Supporting Statement

for

Improving Quality of Care in Long-Term Care Preventing Falls in Assisted Living

Sponsored by

The Agency for Healthcare Research and Quality

HHSA290200600001I Task Order # 2

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RTI INTERNATIONAL

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Supporting Statement for "Improving Quality of Care in Long-Term Care"

A. Background and Justification

1. Need for Information

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve under the Paperwork Reduction Act of 1995 AHRQ's intention to collect information to improve the safety of residents of assisted living facilities. This collection is responsive to AHRQ's request for research released under its ACTION initiative.

The purpose of the AHRQ Long-Term Care (LTC) Portfolio is to improve the quality and safety of long-term care services, reduce unnecessary services and associated hospitalizations, and provide tools to better inform consumer decisions regarding long-term care. To meet these goals the Portfolio is focusing on four areas: preventing pressure ulcers; preventing injurious falls; improving care management of persons discharged from hospitals to LTC; and improving tools to help consumers of assisted living to make informed choices. The Portfolio is focused on ultimately improving the day-to-day practice in LTC settings so that consumers receive the best care possible. Collecting and analyzing the information collected as part of this effort has the potential to do just that.

Falls are significant problems for older persons who reside in the community and in long-term care facilities because they are the primary cause of fractures, which in turn result in reduced function and quality of life, increased morbidity and mortality, and related health care utilization and costs (Boustani et al., 2003; Chang et al., 2004; Magaziner et al., 1998; Finkelstein et al., 2005; Finkelstein, et al. 2006). Risk factors for falls include prior falls, increased age, muscle weakness, gait deficit, balance deficit, use of assistive devices, visual deficits, arthritis, depression, cognitive impairment, a variety of medications, and environmental hazards (American Geriatrics Society, 2001; Boustani et al., 2003). The problem of fall-related injuries is especially relevant in assisted living settings, because this population has a high prevalence of all of the major known risk factors for falls; in fact, their rate of fracture is similar to that in nursing homes (i.e., 101 per 1000 person-years). Further, assisted living staff are motivated to reduce falls because doing so improves functional outcomes and reduces transfer out of the facility (Bonner 2006; Jensen et al., 2002; Becker et al., 2003).

Fortunately, guidelines and evidence-based interventions exist to reduce falls. A variety of randomized trials in older persons have shown that the most effective interventions involve multiple components, such as preventing postural hypotension, reducing polypharmacy, eliminating environmental hazards, and improving balance, transfer, and gait (American Geriatrics Society, 2001; Becker et al., 2003; Chang et al., 2004). Successful fall interventions have been implemented in many community settings and nursing homes; however, limited interventions exist in assisted living. Given practice differences between assisted living and nursing homes (e.g., monthly pharmacy review is not mandated and physical therapists are not regularly available in assisted living, in contrast to nursing homes) successful interventions must be tailored for this setting (Boustani et al., 2003; Bonner 2006).

AHRQ, through a contract with RTI International (and its subcontractor, the University of North Carolina at Chapel Hill [UNC]), are designing and will evaluate an intervention program intended to prevent injurious falls in assisted living facilities. The research team will also train the intervention facilities to implement a falls prevention program as a quality improvement activity. The goals of this pilot are to test the feasibility and acceptability of a multifaceted falls prevention quality improvement program and generate information that could be used for a for a larger, future project. The project focuses on effecting falls risks and involves four major activities: (1) adapting a multifaceted, evidence-based falls prevention program to a protocol tailored to the assisted living environment; (2) implementing the pilot protocol and collecting clinical and process data pre-post intervention; (3) evaluating the results of the intervention; and (4) developing a protocol and materials based on the experience of this pilot for use in testing the intervention on a larger scale in the future.

The project design is a multi-component falls intervention program that includes medication review, resident assessment, environmental modification, and exercise—each of which will be implemented by the facilities. Its goal is to reduce risk factors for falls, which in turn, is expected to reduce fall and fracture rates, among residents of assisted living facilities. The project is adapting existing evidence-based falls prevention interventions to the assisted living setting, and will collect data to track the progress and impact of the intervention program. Data collection for the falls intervention project will be approved by the University of North Carolina - Chapel Hill and RTI International Institutional Review Boards, and will be conducted in accordance with the Health Insurance Protection and Portability Act (HIPAA) Privacy Rule and with the Protection of Human Subjects regulations, 45 CFR Part 46. In addition, the identifiable data collected in this study about provider organizations and individuals will be used only for the above-stated purposes and will be protected and kept confidential by project staff.

The aims of this project are as follows:

1. Using a model of quality improvement and adapting evidence-based interventions that have been used in long-term care and community settings, develop a multi-component intervention program of medication review, assessment, environmental modification, and exercise, to reduce risk factors for falls, and fall and fracture rates, among residents of assisted living facilities.

2. Within two matched pairs of assisted living facilities, randomly select one of each to receive training in the multi-component intervention program—the other will receive an educational intervention—and over the course of 1 year of implementation by the treatment facilities, determine the following:

    a. Related to implementation: the degree to which the facility implements the multi-component intervention; the degree to which residents accept and adhere to the intervention; and facility- and resident-level facilitators for and obstacles to implementation and maintenance of the intervention

    b. Related to outcomes: change in modifiable resident risk factors. We provide power calculations in Section B for changes in modifiable resident risk factors related to balance, gait and transfers.

