WHI

Dietary Modification (DM) Trial

WHI – DM Trial

Leslie Ford, MD
Session Moderator

Associate Director of Clinical Research
Division of Cancer Prevention,
National Cancer Institute
National Institutes of Health
Rockville, Maryland

Carolyn Clifford   1941-2001

DM Trial Morning Session I
The Intervention

- ☐ Background
- ☐ Hypothesis and Design
- ☐ The Dietary Change Program
- ☐ Personal Accounts of Dietary Change Participants
- ☐ Audience Questions

WOMEN'S HEALTH INITIATIVE

Dietary

DM Trial
Background and Hypothesis

☐ Background
   Maureen Henderson, OBE, MD, DPH

☐ Hypothesis and Design
   Ross Prentice, PhD

Dietary Modification Trial Background

Maureen Henderson, OBE, MD, DPH
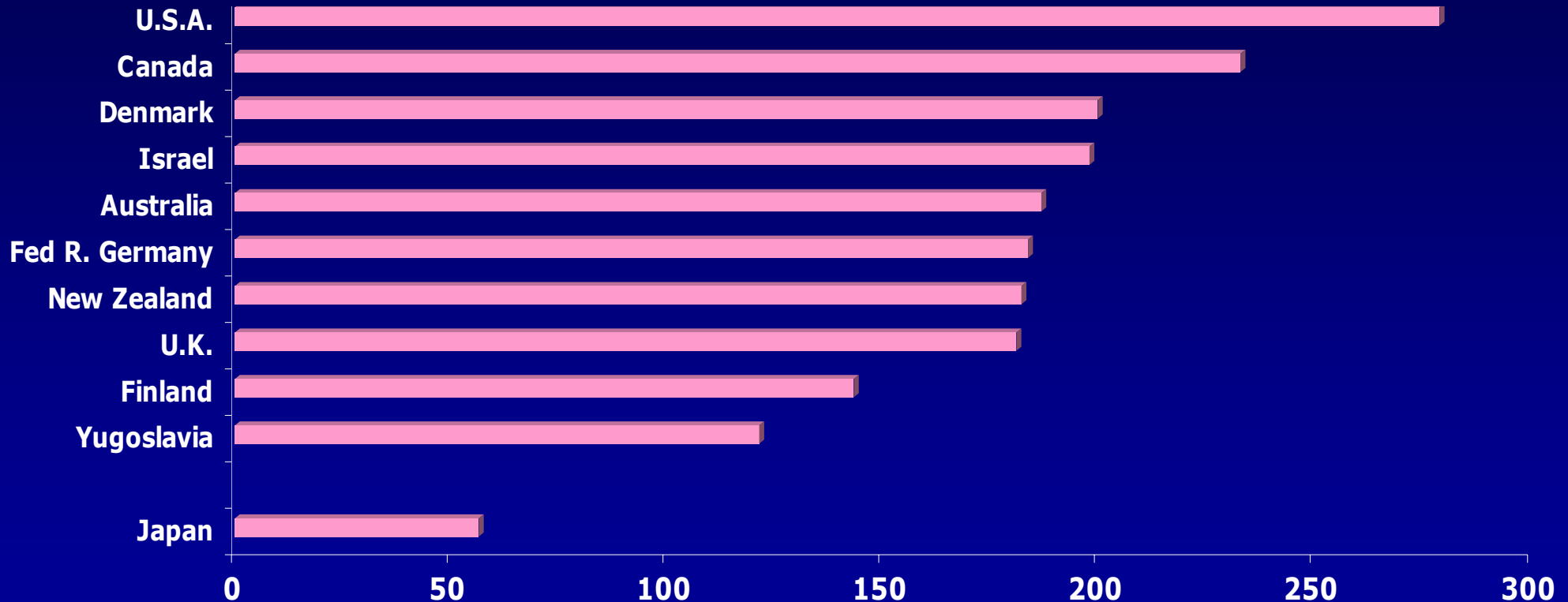
Past Principal Investigator

Seattle Clinical Center

Emeritus Professor of Epidemiology and Medicine

University of Washington

Seattle, Washington

Dietary

Breast Cancer Rates by Country

Country	Breast cancer incidence per 100,000 women 55-69 years of age
U.S.A.	~280
Canada	~233
Denmark	~200
Israel	~199
Australia	~188
Fed R. Germany	~185
New Zealand	~183
U.K.	~182
Finland	~145
Yugoslavia	~123
Japan	~58

**Breast cancer incidence per 100,000 women
55-69 years of age**

Cancer Incidence in Five Continents **vol. V. WHO, IARC, 1987**

Dietary

Feasibility & Safety of the Intervention

❑ **Feasibility**

■ Low-fat eating patterns can be achieved and maintained by women of all ages, income, breast cancer risk levels, and racial and ethnic backgrounds

❑ **Safety**

■ No serious side effects during either two year study or among a sample of study women 2 years later

■ Eating 5+ servings of fruit and vegetables and 6+ servings of grains were made into specific goals for the WHI instead of recommendations as in the two pilot studies.

Colorectal Cancer

Coronary Heart Disease

☐ WHI designed primarily for breast cancer

☐ However, WHT pilot studies showed:

  ■ A persistent reduction in:

    ☐ Total fat intake

    ☐ Saturated fat intake

    ☐ Total blood cholesterol

  ■ No increase in polyunsaturated fats

☐ For safety reasons no further changes in P/S ratio were proposed for the WHI

Women's Health Trial Vanguard Pilot Study: Intervention Group

Measure	Baseline	Year 1	Year 2
Total fat, percent of calories	39.1%	21.6%	22.6%
Saturated fat, percent of calories	13.8%	7.0%	7.2%
Blood cholesterol	221 mg/dL	207 md/dL	210 mg/dL

Dietary

Dietary Modification Trial Hypothesis and Design

Ross Prentice, PhD

Principal Investigator

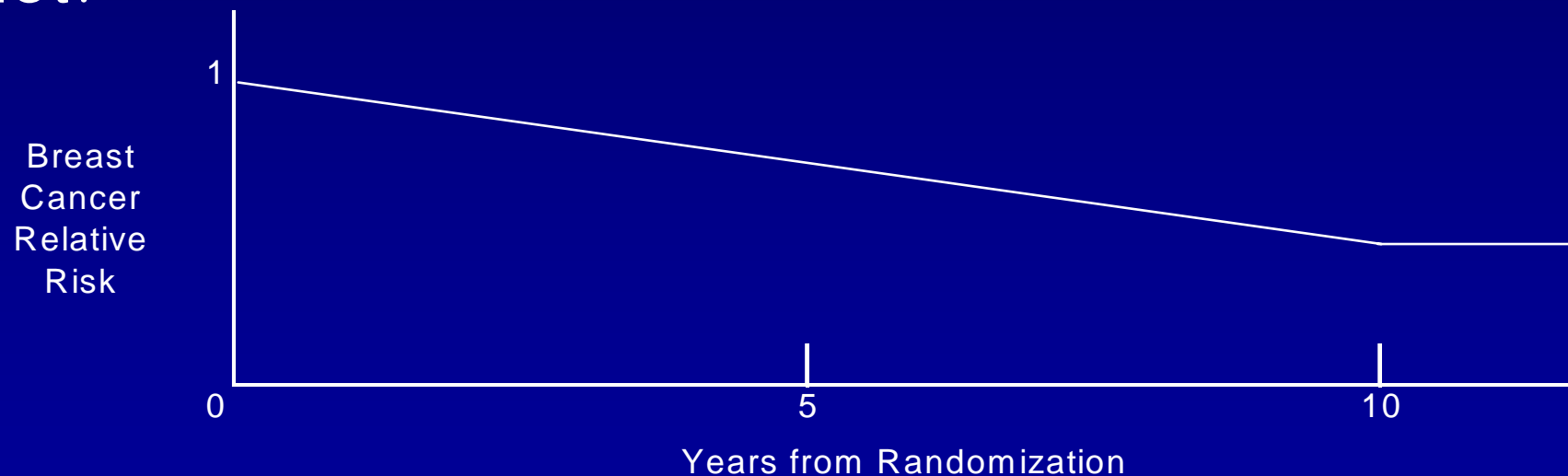Clinical Coordinating Center

Member, Public Health Sciences Division

Fred Hutchinson Cancer Research Center
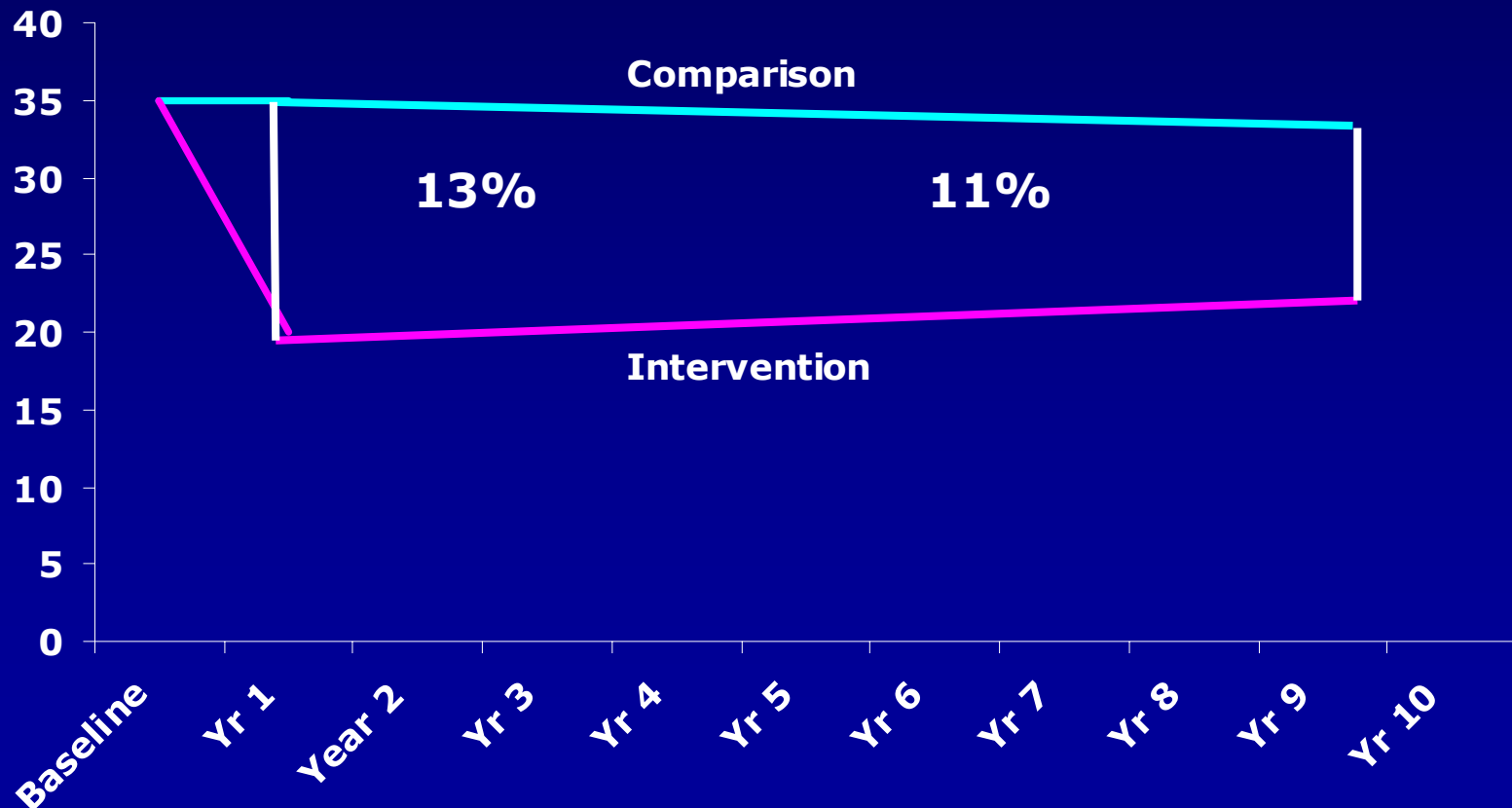
Seattle, Washington

Dietary

Premise of the DM Trial

International comparisons, time trend and migrant studies, motivated the trial, and led to the basic trial hypothesis for a 20% versus a 40% energy from fat diet.
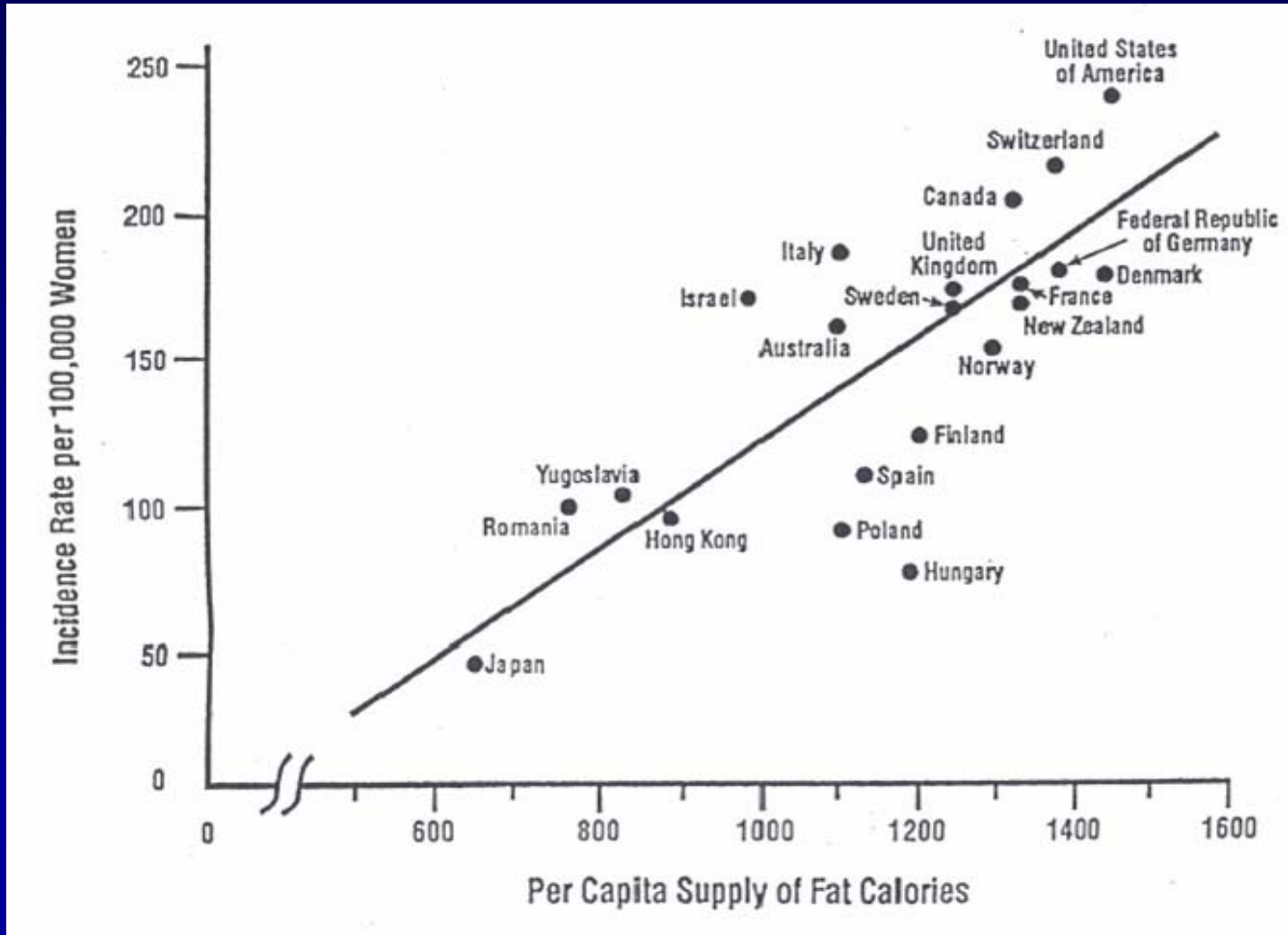
Adherence Assumptions

Feasibility study data were used to specify an adherence assumption.

