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Tailoring Protocols to Successfully Recruit and Retain Elders in a Longitudinal Study of Sleep and Cognition

Barbara Waag Carlson, RN, Ph.D.[Associate Professor and Associate Director],
Biobehavioral Laboratory, School of Nursing, CB# 7460, Carrington Hall, The University of North Carolina at Chapel Hill, Chapel Hill, NC 27599

John R. Carlson, MS[Research Associate Professor],
Research Support Center, School of Nursing, The University of North Carolina at Chapel Hill, Chapel Hill, NC 27599

Virginia J. Neelon, RN, Ph.D.[Associate Professor and Director], and
Biobehavioral Laboratory, School of Nursing, The University of North Carolina at Chapel Hill, Chapel Hill, NC 27599

Marilyn Hartman, Ph.D.[Associate Professor and Senior Research Scientist]
Department of Psychology and Institute on Aging, The University of North Carolina at Chapel Hill, Chapel Hill, NC 27599

Barbara Waag Carlson: bcarlson@email.unc.edu

Abstract

Many studies attest to the challenges of recruiting and retaining older adults in longitudinal studies. This article presents the methods used by the Physiological Research to Improve Sleep and Memory Project to recruit and retain 115 adults (70+ years) in a 2-year study that involved yearly administrations of two neurocognitive test batteries and two nights of polysomnography. The paper describes strategies which are built on knowledge obtained from participant informants and the use of tailored, individualize protocols. Together, these strategies enabled participants to become vested in the research process and to fully participate in all aspects of the study.

Keywords

Research Subjects; Cognition; Sleep; Frail Elders; Prospective Studies

Introduction

This article presents the methods used to successfully recruit and retain participants in a 2-year study that assessed the effects of cerebral oxygenation during sleep on cognitive function in older adults. Longitudinal studies that track participants over a number of years are crucial for understanding cognitive decline in older adults. However, recruitment and retention of persons with declining cognitive abilities are challenging. Not surprisingly, older adults who suspect they are experiencing cognitive decline are often anxious or depressed by their loss of abilities (Sinoff & Werner, 2003), and they may fear being exploited, or getting lost or injured (Cassidy, Baird, & Sheikh, 2001). Because of these feelings of vulnerability, many older adults cease to participate in community events and

Correspondence to: Barbara Waag Carlson, bcarlson@email.unc.edu.

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they are hesitant to seek medical evaluation of their memory (Cassidy et al., 2001). These issues make it difficult to recruit older adults with mild declines in health and cognition, especially in studies of cognitive decline and studies that combine physiological monitoring and extensive neurocognitive test batteries (Williams et al., 1988).

Even when these individuals are successfully recruited, it may be necessary to tailor the study protocol to enable participants with limitations to complete the study. Many persons with even mild cognitive decline have difficulties performing tasks (i.e. handling money, arranging transportation and maintaining a schedule) that are key for simply arriving at the laboratory (Njegovan et al., 2001). Even if not experiencing cognitive deficits, participants may have other problems (such as vision, hearing or mobility) that make participation difficult. Nevertheless, older adults experiencing cognitive decline and those with other deficits represent the population at large and thus are needed in order to draw valid conclusions about this population.

Given the difficulties that older persons face, it is not surprising that rates of attrition of older adults in studies of cognitive decline are as high. In studies that do not use physiological measures, attrition rates are reported to be as high as 30% to 95% (Park, O'Connell, & Thomson, 2003). In those that use polysomnography, attrition rates tend to be even higher, ranging between 67% and 70% (Foley et al., 2003; Redline, Schluchter, Larkin, & Tishler, 2003; Williams, Vitiello, Ries, Bokan, & Prinz, 1988). Clearly, some attrition is unavoidable because cognitive impairment is associated with increased comorbidities (Marquis et al., 2002), hospitalization (Chodosh et al., 2004), nursing home admission (Burdick et al., 2005), and mortality (Lee et al., 2006; Ganguli, Dodge, & Mulsant, 2002). In research on cognitive decline, the participants most likely to be lost to follow-up tend to be older, have lower educational levels, perceive themselves to have poorer health, and demonstrate functional and cognitive impairments in testing sessions (Cooney, Schaie, & Willis, 1988; Matthews et al., 2004). Unfortunately, these are also the people that researchers most need to study to understand decline over time.

