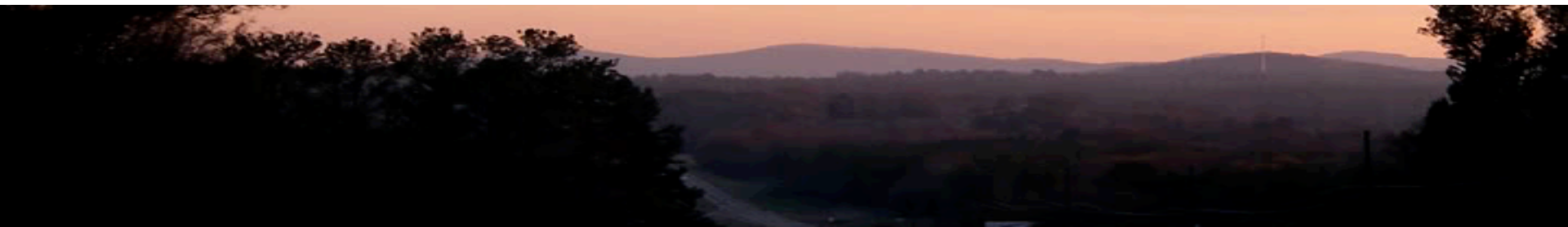


WORKING EVERYDAY TO PROVIDE THE HIGHEST QUALITY OF LIFE FOR PEOPLE WITH CANCER

Intervening to Improve Diet and Exercise Behaviors in Cancer Survivors: What Works?...what doesn't

WENDY DEMARK-WAHNEFRIED, PHD, RD
PROFESSOR AND WEBB CHAIR OF NUTRITION SCIENCES
ASSOCIATE DIRECTOR OF CANCER PREVENTION & CONTROL
UNIVERSITY OF ALABAMA AT BIRMINGHAM



Objectives

- What lessons have we learned over the past 20 years of doing diet & exercise interventions in cancer survivors?
- What are potential areas for future research?
 - factors affecting accrual
 - factors affecting intervention impact
 - factors affecting intervention sustainability

Initial Study in Cancer Survivors **Why do Women Gain Weight After Breast Cancer Diagnosis?**



- **Associated with chemotherapy**
- **Most research focused on weight gain in patients with breast cancer who were treated with chemotherapy**
 - Early studies show mean gains of 2.5-6.2 kg; recent studies show mean gains of 1.4-1.7 kg
- Early reports suggested increased dietary intake is responsible for weight gain – studies were small and not well-controlled

53 Young Women w/Breast Cancer Observed During Year Following Diagnosis (36 on Adjuvant Chemotherapy & 17 Localized Treatment Only) measured....



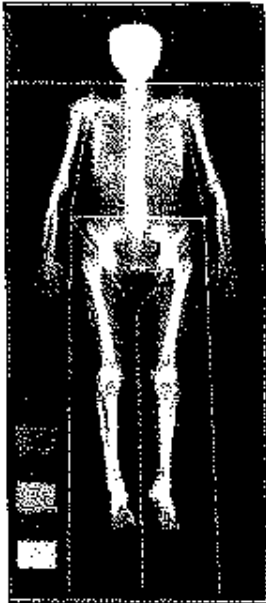
Dietary Intake (3-day recalls)

Physical Activity (Stanford 5 City)

Metabolic Rate (Indirect Calorimetry)

Body Composition (DXA)

Done
k = 1.338 d0 = 118.8(1.000)



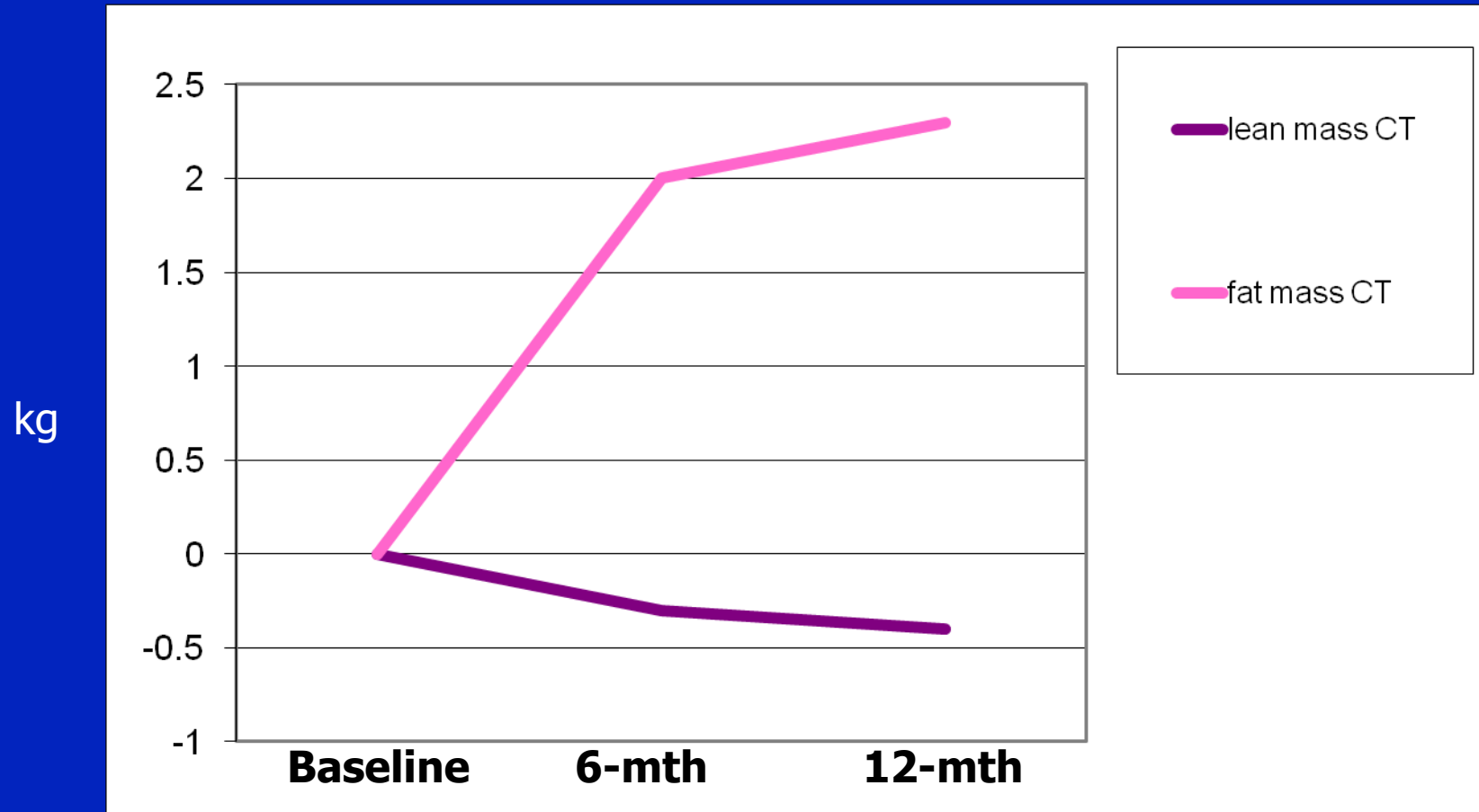
F.S. 68.00% 8(18.00)%
Head assumes 17.0% brain fat
LBM 73.2% water