Dietary

Breast Cancer Incidence
Age-Adjusted

Women of ages 45-69 1973-1977 versus per capita fat consumption 1975 -1977

Dietary

Dietary Fat & Postmenopausal Breast Cancer

Fat Consumption Quintile

Case-control Studies

Howe et al *(1990, JNCI)*	1	1.20	1.24	1.24	1.46	(p<.0001)

Cohort Studies

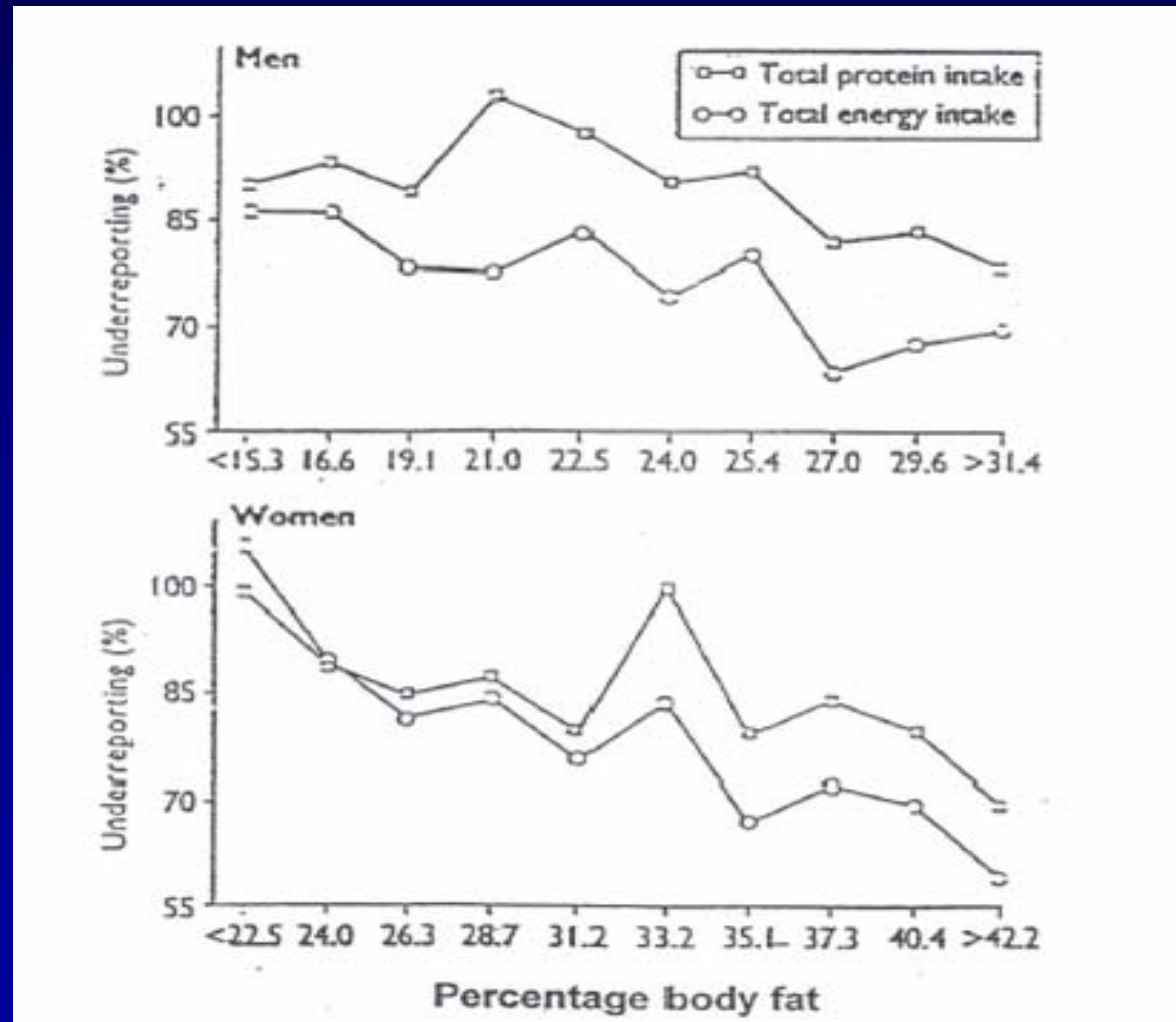|						
Hunter et al *(1996, NEJM)*	1	1.01	1.12	1.07	1.05	(p=0.21)

Ability to adequately characterize and adjust for measurement error?

Dietary

Underreporting of Energy and Protein

Dietary

DM Eligibility & Assumptions

- ☐ Women having FFQ% energy from fat <32% were excluded.

- ☐ National breast cancer incidence rates projected for control group.

- ☐ Loss to follow-up and competing risk assumptions incorporated.

- ☐ Assumptions combine to give a projected **14%** lower breast cancer incidence in the intervention (I) versus the comparison (C) group

Dietary

Some Elements of Study Design

- Target sample size 48,000
- Excludes women with prior breast or colorectal cancer
- Age and ethnicity goals
- 40% Intervention; 60% Comparison
- Projected power
  - Invasive breast cancer   86%
  - Colorectal cancer   90%
  - Coronary heart disease   86%
- Dietary intervention program based on NCI-sponsored feasibility studies

DM Trial
Dietary Change Session

- ☐ Dietary Change Program
  Deborah Bowen, PhD

- ☐ Predictors of Change
  Lesley Tinker, PhD, RD

The Dietary Change Program

Deborah J. Bowen, PhD
Co-investigator
Clinical Coordinating Center

Professor – University of Washington
Member - Fred Hutchinson Cancer Research Center
Seattle, Washington

Dietary Change Goals:
Intervention Group

- ☐ 20% energy from fat

- ☐ 5 or more fruit and vegetable servings daily

- ☐ 6 or more grain servings daily

Photos courtesy of USDA Agricultural Research Service

Dietary

Packaging the Strategies:
Structure of the Intervention

CORE

**18 group sessions
Year 1**

**Quarterly maintenance sessions
Year 2 and beyond**

BASELINE ⟶ **END OF DM TRIAL** ⟶

AUGMENTATIONS

• <u>Motivational Interviewing</u> –3 personal contacts
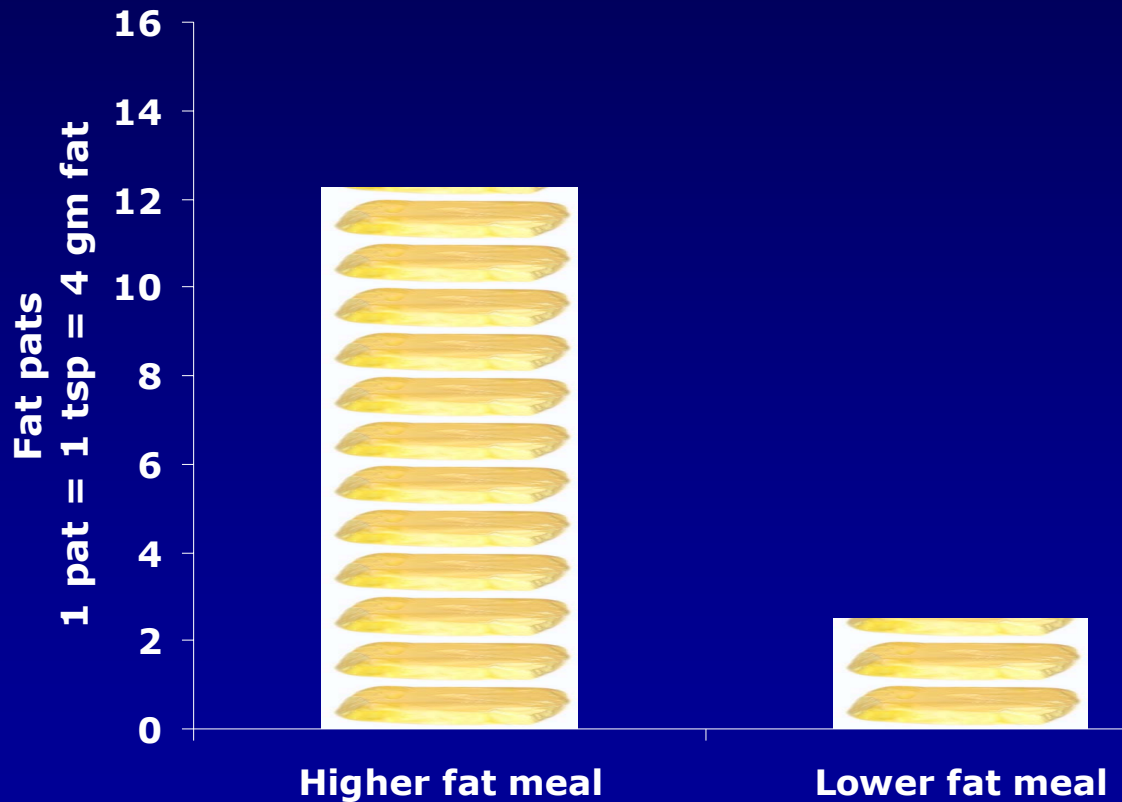
• <u>Targeted Messaging</u> – Mailing

• <u>Tailored Feedback</u>: Personal Evaluation of Fat Intake – Group sessions

• <u>Tailored Feedback</u>:
Personal Evaluation of Fat Intake–Mailing

• <u>Clinical Center augmentations</u>

WOMEN'S
HEALTH
INITIATIVE

Dietary

Fats of Life – Fats in Foods

**Higher fat meal =
49 fat grams**

Fried chicken breast (3 oz)

Potato salad (1/2 cup)

Green beans and bacon (1/2 cup)

Cornbread (3 by 3 1 inches)

**Lower fat meal =
10 fat grams**

Roast chicken breast no skin (3 oz)

Brown rice (1/2 cup)

Green beans (1/2 cup) with 1 tsp seasoned oil

Whole wheat roll, 1 medium

Fat pats
1 pat = 1 tsp = 4 gm fat

16
14
12
10
8
6
4
2
0

Higher fat meal   Lower fat meal

Dietary

Nutritional strategies

- ☐ Fat identification

- ☐ Food purchasing

- ☐ Food preparation

- ☐ Fat budgeting

Behavioral strategies

- ☐ Self-Management

- ☐ Cognitive behavioral strategies

- ☐ Social support and interaction

- ☐ Relapse prevention

- ☐ Self-determination and self-efficacy

WOMEN'S
HEALTH
INITIATIVE

Dietary

Adherence strategies

- **Regular contact**

- **Record keeping**

- **Reinforcement of progress**

Women's Health Initiative Picture Tracker

Name:_____ Date:_____ Day:_____

5 or more Fruits/Vegetables – Circle

6 or more Grains - Circle

Low fat foods eaten…

High fat foods eaten…

Dietary

Augmented interventions

- ☐ Motivational interviewing techniques

- ☐ Enhanced intervention messages

- ☐ Enhanced interventions for special populations

Predictors of Dietary Change

Lesley Tinker, PhD, RD

Co-investigator

Clinical Coordinating Center

Nutrition Scientist

Fred Hutchinson Cancer Research Center
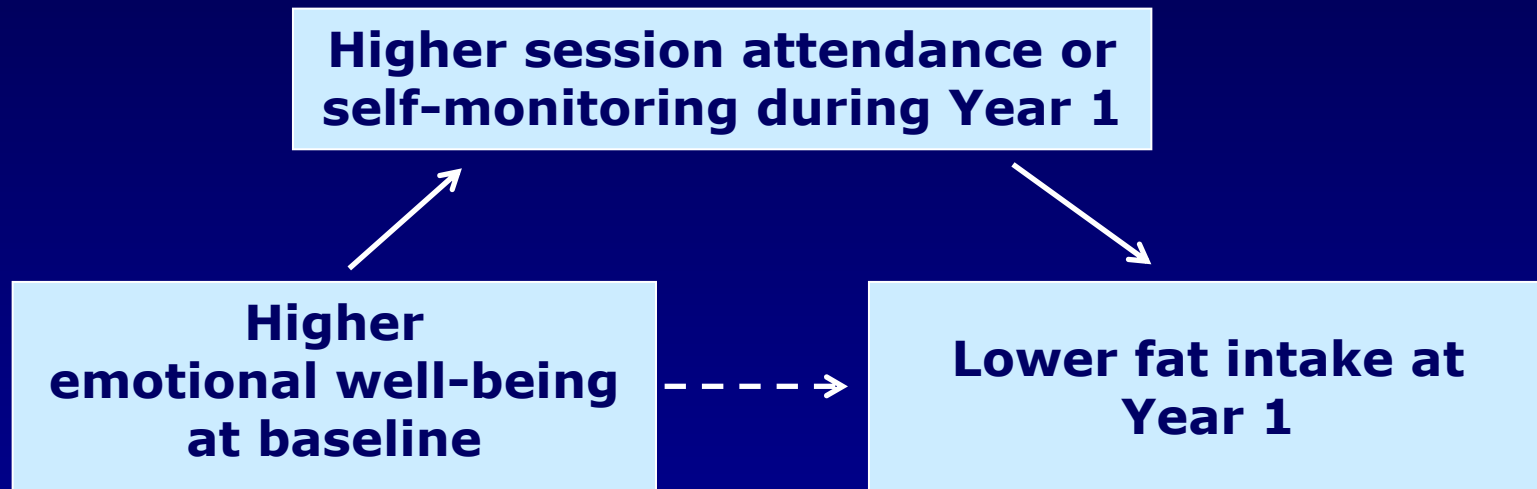
Seattle, Washington

What Have We Learned?

☐ <u>More</u> lowering of % calories from fat among:

- ■ ■ *** Women who attended more dietary sessions
- ■ ■ *** Women who self-monitored their food intake
- ■ ■ Women less than 65 years of age at baseline
- ■ ■ White women compared to African American women
- ■ ■ Women with BMI <35
- ■ White women compared to Hispanic women
- ■ Women with household incomes above $20,000 annually
- ■ Women also randomized to the HT Trial

■ Yr1 ■ Yr5

Dietary

Physical & Emotional Predictors of Dietary Change

Higher session attendance or self-monitoring during Year 1

Higher emotional well-being at baseline

Lower fat intake at Year 1

Some of the effect of emotional well-being on fat intake is mediated by session attendance and self-monitoring.

