The Lifestyle Redesign® Intervention:

The Design Process & Evidence for Effectiveness

Dr. Florence Clark, PhD, OTR/L, FAOTA

USC Chan Division of Occupational Science and Occupational Therapy

University of Southern California

Aging, Health, and Chronic Disease

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University of Southern California

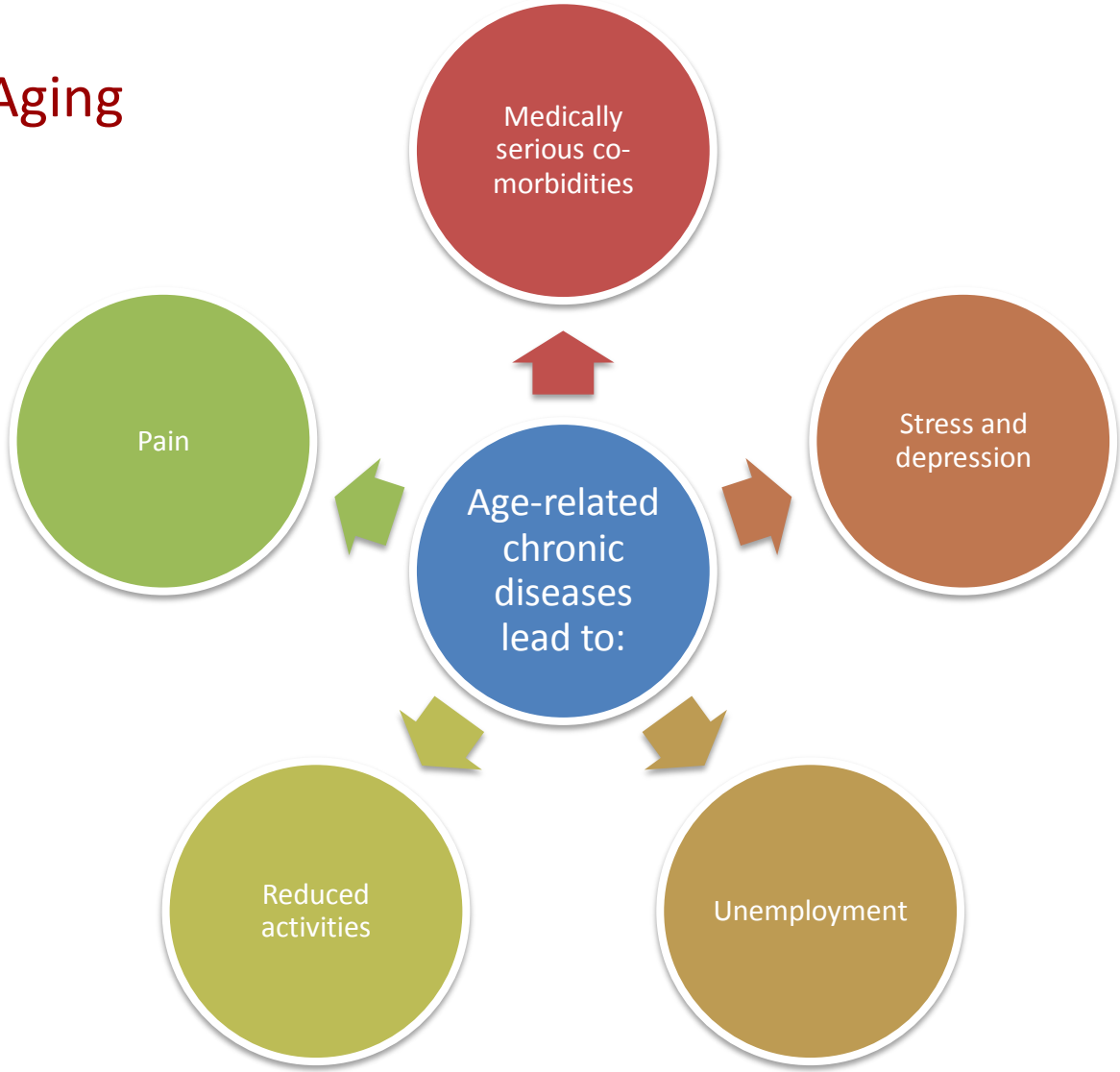
What's the big deal?

- Chronic disease
- Disability
- Prevention

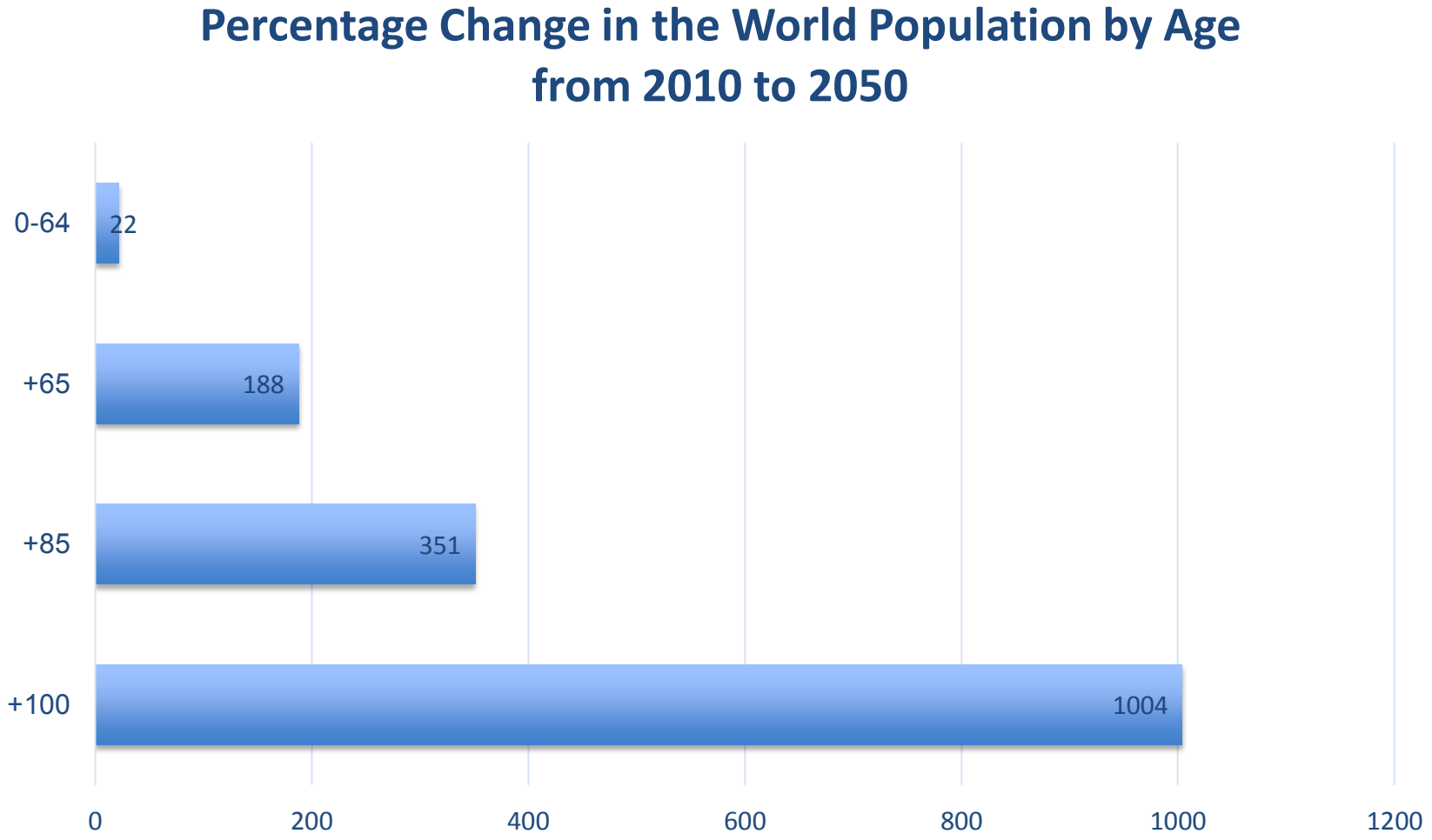
"Apparently they're better than The Cure"

Image from: http://semedisalute.files.wordpress.com/2012/06/cartoon-on-prevention-the-preventione-and-the-cure.jpg

Health and Aging



The Aging Global Population



Living with Chronic Disease

- Chronic disease = #1 global cause of death
- 2/3 Israeli adults have *2 or more chronic diseases*

Top 5 Causes of Death (Israel, 2012)
1. Cancer
2. Heart diseases
3. Cerebrovascular diseases (stroke)
4. Chronic respiratory diseases
5. Diabetes

