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Confronting Challenges in Intervention Research with Ethnically Diverse Older Adults: The USC Well Elderly II Trial

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Abstract

Background—Community-dwelling older adults are at risk for declines in physical health, cognition, and psychosocial well-being. However, their enactment of active and health-promoting lifestyles can reduce such declines.

Purpose—The purpose of this article is to describe the USC Well Elderly II study, a randomized clinical trial designed to test the effectiveness of a healthy lifestyle program for elders, and document how various methodological challenges were addressed during the course of the trial.

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Methods—In the study, 460 ethnically diverse elders recruited from a variety of sites in the urban Los Angeles area were enrolled in a randomized experiment involving a crossover design component. Within either the first or second six month phase of their study involvement, each elder received a lifestyle intervention designed to improve a variety of aging outcomes. At 4–5 time points over an 18–24 month interval, the research participants were assessed on measures of healthy activity, coping, social support, perceived control, stress-related biomarkers, perceived physical health, psychosocial well-being, and cognitive functioning to test the effectiveness of the intervention and document the process mechanisms responsible for its effects.

Results—The study protocol was successfully implemented, including the enrollment of study sites, the recruitment of 460 older adults, administration of the intervention, adherence to the plan for assessment, and establishment of a large computerized data base.

Limitations—Methodological challenges were encountered in the areas of site recruitment, participant recruitment, testing, and intervention delivery.

Conclusions—The completion of clinical trials involving elders from numerous local sites requires careful oversight and anticipation of threats to the study design that stem from: (a) social situations that are particular to specific study sites; and (b) physical, functional, and social challenges pertaining to the elder population.

Keywords

Older adults; randomized clinical trials; lifestyle intervention; health-related quality of life; methodological challenges; recruitment strategies

Introduction

Older adults frequently experience downward changes in such domains as physical health, cognition, subjective well-being, and functional ability [1–6]. However, such declines can be delayed by engagement in a more active and healthy lifestyle [6,7]. Consistent with this notion, in the original USC Well Elderly Study, a randomized clinical trial (RCT) conducted with 360 ethnically diverse elders residing in federally subsidized low income housing, an activity-based lifestyle intervention reduced declines in a wide variety of health-relevant outcome areas including life satisfaction, vitality, physical health, social functioning, and mental health [8]. These positive results were maintained over a six-month follow up period [9] and the intervention was cost-effective [10].

Building on the results of the above study, a further investigation, the USC Well Elderly II Study, was designed to (a) assess the generality of the intervention's effect across a wider study population and expanded set of outcome variables; and (b) test an explanatory model of mediating mechanisms that link the intervention to improved outcomes. To accomplish these aims, the Well Elderly II study integrated several new components including the enlistment of numerous community-based research sites; a Spanish language adaptation of the study protocol; salivary biomarker assessment; a battery of cognitive outcome measures; assessments of stress, activity, and coping; and use of a crossover design component with a one-year post-intervention follow-up period. Due to the emphasis on practical application of the intervention in a wide array of real-world settings, the Well Elderly II study goes beyond our prior effort by focusing on the effectiveness (as opposed to the efficacy) of the intervention [11]. The purpose of this article is to present the study's methodology and describe how we addressed the challenges inherent in conducting a long-term research project involving an ethnically diverse sample of older adults drawn from multiple community settings. At the time of this report, participant recruitment and intervention delivery have been completed, and longitudinal testing is being undertaken.

Overview of Study Methodology

Set-up Phase

Prior to undertaking the study, a multidisciplinary research team was organized. This team included a gerontologist, a biopsychologist, a cognitive psychologist, a social psychologist, a nursing scientist, a psychometrician, a biostatistician, and two occupational therapy research scientists with extensive experience in lifestyle intervention for elders. The need for an interdisciplinary team of experts is supported by recent theory that highlights the importance of harmonizing multiple levels of understanding in the development of effective behavioral interventions [12]. In addition to the investigative team, various support personnel were hired including a project manager, an assistant project manager, four occupational therapists, two recruiters, four testers, a programmer/data analyst, a database manager, and a project physician. A data safety and monitoring board (DSMB) was also formed to periodically review the study and monitor the safety and rights of the research subjects.

Study Design

The study design involved two components: (a) an RCT of the effectiveness of a lifestyle-based intervention's ability to positively affect elders' self-perceived health, psychosocial well-being, and cognitive functioning; and (b) an analysis of processes that mediate the intervention's effects. Figure 1 overviews the design. In connection with the clinical trial component, 460 participants were randomly assigned to the treatment group or control group. For the first six months participants in the treatment group received the intervention, while participants in the control group remained untreated. During the second 6-month participation phase, the roles of the two groups were reversed. Following receipt of the intervention, all participants were untreated for a 12 month follow-up period. At study baseline and at all subsequent 6-month intervals an assessment battery was administered that included measures of: (1) background and demographic variables (baseline only); (2) mediating variables (meaningful activity, active and positive reinterpretation-based coping, social support, perceived control, stress-related biomarkers, and subsidiary mediators such as domain-specific perceived stress and religious coping); and (3) outcome variables (perceived physical health, psychosocial well-being, and cognitive functioning).