Region	Fat (grams)	Lean+BMC (grams)	% Fat (%)
L Arm	977.2	1435.7	40.5
R Arm	1061.3	1553.8	40.6
Trunk	4551.7	17590.8	20.6
L Leg	3764.7	4857.6	43.7
R Leg	3856.5	5892.7	43.1
SubTot	14211.3	38529.9	31.8
Head	646.4	3211.7	16.8
TOTAL	14857.7	33741.6	38.6

-No difference in intake or RMR

-Significant decrease in PA
among women receiving adj.
chemo

Change in Body Composition Post-Diagnosis among Breast Cancer Patients receiving Adjuvant chemotherapy

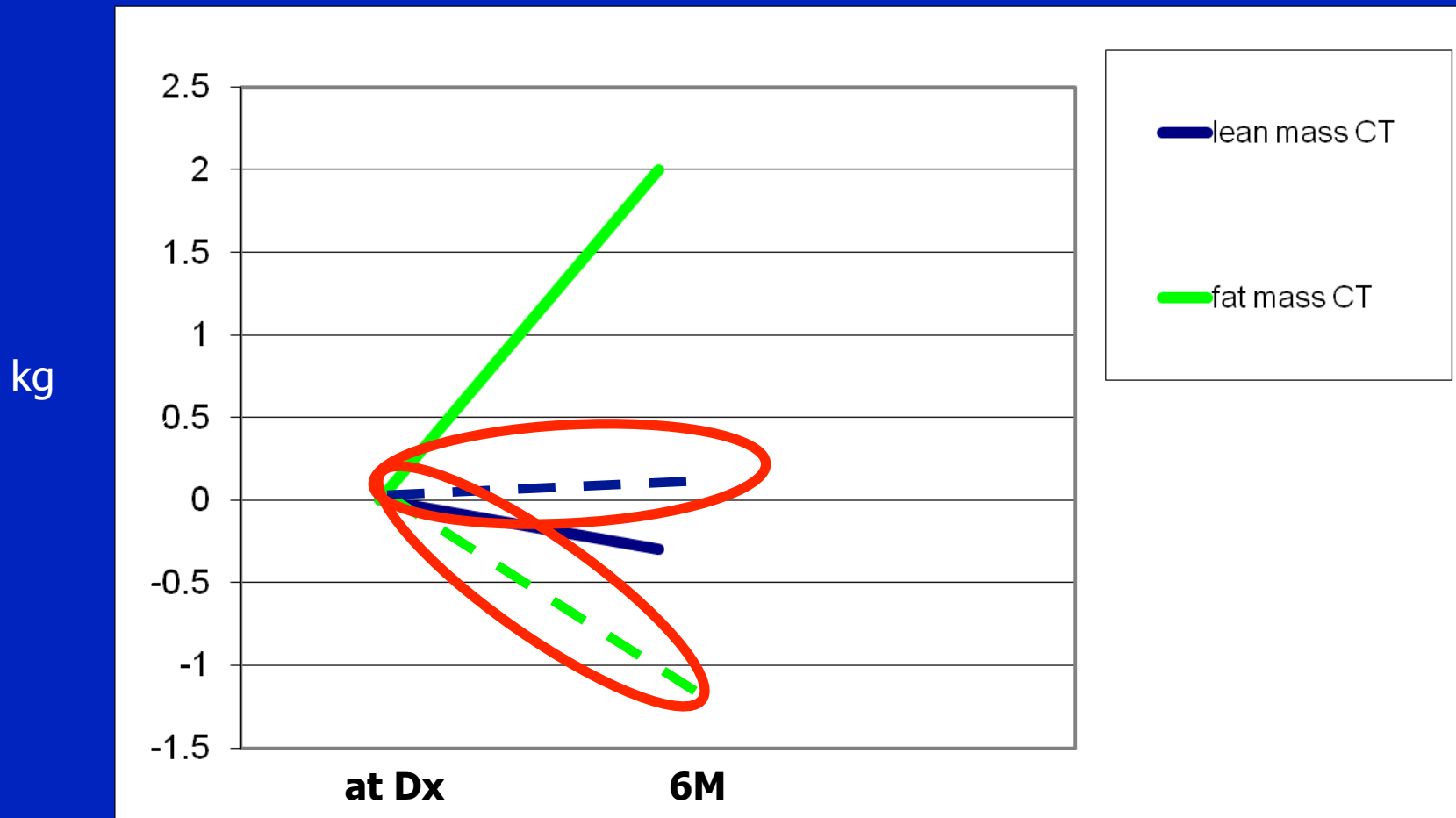


Pilot Study (N=10)

- To determine whether an exercise (strength training + aerobic activity) - diet (\leq 20% fat, plant-based, calcium-rich diet) is feasible & shows promise of preventing adverse body composition changes among premenopausal women who receive adjuvant chemotherapy for breast cancer.



Body Composition Changes Post-diagnosis in Premenopausal Breast Cancer Patients on Adjuvant Chemotherapy: Pilot Study Results



Our 1st clinic-based program: Highly effective at improving body composition

- Scientific Writer
- Magazine Editor
- Foreign Translator
- College Professor

....(worried, white, & wealthy)

Home-Based Interventions

Survivor TRaining for ENhancing Total Health (STRENGTH)

R21 CA92468

**90 Premenopausal Breast Cancer Pts on Chemotherapy
Feasibility/% Body Fat**

FRESH START

R01 CA81191

**543 Breast & Prostate Cancer Survivors within 9M of dx
Achievement of Diet & Exercise Goals**

Reach-Out to EnhancE Wellness among Older Survivors

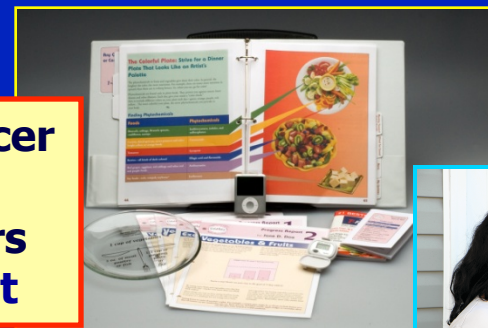
R01 CA106919

**641 Older Longterm Breast, Prostate & Colon Cancer Survivors
Physical Function**

DAMES: Daughters And MothErS Against Breast Cancer

R21 CA122143

**67 Overweight Breast Cancer Survivors & Daughters
Feasibility Team vs. Independent Approach/Weight**



What is the FRESH START Trial?



