Challenges Implementing Social/Behavioral Intervention RCTs in Community Settings

Sara J. Czaja Ph.D.
Department of Psychiatry and Behavioral Sciences
Center on Aging
University of Miami Miller School of Medicine

Annual Meeting of the Gerontological Society of America
November, 2012

Research presented in this presentation supported by NIA/NINR, the Langeloth Foundation, Administration on Aging, Cisco, Johnson & Johnson, and AT&T
Background

- Aging of the population has created numerous clinical and societal challenges.
- There are an increasing number of studies aimed at developing and evaluating interventions for older adults and caregivers across a broad array of domains:
  - Cognitive enhancement/remediation
  - Physical well-being
  - Emotional well-being
  - Health promotion
  - Family caregiving
  - Productive engagement
Background

- Increased emphasis on adoption of evidenced-based approaches within clinical practice and community programs.

- Higher bar for intervention research design.

- Increased emphasis within funding agencies on “translational research”:

  research that transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to improve some health outcome – e.g. risk for disease, incidence of illness or behavior, symptoms, mortality

  (Adapted from NCI).
The Challenge for the Intervention Research

Designing interventions programs and research protocols that:

- meet the standards for **rigorous evaluation**
- are **effective**
- can ultimately be **implemented** in community and clinical settings
- are **cost-effective**.
The general “gold standard” of effectiveness trials is the Randomized Control Trial (RCT).

Large number of challenges associated with implementing RCTs in community settings.
# Issues in Intervention Development and Research

| Treatment Content | What content should be delivered  
| | What factors shape content  
| | Who is involved in content decisions  
| | How should the content be delivered  
| | Participant burden/retention  
| | Equipment/material requirements  
| | Flexibility/Adaptability  
| | Feasibility  
| | Replicability  

| Treatment Dosage | How much content should be delivered  
| | Duration  
| | Delivery schedule  
| | Flexibility in schedule  
| | Booster sessions  
| | Cut-off or Criterion for “completer”  

| Staffing | Who will deliver the intervention  
| | Skill requirements  
| | Training  
| | Who will conduct the assessments  
| | Characteristics (e.g., language skills, race/ethnicity)  


# Issues in Intervention Development and Research

<table>
<thead>
<tr>
<th>Trial design: control group decisions</th>
<th>Inclusion of control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type of control group</td>
</tr>
<tr>
<td></td>
<td>Ethical considerations</td>
</tr>
<tr>
<td></td>
<td>Scientific considerations</td>
</tr>
<tr>
<td></td>
<td>Feasibility</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
</tr>
<tr>
<td></td>
<td>Participant accrual and retention</td>
</tr>
<tr>
<td></td>
<td>Active ingredients in control condition</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant Criteria</th>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Demographic parameters (age, gender, race/ethnicity)</td>
</tr>
<tr>
<td></td>
<td>Language requirements</td>
</tr>
<tr>
<td></td>
<td>Health status and functional status</td>
</tr>
<tr>
<td></td>
<td>Skill level/experience</td>
</tr>
<tr>
<td></td>
<td>Living arrangement</td>
</tr>
<tr>
<td></td>
<td>Requirements for an informant or partner</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant Recruitment and retention</th>
<th>Sources for recruitment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recruitment strategy</td>
</tr>
<tr>
<td></td>
<td>Characteristics of recruiter</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Informed Consent</th>
<th>Consent process for the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incentive</td>
</tr>
</tbody>
</table>
## Issues in Intervention Development and Research

| Treatment Fidelity                      | Monitoring delivery  
|                                      | Documentation of what was delivered  
|                                      | Feedback protocols            |
| Data and Safety Monitoring/Participant Protection | Strategy for monitoring  
|                                      | Data Reporting               |
|                                      | Definition of adverse events  
|                                      | Strategies for resolving adverse events |
| Measurement Issues                    | Choice of outcome measures  
|                                      | Appropriateness for population  
|                                      | Consistency with research goals  
|                                      | Psychometric properties  
|                                      | Blinding                     |
|                                      | Administrative issues        |
|                                      | Participant burden           |
| Intervention Context                  | Where the intervention will be delivered  
|                                      | Cost                         |
|                                      | Feasibility                  |
|                                      | Participant logistic constraints  |
|                                      | Safety                       |
|                                      | Generalizability             |
Case Studies

- Videocare
- PRI SM
- OASIS Project
Supported by the Langeloth Foundation, AT&T, Administration on Aging, Cisco
Project Objectives