WE BECOME WHAT WE HAVE DONE: AGING WELL

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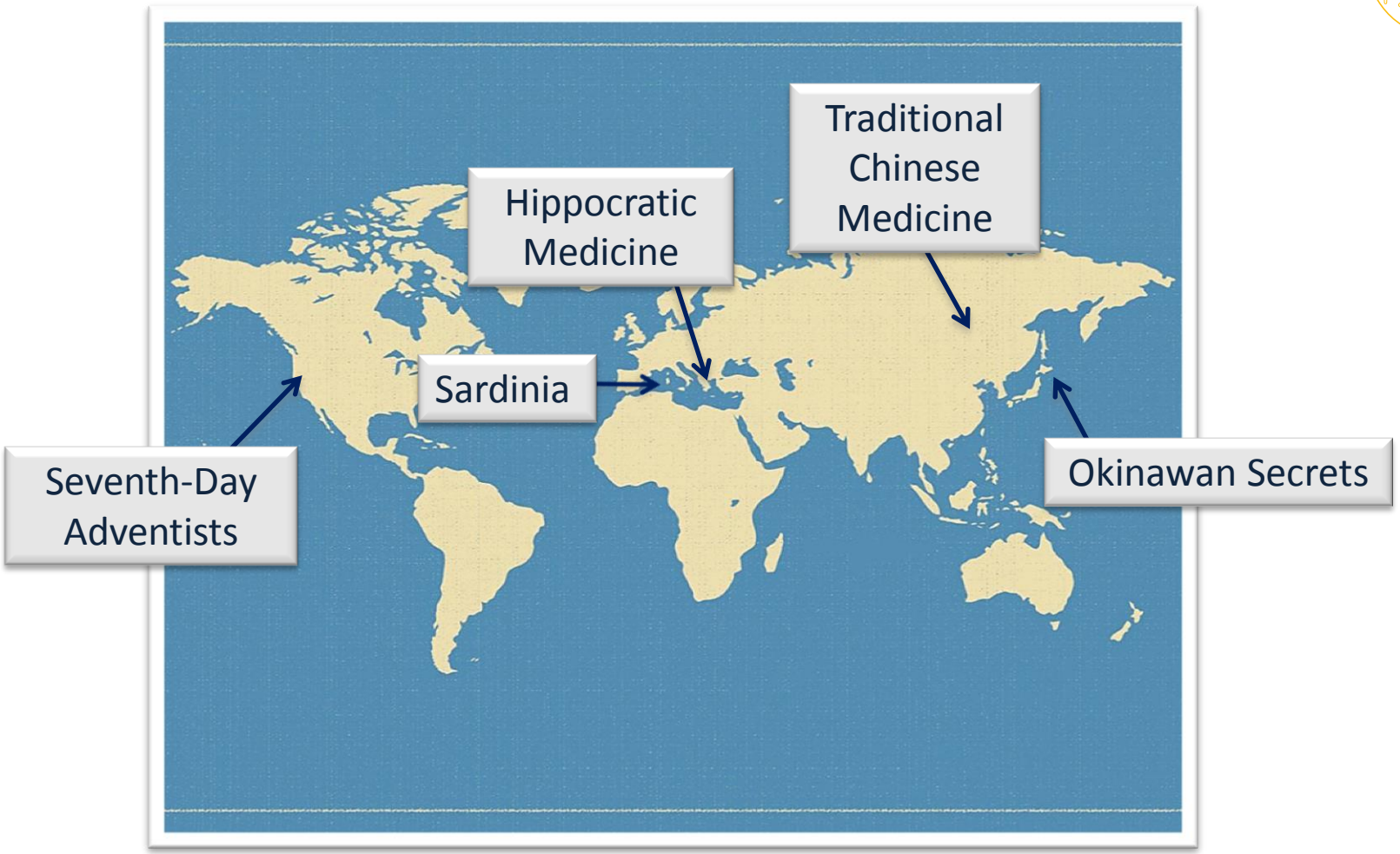
Aging Around the World



Seventh-Day Adventists: Loma Linda, CA

Lifestyle Factors

- Abstinence from tobacco, alcohol, caffeine, & other drugs
- Low stress lifestyle
- Vegetarian diet and high level of spring water intake
- Weekly day of rest on the Sabbath
- Regular exercise
- Close-knit family structure
- Prayer and worship within the church community

Life expectancy of Vegetarian Adventists:
- Male: 83.3 years
- Female: 85.7 years

US Average Life Expectancy = 78.8 years

Early Health Habits have Long Term Consequences

Deficits in brain, cognitive, and behavioral development early in life

- Cardiovascular disease
- Stroke
- Hypertension
- Diabetes
- Obesity
- Smoking
- Drug use
- Depression

Two Different Trajectories

Eats a balanced diet

Exercises 5 days/week

Chooses healthy, meaningful routines and habits

Adds quality years to life

Eats a diet high in refined sugars and processed foods

Engages in mostly sedentary activities

Increases BMI, Diagnosed with Diabetes

Reduces ability to participate in meaningful activities

Decreases quality of life

"What we need are innovative solutions to stop people from getting sick in the first place and policies to provide people with the opportunity to lead healthier lives."

- Risa Lavizzo-Mourey, M.D., M.B.A., president & CEO of the Robert Wood Johnson Foundation

The USC Well Elderly Study Research Program (WE)

Process of Conducting Translational Research

Result:

- Build theory
- Demonstrate treatment effectiveness and cost-effectiveness

Translational Research Blueprint

Step 1: Identify problem

↓

Step 2: Develop theoretical understanding of the problem

↓

Step 3: Develop intervention

↓

Step 4: Test intervention efficacy (RCT)

↓

Step 5: Evaluate cost-effectiveness ↗

Step 6: Test intervention effectiveness (RCT)

↓

Step 7: Study theoretical model for why outcomes were produced

↓

Step 8: Knowledge translation, transportation, and dissemination

Funding for Translational Research

Grant Title	Funding Agency	Award #	Amount	Years
Health Mediating Effects of the Well Elderly Program	**NIH/NIA**	**#1 R01 AG021108-01A2**	**$2,247,187**	**2004-2010**
The Effectiveness of Two Occupational Therapy Treatments for the Elderly (inc. Minority Supplement)	**NIH/NIA & NCMRR; ACHPR; AOTF**	**#R01 AG11810; #R01 AG11810-01S1**	**$926,890**	**1994-1997**
Lifestyle Redesign® for Pressure Ulcer Prevention in SCI (LR-PUPS)	NIH/ NICHD/ NCMRR	#1 R01 HD056267-01	$2,865,317	2008-2013
LR-PUPS Administrative Supplement	Same as above		$223,852	2010-2011
Daily Living Context and Pressure Sores in Consumers with SCI	DOE/ NIDRR	#H133G000062	$467,851	2000-2003

Total: $6,731,097

Importance of RCTs

- Random allocation of participants to intervention or control group
- Both groups treated identically, except for the experimental intervention
- Blinding:
  - Hypothesis blinding (interveners)
  - Condition blinding (testers)
- Strongest form of evidence for treatment effect

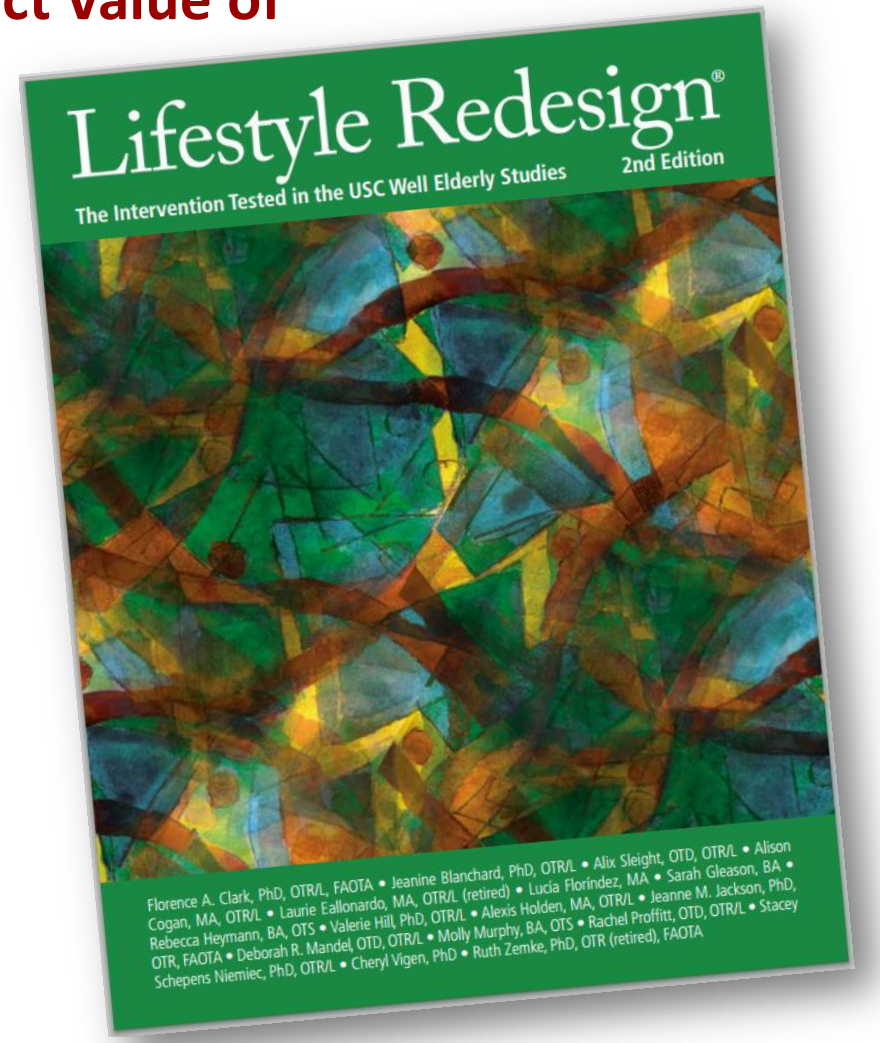
Overview

- Specific aims
  - To assess the efficacy, effectiveness and cost effectiveness of the Lifestyle Redesign® intervention
  - To investigate the mediating mechanisms that account for its health outcomes
  - To build a robust data set for future secondary analyses by gerontological researchers

Lifestyle Redesign® Intervention

- Lifestyle Redesign® enables patients to design, practice, and ultimately enact a personalized, sustainable health-promoting daily routine that is tailored to address CD risk factors as well as promote health and well-being more generally
- Lifestyle focused (activity based)
- Group & individual sessions
- Goal: Assist each participant to develop
  - A personally feasible, healthy lifestyle
  - Sustainable within the fabric of his or her everyday routines

Evidence for the Distinct Value of Occupational Therapy



Design Process

Qualitative study

↓

Identify domains

↓

Literature review

↓

Intervention design

Life Domains and Adaptive Strategies of a Group of Low-Income, Well Older Adults

Florence Clark, Mike Carlson, Ruth Zemke, Gelya Frank, Karen Patterson, Bridget Larson Ennevor, Allyn Rankin-Martinez, LuAn Hobson, Jennifer Crandall, Deborah Mandel, Loren Lipson

Key Words: aged • qualitative method

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Ruth Zemke, PhD, OTR, FAOTA, is Associate Professor, Department of Occupational Therapy, University of Southern California, Los Angeles, California.