- RCT to test sequentially tailored print material diet (\uparrow F&V, \downarrow fat-saturated fat) & exercise intervention on improving health behaviors of breast & prostate cancer survivors newly dx'd w/ early stage disease
- Randomized to Tailored vs. Standardized Material Arms

Eligibility

- Individuals with loco-regionally staged breast & prostate cancer diagnosed within past 9 months
- Able to speak or write English; and
- No conditions precluding unsupervised exercise program
 - uncontrolled CHF or angina
 - recent MI or breathing difficulties requiring oxygen-use or hospitalization
 - use of a mobility aid other than a cane
 - plans to have hip or knee replacement
- No conditions precluding high F&V diet (kidney failure or warfarin-use);
- No progressive malignant disease or additional primaries;
- Not exercising \geq 150 min/week or eating a low fat, high F&V diet



Fresh Start Study Schema

Self- or Physician-Referred Cases
N=343

Cases Ascertained from Cancer Registries
N=1812

Physician-Approved Cases
N=343

study staff contacts physicians

Physician-Approved Cases
N=1460

Total Cases Approved for Contact
N=1803

Invitation to participate, screener, consent forms, preaddressed, postage-paid return envelope

Respondents consenting to participate
N=762 (42% response rate)

Non-
Respondents
N=961

Respondents refusing to
participate
N=66

Returned Letters
Unusable Address
N=14

*Screening & Baseline Surveys (N=678)
Subset (N=154) blood draw, vitals, ht/wt,
& accelerometer assessment*

Ineligible Cases (219): heart/pulmonary (54), warfarin (20); another CA (13); mobility (12); & dialysis (2) OR already adhere to routine exercise (88); low fat diet: (80) or F&V-rich diet (127)

Eligible Breast & Prostate Cancer Survivors
N=543

Tailored Intervention Arm
N=271

Randomization

Standardized Intervention Arm
N=272

Drop-Outs (N=18/6.6%): lack of interest (13); death (2); Illness (2); lost-to-follow-up (1)

*10-Month
Intervention
Period*

Drop-Outs (N=6/2.2%): lost-to-follow-up (4); lack of interest (2)

12.9%
Overall
Drop-out

Tailored Intervention Arm
N=253

*1-year
Follow-up*

Standardized Intervention Arm
N=266

7.0%
Overall
Drop-out

Tailored Intervention Arm
N=236

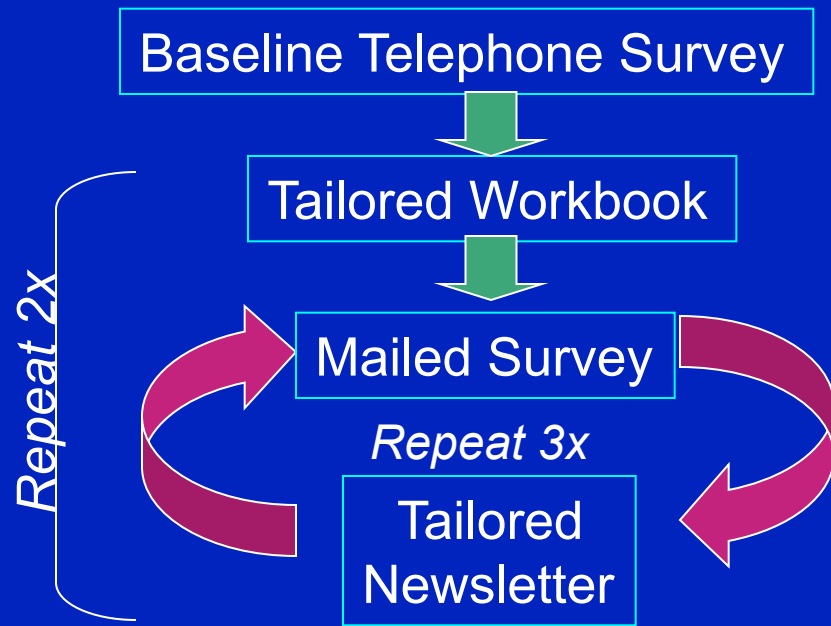
*2-year
Follow-up*

Standardized Intervention Arm
N=253

Tailoring – Experimental Arm

Tailored using data from baseline survey and updates from interim surveys

Social Cognitive Theory and Transtheoretical Models Employed



H

Hello, John Doe!

This is your first newsletter on eating more vegetables and fruits. We hope that you give some serious thought into trying to eat **at least 5 or more servings** each day!

Vegetables and fruits have more nutrients and cancer-fighting substances than all other food groups. They have many great benefits. We hope the information in this newsletter will give you reason to believe that eating more vegetables and fruits is important for YOU.

*In about two weeks, you will receive an update card, like the one you returned to us. It is **very** important that you complete and return the update cards. That way, we can send you newsletters that BEST FIT YOU.*



H

Hello, Jane Doe!

This is your first newsletter on eating more vegetables and fruits. You did well on the previous unit on low-fat eating. The changes that you made in the way you eat, may make it even easier to reach the goal of eating **at least 5 servings of vegetables and fruits** each day. We hope that you give some serious thought into eating more of these healthy foods!

Vegetables and fruits have more nutrients and cancer-fighting substances than all other food groups. They have many great benefits. We hope the information in this newsletter will give you reason to believe that eating more vegetables and fruits is important for YOU.

*Please know that the information in this newsletter may not be up-to-date because we did not get your last update card in time. In about two weeks, you will be mailed another update card. It is **very** important that you fill out and return the update cards. That way, we can send you newsletters that BEST FIT YOU. We also will pay you **\$5** if you return it to us within one week of receiving it.*



Where does John Doe stand?

Look at the graph below to see your progress!

- The first three bars on the left show your previous level of exercise. If you see any big “?”s, it’s because we didn’t get your update cards.
- The bar on the far right shows the number of minutes of exercise you reported on your last update card.
- Your ultimate goal is to exercise AT LEAST 150 minutes each week—see the top dashed line.

Congratulations, John Doe. You’re taking action! Great job!

Average number of minutes you exercise each week...



Where does Jane Doe stand?

Look at the graph below to see your progress!

- The first three bars on the left show your previous level of exercise. If you see any big “?”s, it’s because we didn’t get your update cards.
- The bar on the far right shows the number of minutes of exercise you reported on your last update card.
- Your ultimate goal is to exercise AT LEAST 150 minutes each week—see the top dashed line.
- During the next month, try to get just 10 minutes more of exercise each day. The bottom dashed line shows this goal. You CAN do it!

You’re heading in the right direction, Jane Doe! Keep with it.

Average number of minutes you exercise each week...



Ask Ms. Greene



Dear Jane Doe,

When you spoke to us over the phone, you said that eating more vegetables and fruits was hard for you because it's hard to get vegetables and fruits when you eat out. Here is what our Health Educator, Sonya Green, says.

Eating out doesn't mean you can't eat healthy.

- ✔ Visit the salad bar or order a vegetable salad with your meal (remember to order the dressing on the side).
- ✔ Choose restaurants with salad bars, and choose wisely by piling lots of plain vegetables and

ese and other items.

dishes. Many restaurants make ask!

and sandwiches.

getting more vegetables and

Ask Ms. Greene



Dear John Doe,

On your last update card, you told us that eating more vegetables and fruits was hard for you because they cost too much. We told our Health Educator, Sonya Green, about your concern and this is what she says.

Eating more vegetables and fruits doesn't have to be expensive.

- ✔ Shop for vegetables and fruits that are "in season." In the summer, buy cucumbers, summer squash, peaches and plums. It is best to buy apples and oranges during the winter.
- ✔ Buy canned and frozen vegetables, which are much cheaper and are often just as nutritious.
- ✔ Try buying vegetables and fruits from a produce truck or stand. You will usually get more for your money while saving trips to the grocery store.