To study the effectiveness of the intervention, the chief comparison was between the outcomes of the treatment and control groups as obtained over the first six months of each participant's study involvement. In conducting the analysis of the mediating processes, data from all subjects were combined to generate a potential total N of 460 subjects assessed over an 18 (treatment group) or 24 (control group) month period.

The study sample was comprised of two cohorts of participants (consisting of 205 and 255 elders, respectively) who entered the study approximately one year apart. In analyzing the study results, data from the two cohorts were combined while controlling for any relevant between-cohort differences. To accommodate Spanish speakers, within the second cohort a Spanish language arm was added to the study.

Research Participants

Through the use of sample size calculations, it was determined that a total of 440 elders would produce sufficient power (80% or more), given an attrition rate of 30%, for both the intent-to-treat analysis of the intervention's effectiveness and the analysis of the mediation model. Participants consisted of men and women aged 60 to 95 years old who were sampled from 21 different sites in the greater Los Angeles area, including senior housing complexes, senior community centers, and retirement communities. Ethnic representations included 149 African-Americans, 172 Whites, 18 Asians, 92 Hispanics and 29 Other or Unspecified.

Nearly two-thirds of the participants were women, and more than one-half had less than $12,000 in annual income. All participants were fluent in either English or Spanish. Individuals who were unable to comprehend or complete the assessment battery with assistance, or were incapable of properly participating in the intervention (e.g., due to problems with orientation), were study ineligible.

Study Intervention

The intervention, Lifestyle Redesign®, utilized principles of life management, healthy living, and habit change to meet the needs of community-dwelling elders at risk for health-related decline [13]. The conceptual rationale for the intervention was based on research demonstrating that older adults' activity and lifestyle patterns are modifiable and predict aging outcomes [7,12,14,15,16,17]. Consistent with this notion, health care professionals such as nurses and occupational therapists have recently placed increased emphasis on activity and lifestyle in attempting to enhance older adults health and well-being [18,19,20,21].

In the intervention, two-hour group treatment sessions, involving 8 to 10 elders, were administered by an occupational therapist over a six month period. Within the group sessions, participants were exposed to programmatic units that centered on daily living topics such as use of time, home and community safety, personal finances, transportation utilization, goal setting, social relationships, use of adaptive equipment, changing routines, and habits. In addition to participating in group sessions, each elder was offered up to 10 hours of individualized treatment in which he or she had the opportunity to meet with the therapist to discuss group topics in more depth, explore personal goals, and develop a personally customized plan for healthy lifestyle change.

A key intent of the intervention was to enable participants to adopt lifestyle changes through engagement in activities that enhance physical and mental well-being [8,13]. To promote this goal, participants learned principles related to the importance of activity and self-analyzed their daily activities and the effects these had on their own health and well-being. Also, the elders participated in a number of novel, challenging, and skill building events and activities, and with the collaborative support of the therapist, engaged in an active process of lifestyle improvements by developing new health-related habits [13,22].

Data Collection

Data were collected on background participant characteristics, dependent variables and potential mediators of the intervention's effectiveness. The dependent variables included measures of perceived physical health, psychosocial well-being, and cognitive functioning, which on theoretical grounds are expected to be affected positively by the intervention [8,13]. The proposed mediators, as shown in Figure 2, included healthy activity, coping, social support, and perceived control, which span the psychosocially based adaption framework advanced by Pearlin [23,24], and are also specifically targeted areas of change within the intervention. In addition, stress-related biomarkers and a set of subsidiary variables were incorporated to document additional concerns (e.g., perceived stress) that could mediate or moderate the intervention's effects on the dependent variables.

As noted in Figure 1, with the exception of certain demographic variables, each of the main study variables was assessed at six month intervals. Prior to baseline testing, the process of informed consent, approved by the University of Southern California Institutional Review Board (IRB), was administered by one of the program coordinators. Testing was undertaken at the 21 intervention sites, generally, in groups of 5 to 15 participants. Trained testers were present to assist the elders, as necessary, in completing the questionnaires. To avoid bias in

evaluating the intervention, both treatment and control group participants undertook testing in the same sessions. Each participant completed a packet of 16 questionnaire measures, was assessed on a set of cognitive tests, and was given a kit for saliva collection if he or she agreed to participate in this portion of the study. To avoid systematic bias due to testing order effects, the questionnaire packets contained six orders of the instruments.