3. As a pilot, use the information gathered to: evaluate the feasibility and acceptability of the components of this falls prevention program in the assisted living setting; to estimate probable ranges in effect sizes for the impact on reducing falls risk factors, falls, and falls-related injuries for future large scale study; and to develop a revised protocol for a larger scale study taking into account lessons learned from this pilot project.

In both treatment facilities, all residents who consent to participate in the intervention will be screened for falls risk, using a medication review and a physical function evaluation, and receive an environmental assessment. Based on information from the assessment, residents will be categorized as low, medium or high risks for falls. Staff in intervention facilities will be trained to implement the intervention program. Similar procedures will occur in control facilities; however control facilities will receive one educational session instead of the intervention.

The flow diagram in Figure 1 provides a snapshot of the project that will be implemented.

2. Information Users

Information for this project will be collected from several sources by researchers from RTI International and UNC. Methods of data collection are discussed in this section.

The evaluation will use several methods to examine the efficacy of the intervention, including record review, in-person surveys, and in-depth interviews. Data for the process evaluation of the intervention implementation will be collected at baseline, 6 and 12 months at the facility-level (e.g., fall and fracture rates, intervention adoption) and the resident-level (e.g., risk factors for falls, adherence to intervention regimens). Data will be collected from four facilities; two intervention facilities, and two control sites.

The quantitative data will be collected using a series of questionnaires to collect information about the facility, its staff, and the participating residents. Information about residents' cognitive, medical, and functional status, and risk for falls will be collected using resident medication records and charts, performance based physical assessments, and standard measures of activities of daily living and cognition. This information will be collected from both the intervention and control sites.

Figure 1
Preventing Injurious Falls in Assisted Living: Control Facilities Flow Chart

