# Subject Recruitment, Retention and Protocol Feasibility in a Prospective Study of Nutritional Risk Among Urban, Frail Homebound Elders

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**ABSTRACT.** The feasibility of performing comprehensive in-home nutritional risk assessments in a prospective research study of urban, frail homebound elderly patients (aged 65-105) is important, given prior reports of difficulties conducting research with older adults. Trained field teams conducted nutritional and health status assessments on 239 subjects, patients of the Boston University Geriatric Services clinical home care program. Baseline data were obtained on 153 of the 159 inter-

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view items from 91% of respondents; three 24 hour dietary recalls from 73%; anthropometry from 60-93%; and other physical assessments from 63-94%. Attrition was 21%, and mortality was 9% over 12 months. Well-designed, flexibly administered study protocols, modest financial incentives and careful follow-up contributed to follow-up interview response rates of 81 to 89% among enrollees over the study's duration. Clearly, it is feasible to recruit frail, older subjects and for well-trained, two person field teams to conduct comprehensive in-home assessments of nutritional risk in under two hours with good retention over 12 months of follow-up. *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-342-9678. E-mail address: <getinfo@haworthpressinc.com> Website: <http://www.HaworthPress.com> © 2001 by The Haworth Press, Inc. All rights reserved.]*

**KEYWORDS.** Feasibility, elders, in-home assessments, elder nutrition

## *INTRODUCTION*

Persons aged 85 years and older comprise the most rapidly growing segment of the US population (U.S. Dept of Health and Human Services, Healthy People 2010, 2000). Individuals of advanced age are likely to be homebound; living in poverty; have multiple, more complicated medical conditions; have higher rates of institutionalization, longer hospital stays and higher rates of health and related services utilization, including home care (U.S. Dept. Health and Human Services, Publication 91-28001). Experts have recommended research initiatives to optimize the development of home and community-based services for older adults, that promote improved health and quality of life, can reduce risks for chronic diseases and their complications, and will maintain functional independence (NIH Publication 94-088). Further, the Healthy People 2010 goals have identified malnutrition as a major concern for health promotion and disease management in older adult populations, especially the very old.

Researchers' attention has been given to successful recruitment methods for women and minorities, particularly since the National Institutes of Health 1994 mandate to obtain better research representation of women and minorities (NIH publication 94-5435). However, less attention has been given to the recruitment (Carter, Elward, Malmgren, Martin & Larson, 1991) and retention of older subjects, especially mi-

norities, in longitudinal, prospective studies (Areán & Gallagher-Thompson, 1996; Wrobel & Shapiro, 1999; and Gauthier & Clarke, 1999). Little information is available on feasibility issues that researchers encounter in conducting comprehensive field research with elders. The Women's Health and Aging Study did examine the feasibility of comprehensive in-home medical assessments on disabled community-living women over age 65 (Simonseck et al., 1997). However, little is known about feasibility and retention in comprehensive, prospective studies of health and nutritional risk involving in-home and telephone-administered protocols with urban, homebound elder populations.

The Nutrition and Healthy Aging Project is a prospective study of the causes and consequences of malnutrition in an urban, homebound, largely minority elder cohort. The study employed comprehensive health assessments for the purpose of monitoring nutritional risk, co-morbidity, functional status, and mortality over time with free-living subjects of advanced age and frailty. Baseline findings have been reported previously and findings in women have been highlighted (Millen et al., in press).

This article describes the challenges associated with the recruitment and retention of older subjects over 12 months, and the feasibility of assessing and monitoring nutritional risk status, its determinants, and health-related outcomes in an urban, frail, homebound cohort.

## *METHODS*

All the research methods were developed or adapted and tested for standardized application with elder subjects in home settings. They have been described in detail previously (Millen et al., in press) and are summarized below.

*Subjects.* Subjects were recruited from the patient population served by the Home Care Program of the Geriatrics Section, Department of Medicine, Boston University. This program provides in-home medical care and case management for homebound elderly patients in collaboration with other community-based social services. Eligibility criteria were as follows: anticipated life expectancy greater than six months; no or only mild cognitive impairment; English-speaking, unless an English-speaking proxy was available; and no severe mental illness. The 572 patients under care in May, 1998, were reviewed for eligibility by a

senior geriatrician-researcher who worked in concert with the patients' primary clinicians. Of the 572 reviewed, 435 were deemed eligible.

Physicians and the researchers sent letters to the 435 eligible subjects or their proxies to introduce the study and invite participation. An experienced research assistant (RA) followed up by telephone to describe the study in detail and to answer questions. For those who were willing, a home visit was scheduled to obtain informed consent and to enroll subjects in the study. The final sample consisted of 239 persons (171 women; 68 men), ages 65 to 105 years for a consent rate of 55%. Volunteer proxies provided less extensive interview data for 44 (18%) of the subjects who could not communicate with research assistants (RAs) in English. Enrollees did not differ from non-enrollees with regard to age and gender. For reasons of patient confidentiality it was not possible to determine if enrolled patients differed in other characteristics from eligible patients who did not enroll in the study.

