

## Response Form for the Final Performance Review Report\*

1. Name of Grantee: Madlyn & Leonard Abramson Center
2. Year of Grant: 2010 Formula Grant

***A. For the overall grant, briefly describe your grant oversight process. How will you ensure that future health research grants and projects are completed and required reports (Annual Reports, Final Progress Reports, Audit Reports, etc.) are submitted to the Department in accordance with Grant Agreements? If any of the research projects contained in the grant received an “unfavorable” rating, please describe how you will ensure the Principal Investigator is more closely monitored (or not funded) when conducting future formula funded health research.***

The Polisher Institute of the Madlyn and Leonard Abramson Center has a dedicated grants administrator who oversees all aspects of reporting on grants. Procedures are in place that involves a system of automated reminders when a grant milestone is approaching to alert investigators as to the need for action for a particular milestone (e.g., annual report, final progress report, audit reports, IRB renewals, etc).

\* Please note that for grants ending on or after July 1, 2007, grantees' Final Performance Review Reports, Response Forms, and Final Progress Reports ***will be made publicly available on the CURE Program's Web site.***

**Project Number:** 1085801  
**Project Title:** Examining Impact of Individualized Positive  
Psychosocial Interventions in Nursing Homes  
**Investigator:** Van Haitsma, Kimberly

***B. Briefly describe your plans to address each specific weakness and recommendation in Section B of the Final Performance Summary Report using the following format.*** As you prepare your response please be aware that the Final Performance Review Summary Report, this Response Form, and the Final Progress Report will be made publicly available on the CURE Program's Web site.

Reviewer Comment on Specific Weakness and Recommendation (*Copy and paste from the report the reviewers' comments listed under Section B - Specific Weaknesses and Recommendations*):

Response (*Describe your plan to address each specific weakness and recommendation to ensure the feedback provided is utilized to improve ongoing or future research efforts*):

Reviewer 1: None.

Reviewer 2:

1. There are methodological issues which limit the generalizability of the study results. First, the consistency of staff assignments needed to reach the same target residents described in the original study methodology is not typical of the vast majority of nursing facility operations in the United States. A methodology which evaluates the feasibility of training multiple different nursing assistants to work with the same resident on implementing the positive interventions would be far more realistic. Second, this is an atypical study population which is quite homogeneous, and the interventions chosen cannot be generalized as being of benefit to other populations who are dramatically different, for example, a Veterans Administration long-term care facility. It would be much more widely applicable if these strategies could be demonstrated to have beneficial outcomes in a more commonly representative facility, such as a community long-term care facility. If the author carries out her stated intent to use the results of this study to support continued research, her study methodology should be modified to address these issues.

Response:

We agree that more work is needed on the feasibility aspects of this intervention, especially focused on the issues of training multiple nursing assistants (NAs) to deliver the intervention. Ideally, the next study would focus on these issues. In the current intervention protocol, two nursing assistants were trained for each resident. This was to ensure coverage of the intervention implementation when one NA was scheduled to be off. This procedure is a step in the right direction, but ideally any NA should be trained to step in and deliver an intervention to a resident under their care. Unfortunately, enrolling, training, and collecting data on multiple NAs per

resident was not possible with the funds allocated. Therefore, we decided to follow only two NAs, realizing that future studies can include multiple nursing assistants.

We also agree that the study population is homogeneous and cannot be generalized to other populations. We have spent the past 10 years building relationships with over 30 facilities in greater Philadelphia in order to conduct future studies in multiple locations with a greater variety of residents in terms of gender, race, ethnicity, SES, and age.

2. The issue of how many residents, in which treatment groups, were on what types of psychoactive medications at baseline, or had them added during the study, or became treated as a result of study observations is a major confounding factor. This could obviously have had a major impact on the potential causality of the behaviors observed in the study. It is of note that there was an unusually low incidence of aggression and high incidence of null behaviors for typical nursing facility residents, leading one to question again whether this population is actually representative of a “typical” nursing facility population or may be overmedicated. It is essential that the author include this data demographically at baseline, track it during the study period, and as much as possible control for psychoactive medication use and baseline psychiatric diagnoses during the randomization process.

Response:

Unfortunately, the scope of this study was limited by budget issues. We wholeheartedly agree that psychoactive medication and diagnoses may play a role in the primary outcomes of this study. In future studies we will include this critical variable in our hypotheses and data collection protocols at baseline and follow up periods.

3. There is no quantitative data available from the original study for this relatively short time period to document the economic impact of the study interventions. Since the training and utilization of one-to-one interventions represents a facility cost in personnel time, it is essential to demonstrate a concrete benefit in health care costs which justifies this investment. Potentially, a decrease in adverse behaviors and perceptions by residents and staff could improve job satisfaction and time management, and perhaps reduce staffing turnover, reducing health care costs. This type of data should be gathered during the next study.

Response:

This is an excellent point and I am creating a cost/benefit analysis to accompany future studies in order to capture and report this critical information. We are working with a health economist to identify critical cost components of this intervention such as personnel time.