Measurement of Control Variables

The demographic variables included participants' sex, race/ethnicity, age, educational level, living status, marital status, employment and income. In addition, due to the sampling of numerous participants within each of the recruitment sites, three Likert scales that assessed verbal interactions between subjects were administered to assess the extent to which communications between intervention and control group subjects could potentially contaminate the experimental manipulation [25,26].

Questionnaire Measurement of Additional Primary Mediators and of Outcomes

A variety of preexisting scales were used to measure most of the mediating and outcome variables in the study. For each construct, we sought to identify a questionnaire that met the following criteria: (a) prior validation for the older adult population; (b) capacity to detect intra-individual change over time; and (c) brevity and instructional simplicity. Table 1 overviews the pre-existing questionnaires that were used.

Meaningful Activity Participation Assessment

Due to a lack of existing validated instruments to measure meaningfulness of engagement in activities common to older adults, a new tool, the Meaningful Activity Participation Assessment (MAPA), was developed for the study. The MAPA contains a list of 29 activities relevant to older adults that are based largely on the Activity Checklist [27], but includes additional items such as use of computers. For each activity item, the respondents self-rate their frequency of participation; degree of experienced meaningfulness, and contribution to health. Separately for both meaning and health, the ratings were multiplied by the frequency score and summed across activity items to produce an overall score. Prior to its use in the study, the MAPA was pilot-tested with a sample of 154 older adults and was found to possess internal consistency, test-retest reliability, construct validity, and criterion-related validity [28].

Stress-related Bio-markers

Salivary cortisol, dehydroepiandrosterone sulfate (DHEA), and the cortisol/DHEA ratio were included as indicators of biologically based stress because: (1) the resulting values validly reflect corresponding serum levels [29]; (2) they provide a less costly, less reactive, and more readily accessible means of assessing the hypothalamic pituitary axis (HPA) stress response than do blood and urine measures [30]; and (3) they are theoretically linked to the intervention and predict physical, behavioral, and cognitive outcomes, which were key study foci [31–34]. Blood pressure was also included as a biomarker because it is theoretically responsive to selected components of the Well Elderly Intervention, including exercise, diet, and relaxation.

At the end of the baseline testing session, participants who agreed to undertake the saliva testing were individually instructed on how to collect sample specimens. Four coded 1.8 ml cryovials (Salimetrics part # 5002-1), four short straws, an instruction sheet, a date and time sheet, and a freezer bag were all packaged in a kit and sent home with each participant. The participants were asked to provide, within one week, four saliva samples over the course of a single day, to be obtained on rising, 30 minutes after rising but before taking anything by

mouth, before lunch, and before dinner. The participants were told to complete all samples on the same day, record the time of day for each sample, and immediately place completed samples in their home freezer. Saliva was collected by passive drool.

A tester retrieved the samples at participants' homes within several days of sample completion. At this time, the participants answered a questionnaire that included items concerning sleep patterns, experienced stress, mood, and medications taken as they occurred on the day in which they performed the saliva test. The participants' blood pressure was also recorded at this time (two recordings at least 10 minutes apart) by the tester. The vials of saliva were transported on ice to a central freezer at USC, and then batched and shipped to Salimetrics, a collaborating laboratory at Pennsylvania State University, for analysis.

Assessment of Cognitive Functioning

We used three tests to assess the age-sensitive cognitive domains of explicit (declarative) memory, selective attention, and psychomotor speed. The 10-item word list from the Consortium to Establish a Registry of Alzheimer's Disease (CERAD) [35] was used to assess explicit memory with trials of immediate recall, delayed recall, and recognition; a visual search task adapted from Lupien et al. [36] was used to measure selective attention; and the Digit Symbol Substitution Test of the WAIS-R [37] was used to assess psychomotor speed.

Measurement of Subsidiary Analytic Constructs

As noted in the lower left hand portion of Figure 2, a number of additional mediating constructs were examined in subsidiary analyses designed to broaden the examination of alternate pathways that could explain the intervention's effect. These constructs, which include domain-specific sources of stress, religious coping, mental disengagement, behavioral disengagement, acceptance coping, volunteer activity, and the size of one's social network, were measured by directly applying item stems contained in previously validated scales that have been successfully used with older adults.

Statistical Analysis

Data analyses were designed for both the intent-to-treat and mediating process components of the study. The intent-to-treat sample included all participants randomly assigned to the treatment and control conditions regardless of their degree of noncompliance, deviations from the study protocol, or withdrawal from the treatment after randomization. The effectiveness of the intervention was tested by comparing outcome differences between the treatment group and the control group present at the conclusion of the first six months of each participant's data collection period. Dependent variables included the indicators reflective of perceived physical health, psychosocial well-being, or cognitive functioning. For each outcome variable, we generated signed change scores by subtracting the baseline values from the values obtained at the time of post-treatment. Potential control variables, including the corresponding baseline values for each outcome variable, were tested to determine their relationship to outcome independent of treatment; variables significantly related beyond the .05 level to one or more outcome indices were included as covariates in subsequent analyses. For each outcome variable, an analysis of covariance was then conducted to test whether the mean adjusted change score was more favorable in the intervention group.

