Methodological Challenges in Behavioral Intervention Research

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Overview of Presentation

• Briefly summarize the domain of behavioral intervention research.
• Discuss the issues and challenges associated with this type of research.
• Discuss some “lessons learned.”
• Discuss future approaches.
Case Examples

• **PRISM Study** *(CREATE; Czaja et al., 2015)*
  - RCT designed to evaluate the efficacy of a computer system designed for older adults on improving outcomes (e.g. social support/connectivity, well-being, quality of life) among adults aged 65+ at risk for social isolation. Two conditions: PRISM and Binder/Notebook condition.

• **Videocare** *(Czaja et al., 2013)*
  - Randomized pilot trial designed to evaluate the acceptability, feasibility and efficacy of a psychosocial intervention delivered via videophone to African American, Hispanic & Haitian CGs of Adults with Alzheimer’s Disease.

• **Caring for the Caregiver Network** *(Czaja et al., on-going)*
  - RCT designed to evaluate a technology based multi-component psychosocial intervention (modeled after REACH II) on improving outcomes for diverse family caregivers of patients with Alzheimer’s Disease.
What do we mean by Behavioral Intervention Research?

- Research aimed at developing, evaluating and disseminating interventions that address a broad range of behavioral, physical emotional, and cognitive health as well as social issues across the life span.

- Overarching Goal: improve the health, well-being of individuals, families, communities.

- Within Psychology - over the past 50 years a broad range of novel and important behavioral interventions, that have targeted numerous issues, have been developed, evaluated and implemented.
Scope of Behavioral Intervention Research

- Interventions may be directed at:
  - Individuals (e.g. older adults, family caregivers)
  - Communities (e.g. community-based support groups or walking spaces)
  - Organizations (e.g. working caregiver programs)
  - Policy (e.g. Family Medical leave Program)

- Interventions may target:
  - Cognition (e.g., cognitive abilities- ACTIVE, Rebok et al., 2014)
  - Behaviors (e.g., medication adherence – Pharmacist Intervention, Murray et al, 2007)
  - Emotional Well-Being (e.g. caregiver well-being – REACH II, Belle et al., 2006)
  - Physical Health and Functioning (e.g., exercise – Fit and Strong, Hughes et al., 2004)
  - Social Issues (e.g., social support- PRISM, Czaja et al., 2015)
  - Physical environment (e.g., enhance home safety – Falls H1T, Nikolaus et al., 2003)
  - Healthcare practices (e.g., care coordination- Partners in Dementia Care – Judge et al., 2011)

- Intervention Strategies may include:
  - Provision of Information, Skill building, Problem solving strategies
  - Counseling, cognitive behavioral therapy, psychotherapy
  - Support groups
  - Motivational techniques
  - Mindfulness
Increasing Importance of Behavioral Intervention Research

- Growing recognition and increased evidence that pressing and costly health issues (e.g., obesity), involve lifestyle and behavioral factors.
- Increased evidence that behavioral interventions are effective in improving behavioral, health and well-being outcomes.
- Paradigm shifts in healthcare
  - Care is moving from clinical settings to non-traditional settings such as the home.
  - Patients are expected to take more active role in the care of their health.
  - Increased reliance on family members to provide care & support to older adults.
- Push for the adoption of evidenced-based practices in health care delivery & community settings
  - Evidence-based interventions are those tested with high quality research that is unbiased, has high internal validity, and the results are generalizable, replicable, and there is a strong link between interventions and outcomes (Guyatt et al., 2000).
Increasing Importance of Behavioral Intervention Research

• Despite the plethora of proven interventions there is ~ a 17 year gap between the the conduct of research and the production and implementation of evidence-based practices (IOM, 2001).

• **Gap between what we know and what we do:** only about 14% of evidenced-based programs are implemented in community and clinical settings (McGlynn et al., 2003).