It's great that you are thinking about eating less fat.

Many others who have had cancer have taken on low-fat eating, and so can you! Here's how YOU too can make a FRESH START.

- ◆ Think about where most of the fat comes from in your diet. When we talked to you over the phone, YOUR problem areas were ice cream, cookies, and chocolate candy. Look up lower fat substitutes for these foods in your workbook.
- ◆ Get in touch with your food cravings, and try to find lower fat foods that will fit the bill. For example, if you know that you crave something sweet after dinner, then look in your workbook for lower fat foods that will satisfy your sweet tooth. If you're more of a snacker, then look for lower fat substitutes for chips.
- ◆ Think about ways that you can trim the amount of fat you eat. Write down the things that you think will be hard entirely—you just think of ways to c

It's great that you're already taking steps to eat less fat.

Here are some more things you may want to consider...

- ◆ When we talked to you on the phone, YOUR main sources of fat were hamburgers, potato chips, and mayonnaise. Look up lower fat substitutes for these foods in your workbook. Make a grocery list of these lower fat food items. The next time you're at the store, pick up some of these lower fat foods.
- ◆ When you cook, try steaming, microwaving, roasting, grilling or broiling instead of frying or sautéing. Use cooking sprays instead of butter, margarine, or oil. Flavor your foods with citrus juices, vinegars, or herb seasonings.
- ◆ Track the amount of fat you eat. Use YOUR Fat Gram Record- and the "T-Factor 2000" Fat Gram Counter booklet—see pages 8–9 of your workbook.
- ◆ Talk to your family and friends about what you are trying to do. Eating less fat is healthy for them too. Together, you can work on eating healthier!

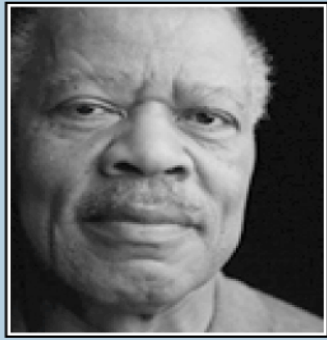
Remember the benefits of eating less fat. Reward yourself when you are eating within your fat gram allowance. You're making good choices for your health. **Keep up the great work!**

Cancer Coping Style (Watson)

- **Fighting spirit**
"I am determined to beat this disease"
- **Fatalism**
"I count my blessings"
- **Cognitive Avoidance**
"Not thinking about it helps me cope"
- **Helpless-hopeless**
"I feel like giving up"
- **Anxious preoccupation**
"I am upset about having cancer"

Tailored on Age, Race, Gender & Cancer Coping Style (Fighting Spirit, Fatalist, Helpless/Hopeless, Cognitive Avoider, or Anxious Preoccupier)

Helpless-Hopeless

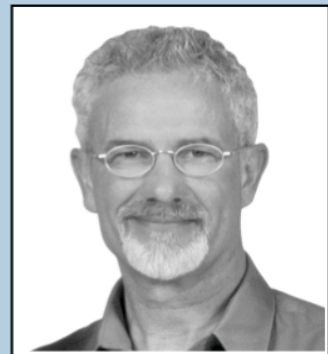


Richard Goode • diagnosed with prostate cancer at age 64, father of five, grandfather of eight.

When I was diagnosed with prostate cancer 3 years ago, I felt like I'd been hit by a truck. Hearing the word "cancer" made me tune out everything else. I was at a loss about what to do. One day, one of my children said to me, "Look at you! Why aren't you trying

I was at a loss about what to do. to fight this thing?" I finally realized that I owed something more to those who care about me, and to

Fighting Spirit



Jeff Preston • diagnosed with prostate cancer at age 49, father of three.

When I was diagnosed with prostate cancer 3 years ago, I made up my mind that I was going to beat this disease. People were counting on me to get better, and I wasn't going to let them down. I saw the cancer as my own personal

My health and my family are battle and knew there were things that I COULD DO to fight it. Three years

Anxious Preoccupier



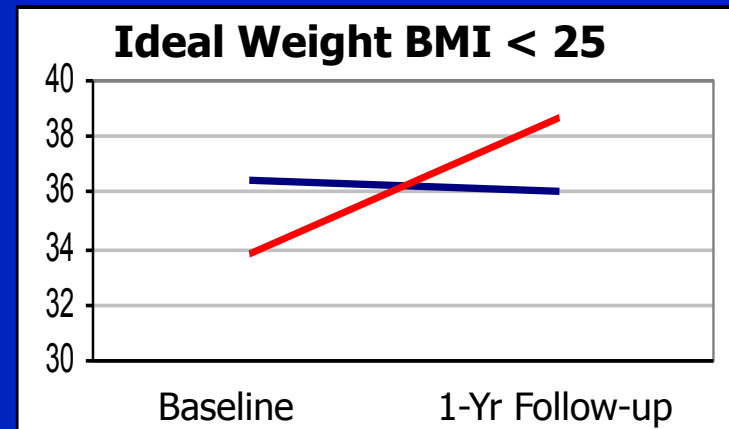
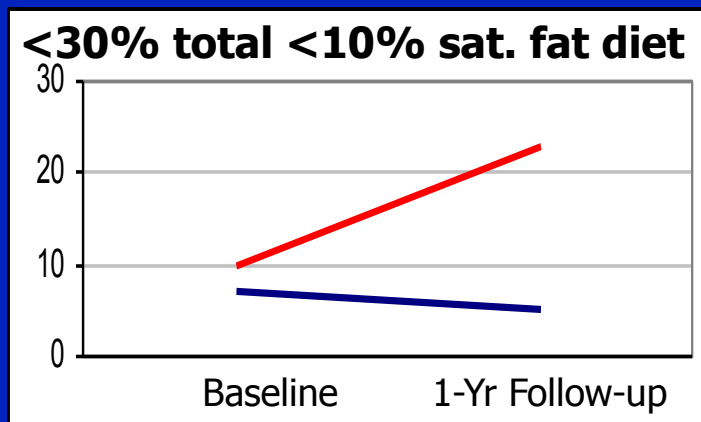
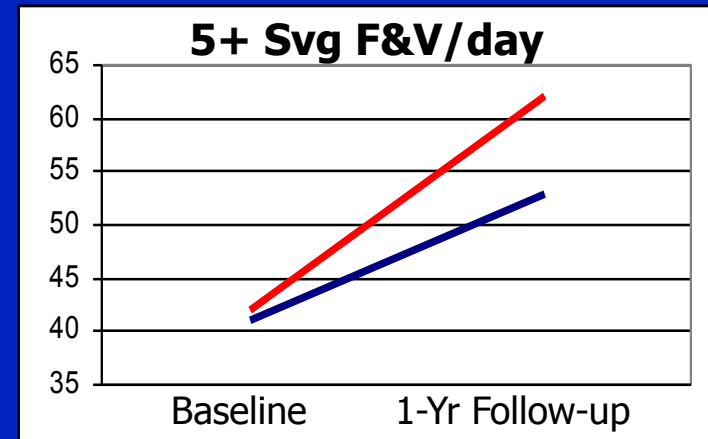
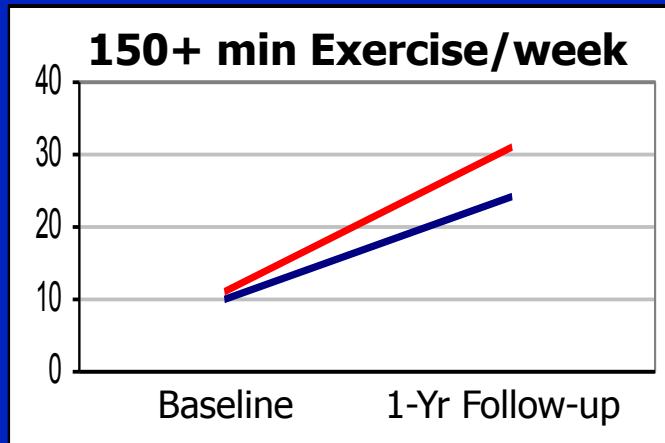
Marian Ward • diagnosed with breast cancer at age 62, mother of four, grandmother of seven.

