

Treatment Fidelity Plan for an Activity Intervention Designed for Persons With Dementia

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The testing of psychosocial interventions in a clinical trial poses many challenges to maintaining a rigorous experimental protocol and to delivering the interventions uniformly throughout the project. These challenges directly affect the reported effectiveness of psychosocial interventions. In this article, the authors describe the treatment fidelity plan developed by an interdisciplinary research team from recreational therapy and nursing for implementing recreational activities during a clinical trial funded by the National

Institute of Nursing Research. The trial tests the efficacy of activities for responding to the behavioral symptoms of dementia. The authors report treatment fidelity strategies to allow comparison of their intervention with that of other studies, to improve effect size in similar studies, and to facilitate replication and translation of this work into clinical practice.

Keywords: behavioral symptoms; dementia; interdisciplinary research; treatment fidelity; recreational activities

Research shows that psychosocial interventions hold great promise in the treatment of behavioral symptoms in persons with dementia, but few well-designed efficacy studies using nonpharmacological approaches have been completed. Those that have generally show modest effects.¹ Testing these types of interventions in a clinical trial poses many challenges to maintaining a rigorous experimental protocol and to delivering the interventions uniformly throughout the project. These factors directly affect the reported effectiveness of psychosocial interventions. In this article, we describe the treatment fidelity plan developed by an interdisciplinary research team from recreational therapy and nursing for implementing recreational activities during a clinical trial funded by the National Institute of Nursing Research. We report these strategies to allow comparison of our

intervention with that of other studies, to improve effect size in similar studies, and to facilitate replication and translation of this work into clinical practice.

The purpose of our ongoing clinical trial is to test the efficacy of prescribed recreational activities for optimal engagement and reduction of behavioral symptoms in nursing home residents with dementia. Our major outcome variables are agitation, passivity, affect/mood, and engagement. We used the model developed by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium² to identify 3 treatment fidelity strategies that we find most salient when implementing recreational interventions for persons with dementia: intervention design issues, training intervention providers, and monitoring delivery of the intervention for uniformity. Receipt of treatment and enactment of treatment skills are not discussed in this article because they are categories that shift the focus to the resident, requiring self-reflection and self-initiation, skills lost as dementia progresses. In the case of persons with dementia, behavioral outcomes may be an indirect measure of effectiveness in these categories.

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Intervention Design Issues

Not all psychosocial interventions are designed in the same manner, an important factor to consider when comparing behavioral outcomes and effect sizes across studies. Before implementing recreational activities, it is necessary to identify the critical components of the treatment itself to ensure that activities are true to their underlying theory and adhere to their conceptual design.

The activities designed for our study were derived from the need-driven dementia-compromised behavior (NDB) model.³ This midrange theory was developed to explain behavioral symptoms commonly associated with dementing disorders. It is strongly influenced by a traditional nursing focus on individual characteristics and basic human needs. In the model, behaviors such as agitation and passivity are viewed as the person's way of communicating an unmet need and result from an interaction of 2 sources of needs: background factors and proximal factors. Background factors are the relatively more stable factors that place an individual at risk for behavioral symptoms. They include pathological changes in the brain due to the dementia, cognitive abilities, health and functional status, and premorbid personality. Proximal factors are changeable situational factors that can precipitate behavioral symptoms in at-risk individuals. They include physiological and psychosocial need states and qualities of the physical and social environment.

Several studies and numerous clinical observations indicate that behavioral symptoms often result from a lack of appropriate stimulation from the physical and social environment, which are proximal factors in the NDB model.^{4,5} Overstimulation from crowding or loud noises as well as understimulation from isolation or boredom may cause persons with dementia to withdraw or become agitated in an effort to establish a level of sensory input that is within their range of tolerance. This range of tolerance is influenced by an individual's cognitive abilities, health and functional status, and premorbid personality, which are background factors in the NDB model. Recreational activities that are individually tailored to these background factors appropriately enrich the physical and social environment because they meet individual needs.⁶ When needs are met, behavioral symptoms are reduced.