Dietary

Changes in Grams of Fat from Foods

Food	Intervention Group		
	Baseline	Yr 1 - Base	Yr 2 – Yr 1
Added fats	16.1	-12.5	0.8
Meats	13.6	-6.7	0.5
Desserts	7.1	-6.1	0.4
Milk, cheese	5.7	-3.5	0.2
Mixed dishes	6.0	-2.3	0.1
High-fat breads, salty snacks	3.7	-2.6	0.2

WOMEN'S HEALTH INITIATIVE

Dietary

DM Trial
Personal Accounts from Participants

Facilitators:

Yasmin Mossavar-Rahmani, PhD (NYC)

Linda Snetselaar, PhD, RD (Iowa)

Participants:

Dolores Buckley (Worcester)

Betty Cintas (Stanford)

Sylvia Grendisa (Buffalo)

Olga Lamarche (Seattle)

Marcia Mazur (George Washington University)

Dietary

Audience Questions

Leslie Ford, MD

Associate Director of Clinical Research
Division of Cancer Prevention,
National Cancer Institute
National Institutes of Health
Rockville, Maryland

DM Trial – The Results

- ☐ Overview and Baseline Demographics
  Norman Lasser, MD, PhD

- ☐ Dietary Assessment
  Cynthia Thomson, PhD, RD

- ☐ Dietary Change and Biomarkers
  Bette Caan, DrPH

DM Trial – The Results

- Breast Cancer
  Ross Prentice, PhD

- Colorectal Cancer
  Shirley Beresford, PhD

- Heart Disease and Stroke
  Linda Van Horn, PhD, RD

- Summary and Dietary Implications
  Peter Greenwald, MD, DrPH

- Audience Questions
  Leslie Ford, MD (Moderator)

WOMEN'S HEALTH INITIATIVE

Dietary

Recruitment, Retention, and Baseline Demographics

Norman Lasser, MD, PhD
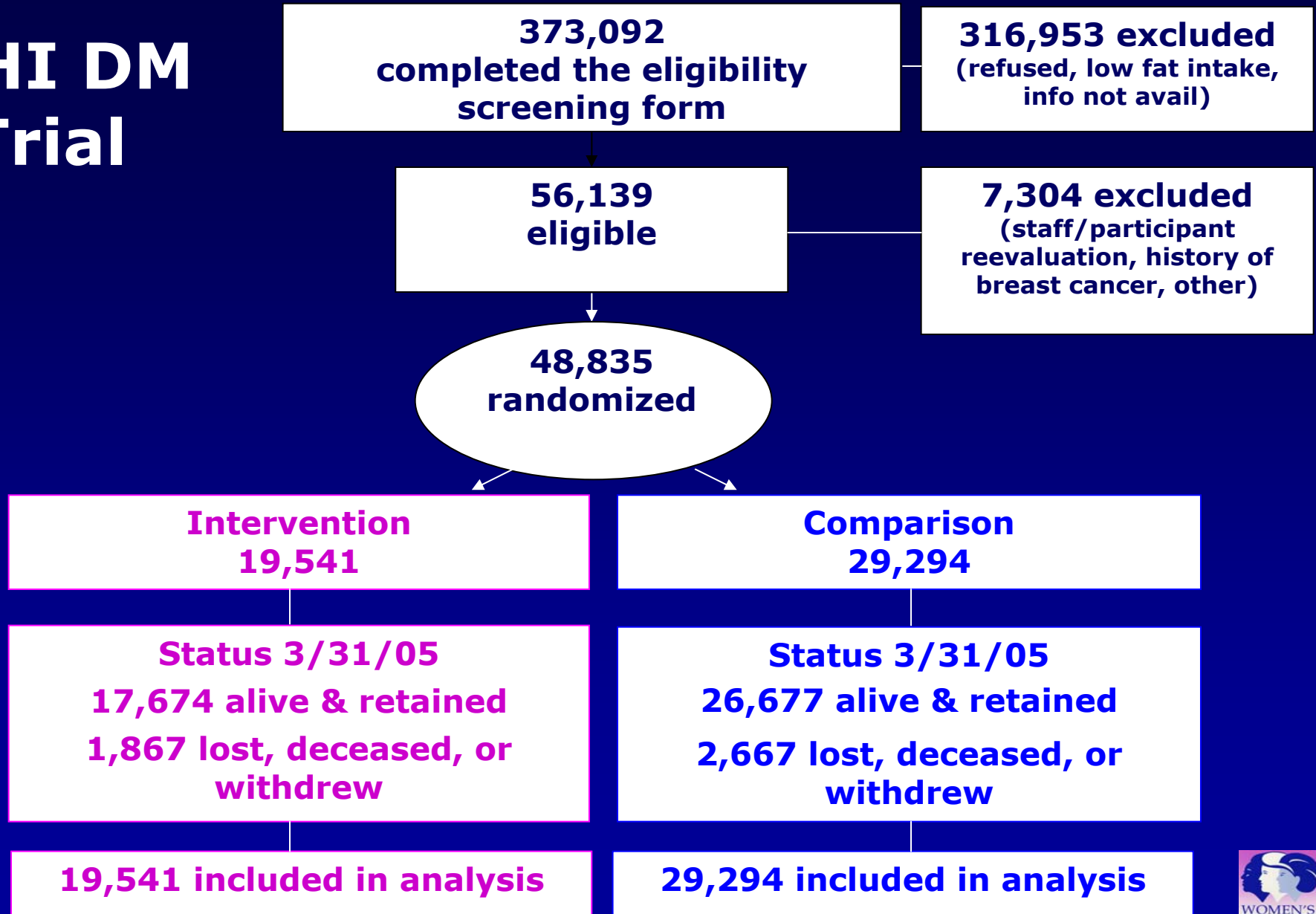
Principal Investigator

Newark Clinical Center

Professor of Medicine

University of Medicine and Dentistry of New Jersey, New Jersey Medical School
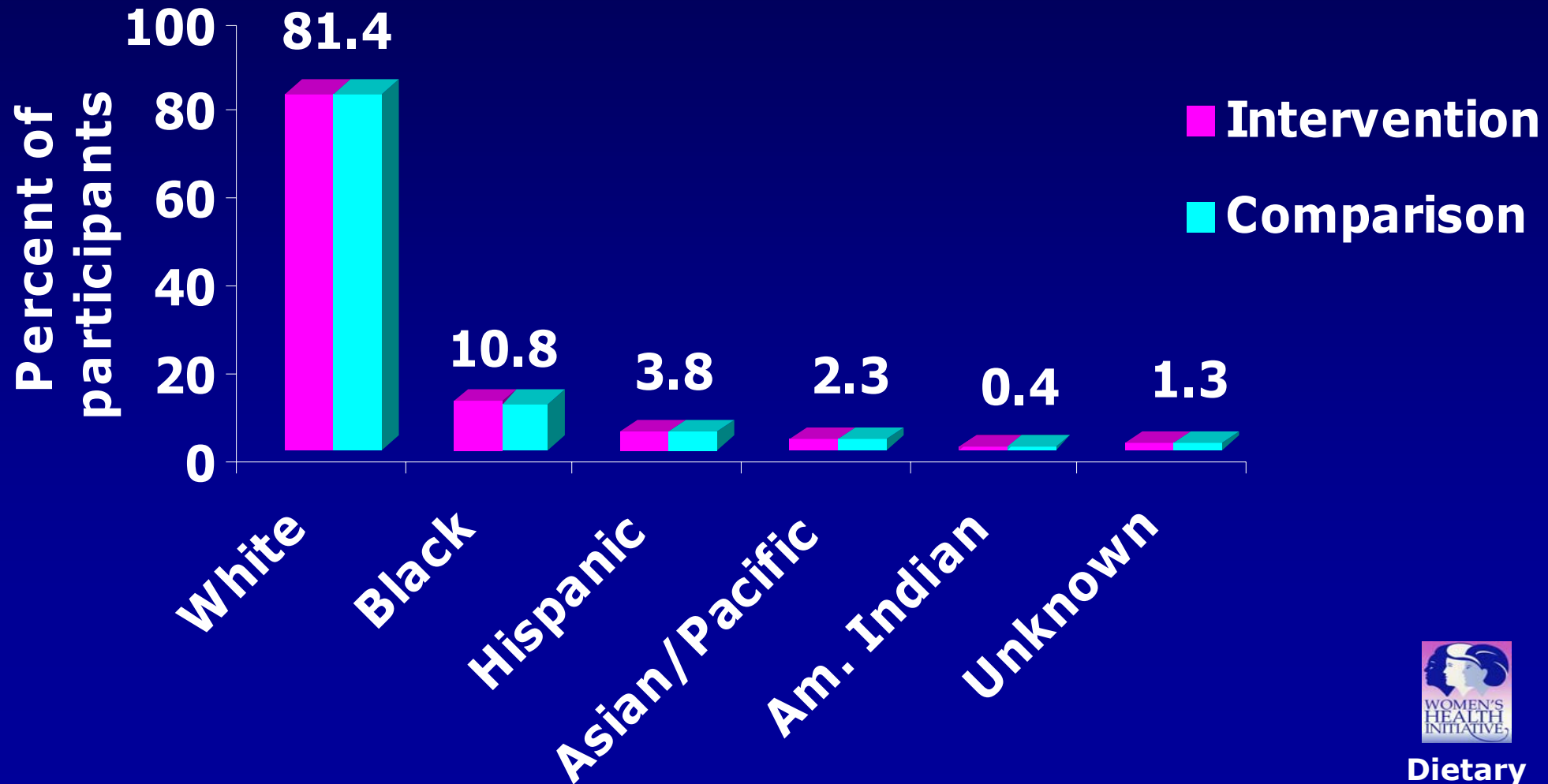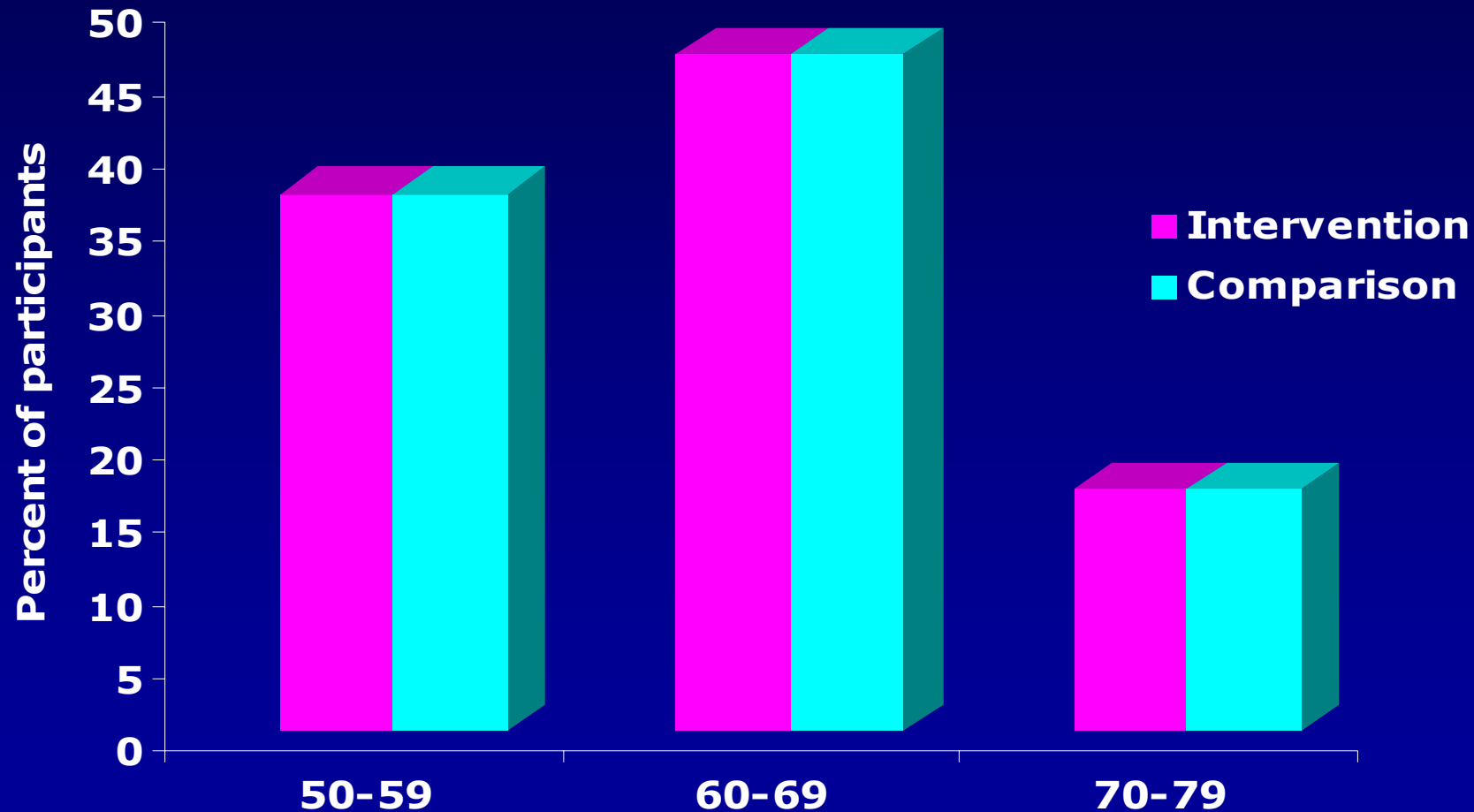
Newark, New Jersey

Dietary

WHI DM Trial

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┌─────────────────────────────┐     ┌──────────────────────────┐
│         373,092             │     │    316,953 excluded      │
│  completed the eligibility  │     │  (refused, low fat intake,│
│       screening form        │     │     info not avail)      │
└─────────────────────────────┘     └──────────────────────────┘
                │
                ▼
┌─────────────────────────────┐     ┌──────────────────────────┐
│         56,139              │     │     7,304 excluded       │
│         eligible            │─────│   (staff/participant     │
│                             │     │ reevaluation, history of │
│                             │     │   breast cancer, other)  │
└─────────────────────────────┘     └──────────────────────────┘
                │
                ▼
           ╱────────────╲
          │   48,835     │
          │  randomized  │
           ╲────────────╱
           ╱           ╲
          ▼             ▼
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Intervention 19,541	Comparison 29,294
Status 3/31/05 17,674 alive & retained 1,867 lost, deceased, or withdrew	**Status 3/31/05** 26,677 alive & retained 2,667 lost, deceased, or withdrew
19,541 included in analysis	**29,294 included in analysis**