When I was diagnosed with breast cancer 3 years ago, I was shocked and scared. I found it hard to concentrate at work and spend time with my friends and family—I was always thinking about my cancer. I felt other people who had cancer dealt with it better than me.

I found it hard to concentrate at work and spend What seemed to help them was taking control over the parts of their lives they could control—

Achieving Goal: Intervention vs. Control Baseline vs. 1-yr. follow-up (all p's <.05)

% of sample



— FRESH START

— Attention Control

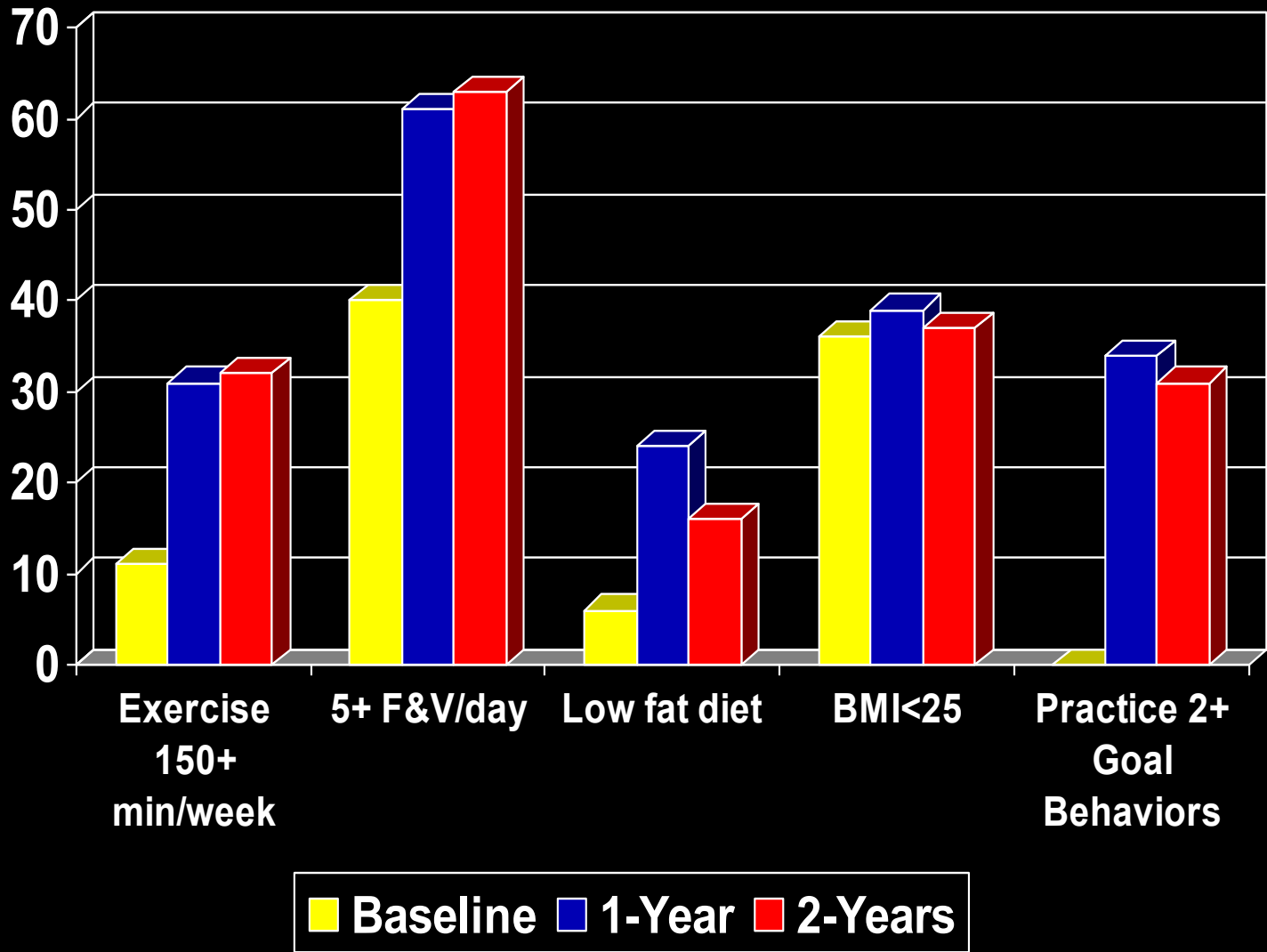
Self-referred & cancer registry subjects differ with regard to several characteristics (FRESH START)

	Self-Referred (n=209)	Cancer Registry (n=334)	P-value
Age (years) - Mean (sd)	54.1 (10.4)	58.7 (10.7)	<.0001
Gender - % male	39%	47%	.07
Cancer-Coping Style (Mini-Mac)			
- Fighting Spirit	50%	30%	.001
- Fatalist	43%	62%	
- Other	7%	8%	
# of Co-Morbidities (OARS)	1.87 (1.60)	2.24 (1.78)	.014
Risk for Depression (CES-D)	2.84 (4.05)	2.24 (3.86)	.07
Quality-of-Life (FACT)	88.2 (15.1)	92.0 (12.9)	.002

Self-referred & cancer registry subjects differ with regard to intervention uptake

	Self Referred (n=209)		CA Registry (n=334)		P-value	
	Baseline	Follow-up	Baseline	Follow-up		
Exercise (min/week)	60 \pm 117	122 \pm 126	42 \pm 90	83 \pm 120	0.002	
% kcal from fat	37.5 \pm 5.6	34.5 \pm 4.9	38.2 \pm 5.6	34.9 \pm 5.4	0.83	
F&V servings/day	4.7 \pm 2.3	6.0 \pm 2.9	5.2 \pm 2.5	5.8 \pm 2.6	0.006	
Practiced Goal Behaviors	- 3 - 2 - 1 - 0	0% 0% 55% 46%	6% 25% 43% 25%	0% 0% 60% 40%	3% 18% 47% 31%	0.003
BMI	27.6 \pm 5.2	27.5 \pm 4.9	27.4 \pm 5.3	27.5 \pm 5.4	0.14	