Gelya Frank, PhD, is Associate Professor, Department of Occupational Therapy, University of Southern California, Los Angeles, California.

Older adults are at increased risk for a variety of physical and functional limitations that threaten their ability to lead independent and fulfilling lives. Consequently, they stand to benefit from personalized strategies of adaptation that enable them to achieve successful outcomes in their daily activities and desired goals. In the current investigation, a qualitative descriptive methodology was used to document the perceived life domains of importance and associated strategies of adaptation of 29 residents of Angelus Plaza, a federally subsidized apartment complex in downtown Los Angeles for low-income, well older adults. On the basis of interview data, 10 life domains were identified, and within each domain, a typology of adaptive strategies was derived. The domains were activities of daily living (ADL), adaptation to a multicultural environment, free time usage, grave illness and death–spirituality, health maintenance, mobility maintenance, personal finances, personal safety, psychological well-being and happiness, and relationships with others. Although the typology should not be generalized to a geriatric population, therapists may wish to refer to it to gain a sense of the extent to which certain adaptive strategies may be applicable to the lives of particular older adults to whom they deliver services. The teaching of these adaptive strategies could then be incorporated into an individualized treatment plan.

The typology also provides a broad picture of the kinds of adaptive strategies used by the older adults as a way of coping and adapting to their setting. Although some of the domains do not differ from those typically addressed in occupational therapy textbooks on geriatric care (e.g., ADL, health maintenance), others seem uniquely tailored to the specifics of the Angelus Plaza context (e.g., personal safety). Finally, certain domains emerged that may be highly relevant to older adults in most settings but are not typically the focus of occupational therapy programs (e.g., grave illness and death–spirituality, relationships with others). The emergence of these domains from our data suggests that therapists may wish to consider them more in treatment if they are convinced that they possess local relevance.

USC Well Elderly 1 Study (WE1) Team

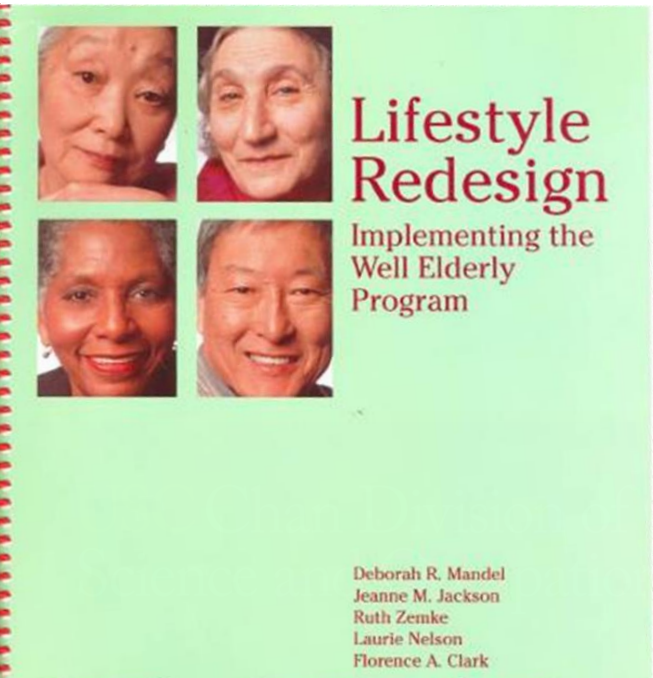
Florence Clark, PhD	Occupational Therapy
Ruth Zemke, PhD	Occupational Therapy
Jeanne Jackson, PhD	Occupational Therapy
Michael Carlson, PhD	Social Psychology
Loren G. Lipson, MD	Geriatric Medicine
Stanley P. Azen, PhD	Preventive Medicine, Biostatistics
Joel W. Hay, PhD	Pharmaceutical Policy & Economics
Barbara J. Cherry, PhD	Cognitive Psychology
Deborah Mandel, OTD	Occupational Therapy
Karen Josephson, MD	Geriatric Medicine

Randomized Controlled Trial

Three experimental conditions

- Occupational therapy (n = 122)
- Social control group(n = 120)
- No treatment control (n = 119)

(n = 361)



Reprinted from JAMA ® The Journal of the American Medical Association October 22/29, 1997 Volume 278

Original Contributions

Occupational Therapy for Independent-Living Older Adults

A Randomized Controlled Trial

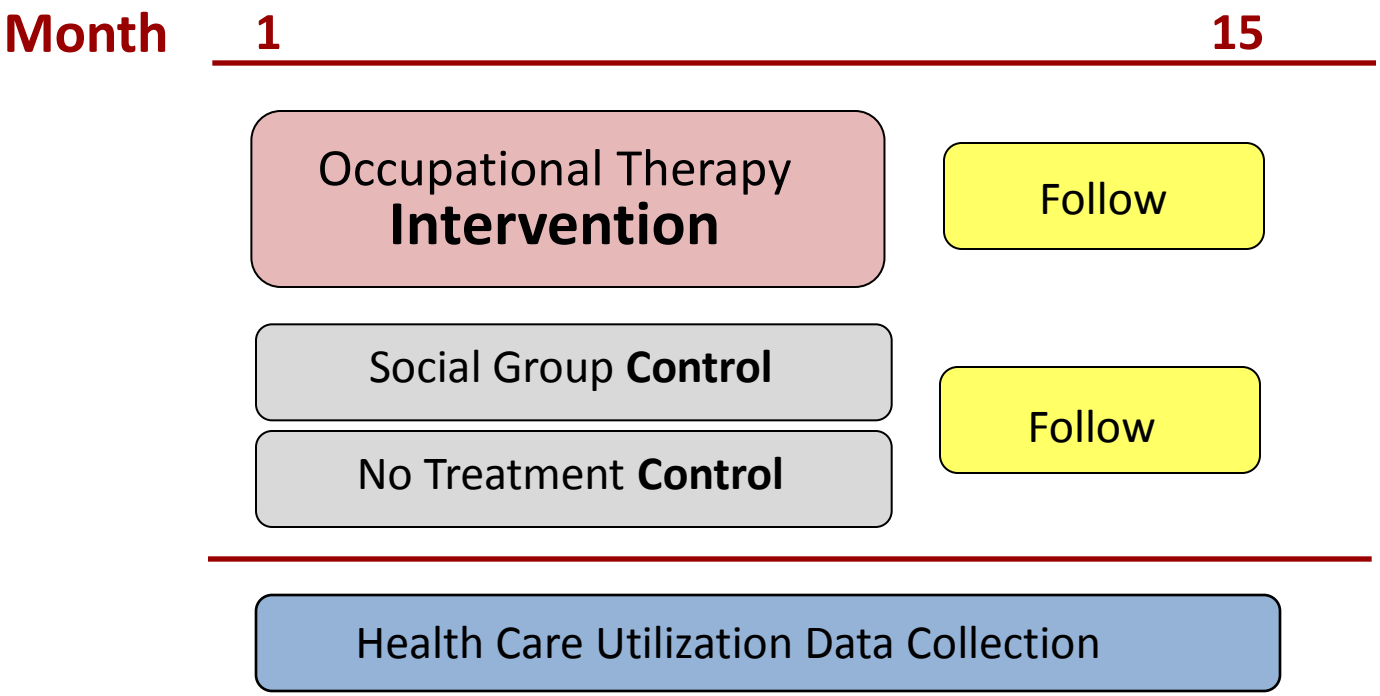
Florence Clark, PhD, OTR; Stanley P. Azen, PhD; Ruth Zemke, PhD, OTR; Jeanne Jackson, PhD, OTR; Mike Carlson, PhD; Deborah Mandel, MS, OTR; Joel Hay, PhD; Karen Josephson, MD; Barbara Cherry, PhD; Colin Hessel, MS; Joycelynne Palmer, MS; Loren Lipson, MD

Context.—Preventive health programs may mitigate against the health risks of older adulthood.

Objective.—To evaluate the effectiveness of preventive occupational therapy (OT) services specifically tailored for multiethnic, independent-living older adults

ability.[8,9] Older adults are also presented with unique psychological stressors (eg, financial hardship, death of a spouse, retirement) that can contribute to psychi-

