                            | 0.0291     | 0.0436 | 0.0471                          | 0.1302     | 0.7185  | 0.0061                            | 0.0332     | 0.8538  | 0.2543                                | 0.1097     | 0.0208  | 0.0758                                 | 0.0281     | 0.0073  |
| ACTPARPR   | 0.0672                         | 0.0423     | 0.1130 | 0.0608                            | 0.0581     | 0.2961 | -0.1714                         | 0.1820     | 0.3498  | -0.0361                           | 0.0494     | 0.4681  | 0.0867                                | 0.1850     | 0.6395  | -0.0736                                | 0.0472     | 0.1196  |
| WALKOUPR   | 0.1419                         | 0.1511     | 0.3480 | -0.0035                           | 0.2071     | 0.9867 | 0.8551                          | 0.7655     | 0.2680  | -0.3236                           | 0.2026     | 0.1149  | 1.5750                                | 0.6942     | 0.0236  | 0.2042                                 | 0.1764     | 0.2474  |
| GROUP      | -1.6056                        | 0.6686     | 0.0167 | -0.2943                           | 0.7726     | 0.7034 | 2.3565                          | 2.0563     | 0.2559  | -0.9558                           | 0.5698     | 0.0981  | -2.4640                               | 1.8641     | 0.1868  | 3.2850                                 | 0.5176     | <0.0001 |
| TIME       | -0.0674                        | 0.0465     | 0.1475 | -0.0259                           | 0.0561     | 0.6445 | 0.0346                          | 0.0932     | 0.7118  | -0.0486                           | 0.0289     | 0.0969  | -0.3127                               | 0.0628     | <0.0001 | -0.0044                                | 0.0297     | 0.8824  |
| GROUP*TIME | 0.0931                         | 0.0693     | 0.1799 | 0.0162                            | 0.0745     | 0.8280 | -0.2864                         | 0.1323     | 0.0341  | 0.0363                            | 0.0402     | 0.3704  | 0.5292                                | 0.0808     | <0.0001 | -0.0020                                | 0.0383     | 0.9583  |

VARIABLES: D1: AGE OF RESPONDENT

MMSEPRO: MMSE PRORATED SCORE (DEVIANT)

PTOTALPR: PADL TOTAL: PRORATED (DEVIANT)

ACTPARPR: ACTIVITY PARTICIPATION: PRORATED (POSITIVE)

WALKOUPR: WALKING OUTSIDE: PRORATED (DEVIANT)

GROUP: GROUP (0 = SP3, CONTROL; 1 = MG1, INTERVENTION)

TIME: TIME IN MONTHS (FOR AFFECT AND BEHAVIOR, TIME CODED AS 0 = BASELINE; 12 = 12

MONTH FOLLOW-UP; 15 = 15 MONTH FOLLOW-UP)

<sup>a</sup> Binary outcome , generalized linear mixed model, random on id.

<sup>b</sup> Repeated measures mixed model with unstructured covariance structure.

<sup>c</sup> Means within a month, Mixed model, random on id.

There was no significant differences between the group in rates of injuries (estimate = 0.02,  $p = 0.828$ ).

The intervention group improved significantly in affective disorder by the end of the project (estimate = -0.29,  $p = 0.034$ ).

There was no difference in rates of behavior change between the two groups over time (estimate = 0.04,  $p = 0.370$ ).

The staff logs showed that the intervention group received significantly more direct care over the duration of the project than did the comparison group (estimate = 0.53,  $p < 0.001$ ). The additional care was about six minutes per month per resident. There was no significant difference in staff-reported burden between the groups over time (estimate = -0.002,  $p = 0.958$ ).

An additional analysis was performed to replicate earlier findings<sup>35</sup> showing a relationship between direct care received on special care units for individuals with dementia and positive resident outcomes. Examination of an interaction term for direct care received over time and group status showed that additional time spent in direct care in the intervention group was associated with decreased affective disorder, thus replicating the earlier findings. (See Table 3.)