<table>
<thead>
<tr>
<th>Pre-Phase Discovery</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of problem, population, target, theoretical base, mechanisms or pathways, expected outcomes</td>
<td>Identification of characteristic; feasibility, safety, manual development</td>
<td>Test conditions to identify feasibility, evaluate safety, effect sizes, outcomes, and approach to fidelity</td>
<td>Test intervention under optimal conditions compared to standard care</td>
<td>Test intervention in pragmatic real-world settings with diverse populations</td>
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(Source: Gitlin and Czaja, 2015)
Behavioral Intervention Research is Complex: What are the Challenges?
Challenges

• The bar for “evidence” is increasing.
• Behavior and health problems are complex.
• Interventions research is:
  – Effortful
  – Time Consuming
  – Costly
• Most problems require multi-disciplinary research teams.
• Health and demographics landscapes are becoming more complex.
• Numerous methodological issues – e.g., choice of control groups.
• Funding for this type of research is challenging.
Elements of Intervention Design

• Defining the problem and the identifying the target population.
• Identifying relevant theory to guide the intervention.
• Identifying potential mechanisms of action.
• Finding a funding source.
• Specification of the intervention delivery characteristics.
• Specification of inclusion/exclusion criteria.
• Choice of control group.
• Measurement issues.
• Informed Consent and IRB
• Recruitment and retention.
• Dissemination and Implementation.
<table>
<thead>
<tr>
<th>Delivery Characteristic</th>
<th>Factors</th>
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<tbody>
<tr>
<td>Treatment Content</td>
<td>• Theory/prior findings relevant to the content</td>
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<td></td>
<td>• Personnel involved in content decisions</td>
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<td></td>
<td>• Content to be delivered</td>
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<td></td>
<td>• Order or sequence of content</td>
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<td>• Number of components</td>
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<td></td>
<td>• Degree of flexibility/adaptability</td>
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<td>• Feasibility issues (e.g. cost)</td>
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<td></td>
<td>• Equipment requirements</td>
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<td>• Replicability</td>
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<td></td>
<td>• Participant burden</td>
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<td></td>
<td>• Safety</td>
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<tr>
<td></td>
<td>• Protocols for informed consent and adverse event monitoring and reporting</td>
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<td></td>
<td>• Treatment Manual of Operation</td>
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<td>Treatment Dosage and Duration</td>
<td>• Duration of treatment</td>
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<tr>
<td></td>
<td>• Amount of treatment</td>
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<td></td>
<td>• Strategy for measurement of dose</td>
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<tr>
<td></td>
<td>• Feasibility</td>
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<td>• Participant burden</td>
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<td>• Criteria for intervention “completion”</td>
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<td>• Delivery schedule</td>
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<td>• Flexibility in schedule</td>
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<td>• Booster sessions</td>
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<td>• Protocol for tracking content</td>
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<tr>
<td>Delivery Characteristic</td>
<td>Factors</td>
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<tr>
<td>------------------------------</td>
<td>-------------------------------------------------------------------------</td>
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<tr>
<td>Delivery Modality</td>
<td>• Format of delivery (e.g., face-to-face; telephone, Internet)</td>
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<tr>
<td></td>
<td>• Multimodal – single modality</td>
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<td></td>
<td>• Use of technology</td>
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<td>• Cost</td>
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<td></td>
<td>• Technical requirements</td>
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<td></td>
<td>• Skill and training requirements (participant and interventionist)</td>
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<tr>
<td>Delivery Setting</td>
<td>• Choice of setting (e.g., home vs. clinic)</td>
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<td></td>
<td>• Logistic requirements</td>
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<td>• Generalizability/external validity</td>
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<td>• Threats to internal validity</td>
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<td>• Single site vs. multi-site</td>
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<td>Delivery Approach</td>
<td>• Prescriptive vs. tailoring</td>
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<td>• Cultural adaptations</td>
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<td>• Aspects of the intervention that can amenable to tailoring</td>
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<td>• Personnel involved in tailoring decisions</td>
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<td>• Criteria for tailoring</td>
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<td>• Protocols for documenting adaptations/tailoring</td>
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<tr>
<td>Staffing Requirements</td>
<td>• Size and nature of team (e.g., recruitment, coordinator, assessors, interventionists)</td>
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<tr>
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<td>• Skill level requirement for team</td>
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<td>• Characteristics (e.g., age, gender, language, culture/ethnicity)</td>
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<td></td>
<td>• Training protocols and criteria</td>
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<td>• Strategies for team building</td>
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<td>• Protocols for communication</td>
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<td>• Protocols for meetings</td>
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<td>• Plan for monitoring and assessment</td>
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<td>• Safety protocols</td>
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<td>• Training for ethical conduct of research; resolution for adverse events</td>
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Some Considerations for Caring for the Caregiver Network