*Retention Strategy*. Respectful and empathic telephone calls to schedule, and sometimes to reschedule, visits were part of our retention strategy, as were modest financial incentives[1] and periodic letters that let subjects know their participation was valued. Communication between the field team and the clinical team was important to retention, especially when subjects had to be admitted to extended-care facilities.

*Protocol Development and Pilot Testing.* An interdisciplinary team of investigators with expertise in geriatrics, clinical nutrition, chronic disease epidemiology, endocrinology, internal medicine, dentistry, neurology, and neuropsychology guided the study. They reviewed published instruments and protocols for possible inclusion. Where necessary, they adapted protocols to meet the needs of older, functionally-impaired subjects and the environments encountered in their homes, apartments, adult daycare centers and, on occasion, nursing homes and rehabilitation facilities.

Table 1 summarizes the data that were gathered through Interview, as well as the frequency of such data collection. In addition, Anthropometry, Physical Performance, and most Oral Health data were collected at Baseline, 6, and 12 months, while dysphagia was assessed at Baseline and 12 months, and vision and hearing were assessed only at Baseline. Abbreviated telephone interviews were performed at 4 and 8 months to minimize the subject burden and to limit resource intensity.

The research team pilot-tested the Baseline protocols with a small group of volunteers who were eligible for home care but were not patients of Boston University Geriatrics Services. Based on experience during the pilot-test, some modifications were made in the protocols.

TABLE 1. Interview Components Conducted at Baseline and Follow-Up Points

| Components/Assessments | Baseline and Point of Follow-up |
|---|---|
| **Interview** | Baseline, 4 Mos.[a], 6 Mos., 8 Mos.[a], 12 Mos. |
| NSI DETERMINE Checklist | Baseline, 6 Mos., 12 Mos. |
| Tobacco, Alcohol Use | Baseline, 6 Mos., 12 Mos. |
| KATZ Activities of Daily Living | Baseline, 4 Mos., 6 Mos., 8 Mos., 12 Mos. |
| OARS Instrumental Activities of Daily Living | Baseline, 6 Mos., 12 Mos. |
| Bed-Restricted Days | Baseline, 6 Mos., 12 Mos. |
| EPESE Social Support | Baseline, 6 Mos., 12 Mos. |
| General Health Perceptions from MOS SF-36, HRQOL | Baseline, 4 Mos. [a]., 6 Mos., 8 Mos. [a], 12 Mos. |
| MOS SF-36 Physical Function 10 | Baseline, 6 Mos., 12 Mos. |
| MOS SF-36 Mental Health Inventory | Baseline, 6 Mos., 12 Mos. |
| MOS SF-36 Bodily Pain Index | Baseline, 4 Mos., 6 Mos., 8 Mos., 12 Mos. |
| Mini-Mental Status Examination | Baseline, 12 Mos. |
| Modified Prime MD (likelihood of depression scale) | Baseline, 4 Mos., 6 Mos., 8 Mos., 12 Mos. |
| Self-reported illnesses/conditions | Baseline, 4 Mos. [a], 6 Mos., 8 Mos. [a], 12 Mos. |
| Self-reported medications and supplements taken | Baseline, 12 Mos. |
| Self-report oral health | Baseline, 4 Mos. [a], 6 Mos., 8 Mos. [a], 12 Mos. |
| Sociodemographics | Baseline, 4 Mos. [a], 6 Mos., 8 Mos. [a], 12 Mos. |

[a]Abbreviated versions of the socio-demographics, oral health, health-related quality of life, and Modified Prime MD, were included in the 4 and 8 month telephone interviews, while Baseline, 6, and 12 month interviews were conducted in subjects' residences.

Hip and abdominal/waist circumference measurements were deleted because of the time required, the difficulty in performing these measures in subjects' home environments, and subjects' feedback. The team established formal interview probes to maximize consistency in coding responses and added the documentation of start and stop times. Protocol segments are described below.

*Dietary Recalls*. Three 24-hour dietary recall interviews were collected from subjects or their proxies using standardized protocols to characterize subject's usual food and nutrient intake (Posner et al., 1992; Posner et al., 1982). The teams collected the first dietary recall during each subject's home interview. Second and third recalls were collected by telephone on randomly selected days. For subjects who had difficulty with the telephone protocol, the research assistants obtained subsequent recalls in-person. Intra-rater coding reliability (comparison of a given research assistant's duplicate coding of selected dietary recalls) ranged from .89 for sodium to .99 for vitamin D. Inter-rater coding reliability was also extremely high, ranging from .92 for protein calories to at least .98 for five other nutrients (energy, calcium, magnesium, vitamin A, and thiamin). Nutrient data cleaning followed standard protocols (Posner et al., 1992) to identify incomplete recalls and verify or correct extreme nutrient outlier values. Recalls containing "zero calorie" daily intakes were included, because they can reflect an acute change in an older person's appetite or food intake.

