The Lifestyle Redesign® Intervention:
The Design Process & Evidence for Effectiveness

Dr. Florence Clark, PhD, OTR/L, FAOTA
Aging, Health, and Chronic Disease
What's the big deal?

• Chronic disease
• Disability
• Prevention

“Apparently they’re better than The Cure”
Health and Aging

Age-related chronic diseases lead to:

- Medically serious co-morbidities
- Stress and depression
- Reduced activities
- Unemployment

Pain
The Aging Global Population

Percentage Change in the World Population by Age from 2010 to 2050

- 0-64: 22
- +65: 188
- +85: 351
- +100: 1004

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Living with Chronic Disease

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

<table>
<thead>
<tr>
<th>Top 5 Causes of Death (Israel, 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cancer</td>
</tr>
<tr>
<td>2. Heart diseases</td>
</tr>
<tr>
<td>3. Cerebrovascular diseases (stroke)</td>
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<tr>
<td>4. Chronic respiratory diseases</td>
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<tr>
<td>5. Diabetes</td>
</tr>
</tbody>
</table>
WE BECOME WHAT WE HAVE DONE: AGING WELL
Aging Around the World

- Hippocratic Medicine
- Traditional Chinese Medicine
- Sardinia
- Seventh-Day Adventists
- Okinawan Secrets
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

Chooses healthy, meaningful routines and habits

Exercises 5 days/week

Adds quality years to life

Eats a diet high in refined sugars and processed foods

Increases BMI, Diagnosed with Diabetes

Engages in mostly sedentary activities

Reduces ability to participate in meaningful activities

Decreases quality of life

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“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.”

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
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<th>Award #</th>
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<td>$223,852</td>
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<td>Daily Living Context and Pressure Sores in Consumers with SCI</td>
<td>DOE/ NIDRR</td>
<td>#H133G000062</td>
<td>$467,851</td>
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<td><strong>Total:</strong> $6,731,097</td>
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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 Ennever, Allyn Rankin-Martinez, LuAn Hobson, Jennifer Crandall, Deborah Mandel, Loren Lipson

Key Words: aged • qualitative method

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
Three experimental conditions

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

Randomized Controlled Trial (n = 361)
WE 1 RCT Design

Month 1

Occupational Therapy Intervention

Follow

Social Group Control

Follow

No Treatment Control

Health Care Utilization Data Collection

Intervention:
- 38 group sessions
- up to 9 hours of individual sessions
Well Elderly Study 1:
Intent-to-Treat

- Occupational Therapy
- Control

Vitality
General Health
Absence of Health-Based Role Limitations
Social Functioning
General Mental Health
Absence of Bodily Pain
Physical Functioning
Absence of Emotion-Based Role Limitations

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University of Southern California
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 Lipson3

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
© 2002 by the American Geriatrics Society

Intervention Outcomes

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

Cost per QALY was $10,666
$50,000 defined cost-effective interventions
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

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

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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

Lifestyle Redesign Intervention

- Improved Psychosocial and Physical Health
- Gains Sustained Six Months Later
- Cost Effective

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Conceptual Model of Positive Effects of Lifestyle Intervention for Older People

Intervention

Healthy Activity
Active Coping
Social Support
Perceived Control

Positive Reinterpretation-Based Coping

Stress-Related Biomarkers

Perceived Physical Health
Psychosocial Well-Being
Cognitive Functioning

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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

Month 1 6 12 18 24

Group A Intervention
Group B Control
Follow
Group B Intervention
Follow
Follow
Follow

Tested every 6 months

Intervention:
• 26 group sessions
• Up to 10 hours of individual sessions
Intent-to-Treat Analysis
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, Jeanne Jackson, Mike Carlson, Chih-Ping Chou, Barbara J Cherry, Maryalice Jordan-Marsh, Bob G Knight, Deborah Mandel, Jeanine Blanchard, Douglas A Granger, Rand R Wilcox, Mei Ying Lai, Brett White, Joel Hay, Claudia Lam, Abbey Marterella, Stanley P Azen

ABSTRACT
Background Elder 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 a 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. 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. 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.

This article reports on the University of Southern California Well Elderly 2 study, which assessed the
Well Elderly 2
Intent-to-Treat Design

Month | 1 | 6 | 12 | 18 | 24
--- | --- | --- | --- | --- | ---
Group A Intervention | Follow | Follow | Follow | Follow |
Group B Control | Group B Intervention | Follow | Follow |

Tested every 6 months
Well Elderly Study 2: Intent-to-Treat
Treatment (n=187) vs. Control (n=173)

<table>
<thead>
<tr>
<th>Health-Related Quality of Life - SF36V2</th>
<th>Life Satisfaction - LSI-Z 0.03</th>
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<tbody>
<tr>
<td>Mental Health</td>
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<tr>
<td>Social Function</td>
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<tr>
<td>Vitality</td>
<td>0.03</td>
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<tr>
<td>Bodily Pain</td>
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<tr>
<td>Composite: Mental</td>
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<td>Composite: Physical</td>
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<th>Depression - CES-D 0.03</th>
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<tbody>
<tr>
<td>Cognition</td>
</tr>
<tr>
<td>Memory - CERAD 0.20</td>
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<tr>
<td>Visual Search 0.49</td>
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<tr>
<td>Psychomotor Speed 0.49</td>
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</table>
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)

<table>
<thead>
<tr>
<th>Month</th>
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<th>6</th>
<th>12</th>
<th>18</th>
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<td>Group A Intervention</td>
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<td>Group B Control</td>
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University of Southern California
Secondary Analysis: Pre-Post Intervention
Group B (Control) Receive Intervention (n = 137)

<table>
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<tr>
<th>Health-Related Quality of Life - SF36V2</th>
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<td>Social Function</td>
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| Life Satisfaction - LSI-Z              | 0.02 |
| Depression - CES-D                     | 0.01 |

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Secondary Analysis: Pre-Post Intervention
All Participants Receiving Intervention

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<td>Group B</td>
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University of Southern California
### Secondary Analysis: Pre-Post Intervention

All Participants Receiving Intervention (n = 326)

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<th>Health-Related Quality of Life - SF36V2</th>
<th>Life Satisfaction - LSI-Z</th>
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### Cognition

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<td>Psychomotor Speed</td>
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A Feature Missed by Usual Methods

Figure 1: Hours $> 5$, strength of association (using Theil-Sen estimator) is .34. (Pearson = .26 and Wincoff = .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®
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)
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<tr>
<th>Component</th>
<th>Comparator (LAC-DHS Usual Care)</th>
<th>¡Vivir Mi Vida!</th>
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<tr>
<td>Primary Medical Care</td>
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<td>Specialty Medical Care</td>
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<td>Weight Management/ Diet</td>
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<td>LAC-DHS System Navigation</td>
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<td>Personalized Health Planning</td>
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<td>Community Health-Related Resources</td>
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<td>Low-Cost Healthy Living</td>
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<td>Family Focus</td>
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<td>Group Classes</td>
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<td>Patient Networking Groups</td>
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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

My Life

My Attitudes

My Behaviors

My Health Status

My Needs

Other Key Information
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.
The Intervention

- Individual Sessions
- Group Sessions
- Phone Calls
- Home Visits
- 9 month tapered design
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