We used structural equation modeling (SEM) for the evaluation of direct and mediating effects of the intervention. SEM is a widely adopted statistical approach in the social sciences for theory testing. In general, SEM has the advantage of permitting more explicit and precise theoretical inferences than traditional linear models, such as multiple regression.

It also allows for testing under different distributional assumptions, enables explicit tests of assumptions of uncorrelated measurement errors, and provides a proven method of controlling for measurement error [38,39,40,41]. Parameter estimation in our measurement and structural models utilized maximum likelihood procedures within the EQS program [38]. For tests of alternative models, we used goodness-of-fit statistics and empirical model fitting indices [41].

We assessed moderator effects for race/ethnicity and gender through the application of SEM with a multiple-group approach. Investigation of moderator effects enabled us to determine if the patterns and influence of the predictive constructs on outcomes were similar between subgroups defined by these variables. Analytically, moderator effects were evaluated by comparing the equality of parameters across subgroups defined by race/ethnicity or gender.

Results and Discussion

The study goals were accomplished in the areas of participant recruitment, delivery of the intervention, and administration of the assessment battery. Despite multiple challenges, the study progressed in a successful manner. Twenty-one sites were identified and included; 460 ethnically diverse participants were recruited, and enrolled participants were randomly assigned to experimental conditions (n = 232 in the treatment group; n =228 in the control group); testing instruments and intervention materials were translated into Spanish; and a large data base was entered, managed, and analyzed.

At the point of post-intervention 1,280 assessment batteries were completed, 824 saliva samples were retrieved from participants, and 46 six-month intervention groups had met weekly. At this six month point, 78.3% (360/460) of the participants were retained in the study. Of the 99 elders who discontinued, 9 moved, 7 died, 20 were lost to contact, 3 were dropped from the study due to problems with orientation; and 60 withdrew. Participants cited the following reasons for study withdrawal: (a) personal illness or illness of a family member (n=15); (b) the time commitment was greater than expected (n=6); (c) the intervention content was other than what was expected (n=19); (d) dislike of another group member (n=1); (e) difficulties scheduling (n=9); (f) insufficient language fluency (n=1); or (g) reason not given (n=9). The study's consort diagram is included in Figure 3. The main challenges that arose during the course of the study, as well as our solutions, are noted below.

Recruitment/Retention

Sites—Insufficient recruitment in randomized clinical trials has been documented as a widespread problem [42–44]. To ensure adequate recruitment in the present study, our first challenge was to find a sufficient number of sites to support the needed pool of older adults. Potential sites were identified through resource books provided by the Area Agency on Aging, registries of senior housing, direct contact with local senior centers and key leaders of the older adult community. For each prospective site, an initial cold call was made to ascertain the number of people who frequented the site and the ethnic ratio. If a site met the recruitment criteria, we identified the person who had the authority to enter into a contract, and a site visit was scheduled. During these site visits, study coordinators provided a formal presentation of the research project and its potential benefits for the clientele.

One-half (21/42) of the prospective sites that were contacted did not participate in the study. Reasons for lack of inclusion were: failure to meet study criteria (too few study-eligible elders) (n = 9); failure to respond to phone messages (n = 8); mismatch with our needs for ethnic representation (n = 1); outside study occurring simultaneously, with the possibility of

confusion at the site or among participants (n = 1); and lack of administrative consent (n = 2).

Previous studies have shown that a strong linkage between the agency managers and research team is an important factor in recruiting participants [45,46]. Therefore, we made a concerted effort to become familiar with the on-site managers and ensure that they understood the research project and its aims. The project coordinators identified aspects of the research that directly intersected with the unique day-to-day concerns of each facility. We found that potential research participants were more likely to trust the researchers when they perceived that there was a congenial relationship between the agency managers and the researchers.

Participants—Recruitment of the targeted number of participants (440) presented a challenge. At the recruitment sites, flyers and brochures that described the opportunity to participate were circulated and posted. Potential participants were also invited to enroll in the project by our project staff, who delivered presentations during group meetings (e.g., monthly resident council meetings) and grant-sponsored festive events. Recruiters offered a variety of reasons to join the study including the opportunity to volunteer to contribute to research, the potential to enhance senior services and affect policy changes, the chance to enhance one's own personal health and wellness, and the opportunity to participate in fun and educational activities.

Most site managers suggested that to stimulate interest it would be helpful to offer coffee, treats, and door prizes. To generate a contact list, raffle tickets were distributed on which each elder wrote his or her name, telephone number, and preference about participating in the project. Using the information from the raffle tickets, the program coordinators telephoned potential participants to schedule a second contact meeting to answer questions and enroll them in the study.