*Anthropometry*. Anthropometric measurements were taken using standardized procedures (Lohman et al., 1988; Chumlea et al., 1989; Sorkin et al., 1999). Subjects wore hospital paper gowns and light undergarments. Measurements were taken on the right side of the body unless amputation, swelling, stroke, or other factors necessitated taking measurements on the left. Measurements included: weight; standing height; knee height; triceps skinfold thickness (TSF); subscapular skinfold thickness (SSF); mid-arm circumference (MAC); and maximum calf circumference (MCC). Standing heights were not obtained for subjects who were kyphotic, those unable to position their head in the Frankfort level plane, and those who had unequal leg lengths or were non-ambulatory.

Tricep skinfold (TSF) and subscapular skinfold (SSF) were measured to the nearest 0.2 mm using a calibrated Holtain caliper (Shorr Productions, Olney, MD) (Chumlea et al., 1989). Subjects were measured standing unless a medical condition confined them to a bed or chair. In the latter instance, they were measured sitting.

Mid-arm circumference (MAC) and mid-calf circumference (MCC) were measured to the nearest 0.1 cm. Both measurements were taken using a metal measuring tape (Shorr Productions, Olney, MD). Subjects were standing for MAC measurement, unless a medical condition necessitated their being measured while sitting. MCC measurements were taken in the sitting position, with the right knee and ankle flexed 90 de-

grees. To minimize effects of edema, MCC was measured at the point of greatest circumference over the gastrocnemius (Chumlea et al., 1989).

Anthropometric inter-rater reliability was extremely high (.96-.99) on all but the two skinfold measurements that were performed with calipers. Reliability for SSF was just below .78, while TSF reliability was .87. Difficulties of using calipers on extremely obese elders contributed to the lower reliability coefficients on SSF and TSF.

*Vision, Hearing, Physical Performance Testing, and Oral Health.* Visual acuity was evaluated according to a standardized protocol using the Snellen Eye Chart (Long et al., 1991). Hearing was assessed by means of self-report as to whether the subject heard the RA rub their fingers together beside each ear in sequence. Grip strength (Daltroy et al., 1995); chair stands; measured 1 and 3 meter walks (Guralnick et al., 1994), and 360 degree turns (Reuben & Siu, 1990) were assessed using standard protocols. The oral health segment included an in-mouth tooth count; and, for those who wore their dentures to eat, an examination of denture stability and retention. Chewing difficulty was assessed within the Interview segment and evaluated according to the Leake Index (Leake, 1990).

*Nutritional Biomarkers*. Fasting blood samples were drawn at Baseline, 6 and 12 months by a trained phlebotomist who prescheduled appointments in subjects' homes. Cooled samples were returned to the NIH-certified medical laboratory at the Boston University Medical Center for processing there or by its affiliated external laboratories. Plasma samples were analyzed and interpreted according to standard laboratory procedures. Serum albumin, complete blood count, plasma lipids (total, LDL, and HDL cholesterol and triglycerides), glucose, hemoglobin, folate, and vitamin $B_{12}$ were measured.

*Training, Documentation, and Monitoring of the Protocols*. Prior to collecting data, the investigative team trained all RAs in methods of administering the assessments. A dental hygienist and dentists with long-standing experience in community-based studies trained the RA's in how to conduct oral health assessments and the hygienist worked with them to establish inter-rater reliability. Training methods for the other protocols included video demonstrations of interviews being conducted with elders; lecture, simulation, and practice; as well as observation of in-home assessments conducted by more experienced RAs and/or the project manager.

Target dates for follow-up were generated by a computerized tracking database that monitored enrollment dates. Up to five telephone contacts were made to schedule a follow-up appointment. Detailed directions

to subjects' homes were also entered into the Tracking System. The project manager used the database to track aggregated progress in data collection across multiple field teams and to re-allocate resources, as well as to monitor and compile data on attrition. Cell phones were issued to each field team for safety and convenience of both subjects and staff.

*Quality Control*. Field-based quality control measures included observation of each team's in-home assessment techniques by a senior research assistant (SRA). She provided clarification, positive or corrective feedback as needed, particularly with performance of anthropometry techniques and in their use of interview probes. In addition, the SRA provided debriefing and further feedback immediately after the observed home visits. The field teams posed questions about data collection and documentation in weekly team meetings with the Project Manager and Principal Investigator. Decisions were subsequently documented in Field Manuals developed especially for this study, which contained procedural information to guide protocol administration. This practice facilitated consistent communication with subjects across the field teams. It also helped to minimize coding errors and unintentional protocol drift over time.