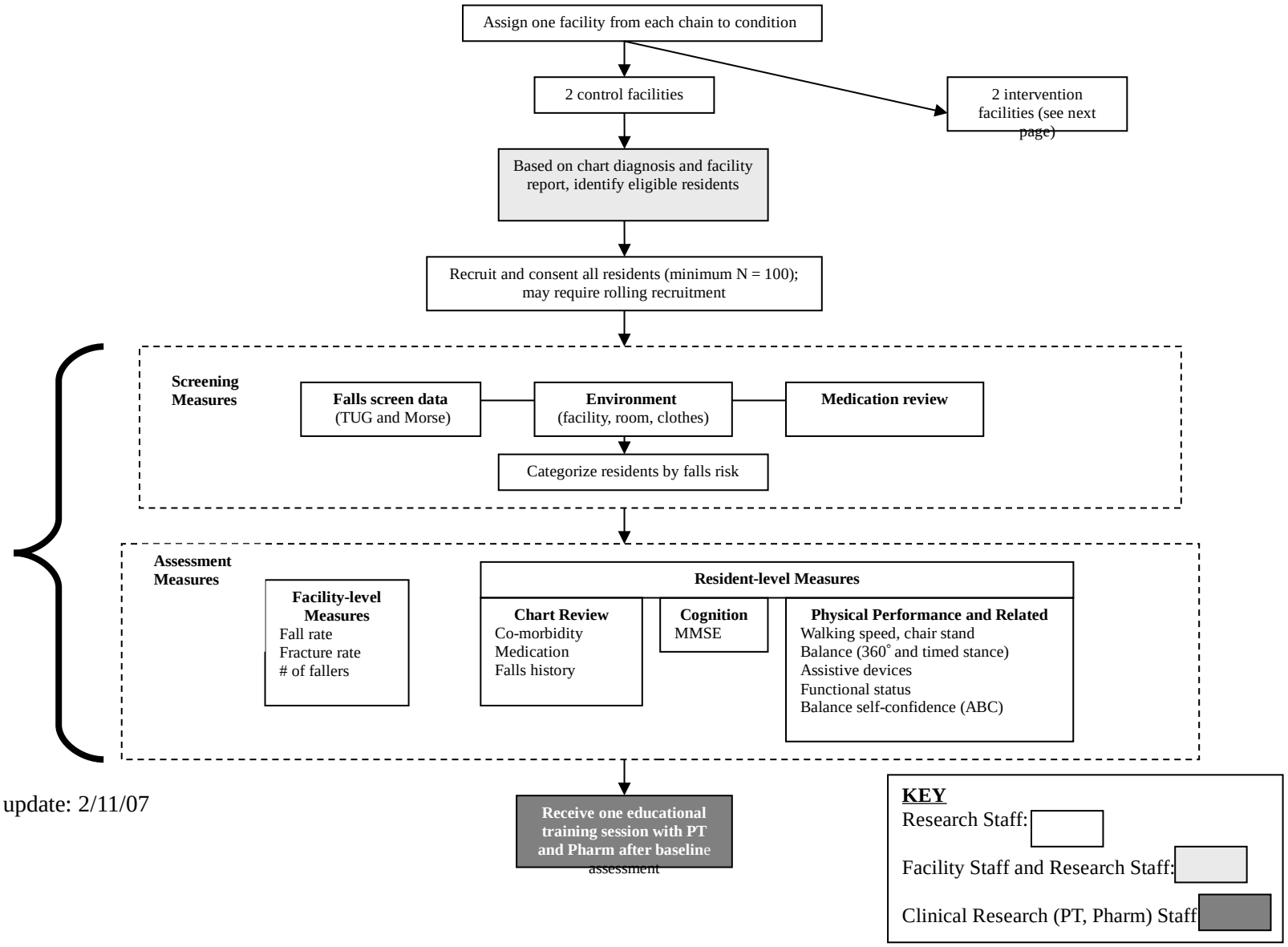

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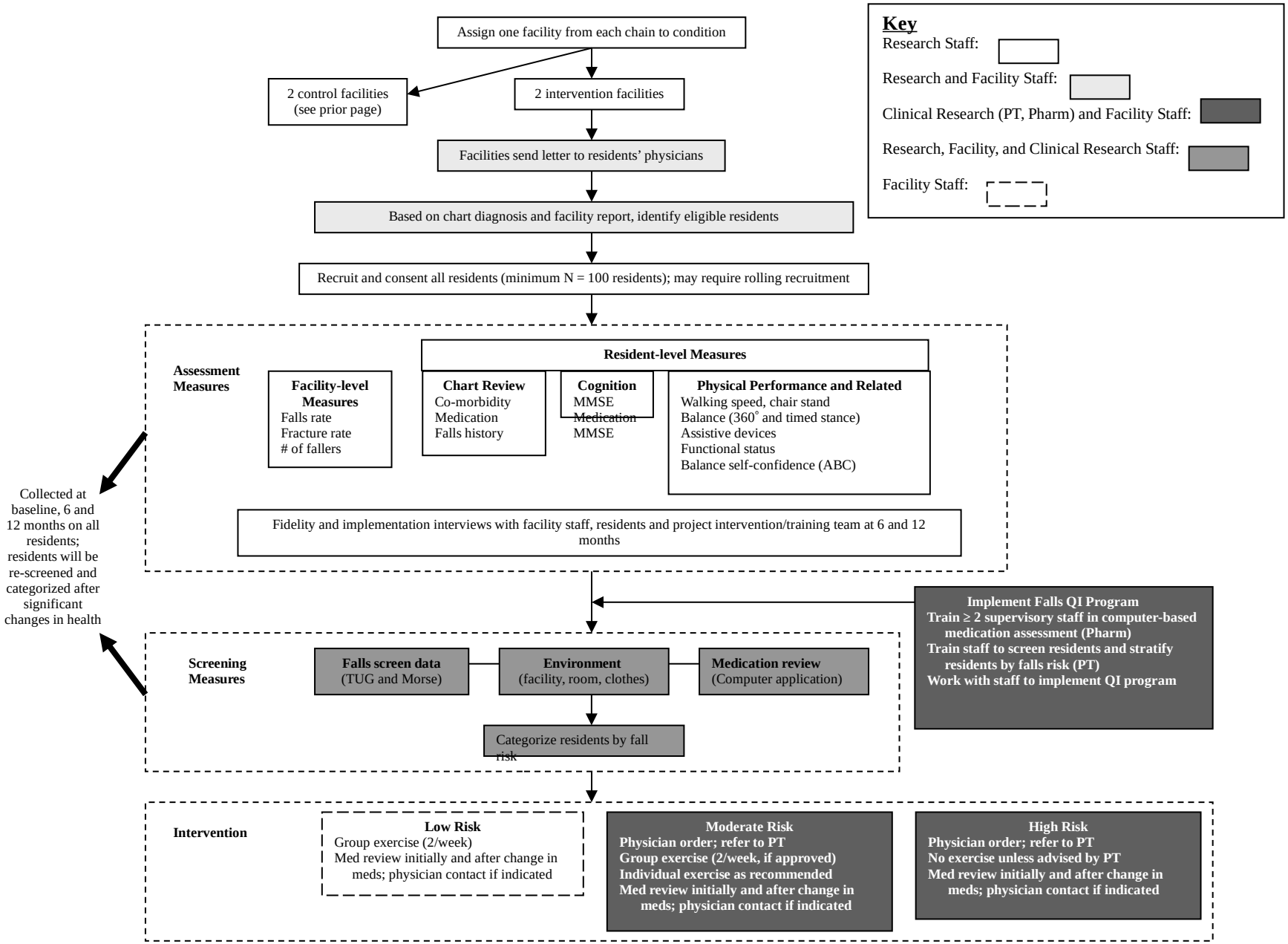
Figure 1 (continued)
Preventing Injurious Falls in Assisted Living: Intervention Facilities Flow Chart



Quantitative data collected from residents will take approximately 35 minutes per resident (approximately 270 residents will be interviewed); data obtained from direct caregiver staff related to resident falls risk will take approximately 6 minutes per resident (caregiver staff persons will be interviewed about approximately 9 residents each). Also, administrators will be asked to provide information about the facility at baseline only, which will take approximately 15 minutes.

Research staff will conduct in-person interviews with 30 physicians, at baseline and again in one year, to understand the issues related to changing medication prescribing practices in light of the falls risk for this population. Physicians will be asked about the population they serve, their knowledge of falls prevention; the importance of falls prevention; their self-efficacy in preventing falls in their patients and their beliefs in others' ability to prevent falls for their patients; outcomes expectations and the need for more information about falls prevention. These interviews will average 20 minutes.