Design of the Study

The Physiological Research to Improve Sleep and Memory is a 5-year study designed to examine the relationships between cerebral oxygenation during sleep and cognitive decline in 115 community dwelling elders, age 70 years and older. Recruiting and retaining participants was challenging because the study involved a complex and demanding set of protocols. All participants underwent a 3-day protocol at baseline that was repeated at 12 and 24 months. On the first day, participants came to our laboratory to undergo 1.5 hours of assessment, which included a history and physical administered by a nurse practitioner and a series of memory tests. Individuals then participated in a time intensive 2-night sleep laboratory protocol. On the first of the 2 nights, participants underwent an extensive 90-minute battery of neurocognitive tests and completed questionnaires (45 minutes). On both nights, the subjects went to bed around 11:00 p.m. and slept until 6:00 a.m. the following morning. Our protocols required much effort from participants, yet 95 of the 115 participants completed the entire protocol, although many exhibited significant declines in both health and cognitive function during the course of the study. Subjects gave informed consent; and the Institutional Committee for the Protection of Human Subjects approved the study.

Recruitment and Retention Methods

Recognizing the many challenges in recruiting older adults for a laboratory study, we relied on our prior experiences with this population as well as suggestions from our participants to help us refine our recruitment strategies to make it easy for older adults to participate.

Related to each of the following subheadings, we provide useful strategies for addressing a number of barriers to older adults' participation in laboratory research, including the inconvenience of leaving home for extended lengths of time, worries that the investigators will judge them based on their cognitive abilities, and participants' belief that they lack the physical and psychosocial endurance to withstand the "rigors" of a laboratory study. Although we divide the paper into recruitment and retention methods, these two activities cannot be easily separated, for they both involve the development of a lasting partnership between the participant and the research team.

Engaging Participants in Participant Recruitment

Based on our experience as well as the review of literature, the team identified a number of ways to make it easy for volunteers to participate in the screening process. A major component to our success involved conducting open ended interviews on 12 participants who had taken part in other studies conducted by the first author. Described below, our former participants identified a number of ways to make it easy for elders to volunteer and participate in the screening process.

Making It Easy to Volunteer—The first issue identified by our former participants was the importance of clearly communicating the time and procedure for appointments. Thus, to avoid miscommunication or errors in scheduling, we developed a password protected, centralized computerized tracking system. This system interfaced with the study calendar and was used to create and track the mailing of form letters and information packets and to prompt project staff to schedule follow-up reminder phone calls and verify transportation arrangements. Because participants often called after business hours, the databases were maintained on two password-protected pocket personal computers so the first author (BWC) and the project manager were able to return calls to participants in the evenings and on weekends.

The former participants also advised us on ways to make transportation and parking convenient. Individuals who chose to drive were given directions in their packets and instructions on where to park. Also, most screening visits were scheduled between 10 a.m. and 12 noon to avoid periods of heavy traffic. For those who were unable or chose not to drive, the project staff arranged for a taxi or the community's public van service to take participants to and from the laboratory. Our research assistants met and escorted the participants to the laboratory, which was on the ground floor with handicap ramp access. To help participants identify the research assistants, the assistants wore name tags and a standard "uniform" consisting of a white tee shirt with the study logo and a pair of dark blue scrub pants.

We suspected, and our former participants verified, that many potential participants would benefit from memory aids to help keep track of their progress as they underwent the screening protocol. The first memory aid was a schedule which the participants could use to keep track of their progress through the screening protocol. On completion of the screen, the potential participants also received a 3" × 3" reminder card that thanked them for coming in for their appointment and stated that we would contact them within 2 working days to let them know if they were eligible to participate. Again, we relied on our computer-based system to remind us to place return calls to the participants. Using this system, we were able to contact 99% of participants within a 48-hour window of their screening appointment.

Engaging Participants as Informal Recruiters—Anticipating that we would need to establish an informal network for recruiting persons, our recruitment protocol also included procedures for engaging participants as informal recruiters. During one of the evenings of

the sleep study, the first author spent dinnertime with each participant and discussed how the findings from this study might help to improve sleep or reduce cognitive decline in older adults. She also discussed the challenges in recruiting people having problems with sleep or memory and elicited the participant's assistance in finding people. About 50% of our participants expressed an interest in assisting us with recruitment, and we provided them with flyers and brochures that they could distribute to friends or leave at public places. Our conversations with participants confirmed that these measures were working to establish an informal network of participant recruiters.

The incentives given to participants proved to be a useful vehicle for participants to tell others about the study. All participants received an attractive tee shirt with the study logo and the slogan "I was catching my ZZZ's at UNC." The tee shirts were often worn to meetings as well as exercise classes at one of the local retirement communities. Participants told us that the tee shirt led others to ask for information about the project, and a recommendation such as "Oh, I had a great time" was enough to convince others to call the research office. To reinforce the importance of their help and keep them abreast of new developments, we mailed participants cards and newsletters that provided information about the project staff, expressed appreciation for what the participants brought to the project, and asked them to encourage their friends and loved ones to work with us on the project.