*Field Teams.* Given the subjects' frailty, urban environmental safety concerns, and the extensive equipment and supplies required, two-person teams were most efficient and effective. Each of the four teams included at least one professional nutritionist. During home visits, one RA conducted the assessment, while the other recorded responses or assisted with equipment. If a subject tired easily, frequent, short breaks were taken; and when necessary, a return visit was scheduled. RAs used a dual function watch to record start and stop times for each segment of the in-home assessment.

*Equipment and Supplies*. Table 2 lists the equipment and supplies used to carry out assessments. Each field team packed the 42 pounds (18.79 kg) of equipment and supplies into grocery-type carts according to standard protocols, and transported them in personal vehicles to and from subjects' residences.

*Data Analysis.* The lowest and uppermost 15% of the Total Times for assessments were reviewed for recording accuracy. Total Time documentation errors occurred mainly when assessments had required more than one visit to complete; and/or when the normal sequence for protocol administration had to be modified to accommodate subject or proxy needs.

Reliability for continuous variables was expressed as intraclass correlation coefficients (Shrout & Fleiss 1979). For non-normal continu-

TABLE 2. Equipment and Supplies for Anthopometry, Dietary, Physical, Oral Health, and Functional Assessments

| Assessment/Usage | Equipment and Supplies[a] |
|---|---|
| Anthropometric measurements | Paper dressing gowns; Anti-bacterial hand gel |
| Weight | SECA 770 Electronic Scale; AA Batteries |
| Skinfolds: subscapular, triceps | Holtain skinfold calipers; Cosmetic marking pencils; Marking pencil sharpener; Alcohol swabs |
| Circumferences: arm, calf | Measuring tape; Cosmetic marking pencils; Marking pencil sharpener; Alcohol swabs |
| Standing height | Shorr Portable Stadiometer |
| Knee height | Ross Knee Height Caliper |
| Sagittal diameter | Holtain-Kahn Sliding Abdominal Caliper |
| Measured walk, chair stand, 360º turn | Masking tape; Cronus Pro Survivor stop-watch |
| Grip strength | Jamar Hydraulic Hand Dynamamoter |
| Vision assessment | MIS Pocket Vision Guide |
| Oral exam | Protective eye-wear; latex gloves; surgical masks; tongue blades; penlight; anti-bacterial hand gel |
| Dysphagia assessment | Disposable paper cups |
| Dietary recall | Nutrition Consulting Enterprises 2-D Poster; magnetic clips to clip poster to Ss refrigerator; measuring cups; ruler; clipboard |
| Sterilization of any instrument used with Subject | Disinfectant wipes |
| Street parking at Subject's home or day care | Quarters for meters |
| Record keeping for monetary gift | Receipt book |
| Navigation to patients home or day care | Map book |
| Call hard of hearing Subject to open door, clarify directions, field emergency | Cellular phone |
| Collection of waste products created during interview | Trash bag; paper towels |
| Documentation of Data as Collected | Data Collection Binder; instruments[b]; pens, including hanging pens; pencils; thank you letter and envelope; monetary gift |

[a]All equipment and supplies were packed and transported in the following: Seca 770 carrying case; folding cart for bungied equipment; and an L.L. Bean back pack. [b]Forms for recording consent and interview, dietary recall , anthropometry, tooth exam, and reliability data were created at Boston University specifically for use in the study.

ous variables, intra-class correlation coefficients were computed on the log transformation of the values. For a limited number of highly skewed variables, Kendall's coefficient of concordance was computed using deciles of the distribution as categories (Kendall, 1955). Data analysis was performed using the SAS system for statistical computing (SAS Institute, Inc., 1990).

## *RESULTS*

Overall, 55% of the subjects were African-American and 18% were of other ethnic groups, while the remaining 27% were white. Enrollees did not differ from non-enrollees in distributions of age and gender. Assessment data were gathered from 80% of the active subjects at Baseline and for all four follow-ups over a twelve-month period. Only about one active subject in five (51 or 21%) missed one or more follow-up visits. About three-fifths (60%) of the missed follow-ups were due to subject/family illness or because subject or proxy was unwilling to schedule the follow-up after five requisite phone contacts had been made. More than a third were missed because the research team was unable to contact them (phone disconnected, or was told that they had moved from the area). However, after they had missed a follow-up interview, nearly 3 out of 5 subjects did participate actively at a subsequent follow-up point. These subjects' interview response rates were consistently high (81-88%) throughout the study, after an initial drop between baseline and the 4-month follow-up phone interview, as shown in Table 3.