After the intervention has been implemented RTI research staff will conduct semi-structured interviews with up to 10 individuals at each site participating in the study. Information from these interviews, described below, will be used to qualitatively evaluate the implementation of the intervention and to assess the attitudes and perception toward the specific intervention. The research staff will interview the administrator at each intervention site, up to two medication staff at each intervention site, up to two exercise staff at each intervention site, and up to six residents at each intervention site.

For this qualitative component of the evaluation, project staff will use open-ended questions and create items with categorical response options to facilitate analysis. Items asked of the facility administrator will include questions about the degree to which the facility has changed its practices; the degree to which residents accept and adhere to the intervention; facilitators for and obstacles to implementation; report of staff and resident satisfaction with the intervention program; reactions and experiences related to the use of volunteers; what changes would they recommend in the approach; whether they plan to continue the program and if so, with what funds and staffing and lessons learned. These data will be gathered through 60-minute interviews with facility administrators.

Medication staff will be interviewed about the process of identifying medications that put residents at risk for falls; to get their feedback about the medication review computer program and the process they used to follow-up with physicians including what worked well and what did not work particularly well. These interviews will last approximately 60 minutes.

Staff who run the exercise program will be asked about the exercise program in general; residents' involvement and participation in the exercise program; what changes were observed in the participants; what worked well; what did not work well; what barriers to participation they identified; and any recommendations for change. These interviews will last approximately 45 minutes.

Finally, residents will be asked their thoughts about the exercise program; what they liked and disliked about it; the impact the program had on them; what facilitated participation or

served as a barrier to participation, their interest in continuing in such a program if offered in their facility; and recommendations for improvements. Resident interviews will take approximately 30 minutes to complete.

The study sample is limited to facilities with 16 or more beds, a reasonable strategy given that larger facilities represent over 80% of resident beds (Zimmerman, et al., 2001). In addition, to improve data reliability and consistency, facilities that routinely maintain the data reporting systems necessary for study (i.e., fall reports and medication records) have been selected. Four facilities were contacted during the proposal phase and agreed to serve as sites for this project. The four participating facilities are within the same geographic area of North Carolina. Consistent with the participatory based nature of quality improvement projects, staff from these facilities will be involved in decisions related to the actual implementation of the program in their facility, to assure that it is consistent with their policies and procedures.

One facility from each chain will be randomized to treatment, and one to control status. The intervention and control facilities will be comparable in many ways. Each of the four participating facilities are categorized as "new-model" residential care/assisted living (RC/AL) facilities (defined empirically through previous work done by the data collectors), to have $\geq$ 16 beds, been built after 1/1/87, and have at least one of four characteristics reflecting resident need and medical-care provision). Also, all four facilities are similar in that they are affiliated with larger, national chains, maintain only RC/AL (non-nursing home) beds, and do not accept Medicaid waivers. Approximately 60% of the residents in these facilities have Alzheimer 's disease or another dementia, and fewer than 4% are mentally or developmentally disabled, have a primary diagnosis of schizophrenia or schizoaffective disorder, and/or are younger than 65 years of age. To help establish the degree of similarity between control and intervention facilities, data on key facility parameters (e.g., staffing levels, resident case-mix) will be collected from each facility.

Quantitative evaluation data from the intervention and control facilities will be collected by research staff who are independent of the intervention team. Evaluation data collection will assess change in resident risk factors as well as facility rates of falls and fractures over the 1-year project period. Data will be collected at baseline, and at 6 and 12 months. This same timetable will be used to collect resident-level data in the control facilities. Because the project is a pilot and the goal is to learn what works best in order to develop a revised protocol, information learned at 6 months may be used to modify the intervention for the subsequent 6 months of implementation.

Appendix A contains all instruments and key informant guides that will be used in this data collection effort and includes a table listing all of the instruments and related citations.

The following list of activities will be conducted by facility staff as part of the actual intervention.

- *A Physical Therapy assessment/intervention*. The goal is to develop a role for a community physical therapist as a member of the falls prevention team in each facility. Project staff from UNC will work with the facility and therapist to cultivate

this relationship, because community therapists may not have an existing role in RC/AL, and facilities may need to learn how to recruit and collaborate with the therapist.

- *Group exercise program led by staff/volunteers for residents at low risk and some residents at moderate risk.* The intent is that the group intervention will be conducted by staff/volunteers (not by the physical therapist), and that it will be safe for the residents. Residents at low risk will participate in group exercise, and residents at moderate risk will participate in group exercise as recommended by the therapist. In all cases, the facility staff will be directed to monitor any need for reassessment if resident status changes.

- *Individual exercise—residents at moderate risk.* The physical therapist will determine the group and any specific individual exercises appropriate for individuals at moderate risk.

- *Exercise to be determined—residents at high risk.* The physical therapist will determine the group and individual programs appropriate for residents at high risk.

- *Medication Intervention.* Facility staff will be trained to use computer software to detect medications which are associated with a high risk of falls. Medication information is maintained by all facilities participating in the intervention. As part of the medication intervention, facility staff will contact a resident's personal physician via fax to communicate potential falls risk associated with the resident's medications and request the physician to review for possible dosage or medication changes.

3. Improved Information Technology

Because this is a small project, investments in improved technology are not planned, nor would they be cost effective.

4. Efforts to Avoid Duplication

Data collection instruments used in this study have been used and validated by others. This study is not duplicative of another information collection.