- Content of sessions – theory, relevance to CG, etc.
- Order of sessions
- Dosage – # of sessions, # of support group sessions, duration
- Content of Educational and Skill building videos
- Degree of adaptability
- Features for website; website security
- Training protocol for tablet
- Type of tablet
- # of home vs. video delivered sessions
- Content for control group – nutrition
- Intervention scripts
- Staffing – bilingual, experience with older adults
- Protocols for blinding
- Adverse events and protocols for resolution
Caring for the Caregivers Network

Select the feature you want to use by touching the name of feature on the left side of the screen.

**Current Session Topic**
- Past Session Topics
- My Discussion Group
- Videoconference
- Community Resources
- Tip of the Week
- Calendar
- Message Center

**Wrap Up & Review**
- Videos
  - Skill Building
  - Experts
    - Review
- Information & Tips
<table>
<thead>
<tr>
<th>Month</th>
<th>Content</th>
</tr>
</thead>
</table>
| Month 1   | • Individual Session #1: Introduction  
• Skill building video: Alzheimer’s Disease  
• Expert video: Memory Disorders  
• Support group #1  
• Individual Session #2: Community resources  
• Skill building video: Community Resources  
• Expert video: Memory Disorders |
| Month 2   | • Individual Session #3: Communication and Behavioral management #1  
• Skill building video: ADLs and IADLs  
• Support group #2  
• Expert video: Safety |
| Month 3   | • Individual Session #4: Behavioral management #2  
• Skill building video: Repeated questioning  
• Support group #3  
• Expert video: Handling common behavioral problems |
| Month 4   | • Individual Session #5: Stress and Caregiving  
• Skill building video: Relaxation techniques  
• Support group #4  
• Expert video: Effects of caregiving stress |
| Month 5   | • Individual Session #6: Emotional well-being  
• Skill building video: Talking about depression  
• Support group #5  
• Expert video: Exercise and Nutrition |
| Month 6   | • Individual Session #7: Caregiving transition  
• Skill building video: Testimonial from caregivers  
• Support group #6  
• Expert video: Legal advice  
• Individual Session #8: Wrap-up |
Inclusion and Exclusion Criteria

• Depends on the research question
  – e.g., evaluating a cognitive training software program – normative age-related changes in cognition and MCI.

• Feasibility
  – Resources, participant pool

• Standardized methods and measures (e.g., TICS, MMSE)
  – Telephone screening
  – Lab or home assessment
  – Pilot testing
  – Training of personnel
  – Data tracking system (e.g., reasons for non-eligibility).
PRISM Challenges

• Specification of inclusion/exclusion criteria:
  – “at risk” for social isolation
    • Living arrangements
    • Amount/degree of participation in community programs
    • Amount/degree of participation in work/volunteer activities
  – Amount of prior computer/internet experience
  – Cognitive status – “oldest old”
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 6th 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
Recruitment and Retention in Intervention Trials

• The success of any intervention study is highly dependent on the recruitment and retention of sufficient numbers of representative research participants – influences:
  – generalizability, reliability and validity of the trial outcomes
  – dissemination and implementation of the program
  – cost of the trial
• Recruitment is often fairly difficult, labor intensive and time consuming.
  – Historically low levels of participation of racial/ethnic minority populations!
• Retention often difficult for those in control conditions.
• Recruitment and retention are often after thoughts in the development of intervention protocols.
• Requires engagement and “buy-in” from the community.
• Different populations resonate to different strategies.
Recruitment Challenges: The PRISM TRIAL

- Locating older adults “at risk for social isolation”
- Locating older adults who met:
  - Computer/Internet criteria
  - Cognitive criteria
- Choice of control group
- Environmental/contextual challenges
  - Internet speed/connectivity
  - Variability in home environments and setting up work stations
- Budget limitations
Sample Recruitment Activities: PRISM

• Outreach activities:
  – Newsletters reaching older adults:
    • City of Miami Beach newsletter
  – Flyers at, clinics and senior housing facilities
  – Relationships with community agencies and clinics
  – Programs serving older adults:
    • Senior Companion, Meals on Wheels
    • Elderly, Disability, and Veterans Services Bureau
    • Area Agencies on Aging
• Participant databases
• Newspaper, TV and Radio Advertisement
• Advertisement on pharmacy bags
• Participation in health fairs
• Purchasing of mailing lists
Lessons Learned