The reasons for attrition during the 12 months of follow-up are summarized in Table 4. Four-fifths (41 of 51) dropped out due to reported illness and/or the explicit unwillingness by subject, family member, or other designated proxy to continue in the study. It was difficult at times to differentiate whether the cause of attrition was illness or lack of motivation, especially when a family member or other proxy expressed the reason rather than the subject directly. Hence, those two reasons have been combined in the report. An additional 10% moved away from the metropolitan Boston area, and five others (10%) left the study for other reasons.

Twenty-two subjects (9%) were lost due to death. Besides these deaths, 5 subjects who had dropped out for other reasons, also died during the 12 month follow-up period. Of all 27 subjects who died, 5 were men and 22 were women, yielding gender-based mortality rates of 7%

TABLE 3. Percent of Subjects Responding to Interview at Baseline, at Follow-Up Points, and Throughout Entire Study

| | Enrollee[a] | Respondents[b] | Percent Responding[b] |
|---|---|---|---|
| Baseline | 239 | 239 | 100.0% |
| 4 month | 222 | 197 | 88.7% |
| 6 month | 210 | 171 | 81.4% |
| 8 month | 194 | 168 | 86.6% |
| 12 month | 182 | 160 | 87.9% |
| Entire study | 163 | 133[c] | 81.6% |

[a]Of 435 eligible patients 239 enrolled in the study after letters and personal contacts had invited them to participate. [b]Response rates for specific items, scales, and assessments varied. [c]These subjects responded to interviews at baseline and at all 4 follow-up points.

TABLE 4. Reasons for Attrition in Twelve Months of Follow-Up

| **Reason** | **n** | **Percent of Attrition n = 51** | **Percent of Cohort n = 239** |
|---|---|---|---|
| Unable or Unwilling[a] | 41 | 80.4% | 17.2% |
| Moved Away[b] | 5 | 9.8% | 2.1% |
| Other[c] | 5 | 9.8% | 2.1% |
| TOTALS | 51[d] | 100.0% | 21.3% |

[a]Subjects were unable or unwilling to continue due to health or unstated reasons. [b]Subjects moved away from metropolitan Boston. [c]Subjects were discontinued to maintain health and safety of either the field team or the patient. [d]Mortality claimed 22 other subjects during the same period.

and 13% respectively. Mean age at death for the 5 men was 85.0 years, while the mean age at death for the 22 women was 83.8 years. We compared those (n = 166) who remained in the study for the entire 12 months with those who dropped out or died (n = 73). Results indicated that those who dropped out or died were twice as likely to be current smokers (26% vs 13%: p = .017). Otherwise the two groups did not differ in any significant way. Enrollees did not differ from non-enrollees in distributions of age and gender.

Table 5 summarizes the time (minutes) that it took to conduct each of the five study segments at Baseline. The comprehensive battery of in-home assessments, excluding phlebotomy, was administered in a Mean Total Time of 100 minutes (SD 28.05). Field teams were able to administer the protocol in 120 minutes or less with 81% of the subjects. The Interview segment consumed a Mean Time of 43 minutes (SD 17.15). The face-to-face 24-hour Dietary Recall and the Anthropometry measures were conducted in mean times of 20 minutes (SD 8.60) and 18 minutes (SD 7.51), respectively. Less time was required for the remaining segments. For 83% of the subjects, it was possible to carry out in-home assessments in a single visit. For 16%, two visits were required, while only three subjects (1%) needed a third visit. More than 91% of the subjects completed at least 153 of the 159 Interview items at Baseline.

Criteria for excluding subjects from any component of the physical and functional assessments are identified in Table 6. Subjects' safety, their observed or self-reported functional limitations, frailty, and instability were the main reasons for exclusion, except for items that were not appropriate to ask proxies.

Table 7 summarizes the Baseline completion rates for the physical assessments and dietary recalls with the sample. Completeness for the physical assessments was defined as the percentage of the cohort (239) who were able to participate in the respective measurement protocols.