5. Small Businesses

The instruments and key informant interview guides are designed to minimize burden on all respondents and will not have a significant effect on small businesses. However, the collection of information under consideration in this supporting statement does not include small businesses as part of the respondent universe.

6. Less Frequent Collection

This request is for a one-time study.

7. Federal Register Notice/Outside Consultation

The 60-day notice was published in the Federal Register on January 16, 2007.The 30 day notice was published on April 24, 2007.No public comments were received. The nature of the project was discussed with assisted living facilities that are potential participants in the study. They believe this study is important to improving quality of care in assisted living and are eager to participate in the study.

8. Payment to Respondent

Participating facilities (both intervention and control) will incur costs related to this project for participating in the evaluation. This payment is in recognition of the time that both types of facilities spend helping identify subjects for study (e.g., screening charts for eligibility), provide information to potential subjects and their families regarding the study (e.g., providing introduction to the subjects and sending a letter, on facility letterhead, to family members), and providing data on behalf of consented subjects. The facilities will also need to purchase a computer that supports the use of the medication review software. Similar incentives have been provided to participants in similar studies in the past and are considered appropriate based on the amount of time required by staff to facilitate the project. Individuals who participate in the interviews will not be paid an incentive.

Itemized payments to each facility fall into two categories: (a) capital costs (i.e., computer, software) which the facilities will need to purchase themselves for the project, and (b) payment to alleviate real costs incurred for the research (i.e., mailings, materials). Labor costs are also expected. These are detailed below:

1. Capital costs:

   Dell small business machine and software necessary to enter and monitor medications and falls, including portable hard drive for backup = $975/facility (includes cost, tax, shipping)

   Subtotal of capital costs: $975/facility

2. Research costs:

   The facilities will send mailings to families and prepare flyers for residents in advance of and throughout the year of data collection. The number of families/residents is estimated to be 450, based on the current number of beds (N=390) and allowing 15% additional for turnover.

   Mailing costs to all families: 450 * 4 mailings (info, consent, follow-ups) = 1800 * $.97 (for manila envelope with enclosures) = $ 1746 = $3.88/family = $436.50/facility

Materials (envelopes, stationary, brochures, newsletters, meeting handouts, flyers): $5/resident = $2250 = $562.50/facility

Subtotal of research costs: $999/facility

Subtotal of capital costs plus research costs: $1974.00/facility

Labor costs also are expected, as the costs above do not include facility staff time (e.g., to prepare the mailings and stuff the envelopes); hence, the original figure of $2000 as originally requested is an appropriate estimate.

9. Confidentiality

All information gathered as part of this data collection effort will be collected in accordance with the Privacy Act (FAR 52.224-1, 52.224-2) and AHRQ requirements. The informed consent forms will include the following statements: The confidentiality of personal information is protected by federal law [Federal Statute, Section 903(c)) of the Public Health Service Act [42 U.S.C. 299a-1 (c).This law prohibits release of personal information outside the public health agencies sponsoring the survey or their contractors without first obtaining the permission of the individual who gave the information. Respondents will be advised that surveys and interviews are entirely voluntary and that any information they provide will be kept confidential. Respondents combined and summarized with information provided by others and no individually identifiable information will be released. In instances where respondent identity is needed to facilitate data collection (e.g., follow-up assessments), the information collection will fully comply with all respects of the Privacy Act. No waiver is necessary for this project. See Appendix B for the consent forms that will be submitted to RTI International and UNC IRB committees for approval.

10. Sensitive Questions

No questions of a sensitive nature are anticipated under this clearance.

11. Burden Estimate (Total Hours & Wages)

Total time burden estimates required to obtain all of the data required to meet the study's objectives are summarized in ***Table 1***. Time required to analyze and prepare the data for reports and publication is not included in these estimates. This estimate also does not include cost to the respondent for participating in data collection.

12. Capital Costs (Maintenance of Capital Costs)

There are no capitals cost associated with this project.

13. Cost to Federal Government

The total estimated one-time cost of this intervention implementation and related data collection to the federal government is $199,600. This funding will be used to support the cost of implementing the intervention, salary and fringe benefits for the research team to conduct the survey interview and in-depth interviews, costs for members of the research team to travel to each site, and the incentives paid to facilities for participation in the intervention. This figure does not include the costs for developing materials and instruments, analyzing the data and preparing the reports and other publications. The project proposes to work with assisted living facilities with which the research team already has established relationships and familiarity and will attempt to minimize burden to the assisted living facility staff by being flexible to schedules and requirements of care practices within the facilities.

15. Program or Burden Changes

This is a new data collection.

16. Plan for Analyses

The purpose of these information collections is to evaluate this pilot falls intervention program. The planned analyses are organized to describe the analyses (a) related to implementation; (b) related to intermediate outcomes such as falls risk factors and to a lesser extent falls and fall-related injury outcomes. As discussed elsewhere, the central focus of this project is on evaluating the feasibility and acceptability of the interventions and to produce descriptive statistics providing information that can guide the development of a revised protocol and future, more definitive intervention studies. Due to the small sample size of this study, particularly for facilities, we do not anticipate finding statistically significant differences between intervention and control facilities; rather, the analyses will provide estimates of effect sizes that could be used in the design of larger, definitive trials in assisted living, and, perhaps most importantly, provide crucial information regarding whether protocols such as this can be implemented successfully in assisted living facilities..