WOMEN'S HEALTH INITIATIVE

Dietary

WHI DM Trial: Race and Ethnicity

Percent of participants

- Intervention
- Comparison

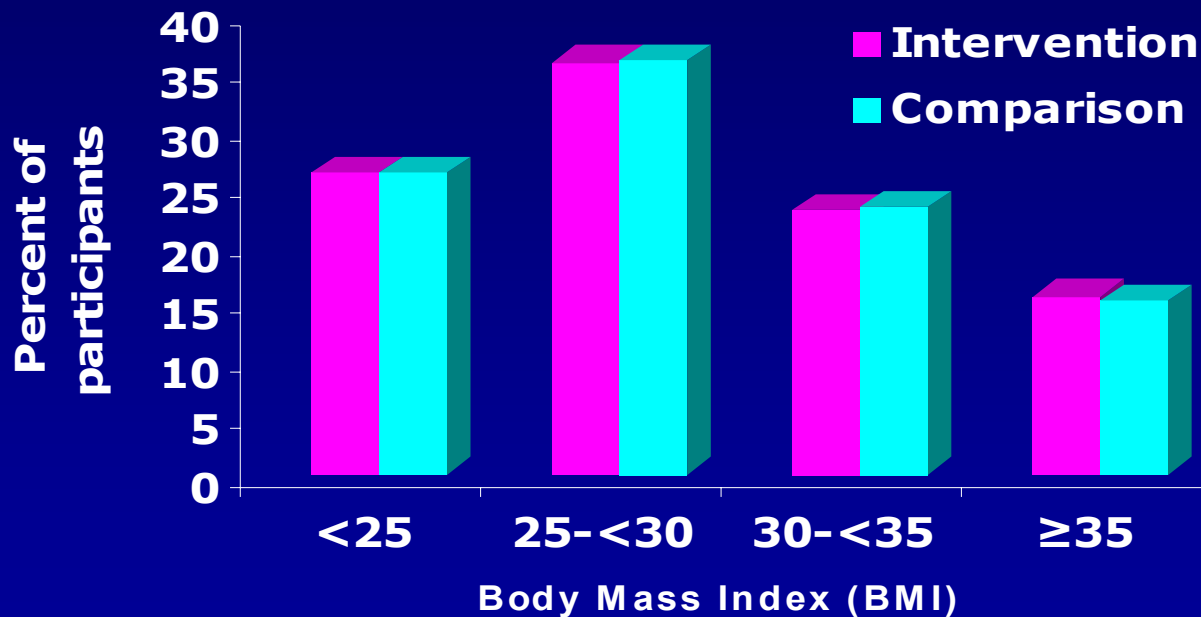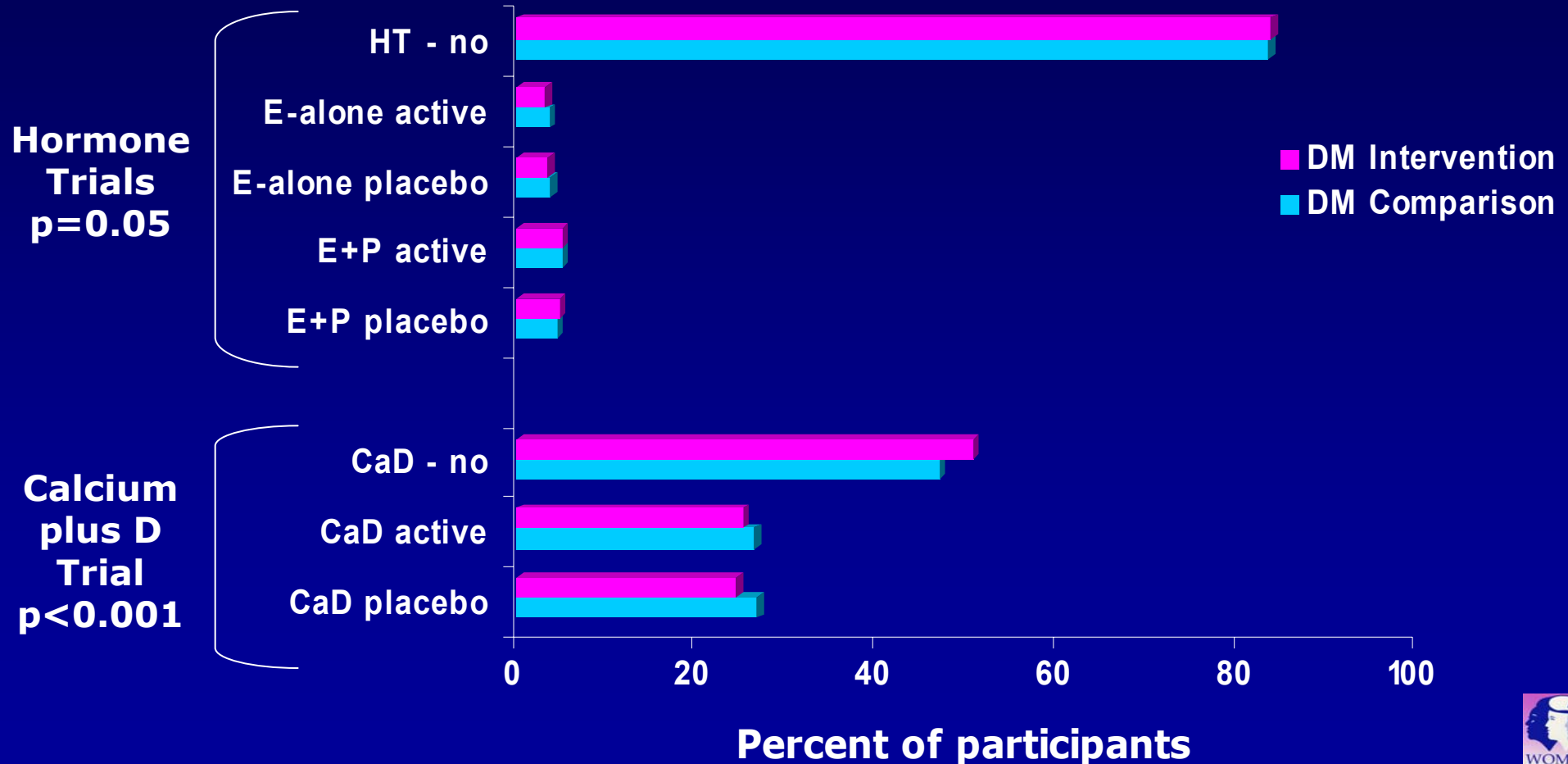| White	Black	Hispanic	Asian/Pacific	Am. Indian	Unknown
81.4	10.8	3.8	2.3	0.4	1.3

Dietary

Baseline Physical Characteristics

☐ **Waist circumference 89 cm**

☐ **Physical activity 10 METS**

☐ **Smoking 93% never or past 7% current**
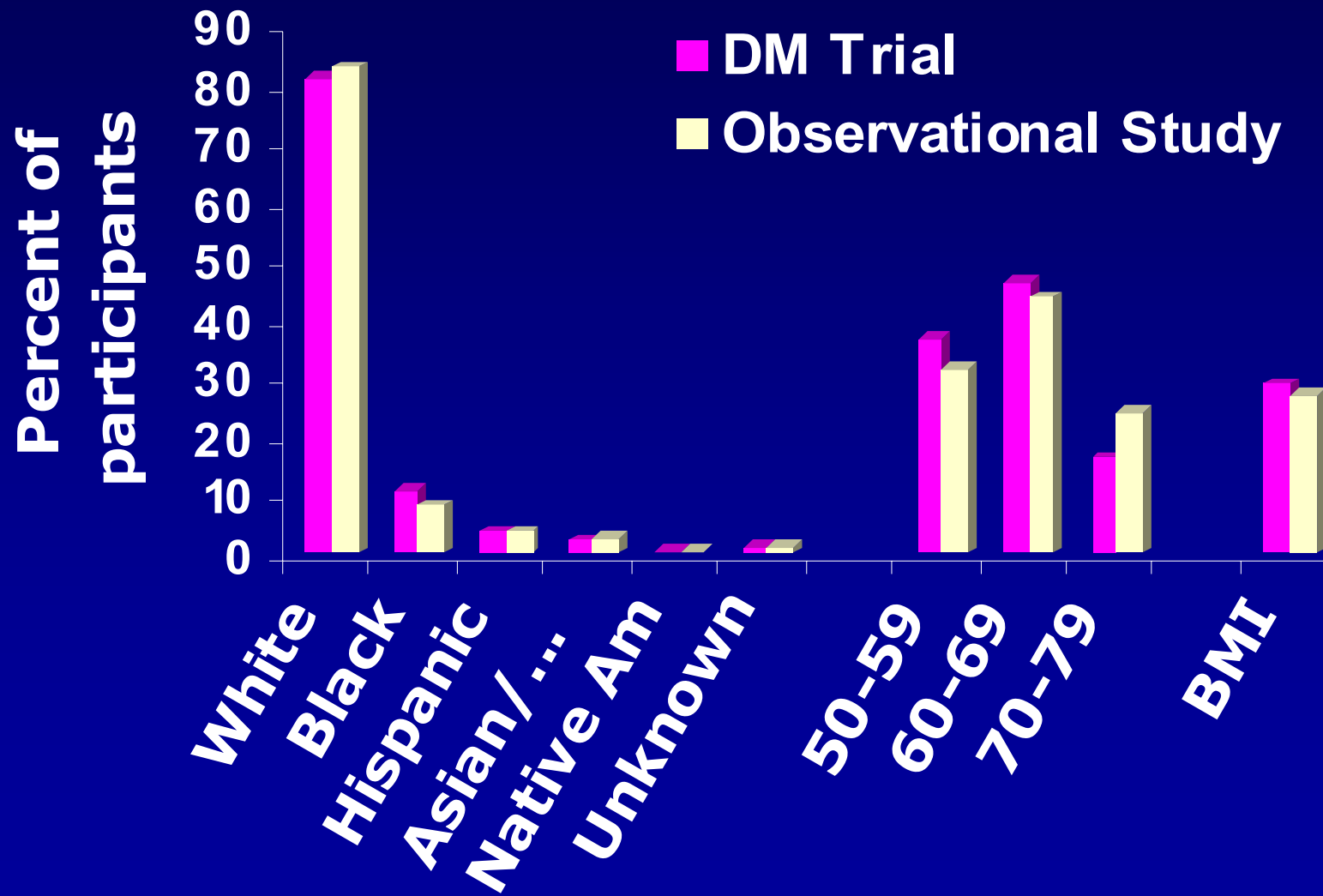
☐ **Alcohol 28% never or past 72% current**

☐ **Calories 1790**

Dietary

Overlap with WHI Hormone or Calcium Vitamin D Trials

Hormone Trials p=0.05
- HT - no
- E-alone active
- E-alone placebo
- E+P active
- E+P placebo

Calcium plus D Trial p<0.001
- CaD - no
- CaD active
- CaD placebo

Legend:
- ■ DM Intervention
- ■ DM Comparison

X-axis: Percent of participants (0, 20, 40, 60, 80, 100)

WOMEN'S HEALTH INITIATIVE

Dietary

Generalizability
Baseline characteristics DM and OS

Dietary

Dietary Assessment

Cynthia Thomson, PhD, RD

Co-Principal Investigator
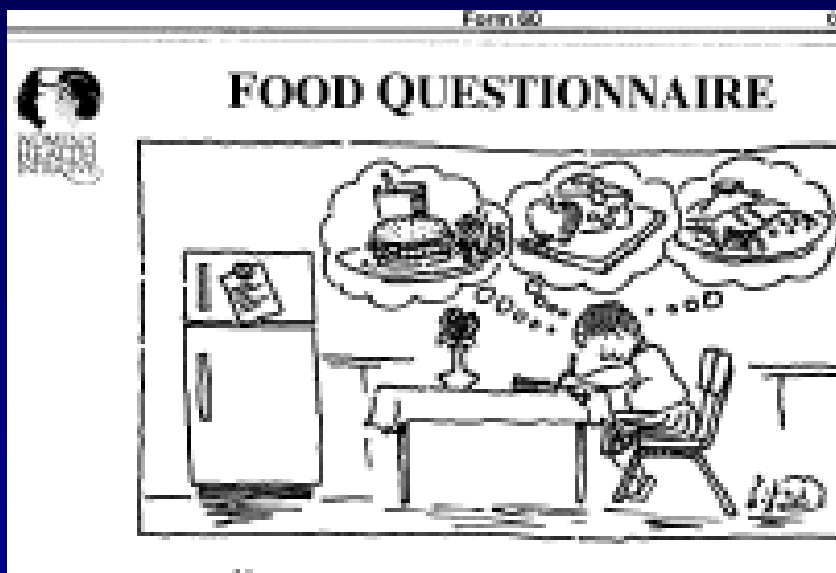
Tucson/Phoenix Clinical Center

University of Arizona

Tucson, Arizona

Dietary

How Was Diet Measured?

Study Start **Year 1** **Year 2→Close-out**

Food Frequency
Questionnaire
All

Food Frequency
Questionnaire
All

Food Frequency
Questionnaire
Rotating 1/3
of participants

**Assess
change
in intake
over time**

Year 3,6,9

4-day food records
Case only analysis

4-day food records
4.6% of participants

Repeat (x2)24 hr Recalls
4.6% of participants

**Assess
intervention
effects**

24 hour recalls
1% of participants

**Calibrate with
other
diet measures**

Dietary

WHI Food Frequency Questionnaire

Advantages and Disadvantages

Food Frequency	Records	Recalls
• Long term eating	• Short term eating	• Short-term eating
• Low participant burden	• More detail	• More detail
• Administer by mail		• Less report bias
• Cost-effective		
• Limited foods	• Participant burden	• Participant burden
• Less detail	• Completeness	• Ability to make contact
• Ability to recall	• Behavior change	• Ability to recall
• Report bias	• More costly	• More costly

Dietary

Dealing with Uncertainty

- ☐ Multiple measures of self-report
- ☐ Biomarkers
    - ■ Double-labeled water – caloric intake
    - ■ Urinary nitrogen – protein
    - ■ Plasma carotenoids – fruit and vegetable intake
- ☐ Composite of self-report and biomarkers
- ☐ WHI DM Nutritional Biomarkers Study
    - ■ Assess factors that influence the accuracy of self-report
    - ■ Develop mathematical formulae for improving self-report of caloric intake

Dietary

Dietary Changes & Biomarkers

Bette Caan, DrPH

Principal Investigator

Oakland Clinical Center
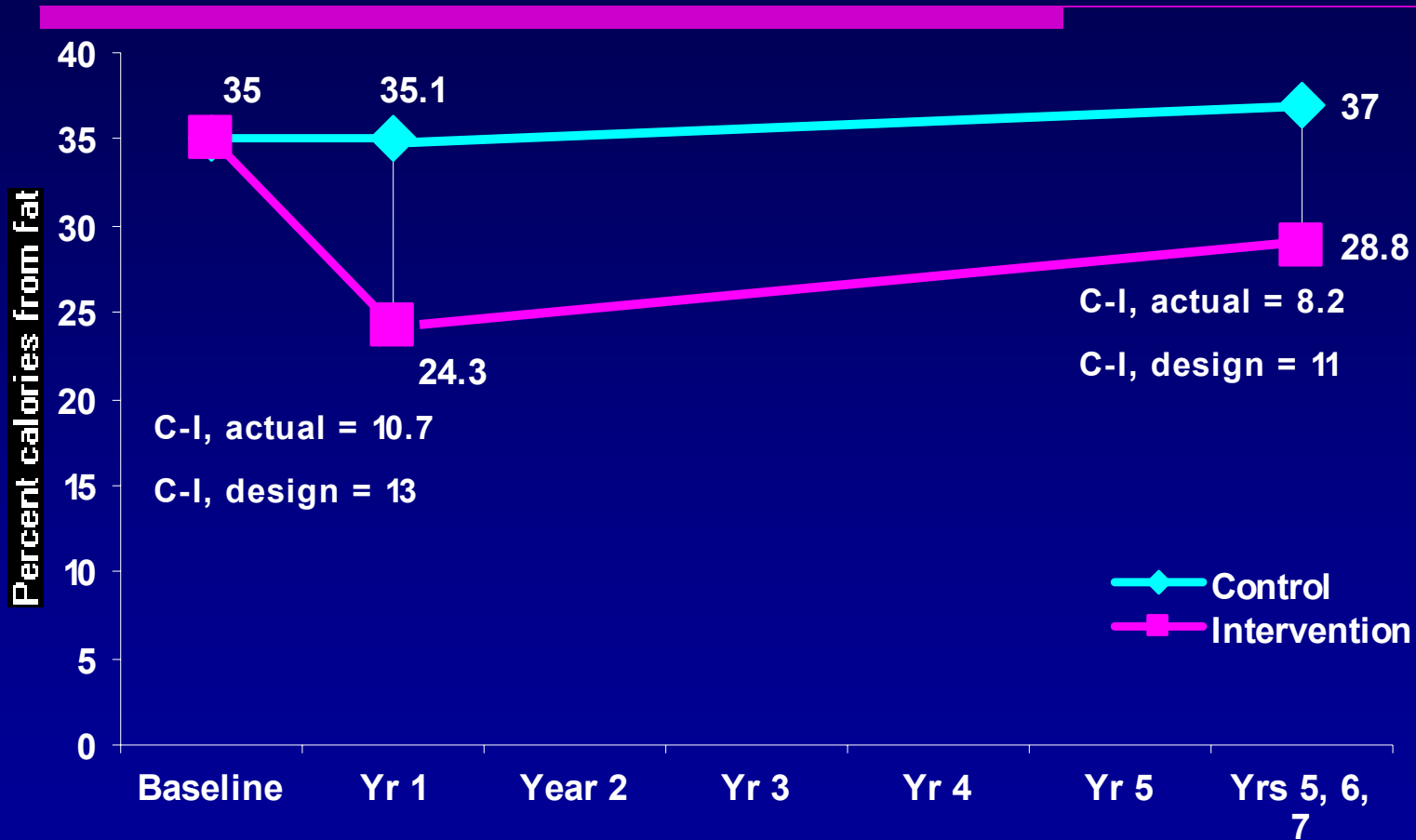
Senior Research Scientist