Another productive recruitment strategy was to tailor the promotion strategies and materials to the demographic make-up of the various community centers and retirement homes [45–48]. Information about the population at each local site was garnered from the managers and used to guide our approach to recruitment. For example, at three centers, the agency managers indicated that the best attended events were barbeques and potluck dinners. For these sites, we sponsored meals that incorporated foods that were reportedly preferred. At two additional senior centers we were informed by the managers that many of the participants did not have phones or were homeless. Because the primary means of contact was limited to the site location in such instances, we attempted to enroll participants immediately following the recruitment event.

Use of Two Cohorts

The decision to use two cohorts was due in part to practical considerations such as the logistic difficulty of providing the intervention simultaneously to 440 or more elders. In addition, the use of two cohorts enabled us to assess the generalizability of the results over two separate years, as well as to make methodological adjustments in response to difficulties encountered with the first cohort. We view this opportunity for methodological iteration as an important safeguard that facilitates the ability to successfully complete key study goals such as recruitment and testing of participants.

At the outset of the recruitment phase, our intent was to limit study participation to English speakers. However, in attempting to recruit Hispanic elders it became apparent that the majority of bilingual Spanish speakers were reluctant to enroll in the study because they were uncomfortable speaking English – their second language – in an English speaking

group setting. In addition, there was a concern that the intervention was not sufficiently sensitive to Hispanic culture. In response, in Cohort 2 we adapted the study protocol to accommodate Spanish-only speakers. Toward this end, all aspects of the study, including recruitment and scheduling, assessment, and the intervention, were provided in Spanish as well as English. Further, based on a qualitative study conducted in the one-year period before the start of the second cohort, aspects of the intervention's content were altered to enhance its cultural sensitivity. Such adaptations included: (a) greater stress on family values; (b) increased emphasis on pictures and demonstrations to accompany intervention-based reading materials; (c) modification of nutrition sessions to incorporate culturally specific food choices; and (d) special consideration of values stemming from the religious affiliation of the Hispanic elders. Of the 92 Hispanics who enrolled in the study, 65 participated in the Spanish speaking segment.

Testing

Questionnaire measures—In planning the study, we recognized that there could be a potential problem stemming from testing burden due to the number of required assessments. In addition to selecting instruments that were brief, large print multicolored assessment forms were used to reduce test-related fatigue. In anticipation of some participants' visual and literacy needs, testers were available to read the questionnaires when necessary. Prior to initiating testing, to document the feasibility of the assessment protocol a pilot test was performed by having 10 non-study enrolled elders complete the assessment battery and answer a questionnaire about their testing experience. Feedback from this pilot assessment indicated that the assessment battery was appropriate and that the testing burden was not excessive.

Saliva samples—A major challenge in the study's data collection process of this study was to find a means of obtaining valid saliva samples. The protocol required that, within his or her own home, each participant provide four saliva samples in a single day during specified time frames, and keep the samples frozen until the time of retrieval. (Special arrangements were made to collect data from homeless individuals (n = 2) and one individual with a broken freezer.) Following each questionnaire testing session, basic schematic instructions were provided, and a study tester assisted each participant to establish an individually specific day and time plan for generating the saliva samples. One of the instruction sheets included the study coordinator's cellular phone number with directions to call with any questions between the hours of 5 AM and 11 PM seven days per week. The tester prompted the participant to identify a reasonable plan that would fit his or her daily routine, including detailing usual times for rising, lunch and dinner; choosing a collection day during which there would be access to a freezer; and determining the possible need to receive a reminder phone call. Vials for the saliva samples were differentiated by colored caps corresponding to the four collection times and these were affixed to matching color bars on a procedure sheet on which subjects recorded actual times that the samples were done. At baseline testing 379 of the 460 participants agreed to provide saliva samples. Three or more saliva samples were successfully collected for 355 (93.7%) of these 379 participants.

Implementation of the Intervention

Implementing the intervention involved potential difficulties. For successful programming, it was necessary to understand the overt and tacit rules that governed each site and the dynamic interrelationships between residents. At times, existing relationships intersected with the operation of the study, resulting in unintended consequences. For example, although our initial criteria excluded couples, in 20 cases we allowed the partner or relative of a qualifying elder to join. One member of each couple was randomized into the study and

the partner was then assigned the same condition. This strategic change enabled us to facilitate recruitment and maintain good will at the sites. (In analyzing the data, one member of each couple was dropped on a random basis to correct for potential statistical dependencies.)

Another problem was that, at times, schisms arose among study participants. In a few situations two people who vehemently disliked each other were randomized into the same small group. In such cases, the therapist was able to resolve the problem by establishing an accepting and respectful group environment. In other, more difficult instances, we enlisted the assistance of the agency managers as a resource to provide suggestions on shaping the groups when there was more than one research unit at a given site.