Table 1
Respondent burden estimates

Type of respondent	Number of respondents	Number of responses per respondent (baseline, 6 months, and 12 months)	Estimated time per respondent (hours)	Estimated total burden (hours)	Average wage rate	Total respondent cost burden
Direct Caregiver Staff*	30	27	0.10 hours (6 minutes)	81 hours	$9.00	$729
Facility Administrator	4	3	0.25 hours (15 minutes)	3 hours	$25	$75
Facility Residents	270	3	0.583 hours (35 minutes)	472 hours	$0	$0
Physicians**	30	2	.333 hours (20 minutes)	20 hours	$81	$1620
Implementation evaluation (intervention facilities only)	**Number of respondents**	**Number of responses**	**Estimated time per respondent (hours)**	**Estimated total burden (hours)**	**Average wage rate**	**Total respondent cost burden**
Residents	12	1	0.5 hours (30 minutes)	6 hours	$0	$0
Exercise Staff	2	1	.75 hours (45 minutes	1.5 hours	$9.00	$13.5
Facility Administrator	2	1	1 hour (60 minutes)	2 hours	$25	$50
Medication Staff	4	1	1 hour (60 minutes)	4 hours	$9	$36
Total Burden				589.5 hours		$2,523.5

*Each direct caregiver staff person will be interviewed about multiple residents (approximately 9 each). These interviews will occur three times - at baseline, at 6 months and at 12 months for a total of 27 interviews. Direct caregiver staff and other facility staff we interview will be similar to certified nurse assistants. We do not include professional level staff in this category. Information on salaries of direct care workers in North Carolina – the location of the participating facilities – was obtained from the following web site below http://www.directcareclearinghouse.org/s_state_det.jsp?action=view&res_id=33

** Information on the average salary of a facility administrator in Durham North Carolina was obtained from Monster.com Information on wages for general internists in North Carolina was obtained from the US Department of Labor, Bureau of Labor Statistics website at http://www.bls.gov/oes/current/oes_nc.htm#b29-0000

Implementation (intervention facilities only). Due to the primarily qualitative nature of the implementation data to be gathered, and their relevance only in the intervention facilities, these analyses will be mainly descriptive.

We will use the data to identify areas of success and failure, and incorporate the stakeholders' assessments of the reasons for why some components were more successfully implemented than others. By obtaining this information from multiple perspectives, we can use the quality-improvement framework to enhance the intervention after the 6-month evaluation and for future dissemination.

We will descriptively evaluate the similarity of the facilities within each intervention-control pair with respect to factors that might impact implementation of the intervention, such as resident-case mix and staffing levels. Our sample size will not be adequate to directly control for any observed differences; however, all resident-level analyses will include a facility indicator, which will serve as a proxy for differences among facilities.

Qualitative data obtained from the semi-structured interviews will be used to refine and revise a protocol and training program that can be disseminated for implementation by the staff of other facilities after the project has ended.

Outcomes (intervention and control facilities).

Falls and fractures. We will be using the existing facility systems (similar within each matched pair) to evaluate whether there has been a change in fall rates and fracture rates from a 6-month period prior to the intervention to each of the two 6-month periods of the intervention. Fall rates and fracture rates will be estimated as the rate per 100 beds per year. We will estimate the "difference in difference" baseline to follow-up between the two facilities in each pair, and, for a summary measure of effect; this difference will be averaged across the two pairs.

Fall risk factors. These are our main outcome measures. Based on baseline and 1-year (pre and post) resident assessments, we will evaluate the extent to which resident risk factors have changed, and compare this change between intervention and control facilities within each facility pair. Specifically, for *medications*, based on chart review, each participating resident will be classified at baseline and at follow-up as to whether he/she is receiving a potentially problematic medication. Even though the use of these medications cannot be eliminated entirely, we expect their prevalence to be reduced in the intervention facilities compared to the control facilities. The analyses will be a resident-level logistic regression model and will estimate the

difference between intervention and control residents in the likelihood of being on a potentially problematic medicine at follow-up, controlling for baseline use. Measures of the other fall risk factors (detailed in the Evaluation Measures section), including performance-based measures of lower extremity impairment, performance-based measures of balance, reported balance self-confidence, and reported ADL function, are all continuous measures. Thus, the primary analytic strategy will be resident-level linear models in which differences in baseline to followup change between intervention and control residents are estimated by treating the followup measures as the dependent variable and controlling for the baseline measures. All of the above analyses will include facility as a control variable.

Association between implementation and risk factors (intervention facilities only). For the facility-level outcomes (fall and fracture rates), these analyses will be exploratory to examine whether the summary measures of implementation success (both overall and for individual components, and at 6 and 12 months) are associated with any observed changes in fall and fracture rates over the same periods. For the resident-level outcomes (risk factors), we will test whether both the facility-level implementation measures and resident-level intervention adherence are related to changes in resident-level risk factors. These analyses will be similar to those for the outcome component (i.e., logistic regression for problematic medication use, linear regression for the other fall risk factors), but will be limited to the intervention residents and will include level of implementation/adherence (rather than intervention vs. control) as the independent variable of interest. As we will have 6- and 12-month measures of implementation/adherence as well as information on implementation of different components of the intervention, we can examine whether certain aspects of implementation appear to be more important in effecting changes in risk factors than others.

For all resident-level analyses, we will control for demographic variables including age, gender, race, and for health and functional status, such as level of ADL impairment and cognitive function.