Enabling Participants to Complete the Study Protocols

While participants identified curiosity, personal benefit, and the desire to support research as reasons for initially joining the study, the success of our retention efforts was based primarily on getting participants to feel secure in the laboratory environment and able to complete all aspects of the protocol. Since many of our research assistants had little experience working with older adults, the first author closely supervised the interactions between the research team and study participants, and early on, provided ongoing instruction to the research assistants in order to ensure that the protocol was continually titrated to the subject's current cognitive and functional abilities. Our goal was to provide participants with a comfortable and rewarding experience, and thus to maximize retention.

Tailoring the protocol—Another key component of our retention plan was tailoring the protocol to the needs of persons with cognitive and functional limitations, thus providing the means for these persons to successfully complete the protocol. The foundation of this strategy was the nurse practitioner assessment, which provided a list of problems (vision, hearing, mobility, memory, attention, and illnesses) that staff used to tailor the environment and their interactions with participants. Prior to the first sleep study night, the nurse practitioner assessment was reviewed by the first author, and a plan based on the information was placed in the participant's research chart for review by research assistants at the start of their shifts.

Making participants feel comfortable and secure—We used a "Bed and Breakfast" model to promote comfort and sleep in the laboratory. Prior to their 2-night sleep study, participants were provided with a meal preference list that allowed them to choose the food to be served at dinner and breakfast. We received our cooked meals from a federally funded general clinical research unit, and a registered dietician worked with participants to meet their dietary requirements. All meals were heated in our kitchen area, and the participants and research assistants sat together to have dinner.

Since the sleep rooms were originally designed to conduct physiological monitoring, it took only a few wall hangings and additional room furnishing to render the sleep monitoring room to simulate a hotel room. As with many laboratory settings, each room had its own

controls for adjusting light and temperature levels, and we worked with the participants to ensure that the settings were similar to those they had at home. In addition to changing the room furnishing, participants were encouraged to bring items from home (such as pillows, blankets, radios, alarm clocks, white noise machines) that would help them sleep. The bedrooms were locked during the day so the participants were able to leave their belongings in their room between study nights. Before they returned for the second night, their bed was made and fresh linens placed in the bathroom. Upon going to bed at night, they found the lights dimmed and their bed linens turned down.

Having the facilities (bedrooms, equipment, and staff) to study two participants at the same time also helped us recruit and retain participants. Thirty percent of the persons enrolled in this study came on the same night as a family member or friend. Two thirds of those who recruited a family member or friend did so because they thought that the person had a memory or sleep disorder that we might detect and help the person seek treatment. The others volunteered because they thought the study would be an opportunity to simply spend more time together. Among those who recruited a spouse or friend into the study, only one pair was lost to follow-up.

Setting aside time to learn how participants felt about each component of the protocol was also important in reducing participants' fears and allowing them to express any discomfort they felt. Some sources of distress, such as those related to cognitive testing, we were able to anticipate. We expected that all participants would feel a degree of anxiety. For this reason, we emphasized that we would not compare their cognitive test scores with others but would follow their changes in scores over time and tell them if we found any change that needed follow up by their physician. One issue that we did not anticipate was participants' fear of ether. Using standard sleep laboratory methods, we initially used an ether-based adhesive to attach sensors to the participant's scalp. Given their age and past experiences, many knew of the anesthetic properties of ether and its distinct odor, and during sensor application, they became worried that the adhesive might affect their cognitive function. Although this particular adhesive is FDA-approved, we took their concerns seriously, and after some experimentation, we were able to devise an alternative, equally effective method to apply the sensors.

Fostering interpersonal connections—Another strategy used to promote participant investment was to maximize social interactions between the participants and members of the research team. Our goal was for participants to leave knowing that we cared about them and valued their effort in teaching us about sleep and aging. From previous experience in conducting sleep studies, we knew that a number of participants would enroll in the study to enjoy the company of others. Thus, we set aside periods during the 2-night study for the participants and research assistants to talk about topics other than the research.

Often, these interactions between participants and the research assistants occurred during and after the evening meal. During this time, the research assistants encouraged participants to share stories about themselves or to discuss current events. Participants found that they had a fresh audience for their stories and an opportunity to talk about the concerns and interests of young people. The opportunity to tell their stories and discuss topics from different points of view often led to stimulating conversations and helped create important bonds between the participants and staff.

Ensuring the competence of research assistants—Successful retention also depended on having staff who were confident in carrying out the protocol and in interacting with older adults. Most were undergraduate students in nursing, psychology, or biology, and thus, they had little or no clinical experience with community dwelling elders or older adults

with diminished function or health. In the first 6 months of data collection, the first author spent 4 hours a week training the research assistants on how to detect physical and mental limitations, provide a safe environment, and resolve conflicts that might arise. This instruction was reinforced through supervision during actual data collection when the author monitored the assistants' interactions with participants and intervened when necessary. Supervision was supplemented by weekly staff meetings in which the team discussed strategies for dealing with difficult situations.