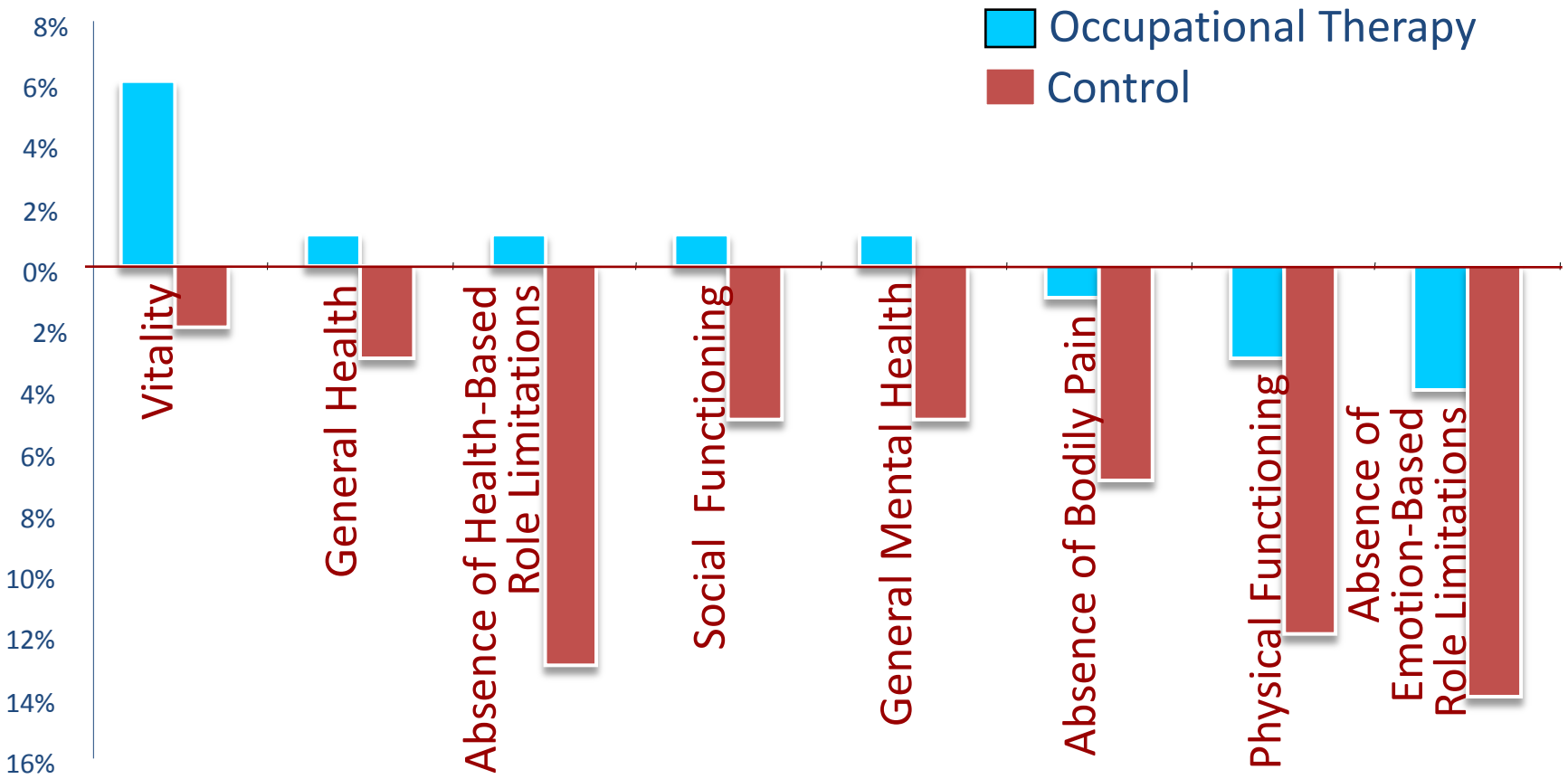
WE 1 RCT Design



Intervention:

- 38 group sessions
- up to 9 hours of individual sessions

Well Elderly Study 1: Intent-to-Treat



The Well Elderly Study: News Clips

Intervention Outcomes

Journal of Gerontology: PSYCHOLOGICAL SCIENCES
2001, Vol. 56B, No. 1, P60-P63

Embedding Health-Promoting Changes Into the Daily Lives of Independent-Living Older Adults: Long-Term Follow-Up of Occupational Therapy Intervention

Florence Clark,[1] Stanley P. Azen,[1,2] Mike Carlson,[1]
Deborah Mandel,[1] Laurie LaBree,[2]
Joel Hay,[4] Ruth Zemke,[1] Jeanne Jackson,[1] and Loren Lipson[3]

90% of the therapeutic gain was retained at 6-month follow-up

Cost per QALY was $10,666

$50,000 defined cost-effective interventions

Cost-Effectiveness of Preventive Occupational Therapy for Independent-Living Older Adults

Joel Hay, PhD, Laurie LaBree, MS,† Roger Luo, PhD,* Florence Clark, PhD, OTR,‡ Mike Carlson, PhD,‡ Deborah Mandel, MS, OTR,‡ Ruth Zemke, PhD, OTR,‡ Jeanne Jackson, PhD, OTR,‡ and Stanley P. Azen, PhD†‡*

JAGS 50:1381–1388, 2002

USC Well Elderly Study 2

Health Mediating Effects of the Well Elderly Program

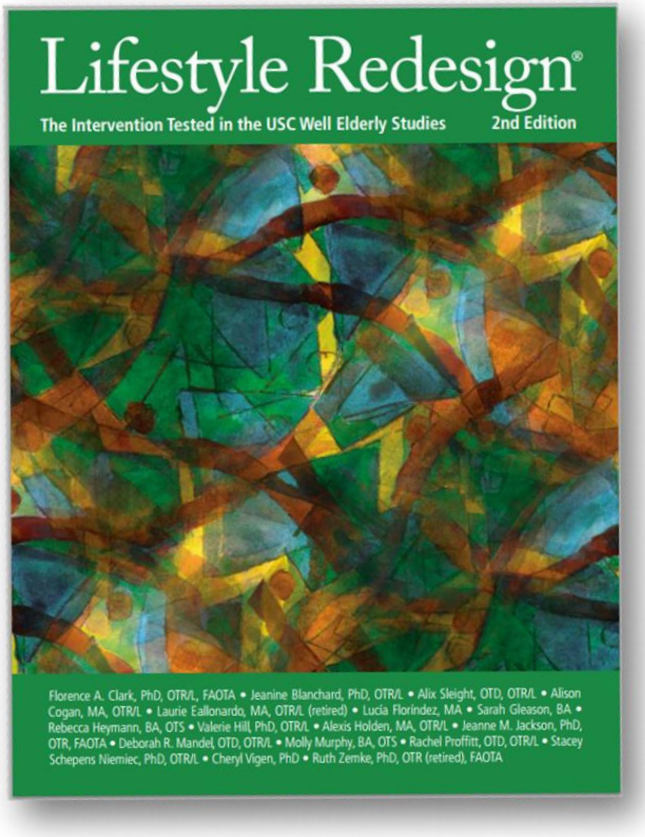
2004-2008

National Institute on Aging

(R01 AG 021108-01A3)

PI: Florence Clark,

PhD, OTR/L, FAOTA



USC Well Elderly Study 2 Team

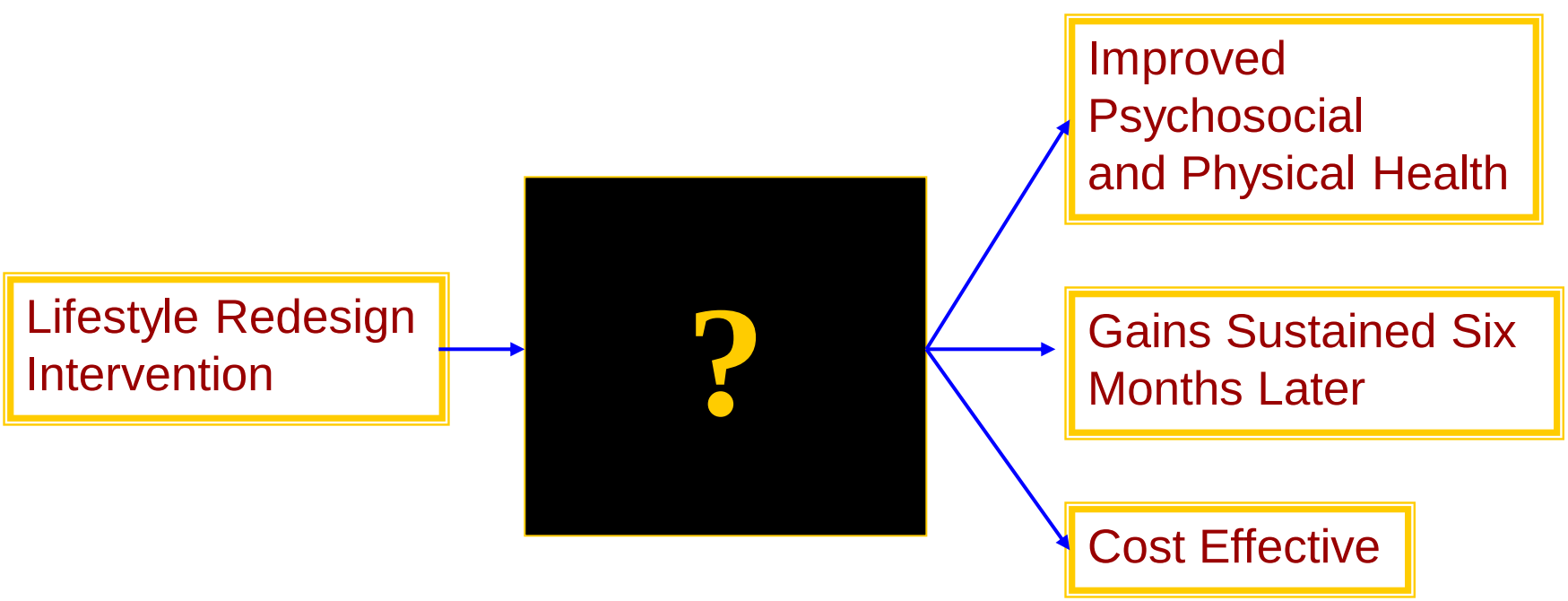
Florence Clark, PhD	Occupational Therapy
Jeanne Jackson, PhD	Occupational Therapy
Stanley P. Azen, PhD	Preventive Medicine, Biostatistics
Chih-Ping Chou, PhD	Preventive Medicine
Barbara J. Cherry, PhD	Cognitive Psychology
Maryalice Jordan-Marsh, PhD	Nursing
Brett White, MD	Family Medicine
Douglas Granger, PhD	Biobehavioral Health, Penn State
Robert Knight, PhD	Psychology, Gerontology
Michael Carlson, PhD	Social Psychology
Rand Wilcox, PhD	Psychology, Statistics
Deborah Mandel, MA	Occupational Therapy
Jeanine Blanchard, MA	Occupational Therapy