• Importance of:
  – development of a recruitment plan
    • Starting early
    • Adequate resources to recruitment efforts
  – using a wide variety of recruitment strategies
    • Not one strategy “fits all”
    • Being creative
  – monitoring of recruitment and screening data
  – being adaptive to meet site level challenges
  – community relationships and “buy in”
Measurement Issues

Choice of outcome measures:

• Appropriateness for population e.g., language, literacy
• Consistency with research goals
• Psychometric properties
  • Reliability
  • Validity
  • Sensitivity
• Feasibility, Cost
• Identification of Primary, Secondary Outcome Measures
• Blinding
• Administrative issues
• Participant burden
Choice of Measures

- Stakeholders and intended use of evidence?
- Characteristics of target population?
  - Age/cohoot
  - Ethnicity, race, culture
  - Experience, literacy
- Currency/relevance of the measure?
- Burden?
- Ease of Administration?
- Measurement context?
- Adherence to measurement criteria?
- Role of measure?
PRISM Battery

• Characterize Sample
  – Demographic and health information
  – Technology, Computer, Internet Experience; Computer Attitudes

• Predictor Variables
  – Component cognitive abilities (memory, reasoning, verbal fluency)
  – Personality

• Outcome measures
  – Quality of life, life engagement
  – Social support, isolation, loneliness
  – Depression, Well-being
  – Technology acceptance, computer proficiency

• System Measures
  – Use and usage patterns, use of help features
  – Usability, System evaluation
**AGITATION**

- Try to assess what is causing your loved one to be agitated.
- Remain calm and redirect them by asking them what they need.
- Try and eliminate the source of the agitation.
- Avoid screaming or confrontation.
- Switch to a new activity.
- Offer something of comfort and speak in a calming voice.
- Walk away and give yourself some space.

**AGITACIÓN**

- Trate de evaluar que es lo que esta potencialmente causando que su ser querido se ponga agitado.
- Manténgase calmado y redirija su atención por medio de preguntarle que es lo que quisiera hacer.
- Trate de eliminar la fuente de agitación.
- Evite gritar, confrontarle, o escalar en la agitación.
- Ofrézcale algo que le dé consuelo y hable con una voz calmada.
- Finalmente, aléjese, y dése su propio espacio.

**AJITASYON**

- Eseye bwèn ki lakòz moun ou renmen’an ajite konsa.
- Rete kalm epi mande yo bisa yo bezwen.
- Evite rele sou moun nan oswa konfòntasyon avèk li.
- Eseye dirije atansyon li sou yon nouvou aktivite.
- Ofri’l yon bagay ka rekonfote’l avèk pale ak yon vwa ki kalm.
- Bay moun nan yon ti distans pa rete trò prè li.
Control Groups

Control Group Decisions:

• Inclusion of control group?
• Type of control group?
  • Usual contact
  • Wait List
  • Attention Control
• Ethical considerations
• Feasibility
• Cost
• Impact on participant accrual and retention
• Active ingredients in control condition
Control Groups

PRISM

• Notebook
  – Resource guide
  – Information/tip sheets, information about community groups
  – Calendar/Organizer, Games – e.g., crossword puzzles
• Same number of planned contacts as PRISM condition
• Offer of basic computer training at study completion

Caring for the Caregiver Network

• Nutrition
  – Same number of sessions
  – Access to support groups
  – Tablet
  – Caregiver notebook at end of the trial
The Future of Behavioral Intervention?
The Future??

• Increased:
  – complexity of health issues.
  – diversity of target populations.
  – use of technology for intervention delivery and assessment
    • Access, Skill
    • Privacy/Security
    • Data issues – e.g. management
  – timeliness of evidence
  – emphasis on comparative effectiveness
  – need for Rigorous alternatives to RCTs
  – emphasis on team science
  – Issues with big data
The Ultimate Challenge for the Intervention Research

Designing interventions programs and research protocols that:

• *meet the standards for* rigorous evaluation
• *are effective with respect to outcomes*
• *can be* replicated
• *can ultimately be* implemented in community and clinical settings.