Durability of Behavioral Change over Time



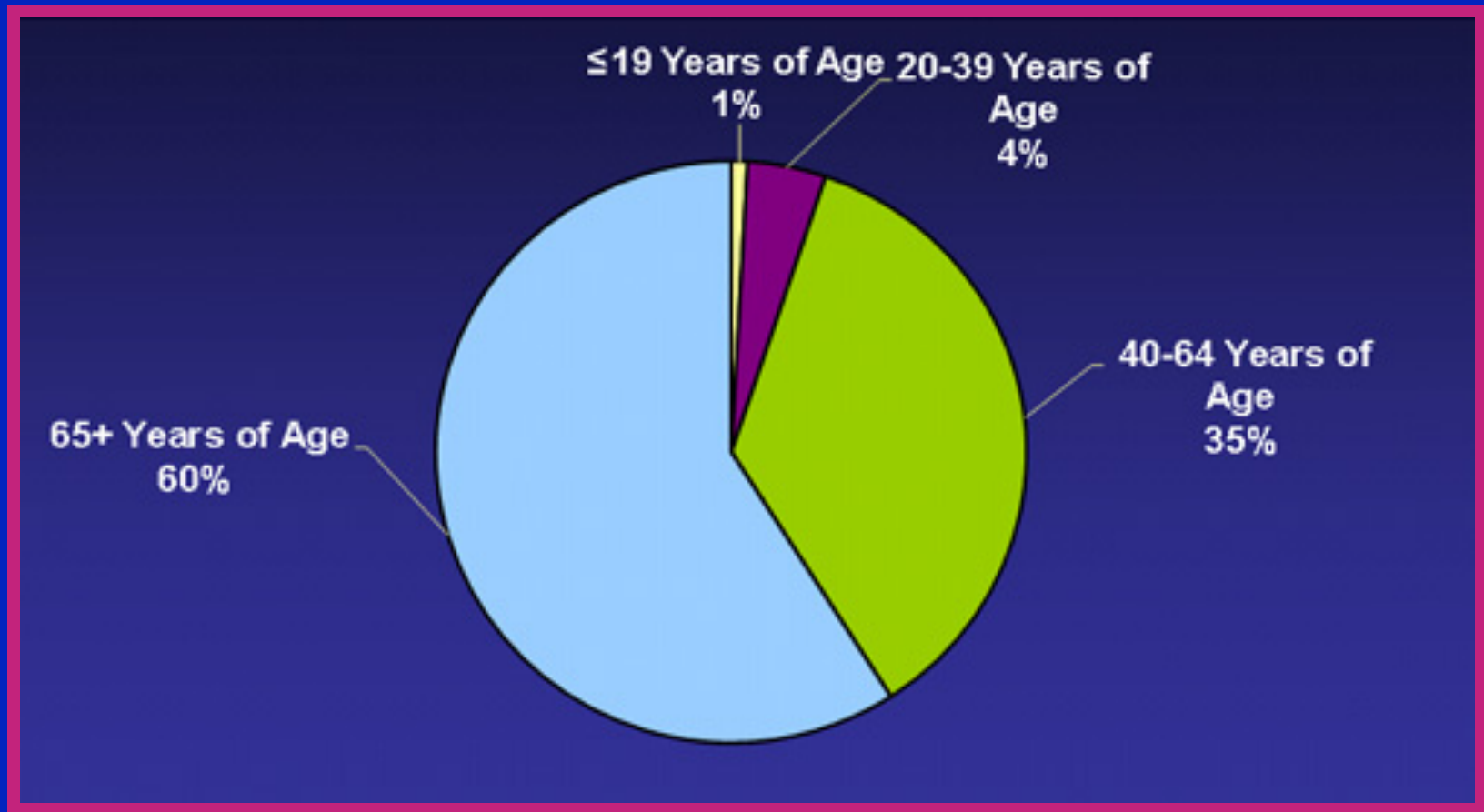


Reach Out to ENhance Wellness in Older Survivors (R01 CA106919)

- Test the impact of a diet-exercise mailed material/telephone counseling program on weight loss & physical functioning in 640 prostate, colorectal & breast cancer survivors
- 65+ years of age & overweight
- 5+ years out from diagnosis



Older Survivors are a Prime Population



Altekruse SF, Kosary CL, Krapcho M, Neyman N, Aminou R, Waldron W, Ruhl J, Howlader N, Tatalovich Z, Cho H, Mariotto A, Eisner MP, Lewis DR, Cronin K, Chen HS, Feuer EJ, Stinchcomb DG, Edwards BK (eds). SEER Cancer Statistics Review, 1975-2008, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2008/, based on November 2010 SEER data submission, posted to the SEER web site, 2011

What do we know about age & participation in clinical trials?

- Unaware of increased risk status
- Lower health literacy
- Transportation issues
- Increased cumulative disease burden
- More likely to view cancer as “beyond their control”
- Functional/sensory deficits (low vision/hearing impairment)
- Value preferences favoring more immediate gratification
- Some studies suggest less likely to change behavior & to maintain change
- There is age-bias in offering clinical trials; and age effect for participation



Overview: Accrual & Screening

Self-Referrals
N=107

NC Cancer Registry
N = 67,054

Confirm case status w/MD

Omit decedents, duplicates, 2nd primaries, contact info

N = 107

Mailed letter of invitation and a screening survey

Potential N = 37,054

Approached N = 26,031

n = 86
80% response

Returned survey/consents
White, males, younger & more proximal to dx more likely to respond

n = 1147
6% response

Undeliverable
n = 6,030

n = 1233

Ineligible n = 567

641 Enrolled

Randomization: cancer site, gender, age (65-74 years vs 75+ years), and race

Immediate Intervention (319)

Delayed Intervention (322)

76 Drop-outs

1-yr Follow-up (269)