At the senior housing complexes, some conflicts arose between residents who participated in the study and those who chose not to join. Perceived ownership of both the resident common spaces and the intervention-related space came into question. For example, in one case the intervention groups were held in the outer parts of a shared patio, and non-participating residents expressed perceptions that they were being displaced. When non-participants wandered through the room or area during a group session, the participants sometimes showed displeasure. In some instances, when an intervention group convened there was a tendency on the part of non-participants to feel excluded. Likewise there was a tendency for the group participants to assume a sense of entitlement. For the most part, the therapists were able to find congenial ways to alleviate such misunderstandings, such as inviting the non-participants to share the group's coffee and refreshments before the private group started.

Conclusion

Useful methodological strategies or concerns identified by our study team are as follows.

- ◊ Recruitment of study sites is facilitated by early identification, establishment of a strong liaison between project staff and site administrative personnel, and careful attention to site-specific needs and concerns.
- ◊ Participant recruitment should be responsive to between-site differences in clientele and local expectations and practices. At the individual level, personalized attention is critical.
- ◊ The process of assessment in the elder population can be enhanced by ensuring that the testing burden is not excessive, employing large print versions of the instruments, providing clear instructions, offering to spread testing over several sessions, providing assistance through the use of trained testers who can answer questions or present assessment questions orally, and creating a familiar and comfortable environment that includes serving refreshments.
- ◊ Maintaining consistency of the project coordinators over the length of the study can facilitate relationships with site managers and retention of participants.
- ◊ The delivery of group-based interventions must account for site-contextual social considerations, such as perceptions regarding use of space, pre-existing conflicts between subgroups or individuals, and expectations about participation that violate planned protocol (e.g., intended joint enrollment of spouses).
- ◊ Collection of salivary-based biomarker data is feasible in an older adult population through the use of carefully constructed kits that use color coding and clear instructions.

- ◊ The use of two or more study cohorts can be a useful means of allowing for iterative problem solving, as the time span between the cohorts allows the investigative team to adopt changes suggested by the methodological experiences encountered with prior cohorts.

The conduct of randomized clinical trials with culturally diverse older adults is fraught with challenges in areas such as participant recruitment and retention, measurement, and intervention delivery. In the USC Well Elderly II Study, a combination of careful oversight and flexibility was critical in attempting to fulfill the stipulated methodological requirements.

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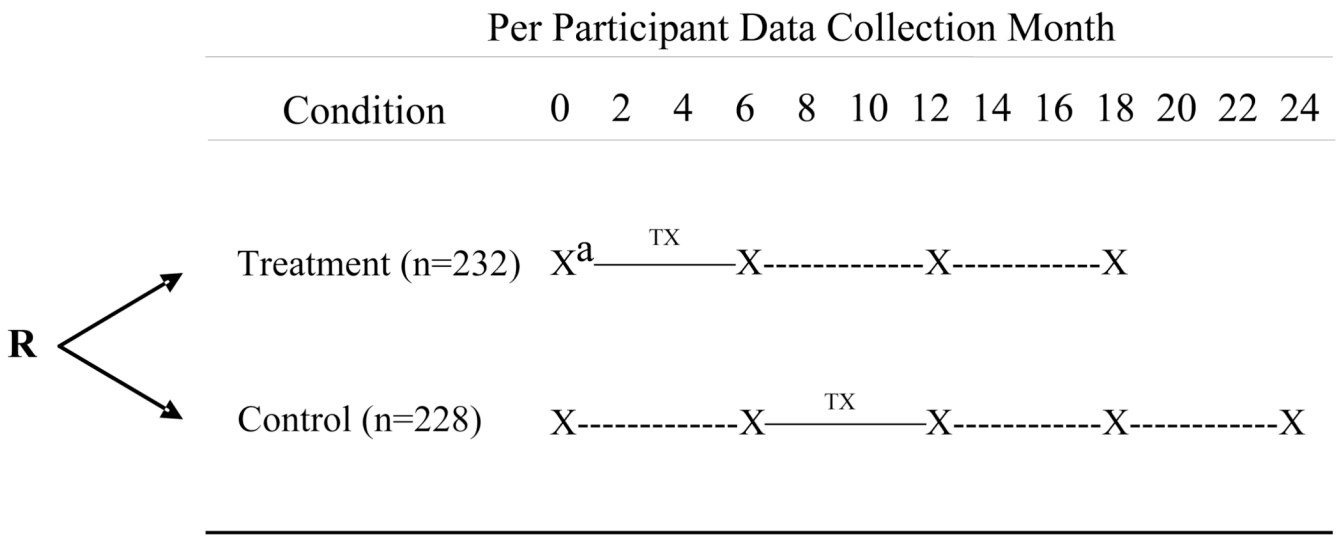

Figure 1.
Overview of study design. [a]X = Data collection. Baseline assessment includes: (a) demographic/background variables; (b) healthy activity; (c) active coping; (d) social support/network; (e) perceived control; (f) positive reinterpretation-based coping; (g) biomarkers; (h) subsidiary analytic mediators (see Figure 2.); (i) perceived health; (j) psychosocial well-being; (k) cognitive functioning. Subsequent assessments include items (b) through (k) only.