Other analyses. We will descriptively evaluate the similarity of the facilities within each intervention-control pair with respect to factors that might impact implementation of the intervention, such as resident-case mix and staffing levels. Our sample size will not be adequate to directly control for any observed differences; however, all resident-level analyses will include a facility indicator, which will serve as a proxy for differences among facilities.

We will also be collecting information on uncommon but important outcomes that can result from falls, namely mortality and health care utilization resulting from falls. These data will be analyzed to estimate the potential impact of this intervention program on these outcomes —information that could be used to inform the design (e.g. estimate effect sizes to determine required sample size to find statistically significant differences) of a larger trial.

To disseminate information about the resulting falls prevention program to the industry, after the evaluation is complete, we will produce a manuscript for a professional journal that is read by the assisted living industry, and provide conference presentations at a patient safety health information technology meeting and conferences attended by long-term care industry

leaders and administrators. We will also create a training DVD and accompanying training manual that facilities can use to train staff in the program.

17. Expiration Date

Expiration date for OMB approval of data collection will be displayed as required.

18. Certification Statement

These activities will comply with the requirements of 5 CFR 13209.9. This collection of information involves no exceptions to the second page of the 83i.

B. Collection of Information Employing Statistical Methods

1. Potential Respondent Universe and Sample Selection Method

As mentioned earlier, because constraints required the study's sample size to be modest, we chose to limit the study sample to larger (>16 bed) facilities, a reasonable strategy given that larger facilities represent over 80% of resident beds (Zimmerman, et al., 2001). The four participating facilities are within the same geographic area of North Carolina and are from two national provider chains that have participated with our team in other projects. Given the small scale of the study and the limited geographic variability in the sample, these results are not generalizable to other facilities, but this sample is a cost effective means of meeting the goals of this pilot program. Consistent with the participatory based nature of quality improvement projects, staff from these facilities will be involved in decisions related to the actual implementation of the program in their facility, to assure that it is consistent with their policies and procedures.

It is anticipated that 270 residents will agree to participate in the intervention, one half of whom will be randomized to treatment, and one-half to placebo control. Facility administrators at each of the four participating facilities will be interviewed,

2. Information Collection Procedures

In this section, we describe how RTI and UNC will identify participants and collect data for this project. All information collections will be conducted in a manner that is consistent with the following guidelines:

- Participation will be fully voluntary, and non-participation will have no effect on eligibility for, or receipt of, future AHRQ-sponsored health services research.
- Information collection will be limited to that needed to implement and evaluate the intervention.

- Given the voluntary nature of the information collections from residents of participating facilities, efforts will be made to obtain the highest possible response rates.

- Each respondent will be assigned a study identification number and any names collected will be destroyed after the identification number has been verified.

- All data will be kept in a secure file and will be kept confidential. Data collected as part of the project will only be shared with staff involved in the project.

Data will be collected from participants using the data collection instruments included in Appendix A. Consent to participate in the project will be obtained from each individual using an informed consent process approved by both RTI International and UNC IRBs and will be consistent with HIPAA regulations. Consent forms will be signed by the participant and copies provided to each participant. (See consent forms included in Appendix B).

Facility administrators at each of the four participating facilities will be asked to participate in an interview. Each administrator will have an informed consent administered to them prior to the conduct of the interview.

Direct care staff who provide care to residents who consent to participate in the project will also be asked to report on matters related to falls risk. Direct care staff will provide information on residents' functional status using the Minimum Data Set Activity of Daily Living (MDS-ADL), and on cognitive status using the Minimum Dataset Cognition Scale (MDS-COGS).

All potential resident participants will be 65 years or older, English speaking, not bed bound, and not hospice patients. Non-English speaking residents will be excluded from the project because we do not have the capacity to provide translators and all research staff are English speakers. Because bed bound residents will not be ambulatory, they will not be at risk for falls. Residents in hospice will be excluded because it is expected that they will not live through the yearlong study or be able to participate fully in the assessments. Consent to participate will be obtained from each resident who is willing to participate.

Family members of residents with cognitive impairment will be contacted to provide consent for their family member to participate in the project, including HIPAA consent to release protected health information. These residents will be identified by facility staff or through the administration of the MDS-COGS.

Physicians who provide care to residents participating in the intervention will be contacted by a member of the project team, who will explain the project in detail, and, if the physician consents to participate, arrange a time to conduct a 30 minute in-person interview base-line interview. Physicians who consent to participate will also be recontacted in 12 months to participate in a follow-up interview.

As described earlier, RTI International staff will also conduct semi-structured interviews with up to 10 individuals at each site participating in the study. Each of these individuals (facility administrators, medication staff, exercise staff, and residents) will be consented prior to the interview and will be reminded that participation is voluntary.

Finally, facility staff will be asked to nominate residents who are cognitively able and may be willing to participate in the semi-structured interviews. Staff will be asked to consider residents for nomination based on levels of participation in the intervention project so the team hears varied views of about the project.

As mentioned earlier, all measures related to falls risk will be collected by interview, chart review, and performance assessment at baseline, 6 and 12 months by research staff. Interviews administered to physicians will be done in person, at baseline and 12 months. The qualitative implementation evaluation interviews will be collected in person once at the end of the study.

Describe methods to maximize response rates.