Division of Research,
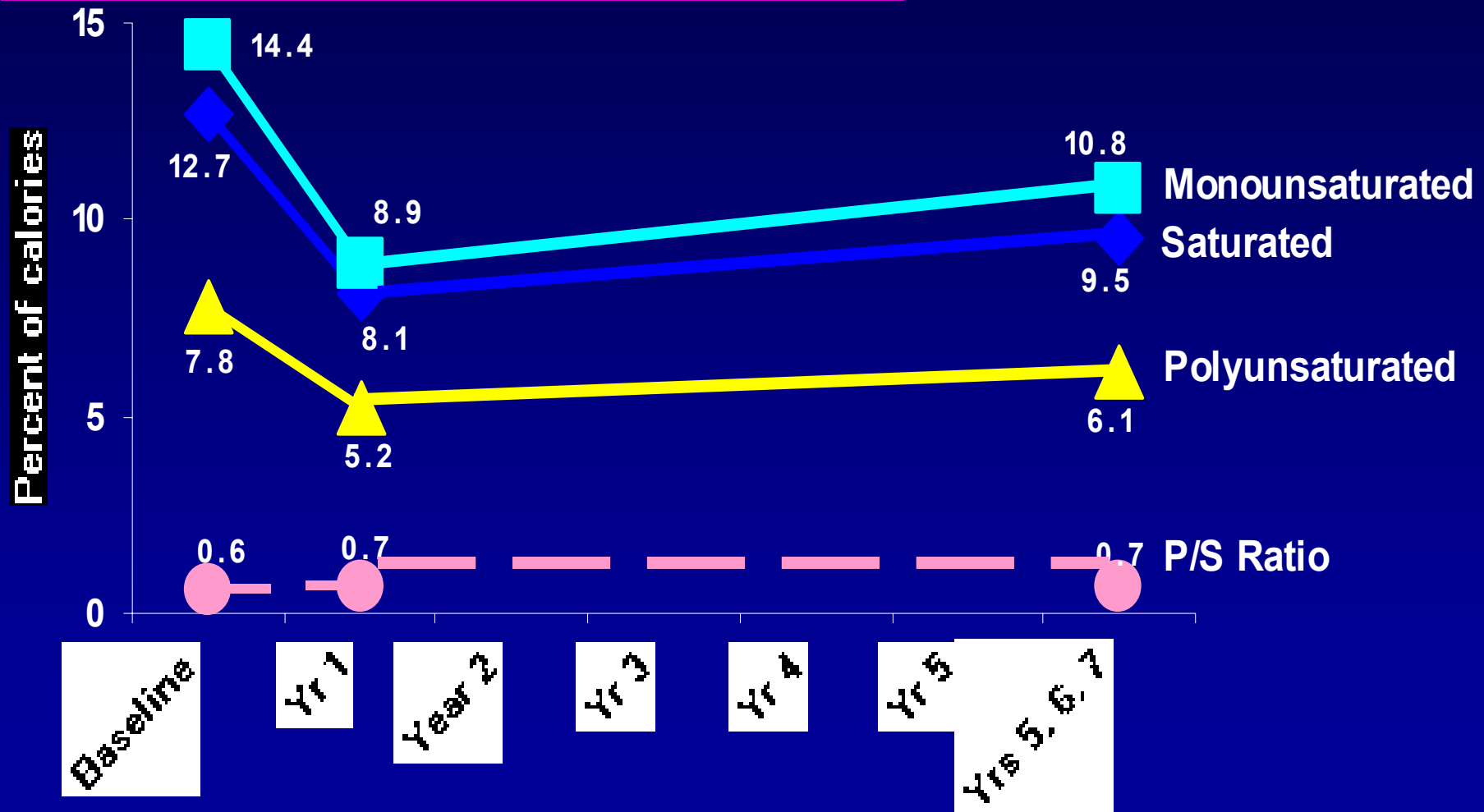Kaiser Permanente Medical Program

Oakland, California

Dietary

Dietary Intake:
Percent Calories from Fat

Howard BV et al. *JAMA* Feb 2006

Dietary

Dietary Changes in the Intervention Group: Types of Fat

Percent of calories

- 14.4 — Monounsaturated
- 12.7
- 10.8 Monounsaturated
- Saturated
- 8.9
- 9.5
- 8.1
- 7.8 — Polyunsaturated
- 5.2
- 6.1
- 0.6
- 0.7
- 0.7 P/S Ratio

Baseline Yr 1 Year 2 Yr 3 Yr 4 Yr 5 Yrs 5, 6, 7

Dietary

Dietary Intake:
Fruits and Vegetables

JAMA 2006; 295; 655-666
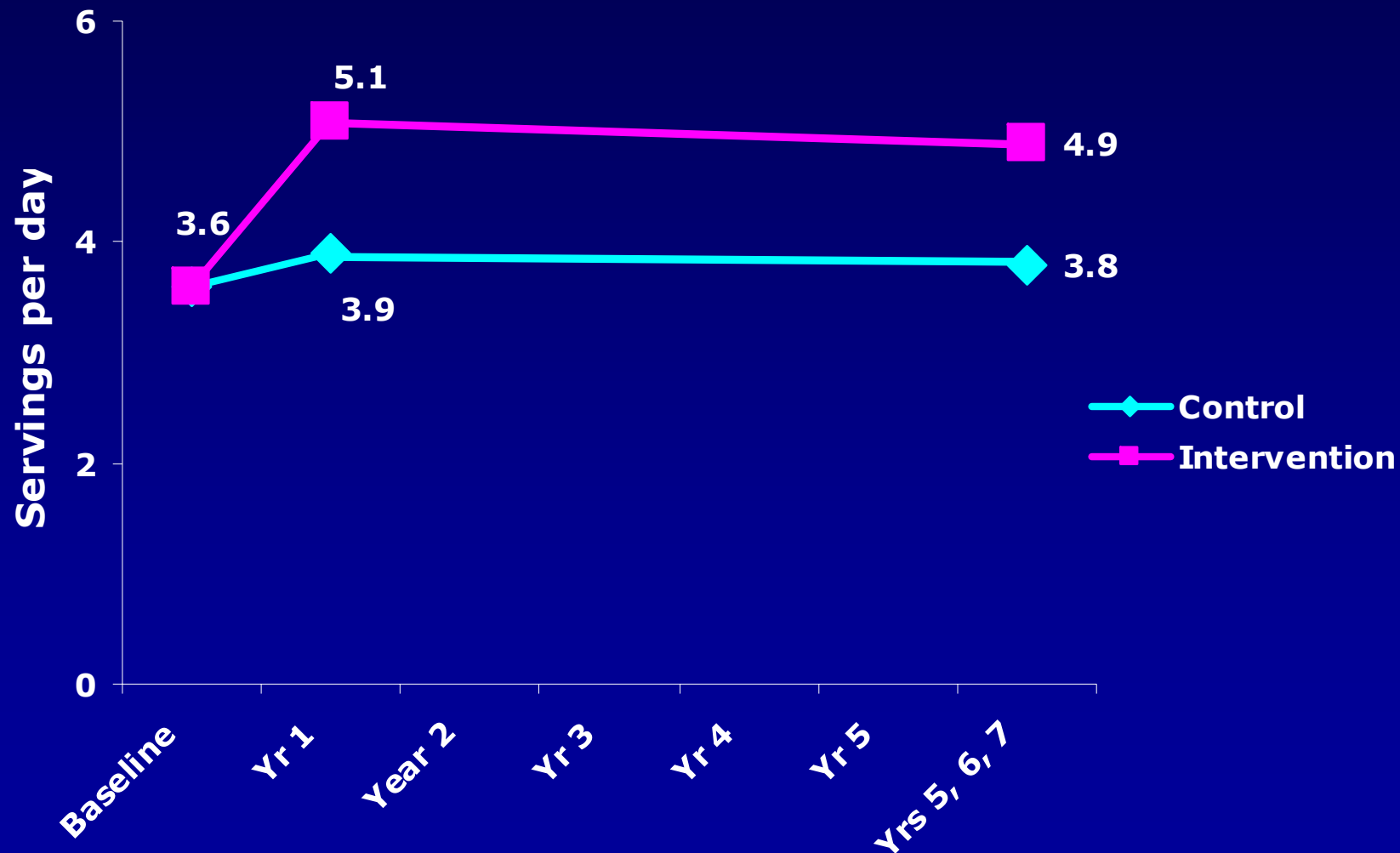
Dietary

Dietary Intake:
Grains & Whole Grains
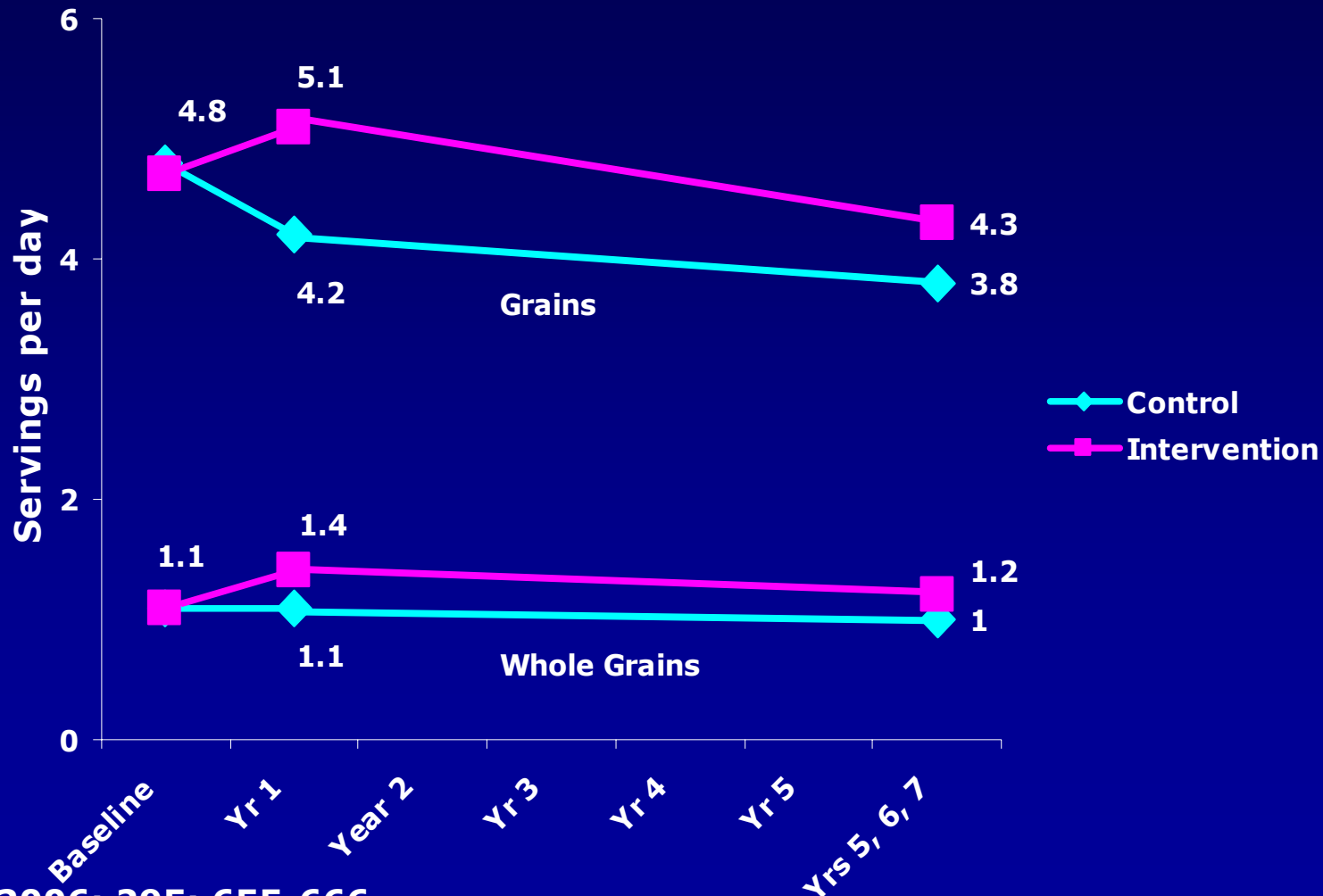
JAMA 2006; 295; 655-666

Dietary

Nutrient Intakes & Blood Biomarkers

	Baseline	Baseline-Year 3, Inter-Cont
Daily Nutrient Intakes		
Folate (dietary), μg	259	+ 62 (+24.5%**)
Fiber, g	15.4	+ 3.1* (+20.0%)
Red meats, servings	0.9	- 0.2 (-22.0% **)
Biomarkers in Blood		
Total cholesterol, mg/dL	224	- 3.3 *
LDL-cholesterol, mg/dL	133	- 3.6 *
HDL-cholesterol, mg/dL	60.1	- 0.4
Total carotenoids, μg/dL	0.88	+ 0.04 (+ 5%)
Gamma tocopherol, μg/dL	2.3	- 0.21 *

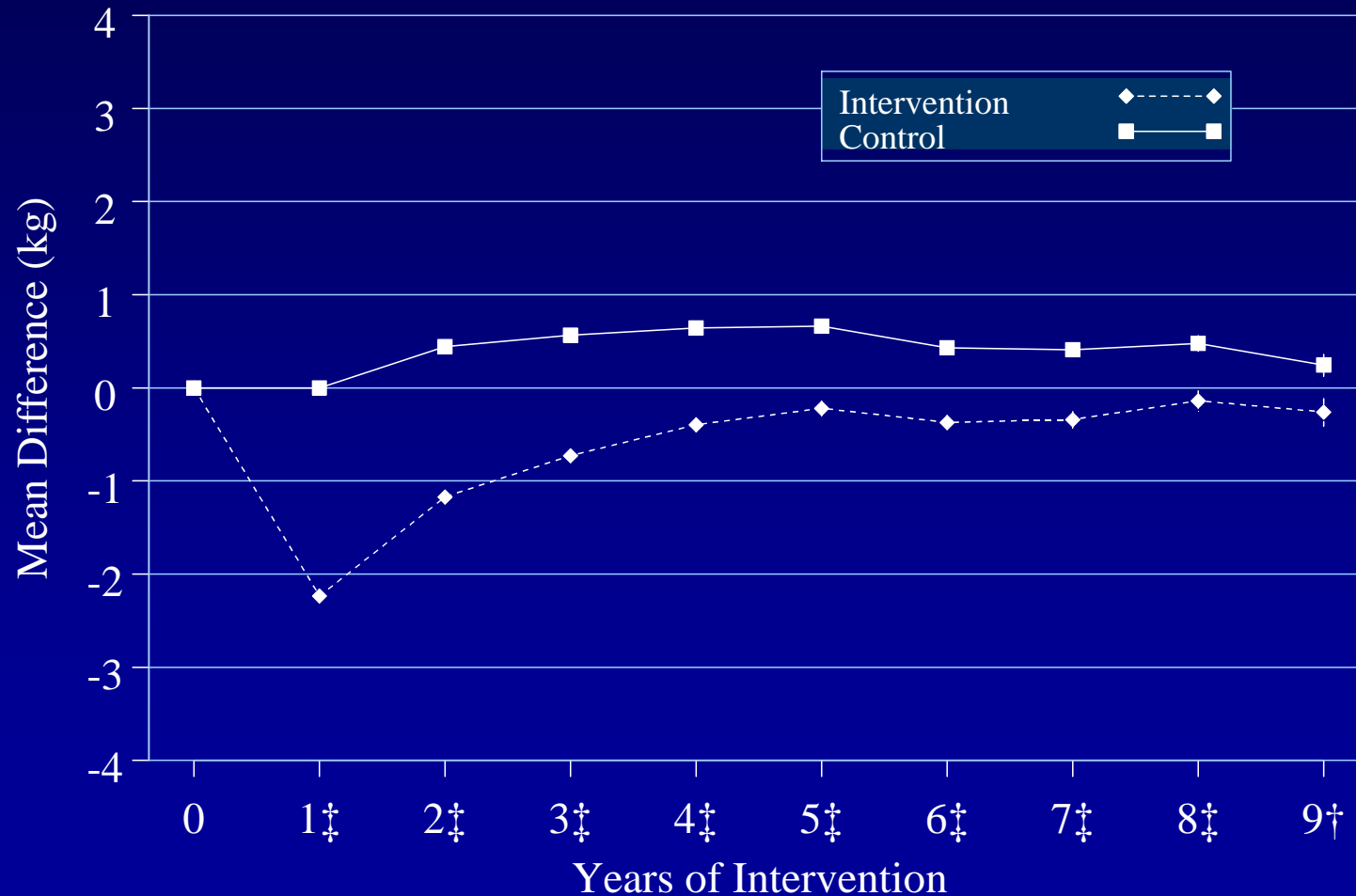JAMA 2006; 295; 629-642; JAMA 2006; 295; 642-654;
JAMA 2006; 295; 655-666