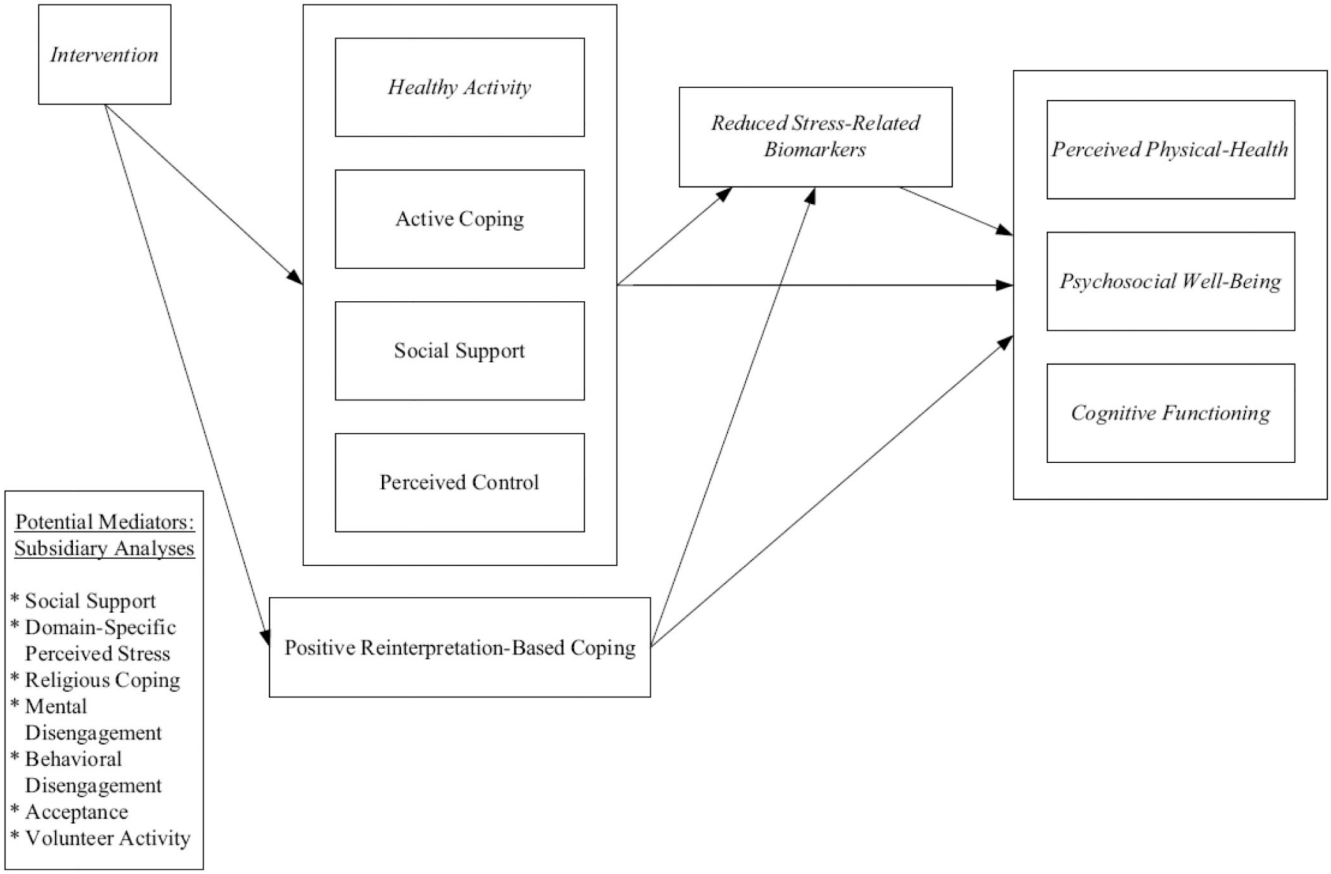

Figure 2.
Conceptual model of positive effects of activity-based interventions for elders.