Purposes of the Study

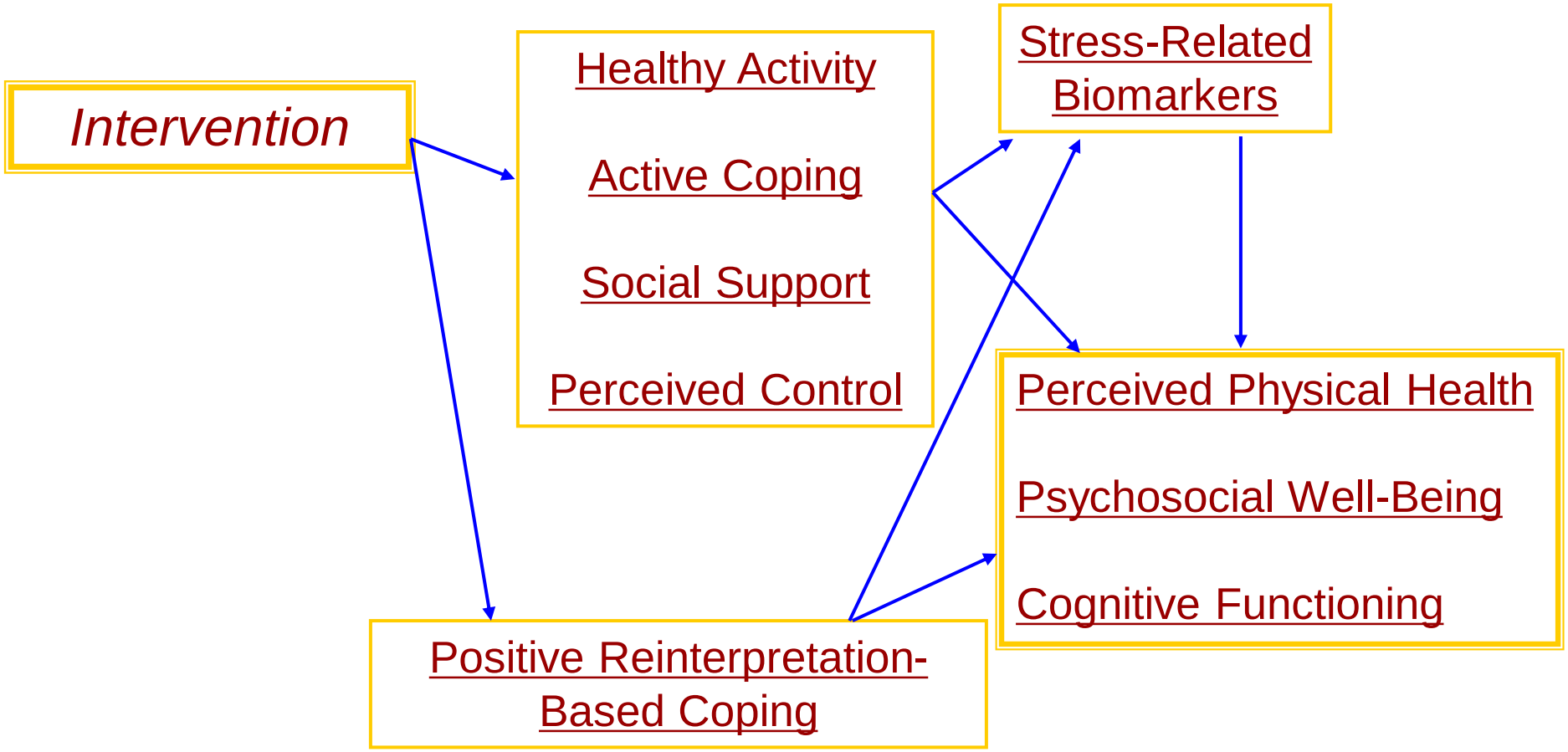
- Examine the mediating mechanisms responsible for its positive effects
- Replicate our previous results on the positive effects of the Lifestyle Redesign® intervention
- Extend focus from efficacy to effectiveness
- Build a robust data set

Examine the Mediating Mechanisms

Theoretical Model of Well Elderly Study 1



Conceptual Model of Positive Effects of Lifestyle Intervention for Older People

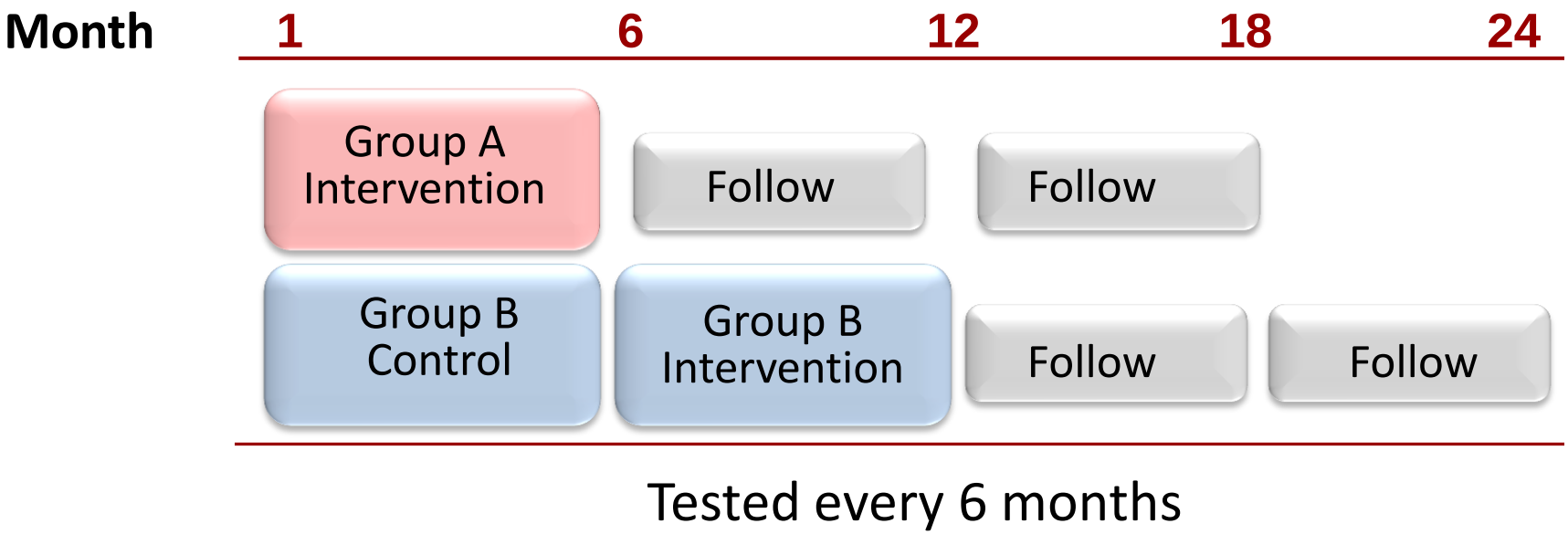


Replicate Our Previous Results

Efficacy vs. Effectiveness

- Efficacy of an intervention: WE 1
  - Favorable conditions that maximize the experimental effect
- Effectiveness of an intervention: WE 2
  - Less tightly controlled
  - More realistic circumstances that characterize complex, real world settings
- Instantiation of effectiveness
  - Expanded the number and type of sites from 2 to 21
  - Treatment period reduced from 9 to 6 months
  - More African Americans and Hispanics
    - At high risk for disparities

WE 2 Semi-Crossover Design



Intervention:

- 26 group sessions
- Up to 10 hours of individual sessions

Intent-to-Treat Analysis

JECH Online First, published on June 2, 2011 as 10.1136/jech.2009.099754

Effectiveness of a lifestyle intervention in promoting the well-being of independently living older people: results of the Well Elderly 2 Randomised Controlled Trial

Florence Clark,[1] Jeanne Jackson,[1] Mike Carlson,[1] Chih-Ping Chou,[2] Barbara J Cherry,[3] Maryalice Jordan-Marsh,[4] Bob G Knight,[5] Deborah Mandel,[1] Jeanine Blanchard,[1] Douglas A Granger,[6] Rand R Wilcox,[7] Mei Ying Lai,[2] Brett White,[8] Joel Hay,[9] Claudia Lam,[2] Abbey Marterella,[1] Stanley P Azen[10]

For numbered affiliations see end of article.

Correspondence to
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fclark@usc.edu

Role of study sponsors: All data acquisition was inspected and reviewed annually by the designated data safety and monitoring board.

Accepted 28 April 2011

ABSTRACT

Background Older people are at risk for health decline and loss of independence. Lifestyle interventions offer potential for reducing such negative outcomes. The aim of this study was to determine the effectiveness and cost-effectiveness of a preventive lifestyle-based occupational therapy intervention, administered in a variety of community-based sites, in improving mental and physical well-being and cognitive functioning in ethnically diverse older people.