- Evaluate the feasibility of using video-phone technology for minority caregiver populations.
- Evaluate the impact of the intervention on caregiver outcomes such as emotional distress, burden, social support, self-care, and quality of life.
- Gather preliminary data on ethnic differences in response to the intervention.
Sample

- Hispanic Caregivers (55)
- African American Caregivers (54)
- Haitian (18)

Preliminary Data on Hispanic and African American Caregivers

- Age: mean = 61.3; SD = 13.2
- Education: < High School: 23%
  High School: 24%
  Some College: 22%
  ≥ College: 31%
- Female: 79%

Care recipient
- Age: mean = 78.9; SD = 10.3
Project Challenges

- **Intervention and Trial Design Challenges**
  - Duration and number of sessions
  - Structure of support groups
  - Number of and format of study conditions
  - Selection and design of control group
    - Developing content for attention control
  - Cost and sample size
  - Participant retention incentives
  - Translation of materials into three languages (English, Spanish and Creole)
    - Assessment instruments
    - Handouts (Videophone and Attention Control and Information Control)
    - Videophone Screens/Voice Menus
    - Videophone educational seminars
    - Cost
    - Time
    - Cultural nuances
Project Challenges

- Recruitment and Retention Challenges:
  - Literacy problems
  - Lack of Trust in the “research process”
  - Recruitment strategy
    - Radio
    - Newspaper adds and flyers
    - Churches/Community Groups
  - Formation of community relationships
  - Identification of primary “caregiver”
  - Caregiver and care recipient health
  - Caregiver relocation and tracking
  - Maintaining the information only control group
**Project Challenges**

- **Implementation challenges**
  - Fostering communication among a multidisciplinary team
    - Engineering
    - Computer scientists
    - Communication support staff
    - Vendors
    - Clinicians/Interventionists
    - Assessors
  - Limited Internet access among the caregivers
  - Limited technology exposure of the older caregivers
  - Scheduling assessments, installations and sessions
  - Scheduling the support groups
  - Blinding of the assessors
Project Challenges

- **Technical Issues**
  - Programming the intervention features
  - Support from vendors (equipment and communication)
  - Installation of the system
  - Unanticipated equipment costs
  - On-going technical support
  - Household and contextual issues (e.g., grandchildren; pets)
CREATE III: Cross-Site Project

A Personal Reminder Information and Social Management System (PRISM) for Seniors
Study Overview

- Cross-site Randomized Field Trial
  - PRISM-C condition
  - PRISM-B condition (control)

- Target Population
  - Older adults aged 65 + yrs. who live alone and at risk for isolation
  - 100 participants per site
Specific Aims

- Obtain information on the usefulness and usability of the PRISM system and interface design issues among a diverse sample of older adults.

- Examine the impact of access to the PRISM system on:
  - Social isolation
  - Social support
  - Well-being

- Examine the impact of access to the system on:
  - Computer attitudes
  - Computer self-efficacy
  - Technology adoption
Specific Aims

- Gather longitudinal data on the impact of access to the system on measures of social isolation, quality of life, well-being and technology adoption.
- Gather usage patterns over time.
- Gather data on system features that are useful to older people.
- Gather data on the relationship between individual characteristics and system use.
Field Trial: Study Design

Recruitment

Screening

Baseline Assessment

Randomization

300 Adults (65-85 yrs)
- 100 UM
- 100 FSU
- 100 Georgia Tech

PRISM Condition

Control Condition

3rd month (Telephone)

6th month

9th month (Telephone)

12th month

18th month (Telephone)

Check-in call

Follow up 1

Check-in call

Follow up 1

Check-in call

Follow up 2

Follow up 2

Follow up 3

Follow up 3
Inclusion Criteria

- 65+ years
- Live alone in the community in an independent residence
- Minimum computer and Internet use in the past three months
- English speaking
- Able to read English at the 64th grade level
- Has a telephone
- 20/60 Vision with or without correction
- Not employed or volunteering more than 5 hrs/week
- Do not spend more than 10 hrs/week at a Senior Center or Formal organization
- Planning to remain in the area in same living arrangements for duration of intervention period

Exclusion Criteria

- Blind or deaf
- Cognitively impaired (MMSE) < 26; Fuld Object Memory Test < 20 or 19
- Terminal illness
- Severe motor impairment
TODAY’S QUOTE:

"The fact is, that to do anything in the world worth doing, we must not stand back shivering and thinking of the cold and danger, but jump in and scramble through as...