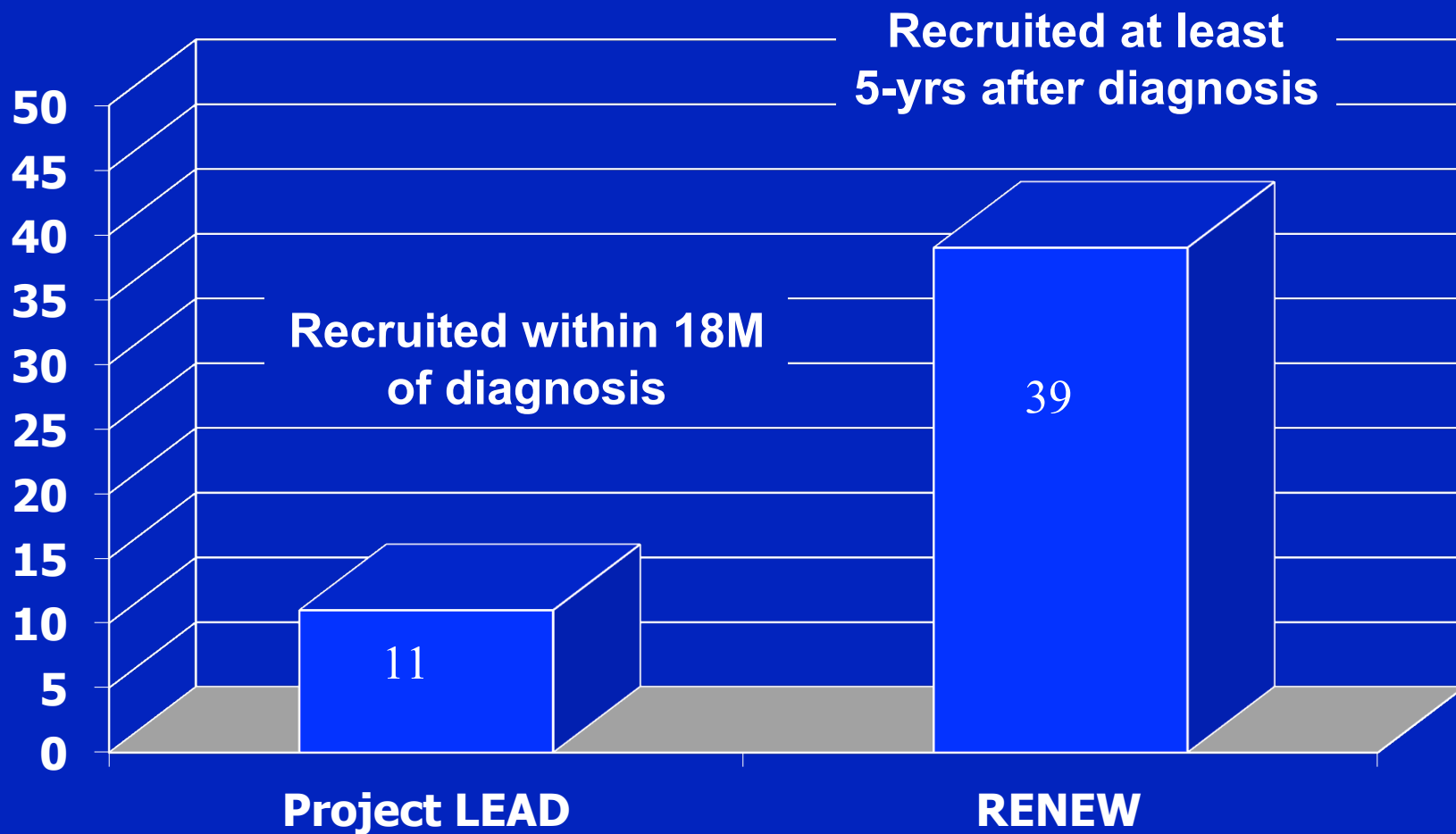
1-yr Follow-up (289)