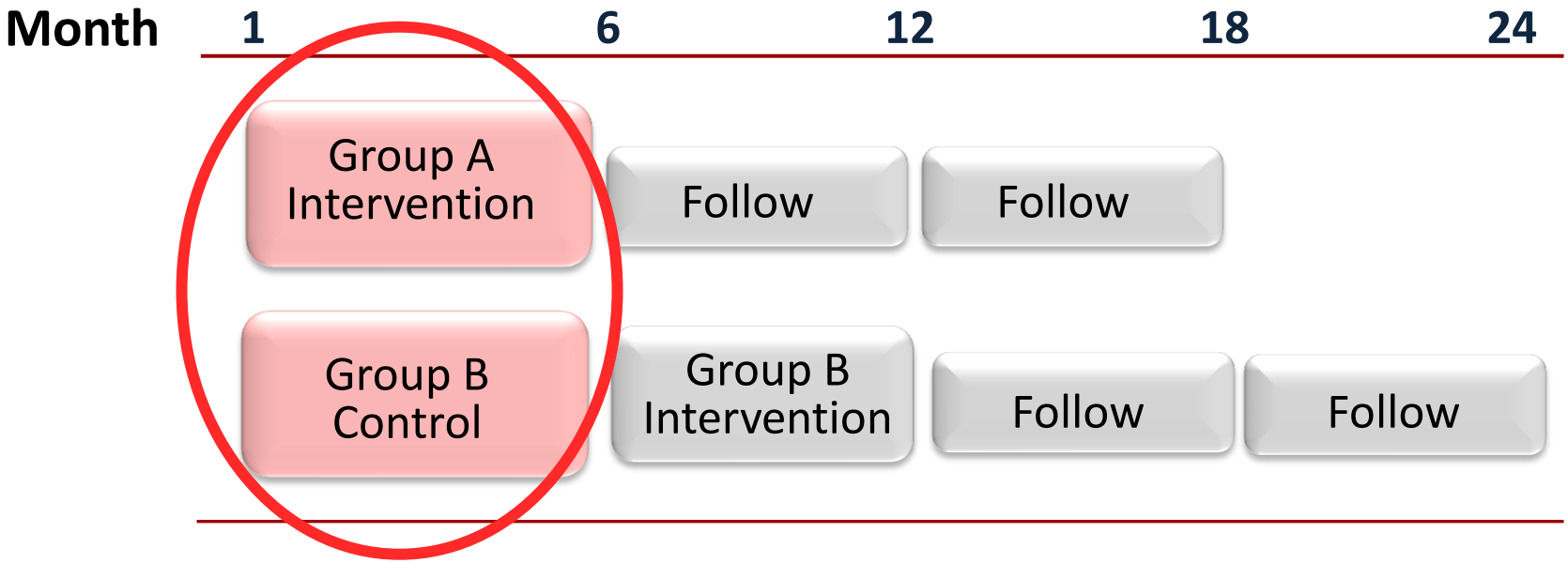
Methods A randomised controlled trial was conducted comparing an occupational therapy intervention and a no-treatment control condition over a 6-month experimental phase. Participants included 460 men and women aged 60—95 years (mean age 74.9±7.7 years; 53% <$12 000 annual income) recruited from 21 sites in the greater Los Angeles metropolitan area.

Results Intervention participants, relative to untreated controls, showed more favourable change scores on

California Well Elderly study (Well Elderly 1), a randomised controlled trial of the efficacy and cost-effectiveness of a 9-month lifestyle intervention (now called Lifestyle Redesign®) designed to slow age-related declines among independently living elders.[6] In this study, which included 361 elders from two large federally subsidised housing complexes, a reliable positive intervention effect was obtained cost-effectively for a wide range of outcomes, such as life satisfaction, role functioning and self-rated physical and emotional health.[6–8] Although additional trials have underscored the value of lifestyle interventions for older people, such research has typically been performed in a single setting only, has involved a relatively small sample size or lacked a cost-effectiveness evaluation.[9–11]

This article reports on the University of Southern California Well Elderly 2 study which assessed the

Well Elderly 2
Intent-to-Treat Design



Tested every 6 months

Well Elderly Study 2: Intent-to-Treat

Treatment (n=187) vs. Control (n=173)

Health-Related Quality of Life - SF36V2	
Mental Health	0.03
Social Function	0.04
Vitality	0.03
Bodily Pain	0.02
Composite: Mental	0.03
Composite: Physical	0.09
General Health	0.25
Physical Function	0.09
Role Physical	0.18
Role Emotional	0.16

Life Satisfaction -LSI-Z	0.03

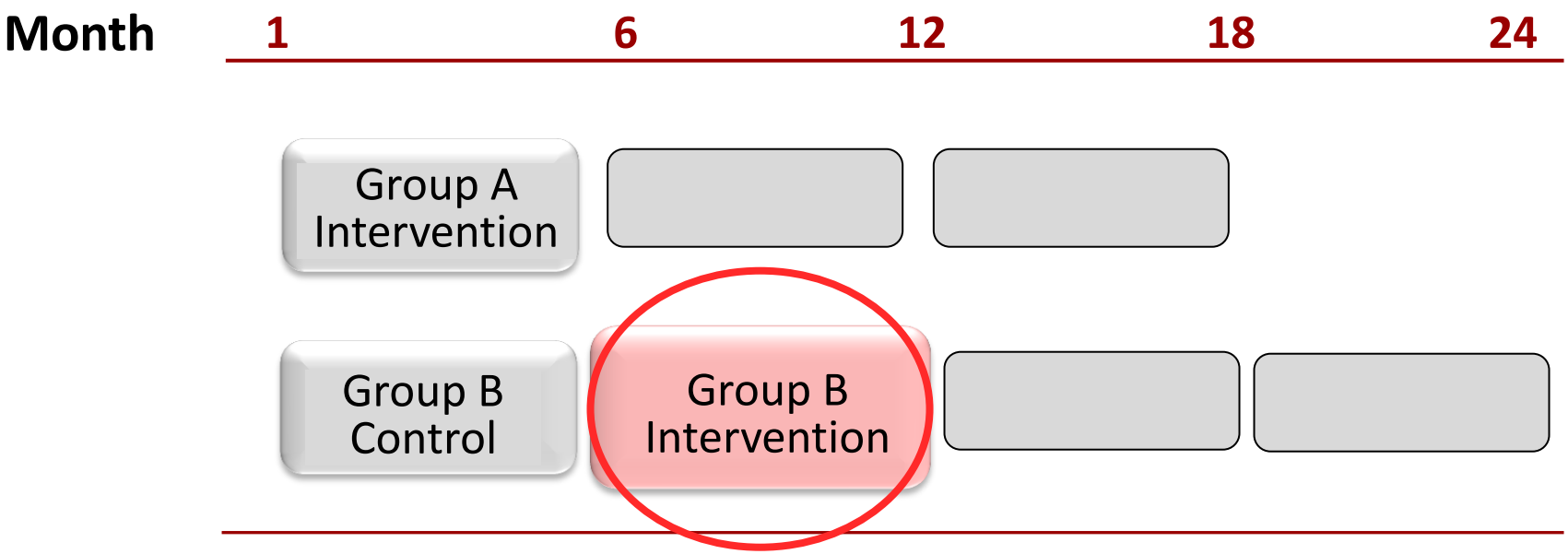
Depression - CES-D	0.03

Cognition	
Memory - CERAD	0.20
Visual Search	0.49
Psychomotor Speed	0.49

Cost Effectiveness

- Cost per QALY was **$41,485**
  - $120,000 to $150,000 currently defines cost-effective interventions

Secondary Analysis: Pre-Post Intervention for Group B (Control)



Secondary Analysis: Pre-Post Intervention

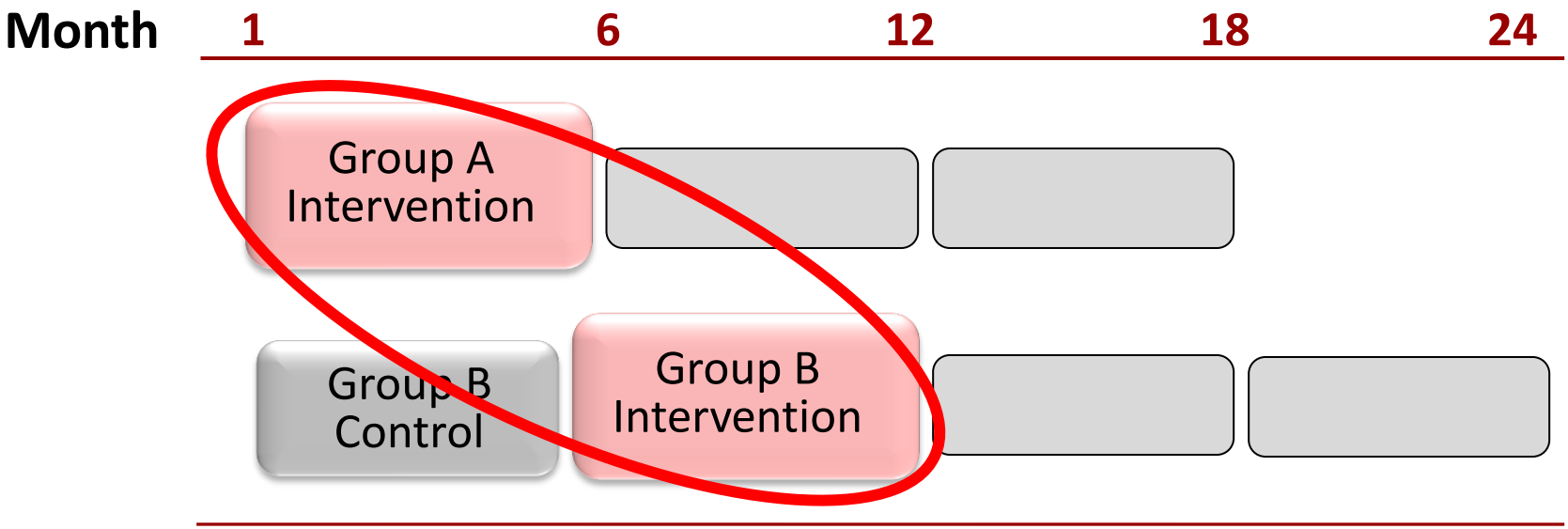
Group B (Control) Receive Intervention (n = 137)

Health-Related Quality of Life - SF36V2	
Mental Health	0.01
Vitality	0.03
Bodily Pain	0.05
Role Physical	0.03
Composite: Mental	0.04
Composite: Physical	0.07
Physical Function	0.07
General Health	0.34
Social Function	0.15
Role Emotional	0.10

Life Satisfaction - LSI-Z	0.02
Depression - CES-D	0.01
Cognition	
Memory - CERAD	
Immediate Recall	0.05
Delayed Recall	<0.0001
Recognition	0.01
Psychomotor Speed	0.01
Visual Search	0.31

Secondary Analysis: Pre-Post Intervention

All Participants Receiving Intervention



Secondary Analysis: Pre-Post Intervention

All Participants Receiving Intervention (n = 326)

Health-Related Quality of Life - SF36V2	
Mental Health	.001
Social Function	.05
Vitality	.003
Bodily Pain	.001
Composite: Mental	.006
Composite: Physical	.007
General Health	.02
Physical Function	.006
Role Emotional	.02
Role Physical	.06