The critical components, or active ingredients, of our NDB-derived recreational activities are a

match to skill level and a match to personality. First, activities are prescribed so they match the individual's current cognitive and functional abilities and are appropriate for their skill level. Skill level–appropriate activities afford the opportunity for participation. Second, activities are prescribed so they match the individual's style of interest as determined by their personality traits of extraversion and openness. Activities prescribed by style of interest provide preferred amounts of social interaction with people and the amount of novelty or creativity sought during an activity. Interesting activities promote engagement. An individual's ranking on the trait of extraversion allows us to prescribe the context of the activity (group vs one-on-one activities), and the ranking on the trait of openness allows us to prescribe the content of the activity (novel, creative vs familiar, more prosaic activities).

When prescribing activities, it is necessary to have measures of the critical components. In our work, we use the Mini-Mental State Examination⁷ and the Psychogeriatric Dependency Rating Scale⁸ to assess cognitive and functional abilities, respectively. These data are obtained by a professional health care provider who is trained in the use of these instruments. Based on scores obtained from these instruments, we select activities that are appropriate for that individual's skill level. We use the NEO-Personality Inventory⁹ to obtain scores for the traits of extraversion and openness to assess style of interest. These data are obtained from someone who knows the individual well, usually a spouse or adult child.

We optimize treatment fidelity by monitoring the dose of the intervention and controlling treatment contamination. Subjects are randomized to 1 of 4 activity conditions: activities matched to interest only, activities matched to skill level only, activities matched to both interest and skill level, and control (no match). To prevent extraneous factors from confounding the treatment effect, we ensure that the prescribed dose of the intervention is the same within each of our conditions and across conditions. All conditions are implemented for up to 20 minutes per session, twice per day for 15 days. We determine dosage during activities by taking measures of subjects' time on task (minutes and seconds) and level of participation (active, passive, null) during the activity. Subjects in our protocol may disengage from an activity they dislike or become bored with and so, in a sense, self-dose. We are interested

in capturing this phenomenon: which activities for which subjects promote willing engagement. The effect of activity match on dose, as well as dose response, is handled in statistical analyses.

Treatment contamination is also a potential design problem that we monitor. In our protocol, we have elected to randomize by subject rather than by nursing home, even though the latter approach controls for possible cross-contamination of treatments within sites. We do this because of evidence indicating that nursing home quality indicators are unstable from one 6-month period to the next.¹⁰ Changes in quality indicators may reflect change in quality of care and/or resident profile. Either could potentially affect our outcomes. We control for possible cross-contamination of treatments within nursing homes by conducting all interventions in an area specifically set aside for these sessions. Only the resident(s) scheduled for a particular session are allowed access to the area for that time period. We have not experienced any difficulties with treatment contamination using this approach in our nursing homes.

Training of the Interventionists

Our interventionists are graduate and undergraduate students from a number of disciplines but primarily recreational therapy and nursing. The interventionist training program is standardized and provides critical knowledge and skills needed for working with persons with dementia. All 3 authors collaborated to identify the needed content. We used a 2-day training workshop to deliver didactic information about dementia symptoms, the use of recreational activities with persons with dementia, and communication and prompting skills useful with nursing home residents. The training sessions also provide opportunities to practice the types of activities that are used in the research protocol through hands-on intervention delivery experiences under the supervision of the lead researchers. A training manual that supplements the lecture/discussion/demonstration approaches was given to each trainee.

The first training day centers on the symptoms of dementia to allow a clear understanding of why the recreational activity interventions are important and how to effectively communicate and deliver activities in this population. A lecture style is used to teach about the pathological changes that occur in the brain of older adults with Alzheimer's disease,

vascular dementia, and Lewy body dementia. Special emphasis is given to the cognitive symptoms of amnesia, aphasia, agnosia, and apraxia and how they affect residents' ability to interact effectively. Since behavior is the major dependent variable for the study, the training includes a review of how the pathological changes relate to agitation and passivity. The mechanisms by which recreational activities affect these behavioral symptoms in dementia are explained.