TABLE 5. Time Required for In-Home Baseline Assessments

| Segments/Assessments | N | Minutes | |
|---|---|---|---|
| | | *Mean +/− SD* | *95% Confidence Intervals* |
| Interview[a] | 237 | 42.98+/−17.15 | 40.79-45.18 |
| Anthropometry | 222 | 18.19+/−7.51 | 17.21-19.16 |
| In-home 24-hr Dietary Recall | 229 | 20.63+/−8.6 | 19.51-21.75 |
| Physical Function & Oral Health | 231 | 6.18+/−2.67 | 5.84-6.53 |
| Physical Performance | 226 | 7.33+/−3.59 | 6.86-7.80 |
| TOTAL TIME[b] | 231 | 100.19+/−28.05 | 96.55-103.83 |

[a]Time also includes the shorter interviews with proxies (44 of 239). [b]Total Time excludes phlebotomy, which was done in separate home visits at Baseline, 6 and 12 months, but Total Time does include preparation time between assessment segments

TABLE 6. Exclusion Criteria for Physical and Functional Assessments

| Assessment Item | Exclusion Criteria |
|---|---|
| Grip Strength | Acute arthritis or tendonitis in hand(s); stroke affected use of hand(s); surgery on hand in past three months |
| Measured Walks | Paralyses; unable to walk |
| Chair Stand | Unable to stand unaided |
| 360 Degree Turn | Non-ambulatory; unable to understand instructions |
| Dysphagia | Subject answered 'no' to question, 'Do you think it is safe to drink a cup of water (3oz)?' |
| Vision | Blindness as reported by Subject or proxy |
| Sagittal Diameter | Unable to lie flat on back |
| Standing Height | Non-ambulatory; kyphotic; unable to position head in Frankfortplane; unequal leg lengths |
| Knee Height | Unable to assume 90º angle of knee |
| Weight | Unable to stand unsupported |
| Calf Circumference | Open wounds or rashes on leg; unable to assume 90º angle of knee or ankle |
| Arm Circumference | Open wounds or rashes on arms |
| Tricep Skinfold | Open wounds or rashes on arm; skinfold thickness exceeded range of caliper |
| Subscapular Skinfold | Open wounds or rashes on area; unable to assume proper posture; skinfold thickness exceeded range of caliper |

On tests of physical function, completion rates varied from a high of 93% cooperating with the hearing test to a low of 61% able to participate in the 360 degree turn and the 64% who completed the 3 meter measured walk. It was possible to obtain tooth counts on 94% of the subjects, of whom 64% were edentulous. Anthropometry completion rates were highest for calf (93%), and arm circumference (89%), knee height (86%), and all assessments that involved use of a tape measure in recumbent or sitting subjects. Completion rates were lower for standing height (63%) and weight (63%); and for measures that involved the use of calipers (TSF, 77% and SSF, 60%). Lowest successful completion rate was for sagittal diameter (15%). While the completion rate for TSF was 85% in men, it was 73% in women ($p < .045$; Chi square, 4.03 with 1df). The SSF completion rate for men was 71%, while for women, it was 56% ($p < .039$; Chi square, 4.24 with 1df).

TABLE 7. Subjects from Whom Physical Data and Dietary Recall Data Were Obtained

| *Assessments* | *Indicators* | *n* | *Percent*[a] |
|---|---|---|---|
| **Physical Performance** | Grip Strength, Dominant Hand | 177 | 74.1% |
| | Grip Strength, Non-Dominant Hand | 180 | 75.3% |
| | Measured 3 Meter Walk | 150 | 62.8% |
| | Chair Stand | 184 | 77.0% |
| | 360 degree Turn | 146 | 61.1% |
| **Physical Function** | Dysphagia/Swallow Test | 206 | 86.2% |
| | Hearing Test, Finger Rub Test, Right | 220 | 92.1% |
| | Hearing Test, Finger Rub Test, Left | 221 | 92.5% |
| | Vision Test, Both Eyes, as usually corrected | 198 | 82.8% |
| **Oral Health** | Tooth Count | 224 | 93.7% |
| | Have Dentures, yes/no (upper, lower, or both) | 224 | 93.7% |
| | Wear Dentures Regularly, yes/no,if applicable | 151[b] | 100.0%[b] |
| **Anthropometry** | Sagittal Diameter | 37[c] | 15.5%[c] |
| | Standing Height | 150 | 62.8% |
| | Knee Height | 206 | 86.2% |
| | Weight | 150 | 62.8% |
| | Calf Circumference | 222 | 92.9% |
| | Arm Circumference | 213 | 89.1% |
| | Tricep Skinfold | 183 | 76.6% |
| | Subscapular Skinfold | 144 | 60.3% |
| **Dietary Intake** | Three 24-Hour Recalls | 173 | 72.4% |

[a]Unless otherwise noted, percents are based on denominator using the entire sample of 239. [b]Regular denture use was asked only of the 151 subjects, who had said they wore dentures at all. [c]Measurement of sagittal diameter was attempted with 141 subjects, but it was only successful with 37 subjects.

Three complete 24 hour dietary recalls were obtained at Baseline for 173 of the 239 subjects (73%). Further, it was possible to do these recalls according to protocol with 147 (85%) of the 173 (first recall face-to-face during the in-home visit, and the remaining two by telephone). Recalls from the 46 others who were able to provide only one or two days' recalls were defined as incomplete.