Life Satisfaction - LSI-Z	.0005
Depression - CES-D	.001
Cognition	
Memory - CERAD	
Immediate Recall	.002
Delayed Recall	.004
Recognition	ns
Visual Search	<.0001
Psychomotor Speed	.01

A Feature Missed by Usual Methods

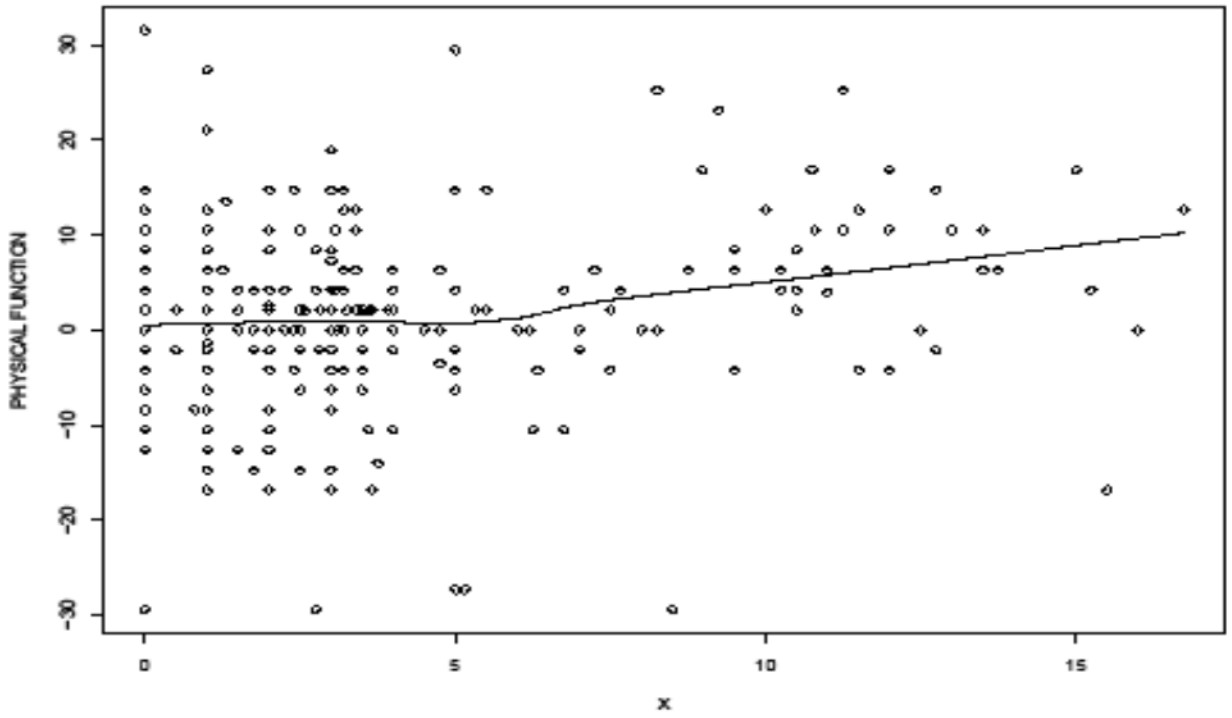


Figure 1: Hours>5, strength of association (using Theil-Sen estimator) is .34. (Pearson=.26 and Wincor=.35.)

Summary of Robust WE2 Analyses

- Association between attendance and various change scores:
  - Low attendance: little or no association
  - Association appears as attendance increases
- Robust methods are important when assessing strength of association and effect size
- Ethnic concordance: medium to large effect size for:
  - Physical function
  - Bodily pain
  - Physical composite
  - Immediate recall

Robust Data Set

- Measurement
  - 17 paper & pencil questionnaires:
    - Health-Related Quality of Life
    - Perceived Physical Health
    - Psychosocial Well-being
  - 3 Cognitive tests:
    - Memory
    - Visual Search
    - Psychomotor Speed
  - Biomarkers:
    - Blood Pressure
    - Diurnal saliva sampling (Cortisol, DHEA, Alpha Amylase)

Robust Data Set

- Data Points
  - 1,517 Questionnaire and cognitive testings
    - 433,128 data points
  - 1,155 Saliva samples, survey and blood pressure collected
    - 39,270 data points
  - Lists of medications
    - range from 0-31 for 1,155 participants

Conclusion

- Well Elderly Study 1 demonstrated the efficacy of a Lifestyle Redesign® intervention
- Well Elderly Study 2 documented the effectiveness of a Lifestyle Redesign® intervention
  - Applied to a sample of older adults at higher risk for experiencing health disparities
  - Implemented in diverse community settings
  - Delivered within a shorter time interval
- Cost-Effective
- Change in activity seemed to mediate the treatment effect
- A minimum of 5 individualized sessions with group sessions increased the treatment effect.
- Ethnic concordance increased the treatment effect.

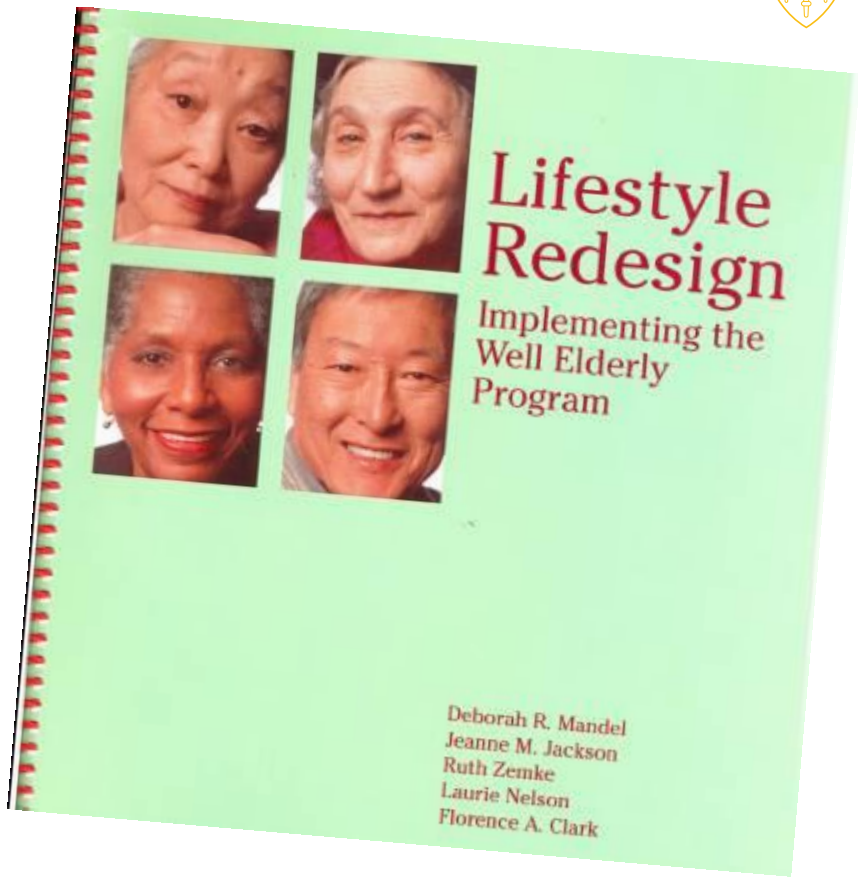
The Well Elderly Intervention Model

Lifestyle Redesign®

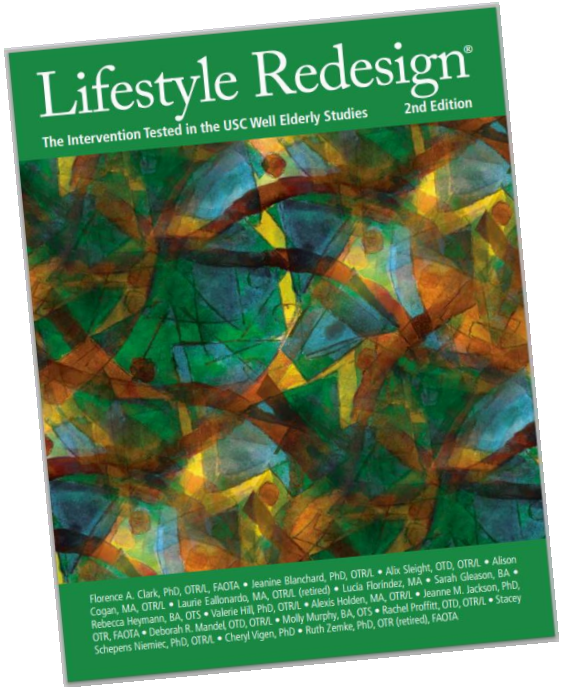
USC Chan Division of Occupational Science and Occupational Therapy

University of Southern California

Lifestyle Redesign® enables patients to design, practice, and ultimately enact a personalized, sustainable health-promoting daily routine that is tailored to address CD risk factors as well as promote health and well-being more generally.