Table 3: Predicting Affective Disorder including Direct Care.

| Effect            | Affect <sup>a</sup><br>(n = 67) |            |         |
|-------------------|---------------------------------|------------|---------|
|                   | Estimate                        | Std. Error | Sig.    |
| Intercept         | 37.3048                         | 5.0223     | <0.0001 |
| MMSEPRO           | -0.0409                         | 0.1480     | 0.7833  |
| PTOTALPR          | 0.1411                          | 0.1335     | 0.2949  |
| ACTPARPR          | -0.2503                         | 0.1614     | 0.1263  |
| WALKOUPR          | -0.1004                         | 0.7436     | 0.8930  |
| GROUP             | 11.0304                         | 3.5987     | 0.0033  |
| TIME              | 0.2343                          | 0.0580     | 0.0002  |
| GROUP*TIME        | -0.4224                         | 0.1305     | 0.0020  |
| DIRECT CARE*GROUP | -0.4498                         | 0.2109     | 0.0372  |

VARIABLES: DIRECT CARE: TIME SPENT CARING FOR RESIDENT (MINUTES)

D1: AGE OF RESPONDENT

MMSEPRO: MMSE PRORATED SCORE (DEVIANT)

PTOTALPR: PADL TOTAL: PRORATED (DEVIANT)

ACTPARPR: ACTIVITY PARTICIPATION: PRORATED (POSITIVE)

WALKOUPR: WALKING OUTSIDE: PRORATED (DEVIANT)

GROUP: GROUP (0 = SP3, CONTROL; 1 = MG1, INTERVENTION)

TIME: TIME IN MONTHS (FOR AFFECT AND BEHAVIOR, TIME CODED AS 0 = BASELINE;  
12 = 12 MONTH FOLLOW-UP; 15 = 15 MONTH FOLLOW-UP)

<sup>a</sup> Repeated measures mixed model with unstructured covariance structure.

## DISCUSSION

The main findings were that the groups did not differ in terms of the odds of falling or rates of injuries over the study period. While there was no difference in observed behavior, resident-reported affective disorder decreased significantly in the intervention unit. Results of the analysis showed that the nursing staff spent significantly more time in direct care for the intervention group than did the nursing staff caring for the comparison group.

The reported staff-burden was significantly higher at the beginning of the project for the nurses caring for the intervention group; however, this burden on the nurses did not get worse

over the time of the project, and there was no significant difference in burden between the groups. Although speculative, it is possible that use of the equipment and/or heightened awareness of and attention to resident needs via the paging system translated into somewhat more direct care, but no appreciable additional burden. The additional care and possible vigilance may have been associated with the increased quality of life as measured by affective status. An examination of the correlations of staff direct care and affective disorder lend support for this speculation. Correlations of affective disorder and direct care were inversely correlated across monthly measurement occasions. The strength of the association was greater (and significant) at the third wave of data; the multivariate findings were that the more time spent in direct care on the intervention unit, the less affective disorder was reported by residents.



## **Section V: Strengths and Limitations**

A limitation of the study is that nursing staff were resistant to implementing the intervention. Because the intervention was implemented on a pre-existing unit, with established routines, staff was reluctant to alter their methods of care. A goal of the project was to reduce the necessity for frequent night rounding, often up to once every half an hour. The rationale for the proposed reduction was that such rounding results in the intrusion of light and noise, and therefore, interrupted sleep, as shown by Schnelle and colleagues<sup>6</sup>. Like Schnelle and colleagues, we were unable to change staff behaviors to the extent desirable. Consistent with the prior protocol for night care, staff continued to check on residents every two hours, and recorded this on the Sleep Logs. Additionally, research staff was required to monitor the implementation and to assist in setting rules for egress because nursing staff did not wish to take ownership of this task.

An additional limitation is a result of the quasi-experimental design; some imbalance occurred between the intervention and comparison groups in terms of baseline characteristics. It was not possible to randomize within units because of contamination, and the cost of wiring two units so that enough subjects could be enrolled.

A strength of the study was that staff received training in VIGIL, and heightened awareness of risk factors for falls. This may have lead to increased time spent with residents, and thus to enhanced quality of care and quality of life, as evidenced by a reduction in affective disorder (improved affect). This conforms with other findings that enhanced staffing and staff time spent in direct care is significantly related to positive outcomes<sup>35</sup>.

## **Section VI: Conclusions**

In conclusion, the findings related to VIGIL are generally mixed. There was no significant, sustained reduction in falls and injuries, but there was a significant difference in affective disorder in the intervention group as contrasted with the comparison group. There was no significant increase in staff-perceived burden, despite the significant increase in the amount of direct care time logged for the intervention group, as contrasted with the comparison group. Possibly, as a result of training related to monitoring residents, the direct care time logged by nursing staff increased. It is possible that the associated increase in affect was related to this increased attention. However, the question remains as to whether the effect was due to VIGIL or vigilance. If the latter, then increased staff time, provided in the context of training and monitoring, may be the important ingredient in the enhanced quality-of-life. Because each hypothesis was treated as a cluster with a pre-specified p value of 0.05 (two-tailed), the possibility of chance findings was reduced greatly, however, as with all research this is always a consideration. An aim for future research involves further examination of the relationship between the intervention, time spent in direct care, and affective disorder.

**Section V: Final Budget Report**

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