A total of 186 subjects (78%) had consented to phlebotomy at the time they enrolled in the study. Baseline blood samples were actually collected from 170 subjects (91% of the 186 who had originally consented). Ten of the remaining 16 refused; two were unable to provide samples due to fragile veins; and no specimen was drawn from four subjects for unspecified reasons.

## *DISCUSSION*

These results demonstrate that it is feasible to recruit, retain, and conduct comprehensive assessments of nutritional risk with frail, urban, homebound elders, even the very old. Nearly 42% of the subjects were 75-84 years old; 35% were 85 years and older; while just 23% were 65-74. At the same time, both this study and the WHAS report of feasibility with more than 1,000 older disabled community-living women aged 65+ (Simonseck et al., 1997) have demonstrated that two-person teams are required to manage the equipment and protocols involved in such comprehensive in-home assessments.

Despite subjects' frailty and advanced ages and the research protocol's conspicuously greater intensity, the overall 55% enrollment rate (239 of 435 eligible) compared favorably with several other studies (Zimmer et al., 1985; Levy et al., 1982; Williams et al., 1988). The study design invited subjects to consent to three in-home assessments plus additional dietary recall interviews by phone, and phlebotomy three times. No age-related decline in study participation was found here, although others have reported such a decline (Herzog & Rodgers, 1988).

Recruitment barriers previously reported in the literature are fear and distrust; access, including transportation; lack of knowledge about the benefits of a study; cultural and language issues; and poor health (perceived and actual), the effects of which have not been studied extensively (Areán & Gallagher-Thompson,1996; Wroebel & Shapiro, 1999). Many of these recruitment barriers were overcome in this study by using previously recommended strategies (Carter, Elward, Malmgren, Martin, & Larsen, 1991; Souder, 1992; Areán & Gallagher-Thompson, 1996; Wrobel & Shapiro, 1999). For example, trust was encouraged by having primary care geriatricians carefully describe study protocols to subjects prior to enrollment (Souder, 1992). Access and transportation barriers were eliminated by conducting the assessments in subjects' homes (Gauthier & Clarke, 1995; Simonseck et al., 1997; Wrobel &

Shapiro, 1999). Further, the aforementioned modest financial incentives were offered to subjects who participated in in-home interviews and for participating in the blood draws, as suggested by Areán and Gallagher-Thompson (1996).

Some studies had indicated that older adults are less likely to respond to telephone interviews than younger subjects (Carter et al., 1991). However, telephone interviews were not a problem for most of the subjects in this study, possibly because field teams had first established in-person relationships with them during the in-home baseline assessments. Further, designated proxies responded for those who had been considered most likely to have communication difficulty due to cognitive limitations, severe hearing problems or facility with the English language. For those who were unable to respond by telephone, field teams conducted the brief 4 and 8 month follow-up interviews, as well as dietary recalls, in subjects' homes. Also, from the baseline experience researchers learned that the sagittal diameter measurement was not feasible for use in subjects' homes, because most homes lacked a firm surface on which the subject could lie down for the measurement.

There is a growing consensus among researchers that successful recruitment and retention for community-based interventions with minority elders requires strong, culturally competent linkages with the subjects' community. One way in which the field teams strengthened their cultural competence was to visit local ethnic supermarkets and restaurants. Their familiarity with the foods and cooking methods facilitated the conduct and coding of dietary recalls.

Additional factors may have contributed to success in establishing feasibility. These subjects were accustomed to receiving home visits from Boston University Medical Center clinicians. Furthermore, the clinical and field teams' ability to share information about changes in the subjects' residence and ability to continue was extremely useful in maintaining subjects in the study, even when they were hospitalized or placed in nursing homes.

Contact was initiated with either the nursing director or the social work director in nursing homes to ensure that they understood the purpose of the study; knew that subjects had consented to be in the study, and to determine whether the subject was well enough to participate in follow-up assessments. This added complexity and time to the scheduling of assessments. Besides the subjects' varying or declining health, a second factor adding complexity was that proxies no longer were in the same household or in daily contact, when the subject was in a nursing home. In most of these cases, proxies could no longer provide dietary

recall data. Nevertheless, when the nursing home judged that the subject would feel well enough to participate, the field team conducted assessments there.

The authors concur with findings from several other studies (Simonseck et al., 1997; Areán & Gallagher-Thompson; Gauthier & Clarke, 1999; Wrobel & Shapiro, 1999) that recruitment of minority elders is likely to be time intensive and costly. Such recruitment is more likely to be successful if the process is carried out in stages, and if the study is introduced to prospective subjects by clinicians and/or others known and respected in the communities, as our study protocol did. Study assessments were designed for administration in segments of 10-20 minutes: this made it easier to provide needed rest breaks at convenient, between segment times (Wrobel & Shapiro, 1999). In addition, field teams prepared for follow-up contacts by reviewing ahead of time their previously taken notes containing information such as unique aspects of subjects' physical and psychosocial environments, including family members and others likely to be present in the home during the visit. Teams also refreshed their familiarity with subjects' sensory impairments and noted any changes in subjects' health status that might have occurred since the previous visit several months earlier, in order to anticipate any potential difficulties with the protocols.