Many participants commented that they were impressed with the attention paid to training the research assistants, and the intense training yielded other benefits. After 1 year of employment, the research assistants were often promoted to a leadership role, either to project manager or lead research assistant, who took on the role of either coordinating or training new research assistants. Employee attrition was minimal; over 80% of the research assistants remained on the project for at least 2 years. With this level of extensive training, we were also able to keep the amount of missing data to less than 2% across all timepoints.

Recruitment and Retention Outcomes

The sample was predominantly female (64%) and Caucasian (86%), and 39% were 80 years and older. Although none had dementia (as indicated by a score <24 on the Mini-Mental State Examination [MMSE], Folstein, Folstein, & McHugh, 1975), 34% scored <28 points on the MMSE, and 29% reported having some functional impairment, as indicated by a score <24 points on the Older Adults Resources and Services Activities of Daily Living Scale (Fillenbaum, 1978). The category on which most points were lost was arranging transportation (80%). Half of the participants had four or more health problems as measured by the Cumulative Illness Rating Scale for Geriatrics [CIRS-G] (Linn, Linn, & Gurel, 1968), and 16% had at least three symptoms of depressed mood, as measured by the 15-item version of the Geriatric Depression Scale [GDS] (Sheikh & Yesavage, 1986).

Of the 115 older adults enrolled in the study, 20 were lost to the study, but 95 completed all three sessions (retention rate = 83%). Seven were lost after the first laboratory session, and 13 after the second datapoint. Five participants died, and others ($n=12$) were lost due to changes in health status, which included stroke, hip fracture, myocardial infarction, and depression. Only three participants withdrew due to lack of interest (1 at 12 months and 2 at 24 months).

Although cognitive and physical function as well as the number of health problems did not differentiate the groups at baseline, those lost to follow-up were older and had more depressive symptoms (Table 1). Of the 95 who completed the study, we obtained complete data on 92. Those who completed the protocol (Table 2) experienced greater declines in cognitive and physical function as well as increasingly more number of health problems. Although not significant, depressive symptoms also tended to increase over the 2 year period.

Summary

Given the complex protocols needed to study cognitive decline and other issues in older adults, researchers need to share approaches that are successful in recruiting and retaining older adults. Clearly, the recruitment and retention of older adults with limitations is an iterative process, requiring constant monitoring of participants' responses to the protocol and tailoring of the protocol to meet their changing needs. Although some of our strategies, such as the extensive training of research staff and the time the PI spent with participants may place added costs, these costs are minor when compared to the cost of hiring and training new research assistance as well as the cost of traveling to community sites to obtain

a sample and the attrition that is most likely to occur if one does not tailor the protocol to meet the needs of participant. We hope that the strategies described in this paper are helpful to others who study this special population of older adults.

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Differences at baseline between those who were lost to follow-up and who completed the protocol.

Table 1

Variable	All Subjects Mean (range)	Lost to Follow-up Mean (sd)	Completed Mean (sd)	t	p
N	115	20	95		
Age (years)	78.2 (70–92)	81.3 (5.7)	77.5 (5.5)	–2.9	.008
Education (years)	14.1 (8–20)	14.2 (1.2)	14.1 (1.9)	0.24	.82
MMSE Total	28.8 (24–30)	28.3 (1.8)	28.9 (1.6)	1.7	.10
OARS Total	27.5 (24–28)	27.4 (1.1)	27.6 (.8)	.97	.34
GDS Total	1.3 (0–5)	2.1 (2.0)	1.2 (1.5)	–2.1	.05
CIRS-G	4.9 (0–8)	6.0 (3.3)	4.6 (3.5)	–1.7	.09

MMSE=Mini Mental Status Examination, OARS= Older Adults Resources and Services, GDS=15-item version of the Geriatric Depression Scale, CIRS-G=number of categories endorsed on the Cumulative Illness Rating Scale-Geriatrics.

Table 2

Change in key variables over 2 years for those who completed the protocol. (n=92)

Variable	Δ Baseline Mean (sd)	Paired t	p
MMSE Total	-.8 (1.7)	-4.2	.0001
OARS Total	-.5 (1.1)	-4.6	.0001
GDS Total	.4 (1.8)	1.9	.06
CIRS-G Total	.2 (.60)	3.1	.002

MMSE=Mini Mental Status Examination, OARS= Older Adults Resources and Services, GDS=15-item version of the Geriatric Depression Scale, CIRS-G=number of categories endorsed on the Cumulative Illness Rating Scale-Geriatrics.