A major training topic for the afternoon session is communication and methods for engaging residents in the planned intervention. Since many residents have diminished activity levels, loss of interest, and apathy, it is imperative that proper and consistent approaches be carried out by the interventionists so the researchers can accurately track engagement. Communication skills and prompting techniques that support residents' cognitive deficits are covered in detail and are listed in Appendices A and B, respectively. Video examples of older adults engaged in a variety of recreational activities with a recreational therapist are viewed and discussed. The communication and prompting techniques used by the expert are identified by the trainees.

Day 2 was planned to strengthen the communication skills and the prompting techniques of the trainees and to provide hands-on practice in leading a recreational activity. Each member of the group is given a specific dementia symptom to role-play during the practice sessions. The researchers preplanned 10 different recreational activities, stocked the necessary supplies, and, one at a time, selected an interventionist to lead an activity. The remaining trainees participate as if they were nursing home residents in the study. During the mock sessions, trainees are rated on their ability to arrange the environment and use communication techniques that support the execution of the activity and maximal engagement by the "residents."

This process continues throughout the day with the different trainees assigned the task of leading a cooking activity, a bowling activity, a craft activity, a sensory-motor activity, a table game, a reminiscence session, a cognitive stimulation program, and a relaxation session. At times, the participants role-play symptoms of agitation, and at other times, they appear passive. After each activity, the group comes together to debrief about the intervention techniques attempted and possible methods of improvement. The lead researchers concurred that the trainees' self-confidence, communication skills, and activity

delivery techniques blossomed during day 2 of the training workshop. There was a high degree of adherence to the intervention protocol, and the team was now ready for the project to begin.

Delivery of Treatment

During implementation of activities it is necessary to ensure that procedures are in place to standardize the delivery of the treatment and to monitor for protocol adherence. There is strong reliance on the methods and procedures developed in the field of recreational therapy for implementing activities in the most effective manner possible. Appendix C outlines our protocol for treatment delivery.

Prior to implementing activities, interventionists complete a pretreatment assessment, the purpose of which is to eliminate any extraneous factors that may influence the delivery and efficacy of the treatment. In this way, subjects are prepared for the activity session so they are maximally receptive to the treatment. We use the system of least restrictive prompts when engaging residents and have behavioral indicators for determining engagement and disengagement.

To ensure that all conditions are delivered with the same emphasis, interventionists are blinded to the activity match. In our experience, we have noted that not every interventionist delivers every activity with the same enthusiasm. Intervention drift is especially problematic with control group subjects who may not enjoy their activity. We make special attempts to prevent interventionist burnout during these occasions by emphasizing the importance of the information we are collecting regardless of subject response, by sharing that persons with dementia are quite variable in their behavior from day to day and to guard against expectations for success when interacting with subjects and by providing interventionists with feedback on their nonverbal and verbal behaviors during random observations of implementation.

We monitor treatment fidelity at each activity session. The components we monitor are listed in Appendix D (treatment fidelity check) and are evaluated after each session by the interventionist and at random intervals for 10% of all sessions by the project director. Random evaluations are done in real time. If the project director notes any deviation from established protocol, retraining of the interventionist is initiated. The treatment fidelity check is also

used to record any interference with the delivery of the activity. The incorporation of treatment fidelity tracking within the context of implementation not only is cost-effective but also, together with our engagement measures, provides data on the dosage of treatment received by each subject. These data are used in our statistical analyses.

We keep a diary of field notes on any other factors that affect treatment delivery. For example, if a resident is discovered to develop a condition, such as a urinary tract infection, we record that information as it may explain a less than successful activity session.

One very critical aspect of preventing interference with treatment delivery is to enlist the assistance and cooperation of nursing home staff. It is vital that the research staff work with the nursing home staff to ensure a mutually satisfying experience and to increase the probability that the activities prescribed for residents will be continued once the project ends.