* p<.05
** p<.001

Dietary

Changes in Body Weight

JAMA 2006; 295; 39-49

Dietary

Breast Cancer

Ross Prentice, PhD

Principal Investigator

Clinical Coordinating Center

Member, Public Health Sciences Division

Fred Hutchinson Cancer Research Center
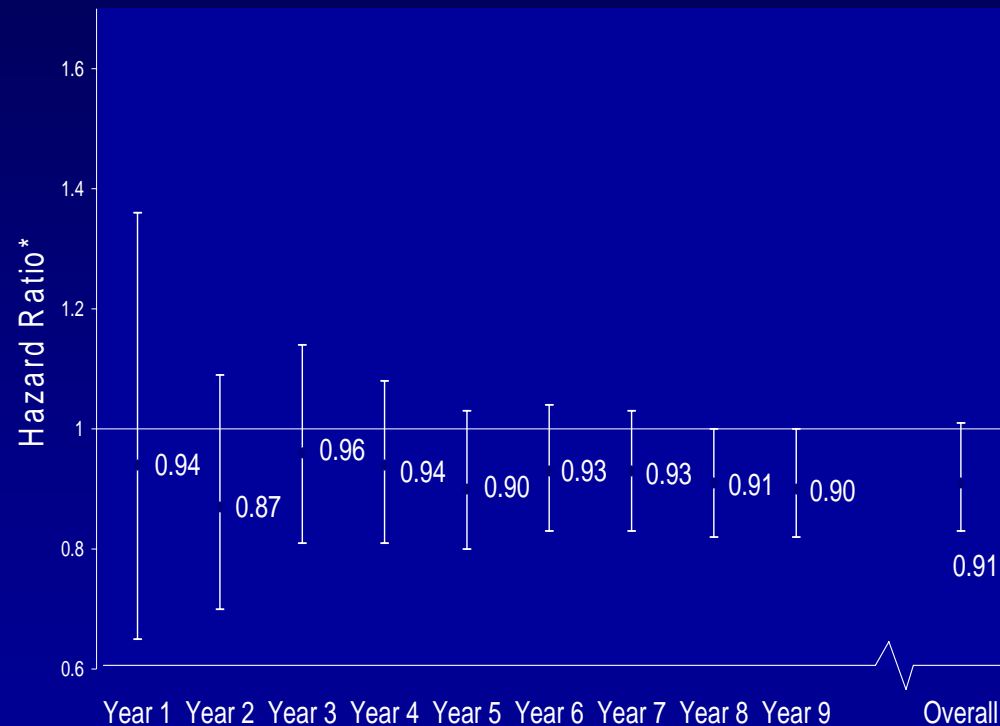
Seattle, Washington

Risk of Breast Cancer and Other Major Clinical Outcomes

	Intervention Cases = 655 Annualized %	Comparison Cases = 1072 Annualized %	Hazard Ratio (95% CI)	Unweighted *p* value
Breast cancer				
Incidence	0.42%	0.45%	0.91 (0.83-1.01)	.07
Mortality	0.02%	0.02%	0.77 (0.48-1.22)	.26
Total cancer				
Incidence	1.23%	1.28%	0.96 (0.91-1.02)	.15
Mortality	0.28%	0.29%	0.95 (0.84-1.07)	.41
Total mortality	0.60%	0.61%	0.98 (0.91-1.02)	.70
Global index	1.30%	1.35%	0.96 (0.91-1.02)	.16

Dietary

Blood Hormone Concentrations

← Reduced   Increased →

	Relative Change from Baseline
Estradiol	0.85
Estrone	0.98
Estrone-sulfate	0.96
Testosterone	0.99
Sex hormone binding globulin	1.09

0.6 0.7 0.8 0.9 1 1.1 1.2 1.3 1.4

Relative Change from Baseline

Dietary

Hazard Ratios by Dietary Factors

	Inter	Comp	Mean I-C			Interaction
Baseline Quartiles (4DFR)	Cases = 655	Cases = 1072	% cal fat	**Hazard Ratio (95% CI)**		p-value
% energy from fat (kcal)						0.04
< 27.9	144	222	- 9.7	0.97	(0.79, 1.20)	
27.9 - < 32.3	186	259	- 10.4	1.08	(0.89, 1.30)	
32.3-< 36.8	160	283	- 11.7	0.85	(0.70, 1.03)	
$\geq$ 36.8	151	291	- 12.2	0.78	(0.64, 0.95)	
Vegetables and fruits (sv/day)			sv/day			0.07
< 2.3	155	259	1.3	0.90	(0.73, 1.09)	
2.3-<3.3	158	268	1.3	0.88	(0.72, 1.07)	
3.3-<4.6	144	264	1.2	0.82	(0.67, 1.00)	
$\geq$ 4.6	197	276	1.0	1.08	(0.90, 1.29)	

WOMEN'S HEALTH INITIATIVE

Dietary

Interpretation

- ☐ Intensive intervention resulted in significant and sustained dietary fat reduction and vegetable and fruit increase.

- ☐ Observed 9% lower breast cancer rate (15% among "adherent women") may be attributable to chance.

Dietary

Interpretation (continued)

- ☐ Longer follow-up needed for a more definitive evaluation of low-fat eating pattern and breast cancer hypothesis:
    - ■ Power reduced by 8.1 rather than 9 years of average follow-up and by less than targeted adherence.
    - ■ Greater evidence of breast cancer reduction among women having higher baseline % energy from fat.

Dietary

Colorectal Cancer

Shirley A.A. Beresford, PhD

Principal Investigator

Seattle Clinical Center

Professor, Epidemiology – University of Washington
Member - Fred Hutchinson Cancer Research Center

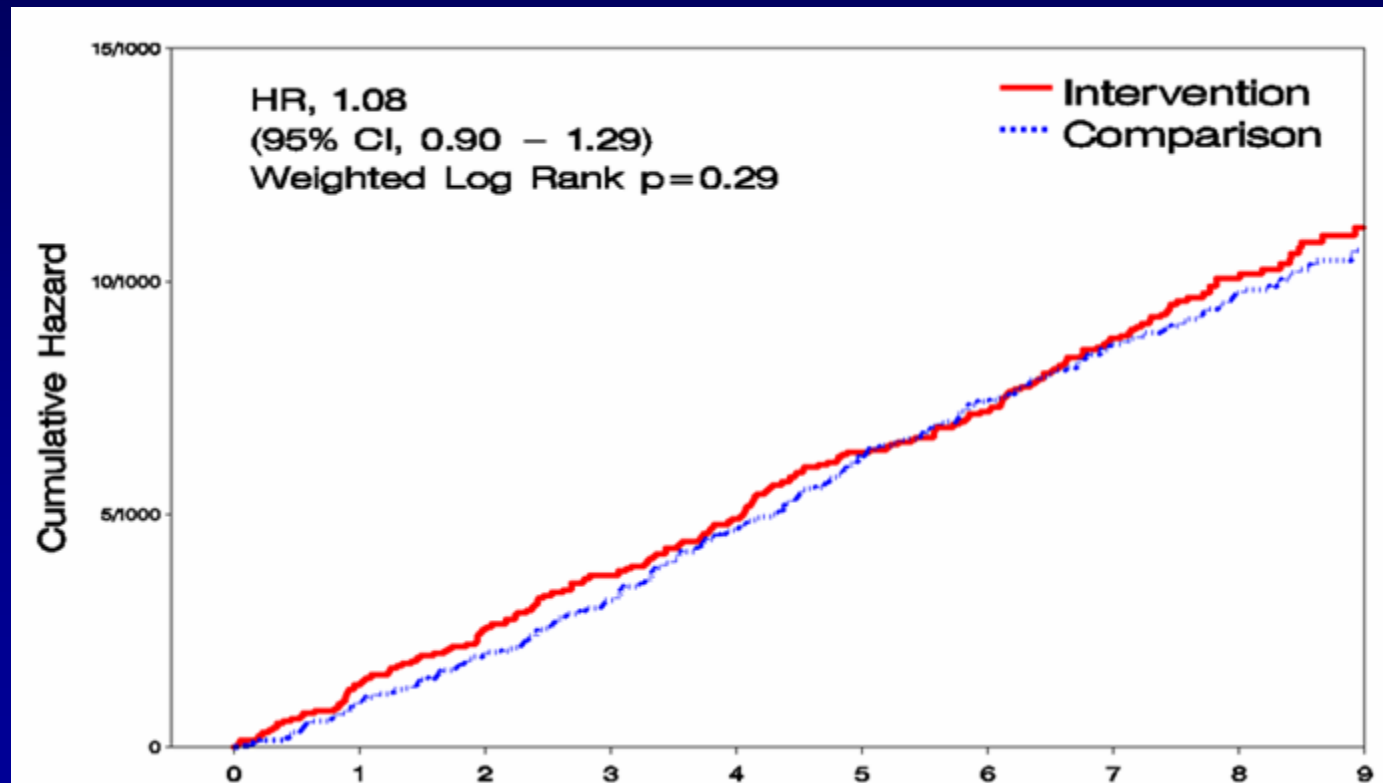Seattle, Washington

Dietary

Colorectal Cancer

Objective:

To evaluate the effects

- of a low-fat dietary pattern

- on risk of colorectal cancer

- in postmenopausal women

Dietary

Colorectal Cancer:
Cumulative Hazard Ratios

HR, 1.08
(95% CI, 0.90 – 1.29)
Weighted Log Rank p=0.29

Intervention
Comparison

480 total diagnoses

(1% of all DM participants)

Dietary

Colorectal Cancer:
Annualized Rates and Hazard Ratios

HR=1.08 (0.90, 1.28)

HR=1.25 (0.96, 1.61)

HR=0.86 (0.56, 1.19)

HR=1.11 (0.77, 1.61)

Cases per year per 10,000 women

- Intervention
- Comparison

Total   Proximal   Distal   Rectal
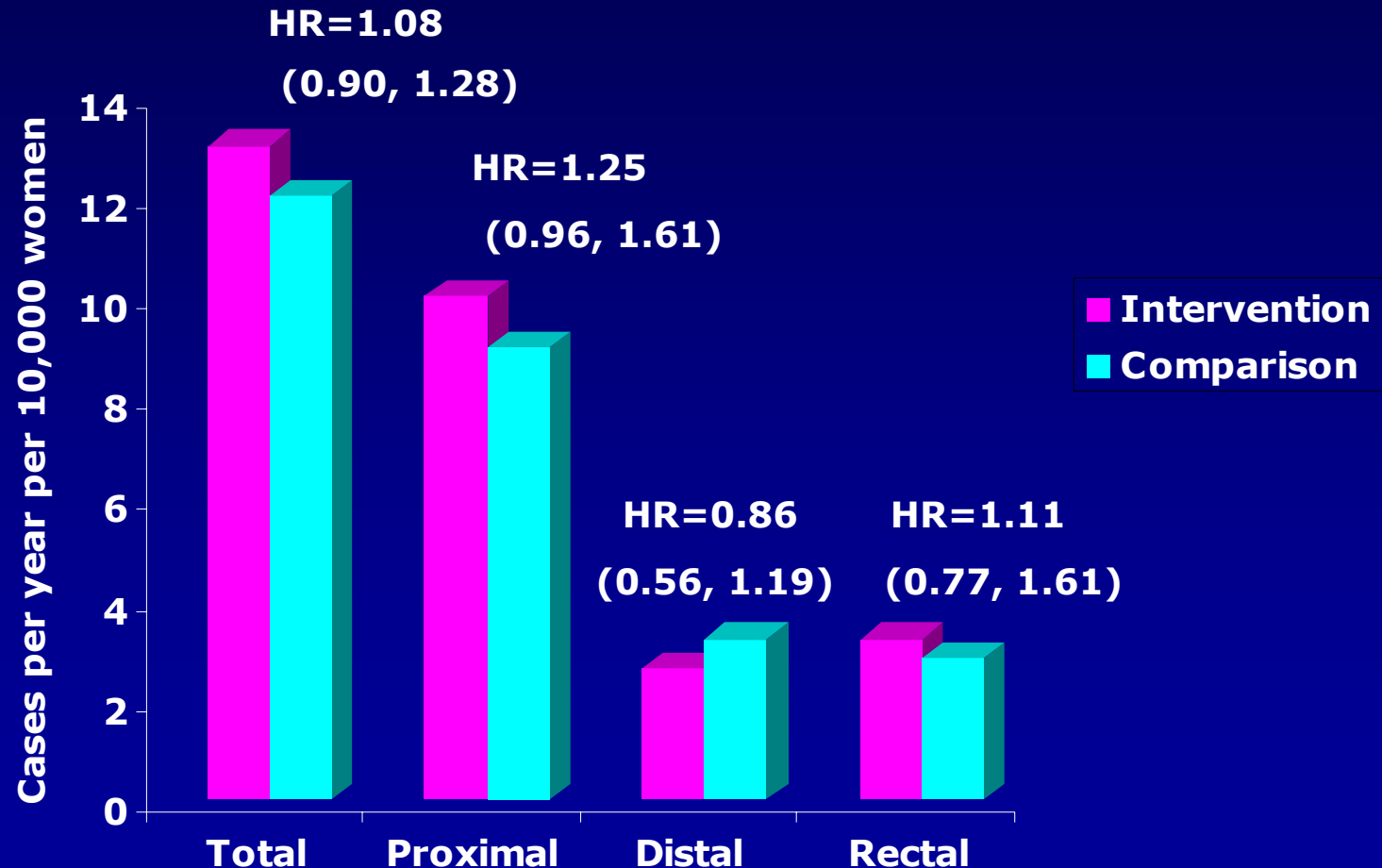
Dietary