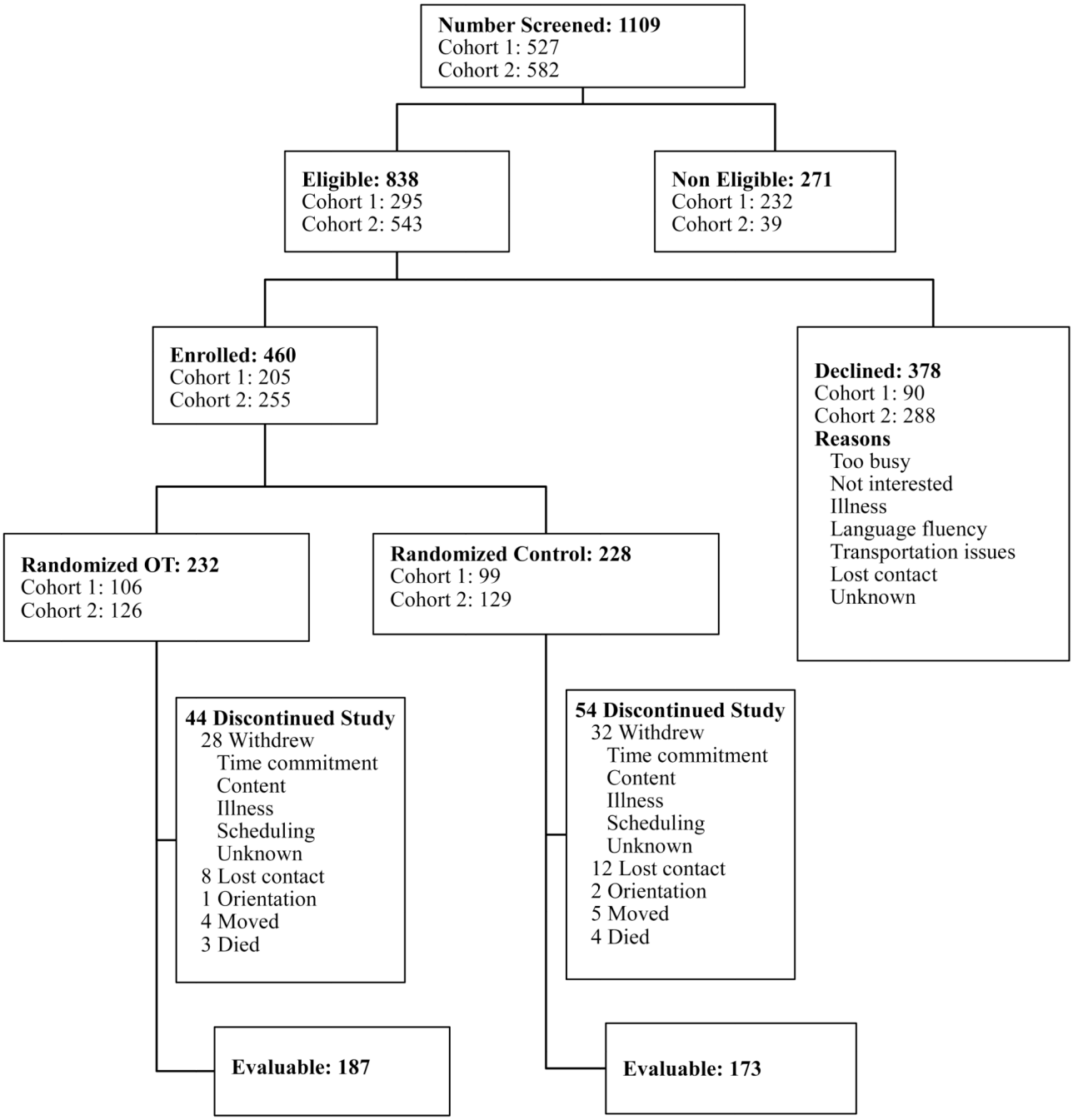

Figure 3.
Consort Diagram

Table 1

Existing Questionnaires Used in the USC Well Elderly II Study.

Construct	Instrument	Total Number of Items
Depression	Center for Epidemiologic Studies Depression scale (CES-D) [49]	20
Life Satisfaction	Life Satisfaction Index-Z (LSI-Z) [50]	13
Health-Related Quality of Life: Physical	SF-36 v.2 Health Survey: Physical Functioning, Role Limitations Due to Physical Health, Bodily Pain, General Health, and Vitality scales [51]	25
Health-Related Quality of Life: Mental	SF-36 v.2 Health Survey: Social Functioning, Mental Health, Role Limitations Due to Emotional Health, and Vitality scales [51]	14
Active Coping	Multidimensional Coping Inventory (MCI): Active Coping, Planning, and Suppression of Competing Activities scales [52]	12
Positive Reinterpretation-Based Coping	Multidimensional Coping Inventory (MCI): Positive Reinterpretation and Growth scale [52]	4
Social Support	Interpersonal Support Evaluation List (ISEL) [53]	6
Perceived Control	Adaptation of Eizenman et al's scale [54]	8