PICTURE OF THE DAY: IMG_0457.JPG

MIAMI, FL WEATHER BY: Yahoo! News

CURRENT CONDITIONS:
Partly Cloudy.
68°F

TODAY’S FORECAST:
Mostly Sunny.
High: 77 Low: 53

Forecast at Yahoo! Weather
(provided by The Weather Channel)
Projects Challenges

- Intervention and trial design challenges
  - Support from vendor
  - Development of participant inclusion/exclusion criteria (computer experience; engagement in activities and work; type of housing)
  - Design of control group condition
    - No computers
    - Content
    - Contact dosage
    - Contact content
    - Incentive
  - Hardware decisions (e.g., mouse vs. trackball)
  - Development of help and technical support
  - Protocol for termination (e.g., computer, Internet)
  - Development of assessment battery and selection of primary outcome measure
  - Development of scripts
  - Identification of and protocol for “adverse events”
Project Challenges

Implementation Challenges

- Participant recruitment
  - Identification of participants
  - Costs
  - Location in terms of Internet availability
  - Cognitive status
  - Computer experience
  - Language
- Training of interventionists and assessors
- Training of participants
  - Computer mouse
- Standardization across the sites
- Travel costs associated with training and installation
- What next with respect to computers
Evaluating a Community-based Computer Training Program for Older Adults

Research funded by the AT&T Foundation
Study objectives

- Evaluate the effectiveness of community-based basic computer and internet training courses designed for older adults among a diverse sample of older adults
  - Basic computer and Internet skills
  - Attitudes towards computers
  - Computer and Internet use
- Provide recommendations for refinement of the courses
- Gather preliminary information on the sustainability of the program
Study design

- 196 participants randomly assigned to:
  - Training group (104), or
  - Control group (92)

- Training held in 4 cities, total of 11 class sites

- Training group took two Connections intro courses
  - 12 two-hour sessions over 6 weeks
  - Class size: 6 – 12 students

- Both training and control groups did assessments before and after the training
## Sample description

<table>
<thead>
<tr>
<th></th>
<th>St Louis</th>
<th>Pittsburgh</th>
<th>Miami</th>
<th>LA</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>72.2</td>
<td>69.6</td>
<td>71.3</td>
<td>69.3</td>
<td>70.5</td>
</tr>
<tr>
<td>Std dev.</td>
<td>10.0</td>
<td>10.7</td>
<td>8.6</td>
<td>10.1</td>
<td>10.0</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17%</td>
<td>17%</td>
<td>19%</td>
<td>40%</td>
<td>23%</td>
</tr>
<tr>
<td>Female</td>
<td>83%</td>
<td>83%</td>
<td>81%</td>
<td>60%</td>
<td>77%</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>2%</td>
<td>0%</td>
<td>8%</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>White</td>
<td>63%</td>
<td>63%</td>
<td>40%</td>
<td>0%</td>
<td>43%</td>
</tr>
<tr>
<td>Black</td>
<td>33%</td>
<td>36%</td>
<td>46%</td>
<td>87%</td>
<td>50%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
<td>2%</td>
<td>6%</td>
<td>6%</td>
<td>3%</td>
</tr>
</tbody>
</table>
Project Challenges

Trial Design Challenges

- Communication with community partner
- Dosage and training schedule
- Selection of control group
- Development of evaluation metrics
- Development of training materials for the course leaders
Project Challenges

Trial Implementation Challenges

- Selection and recruitment of training sites
- Training of community trainers
- Skills of community trainers
- Availability of equipment
- Data collection
- Diversity of training participants
- Engagement of community trainers
- Turnover in community sites
- Monitoring of training delivery
Lessons Learned: Elements Important to Successful Implementation

- Early “buy-in” from all of the partners
- Communication among team members
- Understanding of intervention requirements
  - Staffing
  - Training
  - Monitoring
- Understanding of environmental and equipment constraints
Lessons Learned: Elements Important to Successful Implementation

- Strong community support and partners
- Ethnically/culturally sensitive recruitment strategies
- Flexibility
- Feasible products for monitoring treatment fidelity
Conclusions

- There is a continued need for evidence-based treatments for a wide variety of participant populations and health/behavioral issues
- Effectiveness research needs to go beyond research paradigm and consider issues relevant to translation and implementation of interventions in community settings
- Consideration of other research strategies to evaluate effectiveness beyond RCTs