We expect to recruit 270 subjects from the four facilities. This figure is based on the facility's bed size, occupancy rate, and UNC's similar projects that have achieved participation rates of 73–92%. If fewer than 200 residents agree to participate, we will allow for ongoing recruitment during the year of the study, until we reach a target of 200 subjects. In addition, if any facility is uncertain about its ability to commit the necessary staff resources, for example to participate in ongoing medication management, it will be replaced. UNC belongs to a long-term care consortium that includes more than 350 facilities, thus there is little concern that other facilities could be recruited to ensure an adequate sample size. However, in all cases, we will restrict the number of total facilities to four, as costs would increase exponentially if we were to add additional facilities.

Describe any tests of procedures or methods.

The individuals who will be involved in the statistical design and analysis of this project are Sheryl Zimmerman, PhD, Edith Walsh, PhD, and Phillip Sloane, MD.

Power calculations for resident-level performance measures. We compute power based on a sample of 2 communities per group with 67 residents per community, for a total of 268 residents. Calculations were done for two types of performance outcomes – those based on the proportion of residents able to complete a given task within a specified amount of time (i.e. outcomes that are binary at the individual level) and those that are continuous measures. While the analyses of these outcomes will be done at the individual level, because randomization occurs at the level of the community, our power calculations account for clustering of residents within facilities [1] Actual estimates of this intra-class correlation (ICC) are rarely published, can vary substantially across studies and outcome measures, and are not available for the planned study. Hence, we use several reasonable estimates, based on a review of published community cluster trials [2, 3], and also show calculations for an ICC=0, for comparison to the individually randomized design.

The sources of data follow:

- For continuous walking speed and the dichotomous outcomes (walk speed >0.6 m/sec, able to do 5 chair rises, able to hold a tandem stand for at least 1 second), we use baseline data from the Collaborative Studies of Long-term Care (CS-LTC; [4]). The cutpoints used in these analyses are those that were found to be predictive of important clinical outcomes, including mortality, functional decline, nursing home transfer and fracture in older adult populations.
- Preliminary data for long-term care residents on the timed up and go test (TUG) is from a small randomized study in a single Canadian long-term care facility [5].

For the dichotomous outcomes, estimated power is shown in the ***Table 2***, for a range of effect sizes and intra-cluster correlations; all are for a two-tailed Type I error rate of 0.05. These calculations are likely somewhat conservative, because they are for a post-only comparison, while in our planned study we will have a baseline measure (for which we will adjust) and two follow-up timepoints. These estimates indicate that while our power will not be very good for differences in proportion of around 0.1 (26%-52% difference depending on the control proportions), for larger differences of 0.2 (51%-105%), our power will be quite good unless clustering is quite strong.

Table 2
Power to detect a difference in proportions for several dichotomous performance tests, 2 facilities per study group, 67 residents per facility (two-tailed alpha = 0.05)

Measure	Control proportion *	Difference in proportions (% difference)	Power when intra-cluster correlation is…			
			0.000	0.005	0.010	0.020
Walking speed 0.6m/sec	0.39	0.10 (26%)	38.1 %	30.1%	25.0%	19.2%
	0.39	0.20 (51%)	91.7	82.6	73.7	59.3
Able to do 5 chair rises	0.26	0.10 (38%)	42.9	33.9	28.2	21.4
	0.26	0.20 (77%)	93.7	85.6	77.2	62.9
Able to tandem stand	0.19	0.10 (52%)	48.8	38.7	32.2	24.4
	0.19	0.20 (105%)	95.9	89.4	81.9	68.8

*Source: Giuliani et al [4]

Table 3 shows the minimum detectable difference (MDD) in means for walking speed and for the TUG for the planned study, specifying 80% power and two-tailed type I error rate of 0.05, for the same ICC's shown in Table 1. As standardized effect sizes (SD units), these MDD's range from 0.76 for an ICC of 0.005 to 1.0 for an ICC of 0.02, which are fairly large effect sizes; however, percentage improvements in this range have been seen in some exercise studies. For example, after a 10 week exercise program, Hruda and colleagues [5] found a 32% decrease in TUG time and a 33% improvement in walking speed; Toulotte and colleagues [6] found a

41% improvement in TUG time and a 23% increase in walking speed after a 16-week balance training program for frail persons with dementia and a history of falls.

Table 3.
Minimum detectable difference (MDD) in means for two timed performance tests, 2 facilities per study group, 67 residents per facility (80% power two-tailed alpha = 0.05)

		MDD in means (% difference) for 80% power when intra cluster correlation is…			
Measure	**Control Mean (SD)***	**0.000**	**0.005**	**0.010**	**0.020**
Standardized effect size	*NA*	*0.66*	*0.76*	*0.84*	*1.00*
10' TUG (sec)	25.9 (8.9)	5.8 (22%)	6.70 (26%)	7.50 (29%)	8.90 (34%)
Walking speed (m/sec)	0.41 (0.19)	0.12 (30%)	0.14 (35%)	0.16 (39%)	0.19 (46%)

*Sources: Hruda et al (2003) [5] for TUG; Giuliani et al [4] for walking speed

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Provide name and telephone number of individuals consulted on statistical aspects.

RTI International and its subcontractor, UNC Chapel Hill Scheps Center, will provide input and oversight on design planning and analytic issues.

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APPENDIX A
DATA COLLECTION MEASURES AND INSTRUMENTS