Bowel Examinations: Polyps/Adenomas
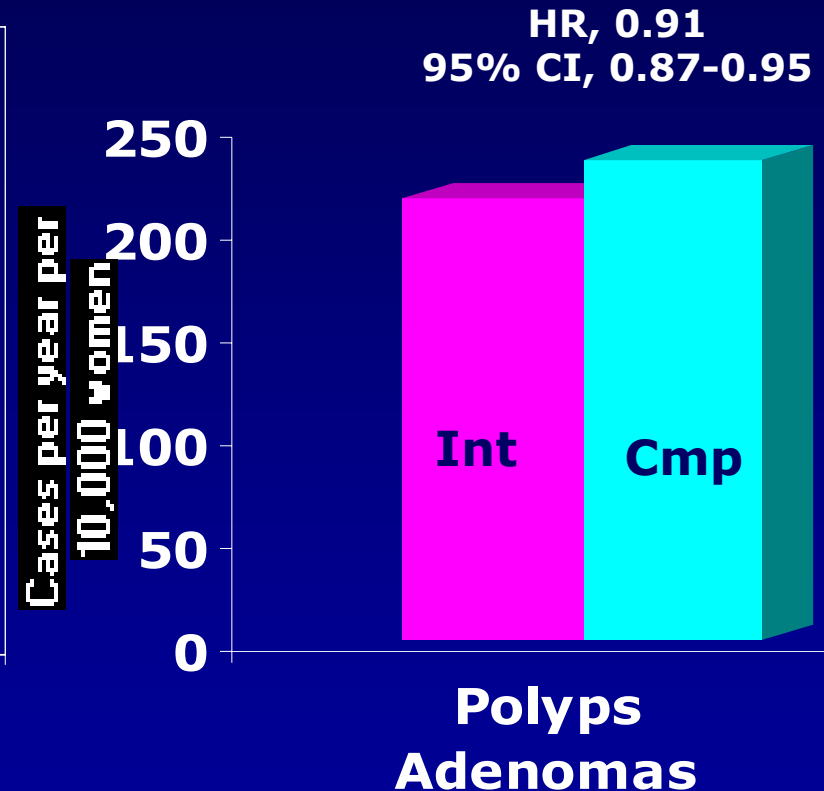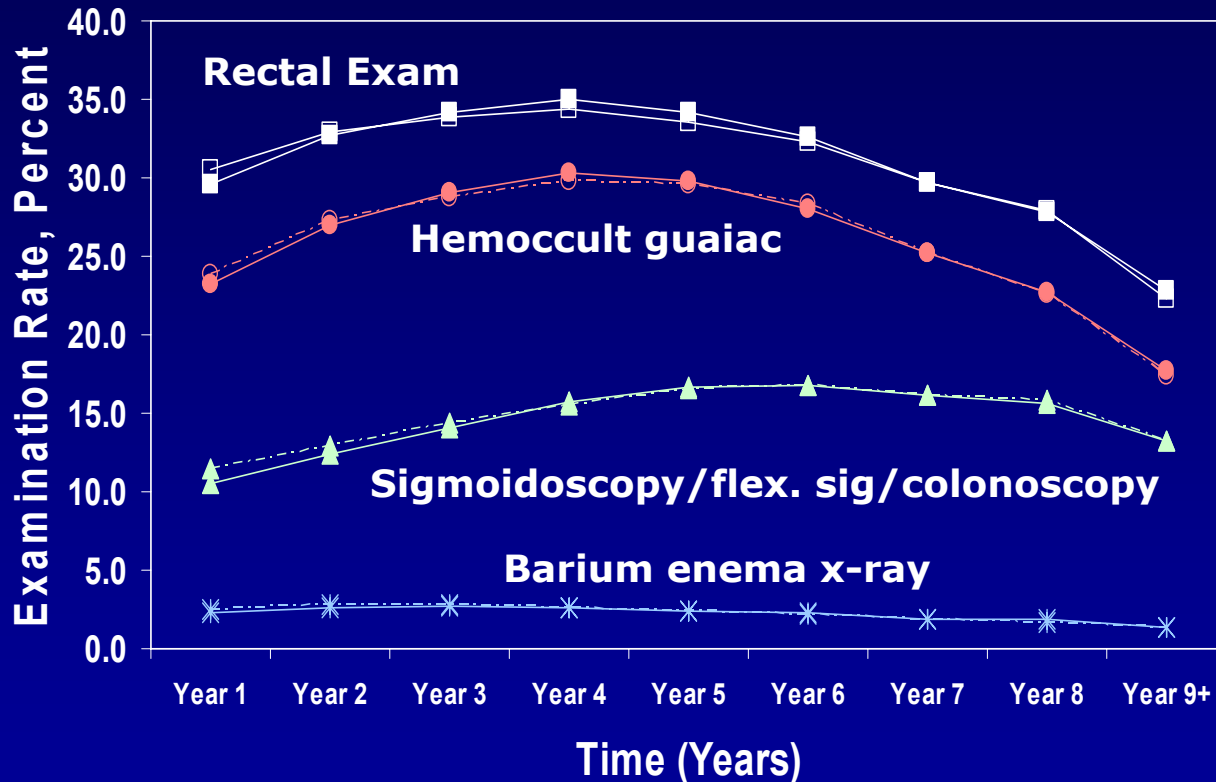
JAMA 2006; 295; 642-654

Dietary

Colorectal Cancer Hazard Ratios
by Baseline Participant Characteristics

Hazard Ratio (------95% CI ------)

	P Value		
		0.1 1.0 10.0	
Age at *enrollment*			
50-59 yr		0.87	
60-69 yr	0.18	1.00	
70-79 yr		1.44	
Aspirin use			
No		1.24	
< 325 mg	0.01	0.90	
≥ 325 mg		0.54	
Baseline current E-alone user or randomized to E-alone active arm			
Yes		1.10	
No	0.92	1.08	
Baseline current E+P user or randomized to E+P active arm			
Yes		0.62	
No	0.01	1.19	

Favors Intervention   Favors Comparison
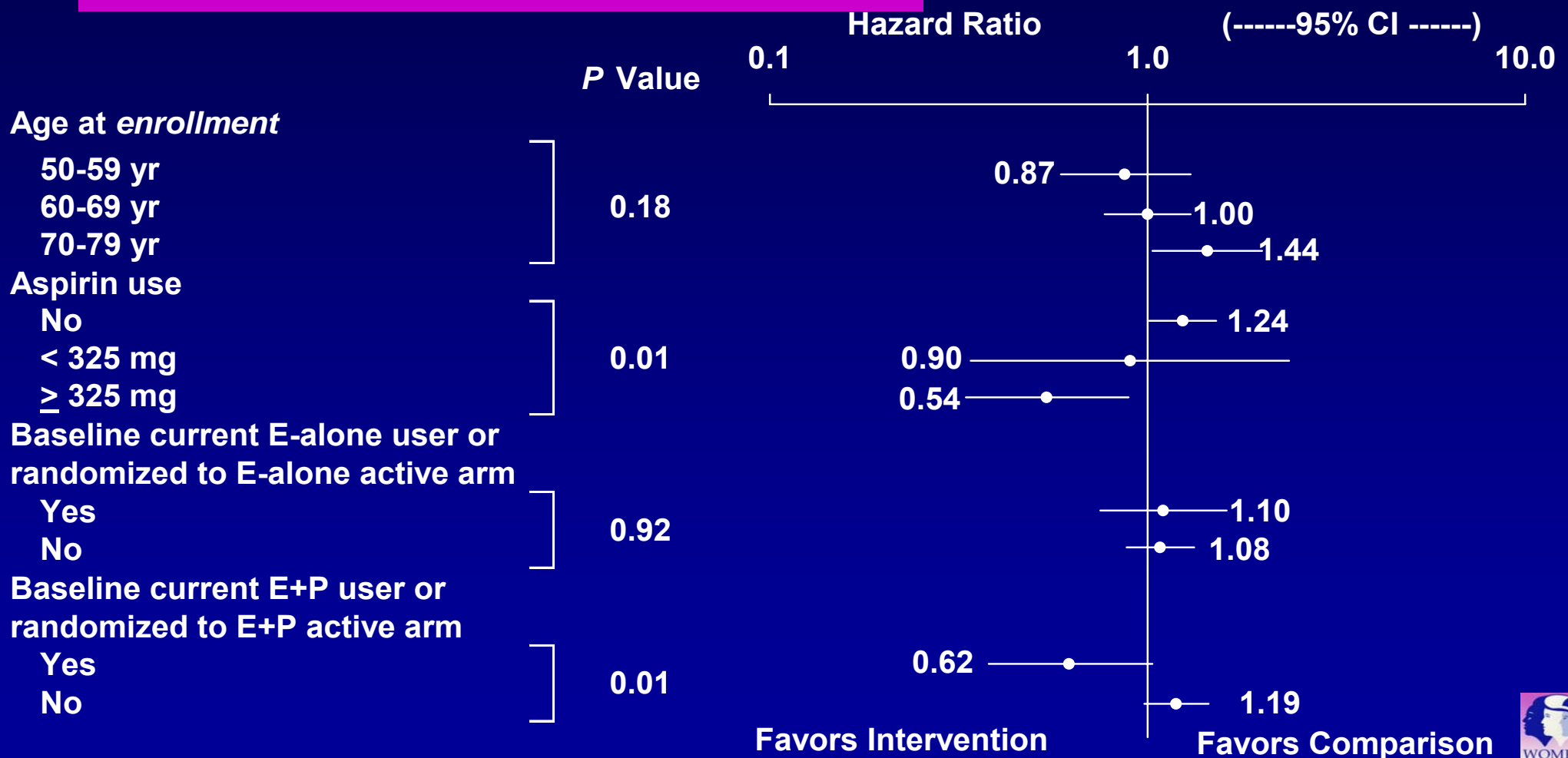
JAMA 2006; 295; 642-654

Dietary

Colorectal Hazard Ratios by Baseline Dietary Factors

Hazard Ratio (------95% CI ------)

	P Value	0.1	1.0	10.0

Dietary energy (kilocalories)
<1391.8 — 1.07
1391.8 – <1663.6 — 1.17
1663.6 – <1958.7 — 1.37
1958.7 + — 0.73
P Value: 0.29

Dietary percent energy from fat
<27.9 — 1.07
27.9 – 32.3 — 1.22
32.3 – 36.8 — 1.01
36.8 + — 0.99
P Value: 0.61

Alcohol intake
Never Drinker — 1.00
Past Drinker — 1.16
< 1 drink per day — 0.92
1+ drink per day — 2.00
P Value: 0.09

Favors Intervention   Favors Comparison

JAMA 2006; 295; 642-654

WOMEN'S HEALTH INITIATIVE
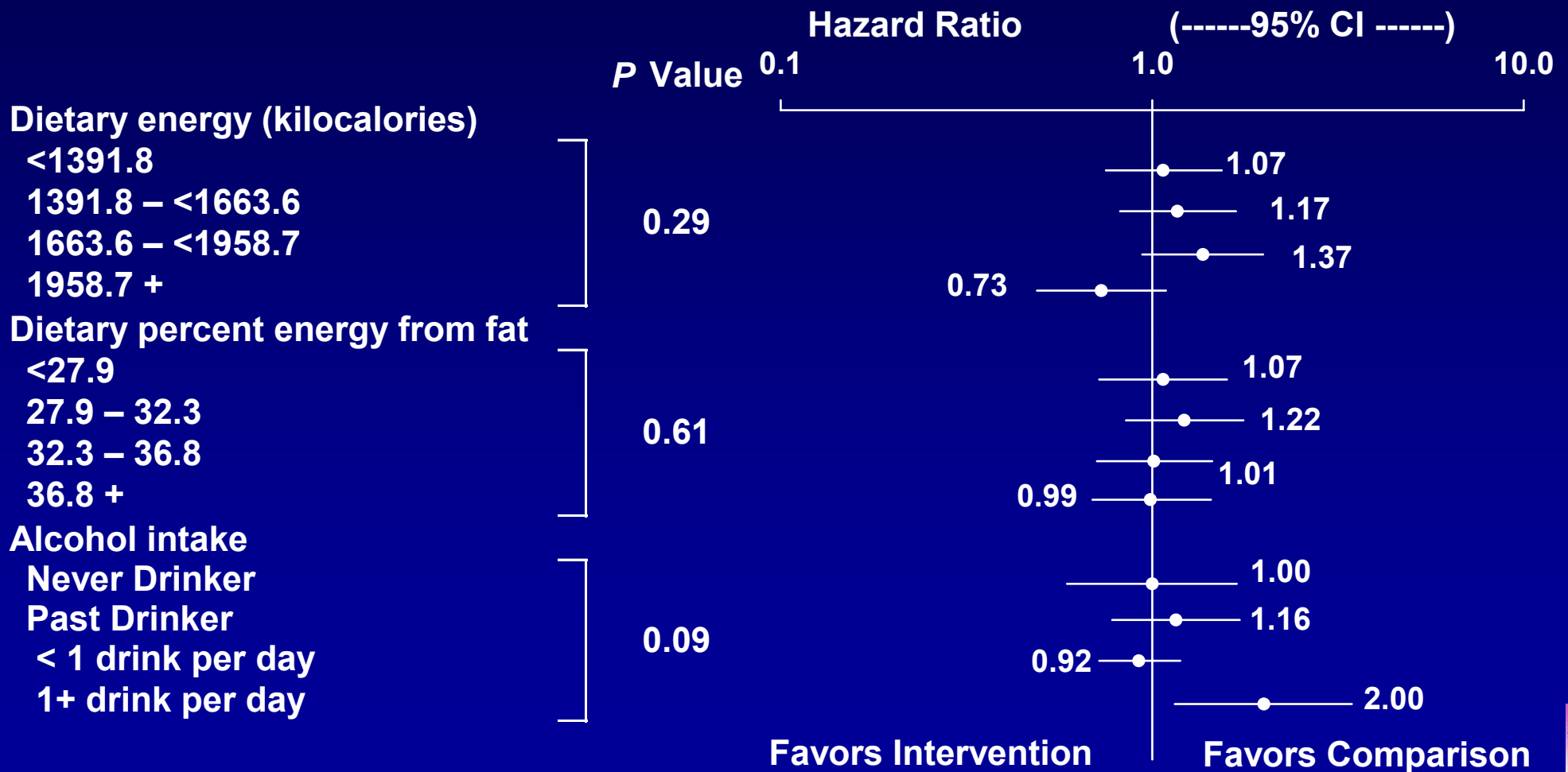
Dietary

Colorectal Cancer – Conclusions

☐ The low fat dietary pattern intervention did not reduce the risk of colorectal cancer over 8.1 years

☐ Reduction in polyps and adenomas associated with the intervention suggest longer follow-up is needed before long term effects can be ruled out.

Dietary

Cardiovascular Disease (Heart Disease and Stroke)

Linda Van Horn, PhD, RD
Principal Investigator
Chicago Northwestern Clinical Center

Professor,
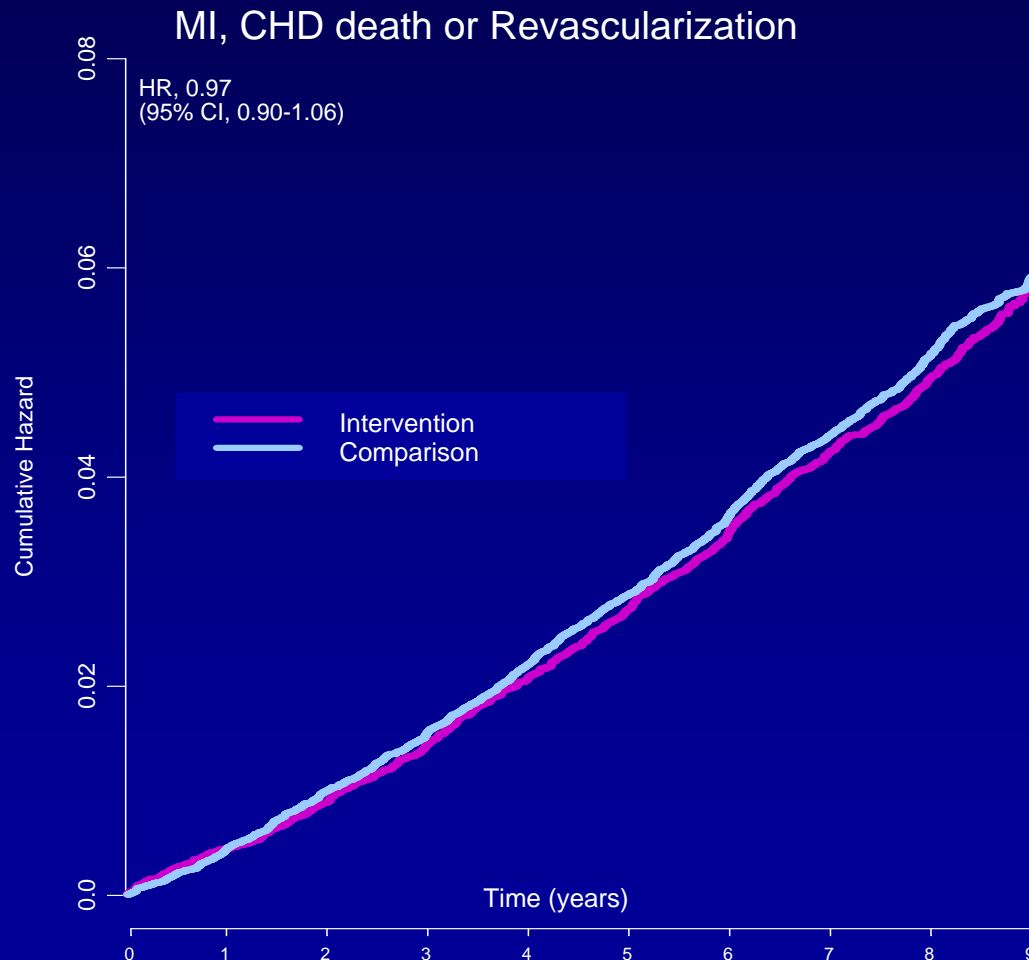Northwestern University Feinberg School of Medicine
Chicago, Illinois

Dietary

Definitions

☐ **Coronary heart disease (CHD):**
Heart attack, heart bypass surgery, stent, or angioplasty

☐ **Stroke:**
Lack of blood flow to the brain or bleeding in the brain leading to weakness or paralysis, and impairment of speech or other functions

WOMEN'S HEALTH INITIATIVE

Dietary

Coronary Heart Disease:
Cumulative Hazard Ratios

MI, CHD death or Revascularization

HR, 0.97
(95% CI, 0.90-1.06)