Conclusion

Nonpharmacological interventions are recommended as the first line of treatment for the behavioral symptoms of dementia.¹¹ In practice, drug therapy continues to be the mainstay of care despite little evidence for the effectiveness of these medications.¹² Although the literature on the efficacy of nonpharmacological interventions for behavioral symptoms of dementia is becoming more convincing, a limitation is that published studies of these psychosocial strategies have paid much less attention to treatment fidelity issues than have clinical drug trials. Our interdisciplinary approach to treatment fidelity has capitalized on the strengths of 2 disciplines, nursing and recreational therapy, to improve precision in the identification of needs and the delivery of activities, respectively. We hope our treatment fidelity strategies will improve the effectiveness of activity interventions and be used as a guide for their clinical and research application.

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Appendix A General Communication Skills

1. Address the client by name and in a respectful adult manner.
 2. Approach the client from the side, if possible, rather than head on.
 3. Maintain eye contact, standing or sitting at the client's eye level.
 4. Speak slowly and clearly but not loudly.
 5. Use simple and short sentences.
 6. Ask one question at a time.
 7. Ask "yes/no" questions rather than open-ended questions.
 8. Allow plenty of time for responses.
 9. Do not interrupt the client when he or she is speaking.
 10. Use the same words when repeating a statement.
 11. Provide instructions in the form of least restrictive prompts. This begins with verbal cueing the resident to engage in an activity. If this attempt is not successful, it is followed by verbal cueing and demonstration of the activity and then by verbal cueing and actively assisting the resident hand over hand.
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Appendix B Prompting Techniques for Cognitive Symptoms

Amnesia: A primary loss for the individual with dementia is in the area of memory impairment. The interventionist needs to provide verbal and written reminders, repeat cues, and reengage the participant in an activity.

Aphasia: Use of language is also diminished in dementia. This affects both the ability to express (expressive aphasia) oneself and the ability to understand what is spoken (receptive aphasia). The interventionist needs to add demonstrations and gesturing to recreational interventions and should observe the residents' body language.

Agnosia: This symptom is displayed as the inability to recognize familiar objects or faces. The interventionist may need to reintroduce himself or herself each time and demonstrate the use of the recreational item for each activity. The resident may put nonedible objects in his or her mouth or use a recreational item in a dangerous way. The resident with agnosia may need the interventionist to assist in starting the movement but may be able to continue it with encouragement.

Apraxia: This is the loss of familiar motor skills. For residents with this symptom, the interventionist needs to use hand-over-hand prompting, and physical assistance is required.

Appendix C Treatment Delivery Protocol

At each session, the interventionist introduces himself or herself to the resident and obtains assent by asking him or her to join in the activity. Residents who are drowsy or passive are alerted by calling their name and using touch. A gentle handheld massager is used if these attempts are unsuccessful.

- A. To control for the effects of other needs and environmental factors on outcomes, the following pretreatment assessment is completed:
 1. All extraneous stimuli are eliminated so that the environment provides the appropriate stimulation levels and reinforcing cues. Radios, TVs, and pagers are turned off; lighting level is adjusted to reduce glare and promote vision; and temperature is adjusted to a comfortable level. The activity is conducted where it is out of the way of foot traffic and visual disturbances in a specially designated area for the study. This strategy also helps prevent cross-contamination of conditions.
 2. Residents are toileted prior to the intervention. Glasses/hearing aides are worn, and assistive devices such as canes/walkers are available. Residents are dressed appropriately with proper foot ware. Hydration and/or food are offered before each session.
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(continued)

Appendix C (continued)