4. It is likely, despite the efforts described in the final report regarding the original study that the original study resulted in some contamination in study behaviors between the intervention and non-intervention groups over time, particularly since the study appears to have been successful in altering behaviors of residents and perceptions of staff as hypothesized. There is no study methodology outlined to adjust for the probable unintentional crossover behaviors by the nursing assistants under study either in the original study or in the statistical methods used to analyze the data in this study. There were no restrictions described about imitating use of the study interventions for usual care residents, for additional episodes, or by theoretically untrained staff. The number of subjects studied would have been sufficient to reach primary conclusions but may not have been adequate to compensate for crossover. Consideration must be given when designing the next study to limiting the use of the study methodology outside of the study in the comparison population and to perhaps increasing the size of the study population to allow for statistical adjustment for effect size.

Response:

I thank you for highlighting this important potential threat to the validity of the study design. One step we took to limiting cross contamination was the complete separation of the two intervention conditions by unit. In doing this, staff were assigned and trained to deliver only one intervention (e.g., either IPPI or AC) per unit. To the extent possible, we tried to blind each unit to its assigned condition. Furthermore, we prevented sharing of staff between units during the intervention period. Our future studies will implement similar protocols to control for possible cross contamination. We will utilize the effect sizes gained in this pilot effort to fully power our next study.

Reviewer 3:

This reviewer has a couple of comments for the authors to consider in developing an article for submission to a scientific journal. These represent areas that are unclear in the description of the study methods, the reporting of analytical results, or the discussion:

1. Under methods, the authors state that three covariates were employed “to control or remove shared influences from the observational variables.” More text is needed to explain why this is scientifically justified and how the variables were chosen. In particular, it is unclear a) how ADL capacity would have an impact on emotional responses independent of MMSE, and b) how and why withdrawal (which is quite similar to some of the outcome variables) was used as a control variable. Was it to control for baseline differences in responses? If so, that should have been unnecessary, since the study was randomized, unless (see #2 below) there were clear baseline differences between groups.

Response:

This is an excellent point needing clarification. Three covariates (centered measures of ADL, MMSE and Withdrawal behaviors) were employed to control or remove shared influences from the observational variables. We selected these covariates because they were significantly related to the primary outcomes of interest. This is in keeping with our previous research that has found cognitive impairment, functional impairment and depressive (withdrawal) symptoms are related to the primary outcomes.

2. There should be a table (new table 1) that compares the characteristics of the treatment groups for variables such as age, sex, race, MMSE, years in the nursing home, comorbidities, and functional status. This is a notable omission.

Response:

We apologize for this grave omission and have included this information below (see Table 1). This table is part of a manuscript that was recently accepted to the Journal of Gerontology: Psychological and Social Sciences.

Table 1. Sample Demographic Characteristics by Group

<b>Characteristic</b>	<b>IPPI Residents N = 44</b>	<b>ACI Resident: N= 43</b>	<b>Usual Care Residents N = 93</b>	<b>Tests for differences</b>
<b>Age (mean)</b>	87.66 (8.37)	88.71 (6.13)	89.21 (6.87)	F(2,175)=.70, p=.50
<b>Gender (N)</b>				Chisq(14,142)=1.10, p=.58
Female	38	37	73	
Male	7	6	19	
<b>Education (N)</b>				Chisq(14,142)=8.02, p=.88
8 <sup>th</sup> Grade or Less	8	8	20	
Attended High School	3	4	8	
Completed High School	19	11	34	
Vocational Training	0	0	1	
Attended College	0	0	1	
Completed College	4	5	5	
Graduate School	0	2	3	
Other	1	2	3	
<b>MMSE (mean)</b> (possible range: 0-30)	7.40 (7.13)	10.35 (7.95)	9.02 (7.64)	F(2,171)=1.62, p=.20
<b>MOSES Withdrawal (mean)</b> (possible range: 8-32)	20.44 (5.92)	20.69 (5.17)	21.96 (5.21)	F(2,177)=1.24, p=.29
<b>MDS ADL (mean)</b> (possible range: 0-40)	25.05 (12.52)	27.41 (10.49)	25.99 (11.18)	F(2,179)=.48, p=.62

3. Table 3 is not adequately labeled. It is not at all clear as presented that it is making pairwise comparisons between treatment groups. This made it confusing because the reviewer (as would be the case with many readers) looked at the table first before consulting the text. Better labeling would solve this issue. The “individualization” reported in the methods was indeed quite standardized. This was useful for the purposes of research; however, theoretically it could be argued that even more individualization and flexibility might be considered. On the other hand, more flexibility might not work as well with nursing assistants as the limited menu provided in the study. The authors are therefore encouraged to continue this important line of research.

Response:

Thank you for pointing out the lack of clarity in Table 3. We have made changes to the table so it is easier to understand and it is part of the manuscript that has been accepted to the Journal of Gerontology: Psychological and Social Sciences.

***C. If the research project received an “unfavorable” rating, please indicate the steps that you intend to take to address the criteria that the project failed to meet and to modify research project oversight so that future projects will not receive “unfavorable” ratings.***

Response: None required.

***D. Additional comments in response to the Final Performance Review Report (OPTIONAL):***

Response: We have recently been notified that our manuscript “A Randomized Controlled Trial for an Individualized Positive Psychosocial Intervention for the Affective and Behavioral Symptoms of Dementia in Nursing Home Residents” has been accepted to the Journal of Gerontology: Psychological Sciences and will be published in a future issue.