Cumulative Hazard

Intervention
Comparison

Time (years)

**2,549 total diagnoses
(5% of all DM participants)**

**Hazard ratio = 0.97
(95% CI = 0.90-1.06)**

Dietary

Stroke:
Cumulative Hazard Ratios

Stroke

HR, 1.02
(95% CI, 0.90-1.15)

0.08

0.06

0.04

Cumulative Hazard

—— Intervention
—— Comparison

0.02

0.0

Time (years)

0   1   2   3   4   5   6   7   8   9

Events

**1,076 total diagnoses
(2% of all DM participants)**

**Hazard Ratio = 1.02
(95% CI = 0.90-1.15)**
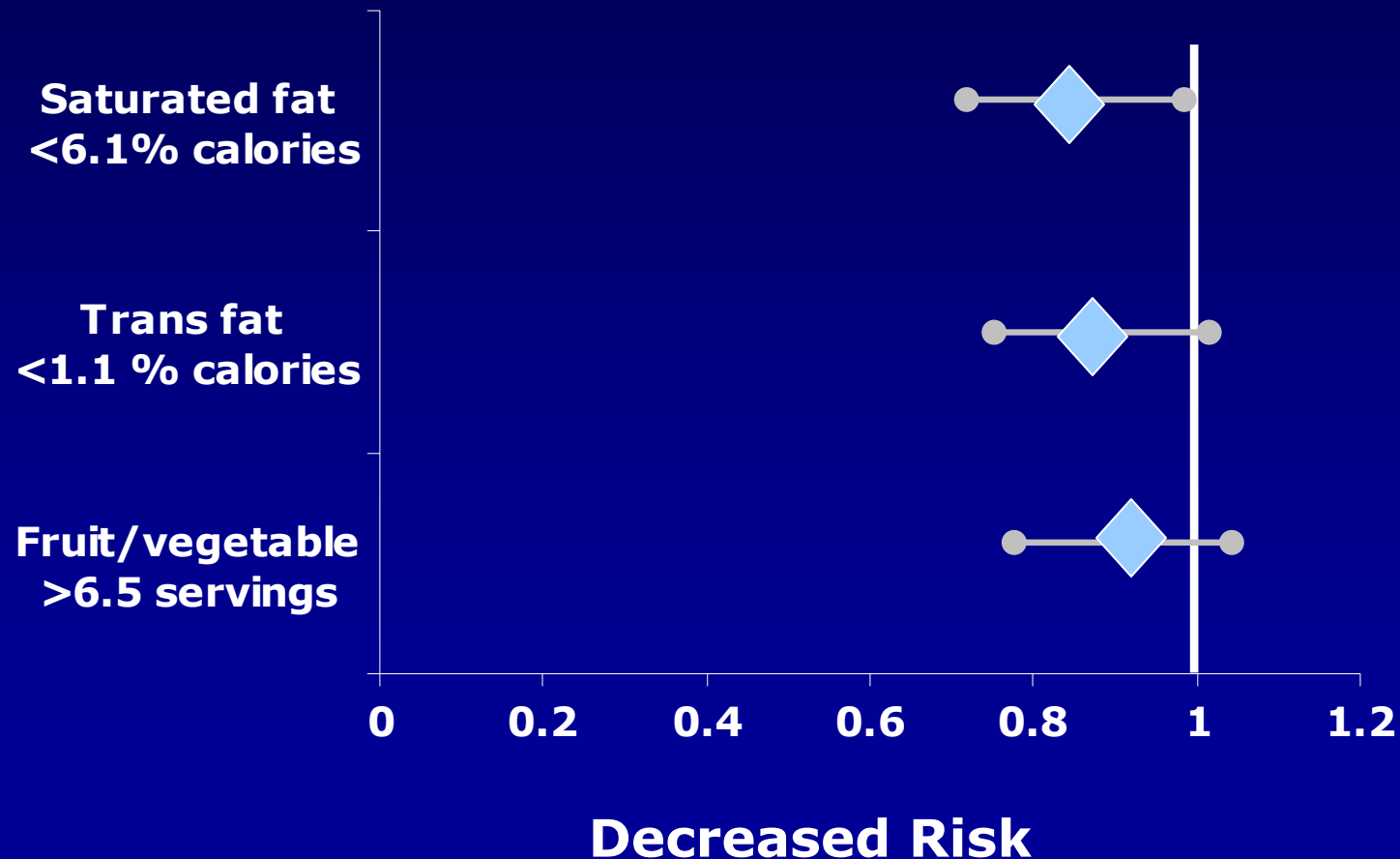
JAMA 2006; 295; 655-666

WOMEN'S
HEALTH
INITIATIVE

Dietary

Changes in Risk Factors

	Risk factor	Baseline	Difference at year 3 (I-C)
IMPROVED	LDL-cholesterol, mg/dL	133	- 3.6 *
	Diastolic blood pressure, mm Hg	76	- 0.3 **
	Factor VIIC, %	131	- 4.9 **
NO CHANGE	Triglycerides, mg/dL`	139	0
	HDL-cholesterol, mg/dL	60	- 0.4
	Glucose, mg/dL	100	- 1.1
	Insulin, µIU/mL	10	0

* p<.05; ** p<.001

WOMEN'S HEALTH INITIATIVE

Dietary

Changes in Types of Fat

Type of fat	Baseline	Difference: Yr 1 (I-C)	Difference: Yr 6 (I-C)
Saturated fat, % calories	12.7	- 3.7 *	- 2.9 *
Trans fat, % calories	2.7	- 0.8 *	- 0.6 *
Polyunsaturated fat, % calories	7.8	- 2.0 *	- 1.5 *
P/S ratio	0.6	0	0

* p<.001

Dietary

Additional Analyses
Heart Disease Risk

Saturated fat
<6.1% calories

Trans fat
<1.1 % calories

Fruit/vegetable
>6.5 servings

0   0.2   0.4   0.6   0.8   1   1.2

Decreased Risk

Dietary

Cardiovascular Disease: Conclusions

☐ Postmenopausal women who initiated a low fat dietary pattern had no significant reductions in coronary heart disease, stroke, or cardiovascular disease (CVD) after 8.1 years.

☐ Some CVD risk factors were modestly improved, especially among women with greater adherence to dietary recommendations.

☐ Interventions on specific dietary factors known to influence risk of CVD and potentially initiated younger in life may be needed to improve risk factors and CVD risk.

WOMEN'S HEALTH INITIATIVE

Dietary

Dietary Fat & Breast Cancer

| Studied	Did Not Study
Eating Fat	Being Fat
% Calories from Fat	Grams of Fat
Total Fat	Type of Fat
Post-menopausal	Pre-menopausal
	Exercise
Breast Cancer Risk	Breast Cancer Prognosis

Fabulous study, BUT some limitations

1. Reductionist thinking hinders dietary research

2. Public message may ↓ reporting of fat intake

3. Lack of lab measures to validate   intake

4. Carcinogenesis takes many years

The Causes of Cancer
– Richard Doll & Richard Peto, 1981
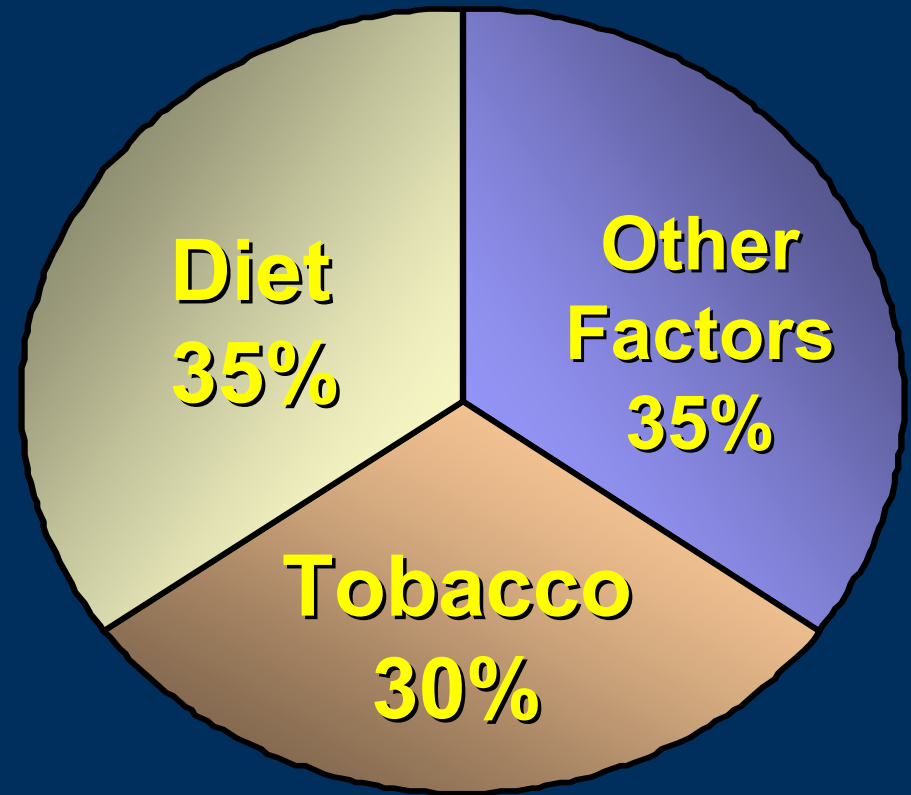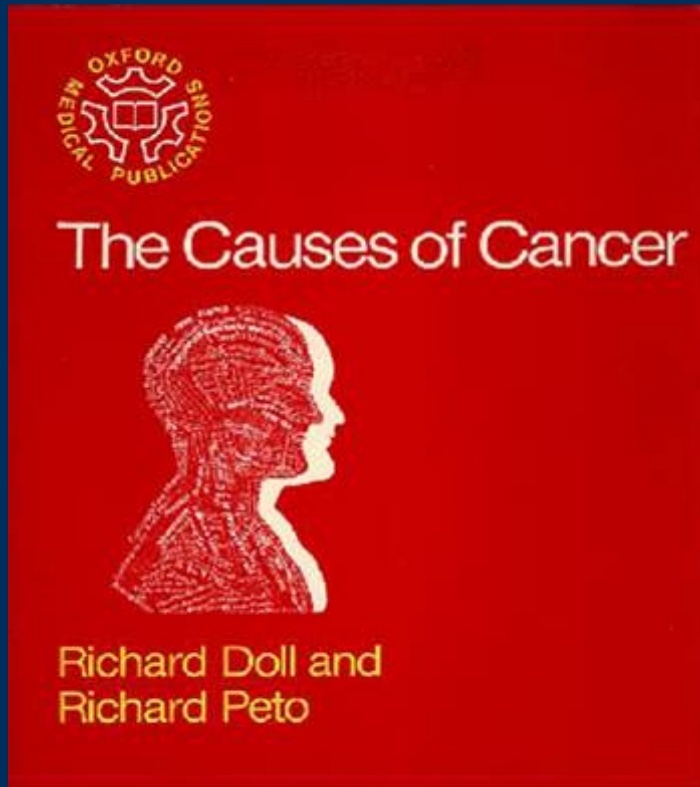
What is the Right Message?

The Surgeon General's Report on NUTRITION AND HEALTH

Reduce consumption of fat (especially saturated fat) and cholesterol

Choose a diet low in fat, saturated fat, and cholesterol

Food, Nutrition and the Prevention of Cancer: a global perspective

Consume nutritionally adequate and varied diets, based primarily on foods of plant origin

Nutrition and Your Health: **Dietary Guidelines for Americans**

Balance the food you eat with physical activity-maintain or improve your weight

Choose a diet with plenty of grain products, vegetables, and fruits

Choose a diet low in fat, saturated fat, and cholesterol

Eat a variety of foods
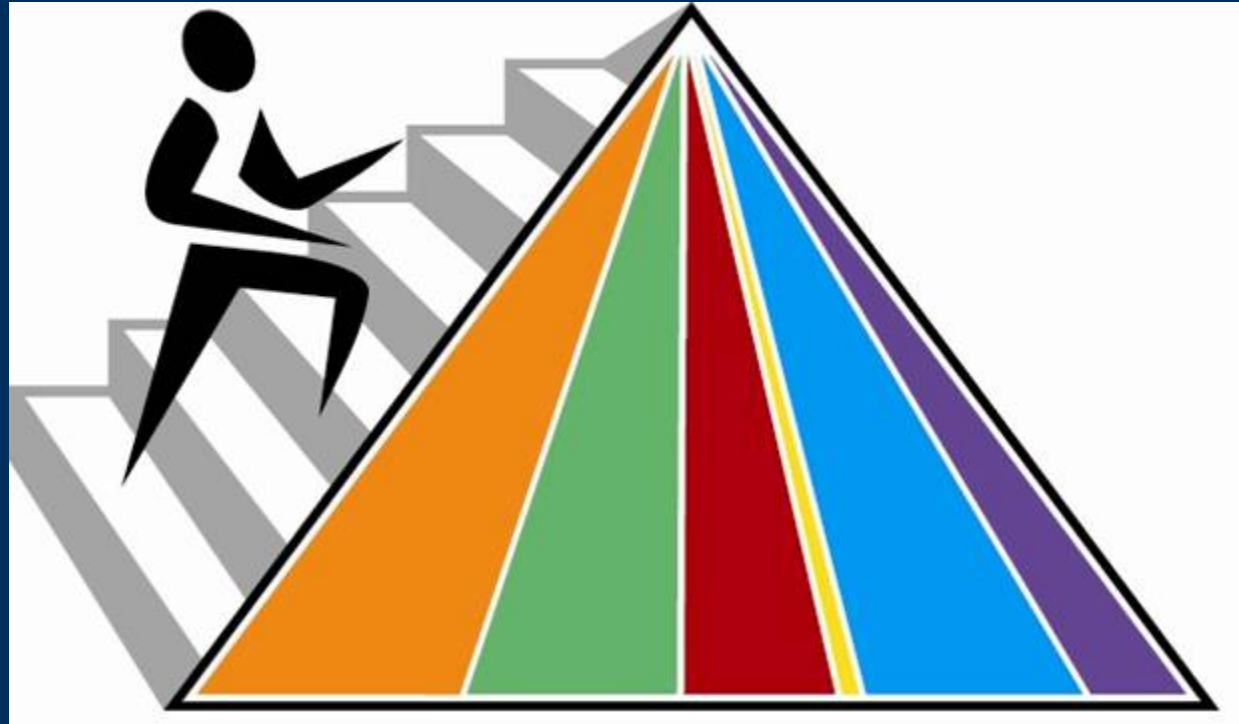
Choose a diet moderate in salt and sodium

Choose a diet moderate in sugars

If you drink alcoholic beverages, do so in moderation

U.S. Department of Agriculture
U.S. Department of Health and Human Services

One Size Doesn't Fit All
Steps to Healthier You

- Make smart choices from every food group
- Find your balance between food and physical activity
- Get the most nutrition out of your calories

Nutrigenomics & Beyond
Mapping Individual Health

DIET &

- **Gene polymorphisms**
- **Nutritional Epigenomics**
- **Transcriptomics**
- **Proteomics**
- **Metabolomics**

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NUTRITION AND GENETICS

Mapping individual health

ILSI
International Life Sciences Institute

Future Needs

1. ↑ Basic Nutritional Science
   - …omics ↔ …ologies
2. Truly Validated Markers of Dietary Intake, Effect (Molecular Targets) & Susceptibility
   - At various times of life
3. ↑ Research on Bioactive Food Compounds
4. ↑ Research & Development of Engineered Foods
5. ↑ Dietary Intervention Trials
6. ↑ Robust Nutritional Science at NIH
   - Intramural & Extramural
7. Long-term Follow-up of WHI Participants

Nutrition "is the ultimate biochemical interaction – the human organism reacting with the environment, daily, in a very intimate sense. And it's been starved for research funding."

Bernadine Healy, 2004

Audience Questions

Leslie Ford, MD

Associate Director of Clinical Research
Division of Cancer Prevention,
National Cancer Institute
National Institutes of Health
Rockville, Maryland

Dietary