3. Residents are positioned properly to maximize free movement and comfort. Residents are asked about their comfort level. Reports of pain are communicated to the nurse in charge so that corrective action can be taken before the start of sessions.
 4. Simple phrases, body language, gestures, and demonstration are used to promote understanding. Residents are not interrupted when communicating a need.
- B. The interventionist begins each session by introducing himself or herself and telling the resident the purpose of the session.
1. All sessions begin with an initial greeting (handshake) to signal the start of the session (timing begins at this point).
 2. To encourage engagement in the activity, the interventionist uses the system of least restrictive prompts beginning with verbal cue ("Mrs Jones, toss this ball to Mr Smith"), followed by verbal cueing and demonstration of the activity (the interventionist tosses the ball to Mr Smith) and then by verbal cueing and actively assisting the subject hand over hand (the interventionist places the ball in Mrs Jones' hand and helps her toss it to Mr Smith).
 3. If still no response, the interventionist tries the second and, if necessary, third activity for that condition, using the sequence of verbal cueing, verbal cueing with demonstration, and verbal cueing with physical prompting for each activity.

The subject is considered "engaged" in a particular activity when he or she attends to the activity for 15 seconds, that is, maintains eye contact with the activity or interventionist, gazes at the activity, vocalizes pleasure with the activity, and/or physically participates in the activity. The interventionist may attempt to reengage the subject 3 times over the 20-minute session if the subject disengages at any point. Disengagement is demonstrated by the subject's dozing, negative remarks about the activity, turning away from the interventionist/activity, asking to leave, attempting to leave, or leaving the area. Timing continues through attempts at reengagement. After 3 attempts at reengagement, no further attempts are made, and the session ends (timing stops).

Appendix D Treatment Fidelity Check

Subject Code: _____

Facility: _____

Date: _____

Time: _____

Interventionist: _____

At the completion of each activity session, please evaluate the extent to which the activity was implemented by answering the following questions:

Was today's activity the one selected for this condition?

Yes _____

No _____

Explain:

Were there any extraneous circumstances that influenced the delivery of the activity?

_____ a. Inability to form group activity.

Explain:

_____ b. Inability of subject to stay by himself or herself for independent activity.

Explain:

(continued)

Appendix D (continued)

_____c. Interference from staff, other residents, visitors, etc.

Explain:

_____d. Subject uncooperative.

Explain:

_____e. Subject ill.

Explain:

_____f. Subject engaged in another activity.

Explain:

_____g. Subject not available.

Explain:

_____h. Interventionist not available.

Explain:

References

1. Verkaik R, van Weert JC, Francke AL. The effects of psychosocial methods on depressed, aggressive and apathetic behaviors of people with dementia: a systematic review. *Int J Geriatr Psychiatry*. 2005;20:301-314.
2. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. 2004;23:443-451.
3. Algase D, Beck C, Kolanowski A, Whall A, Berent S, Richards K. Need-driven dementia-compromised behavior: an alternative view of disruptive behavior. *Am J Alzheimer Dis*. 1996;11:10-19.
4. Cohen-Mansfield J, Marx MS, Werner P. Observational data on time use and behavior problems in the nursing home. *J Appl Gerontol*. 1992;11:111-121.
5. Perrin T. Occupational need in severe dementia: a descriptive study. *J Adv Nurs*. 1997;25:934-941.
6. Kolanowski AM, Buettner L, Costa P, Litaker M. Capturing interest: therapeutic recreation activities for persons with dementia. *Ther Recreation J*. 2001;35:220-235.
7. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975;12:189-198.
8. Wilkinson IM, Graham-White J. Psychogeriatric dependency rating scales (PGDRS): a method of assessment for use by nurses. *Br J Psychiatry*. 1980;137:558-565.
9. Costa P, McCrae R. *Revised NEO Personality Inventory and NEO Five-Factor Inventory: Professional Manual*. Odessa, Fla: Psychological Assessment Resources; 1992.
10. Rantz MJ, Hicks L, Petroski GF, et al. Stability and sensitivity of nursing home quality indicators. *J Gerontol A Biol Sci Med Sci*. 2004;59:79-82.
11. Doody RS, Stevens JC, Beck C, et al. Practice parameter: management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2001;56:1154-1166.
12. Teri L, Logsdon R, Peskind E, Raskin M, Weiner M, Tractenberg R. Treatment of agitation in AD: a randomized, placebo-controlled clinical trial. *Neurology*. 2002;55:1271-1278.