Intervention Modules



1. Occupation, Health, and Aging
2. Community Mobility, Transportation, and Occupation
3. The Building Blocks of Longevity: Various Types of Activity
4. Stress and Inflammation Management
5. Dining and Nutrition
6. Time and Occupation
7. Home and Community Safety
8. Relationships and Occupation
9. Thriving
10. Navigating Healthcare
11. Hormones, Aging, & Sexuality
12. Ending a Group – Finalizing Personal Engagement Plans (PEPs)

Lifestyle Redesign®

- Becoming hyper-cognizant of activity patterns
  - Notice and name activities
  - Learn the relationship of activities to health & well-being
- Activity Pattern Analysis
  - Self-reflect
  - Identify barriers
  - Identify options and alternatives
- Lifestyle Redesign®
  - Select personalized healthy activity options
  - Make changes in daily routines
  - Practice habits and routines
- Personalized Health Plan Engagement (PEP)

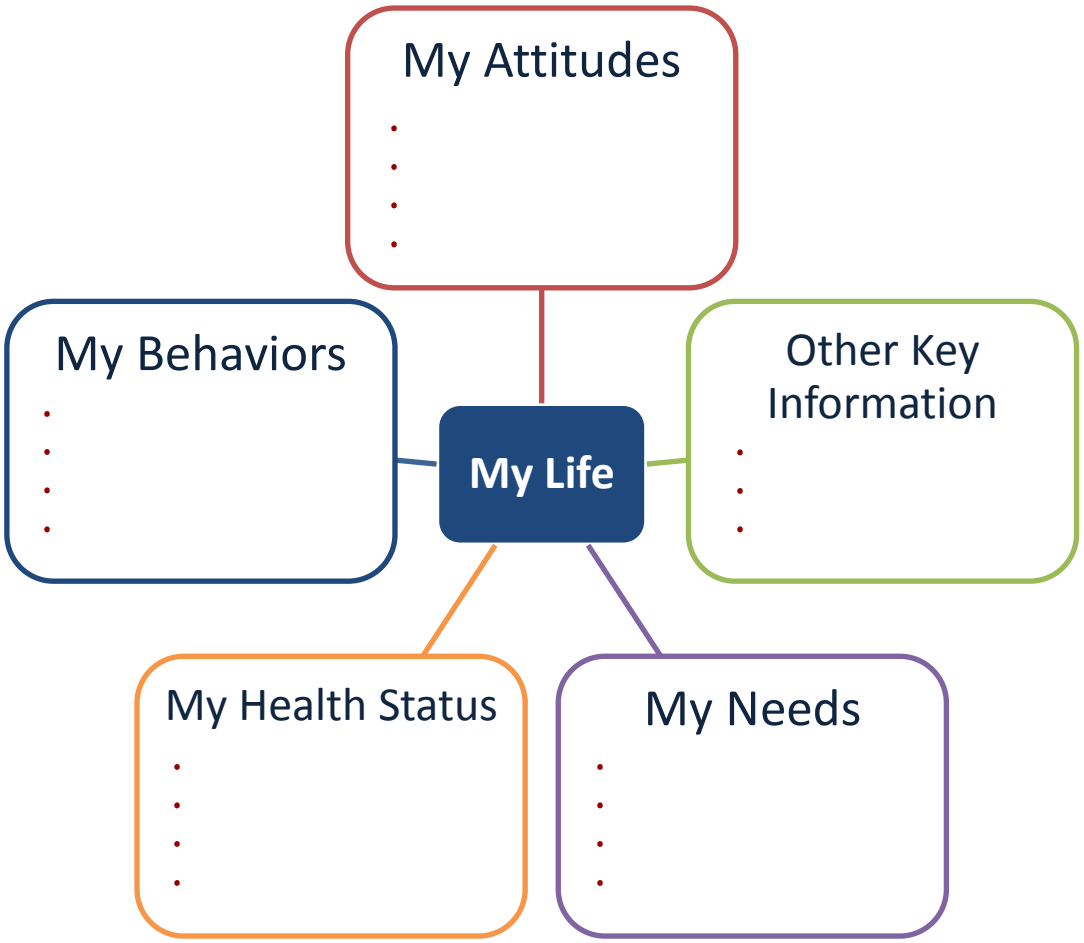
Intervention Comparison

	Component	Comparator (LAC-DHS Usual Care)	*¡Vivir Mi Vida!*
Content	Primary Medical Care	X	
	Specialty Medical Care	X	
	Chronic Disease Risk and Management	X	X
	Goal Setting and Tracking	X	X
	Weight Management/ Diet	X	X
	Management of CVD, Diabetes	X	X
	Behavioral/Mental Health	X	X
	Meaningful Activity		X
	Self-Efficacy		X
	Barriers and Solutions to Care in Daily Life		X
	LAC-DHS System Navigation		X
	Personalized Health Planning		X
	Community Health-Related Resources		X
	Low-Cost Healthy Living		X
	Family Focus		X
Modalities	Group Classes	X	X
	In-Home Sessions		X
	Promotor-Led		X
	Outings		X
	Patient Networking Groups		X

Structure of the Lifestyle Redesign Intervention

- Two-hour group sessions held each week for 9 months (Well Elderly I) or 6 months (Well Elderly II)
- Led by an occupational therapist
- Group ventured into the community once every four weeks
- Up to 10 hours of individual sessions offered to each participant

Personal Engagement Plan (PEP)



The PEP should be:

- Introduced early as part of the group session
- Reviewed regularly at individual sessions

The PEP includes:

- Personal inventory of strengths and weaknesses
- Inventory of relevant personal factors
- Goals worksheet
- Daily health-promoting routine planner

Formulating and Implementing the PEP

Acquiring knowledge of factors related to occupation that promote health and happiness

Performing a personal inventory and reflecting on one's fears and occupational choices, interests, life goals, etc.

Overcoming one's fears by taking incremental risks in the real world of activity in small steps over time

Weaving together the outcomes of the prior steps to develop and sustain a health-promoting daily routine

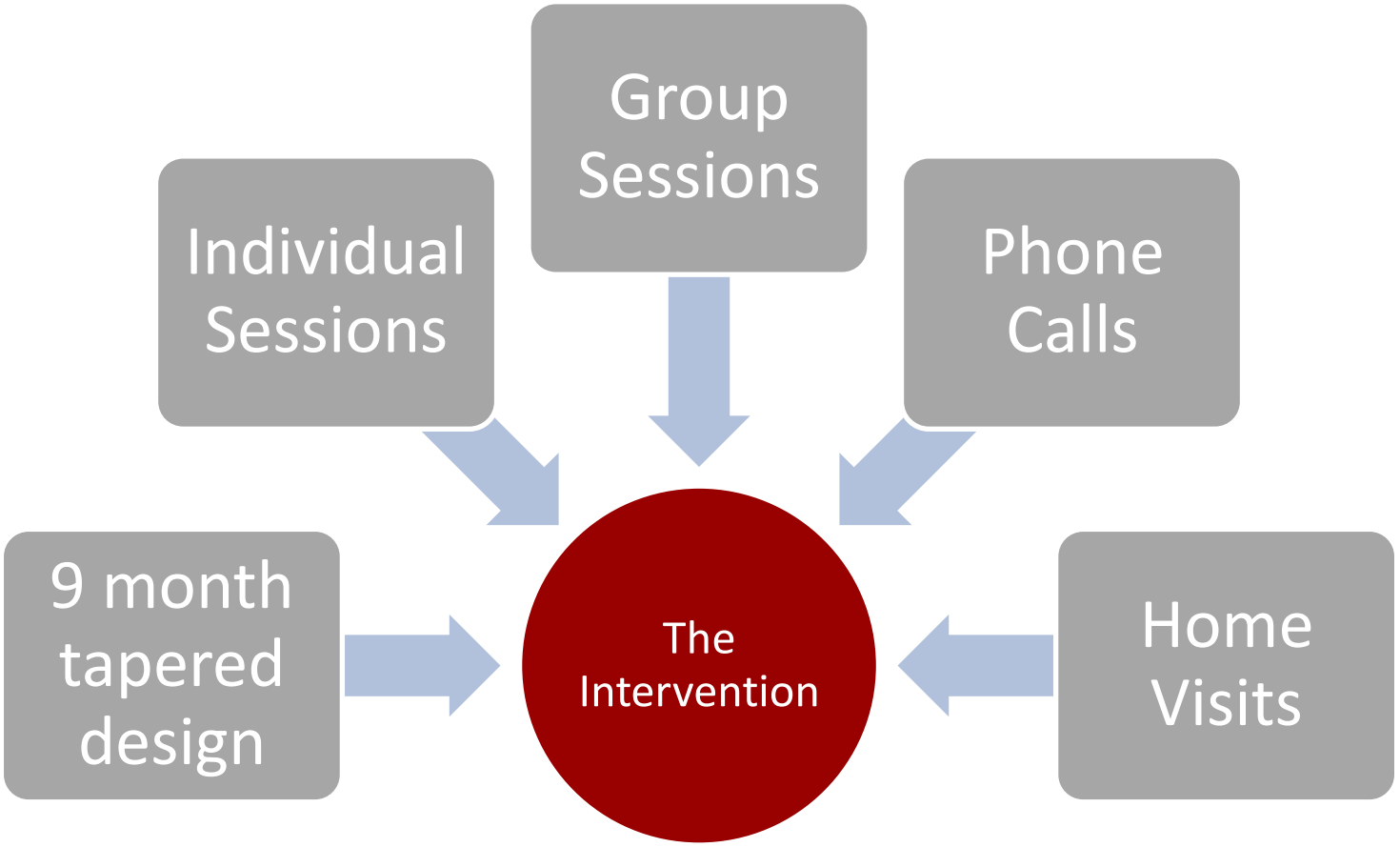
Mechanisms of Change

- Knowledge Acquisition
- Internalization
- Habit Formation

The USC Well Elderly Studies led to…

- Lectures
- Manuals
- Translation in six European nations
- UK National Institute for Health and Clinical Excellence public health guidelines
- Independent analyses

This Lifestyle Redesign® intervention approach is now beginning to be incorporated into public health policy and widely disseminated internationally


Group Sessions
Individual Sessions
Phone Calls
9 month tapered design
The Intervention
Home Visits

OUR VISION:

Lifestyle Redesign® in primary care

The need for comprehensive life management programs in primary care

- Symptom management vs. prevention
- Keeping body systems in good health throughout life
- Changing activity patterns early
- Increasing the overall conditioning of the body
- Reducing inflammation before disease onset

Adopting a healthy lifestyle later in life

- Only 8.5% of middle-aged adults practice healthy lifestyles
  - *Healthy diet*
  - *Regular exercise*
  - *Maintaining a healthy weight*
  - *Not smoking*
- Only 8.4% newly adopt such a lifestyle past age 45
- **After only 4 years**, adopting a healthy lifestyle in middle age can:
  - *Reduce mortality risk by 40%*
  - *Reduce cardiovascular disease risk by 35%*

…IT'S NEVER TOO LATE TO START LIVING A HEALTHIER LIFE