Not surprisingly, completion rates were higher for these frail, homebound elder subjects on verbal self-report assessments than on domains that required them to stand, be mobile, or otherwise exhibit physical and functional capabilities. Subjects' health and frailty, as well as their in-home environmental conditions, were major contributors to variability in the times required for the physical performance and functional assessments. The 62.8% completion rate for height measurements in our disabled, homebound population was lower than the 78% success rate reported in a population of bed-bound subjects on nutritional support (Guenter et al., 1982). Of interest, the completion rates for measures involving use of calipers were significantly lower in women than men. The field teams observed difficulties obtaining SSF measurements with calipers, particularly on women with large accumulated amounts of subscapular fat. Chief barrier to sagittal diameter measurement, that we could not overcome, was the lack of a sufficiently firm surface in most subjects' homes on which they could lie down for that measurement. Per the protocol, stature was estimated from knee height (Chumlea et al., 1998 guidelines for minority men and women), rather than using actual standing height to calculate BMI (weight (kg)/height$^2$ (m$^2$) since many subjects were unable to stand long enough to measure both

weight and standing height. This estimation compared favorably to data published by Chumlea et al. (1998) with a less disabled population. It is also of interest that the correlation between self-reported weight and measured weight at baseline was .95. This high degree of consistency made it possible to use self-reported weight for some analyses. In a recent longitudinal study of weight, weight change, and mortality among 648 community-dwelling women aged 65 and older, the mortality rate was just 16% (106 deaths) over 6 years (Reynolds et al., 1999). That rate contrasts with the slightly over 9% mortality rate at 12 months in the present study. However, nearly 35% of these subjects were already over the age of 85 when they enrolled in the study, and most were homebound.

Assessment of protocol feasibility in this report is limited to data collected at baseline with the exception of attrition and subjects who missed follow-up visits. Detailed analysis of follow-up interviews may provide further insights into feasibility issues in field research with this population. Subjects were recipients of in-home medical services, who were extremely frail and of advanced age. Results are only germane to subjects with similar characteristics. Although men constituted nearly 29% of our sample, their absolute numbers were too small to warrant gender-specific analyses. Gender percentages are similar to those reported by other studies of community-living elders: 63% women in a study of diabetics; and 71-77% women in studies of arthritis patients (Glasgow & Hampson, 1995).

In future studies, it may be useful to differentiate more finely among the reasons for incompleteness, as did the Women's Health and Aging Study. The WHAS used these five categories: partially done; not done for health reasons; not done for other reasons; refused, and not applicable (Simonseck et al., 1997). The authors think that perceptions of what is a socially acceptable reason for non-completion, such as illness or disability, may differ among subjects, as well as among their family members who may not always share their commitment to participating in research. More specific categories for documentation at the time of contact with subjects might be helpful in differentiating inability from unwillingness, thereby aiding our determination of what else, if anything, can be done to minimize missing data and maximize retention.

## *APPLICATIONS*

It is clearly feasible to recruit frail, older study subjects and for well-trained, two person field teams to conduct comprehensive in-home

assessments of nutritional risk in under two hours with good retention over 12 months of follow-up. Of the 239 subjects originally enrolled in the study, 56% provided some data at all five interviews. As expected, subject mortality and attrition accounted for most of this loss, together with illnesses of subjects, proxies, and other family members. However, field teams were able to gather data at all five interviews from over 80% of those who remained in the study throughout the 12 months. These findings point to the feasibility of successful recruitment, retention, and follow-up with older subjects. Even those who are frail and homebound can and will participate, when the study's design takes into account barriers to feasibility, and when protocols are administered with care and empathy by a well-trained field team. The study has demonstrated the feasibility of training research assistants to perform anthropometry and oral health assessments in subjects' homes with highly acceptable reliability; and they were trained to a similar level of reliability on coding of dietary recall data, as well. Researchers need to ensure that adequate time is available prior to data collection for training in these and other field protocols, as well as in database skills. Now that the feasibility of conducting multiple comprehensive assessments over 12 months has been established, the next stage of this research will determine the feasibility of interventions to improve dietary quality and its effects on perceived quality of life.

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## NOTE

1. Respondents were given $20 each for participating in interviews at Baseline, 6 mos, and 12 mos. Those who had consented to blood draws were given $10 each time for permitting blood draws at the same three datapoints.

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