77 Drop-Outs

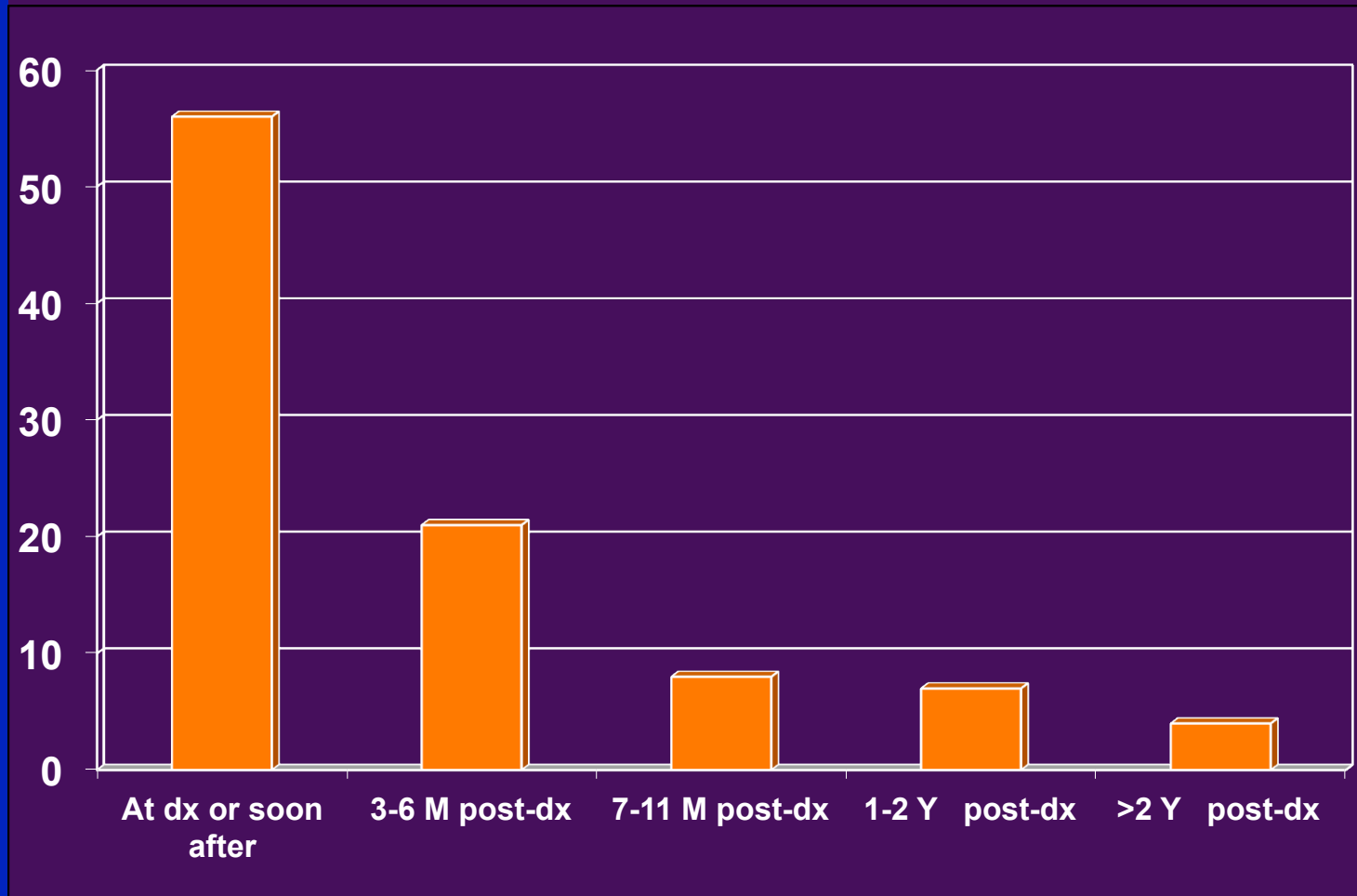
2-yr Follow-up

2-yr Follow-up

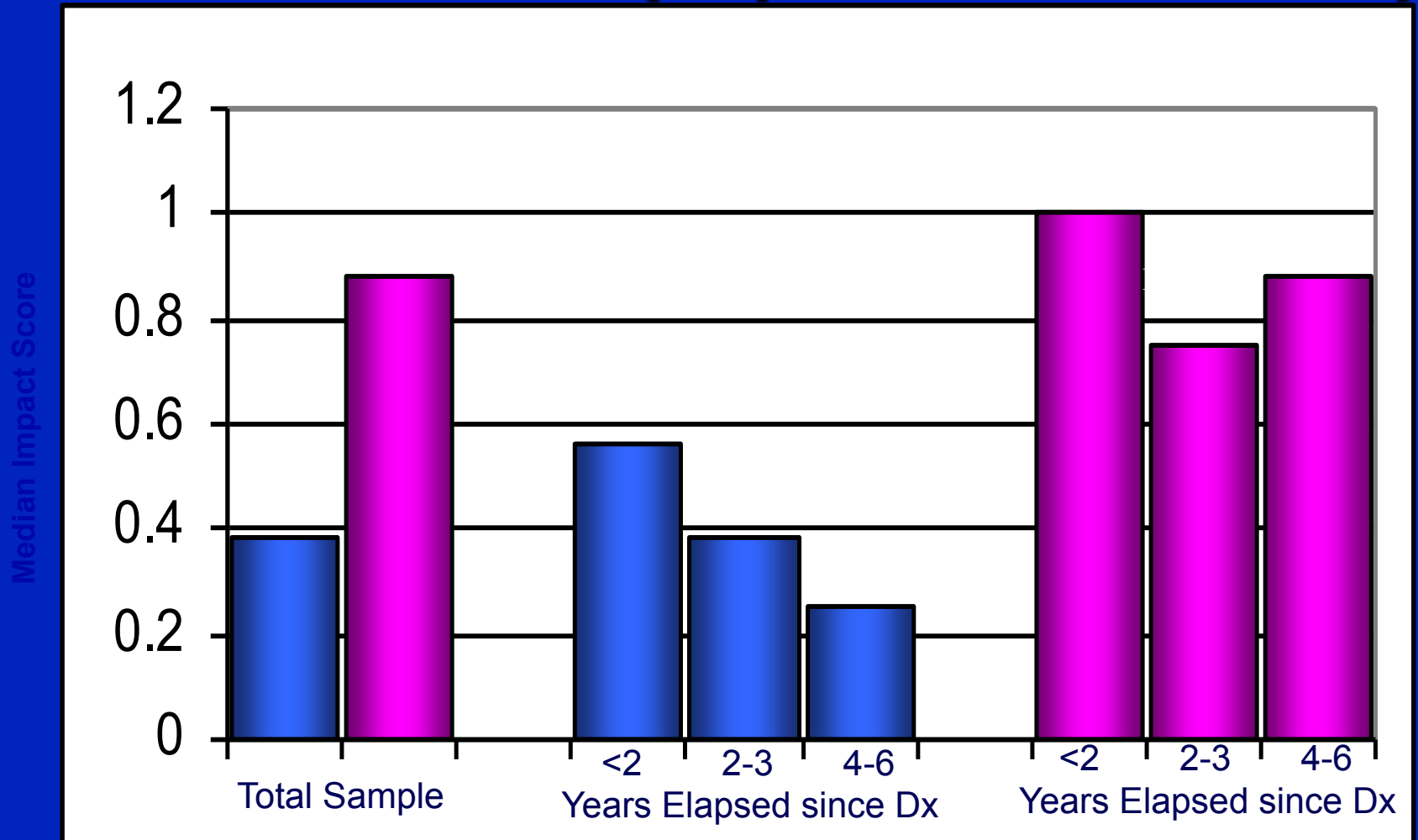
of Letters of Invitation Mailed to Ascertain 1 Analyzable Participant Project LEAD vs. RENEW Telephone Counseling/Mailed Material Diet & Exercise Interventions aimed at Elderly Cancer Survivors



When are Cancer Survivors (n=978) most Interested in Participating in Lifestyle Interventions?



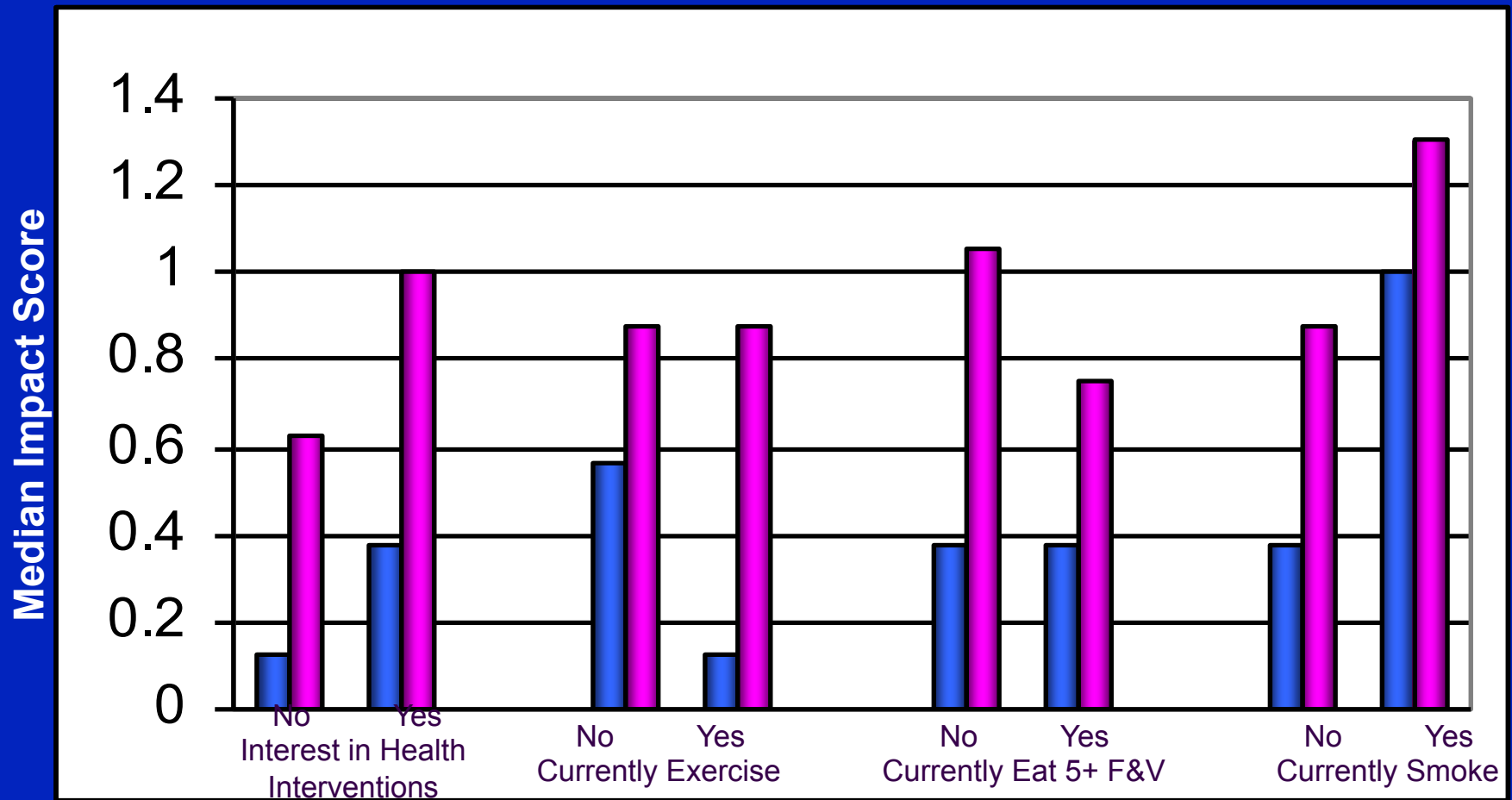
Levels of Distress (Impact of Event Scores)



 Breast Cancer Survivors(n=500)

 Prostate Cancer Survivors(n=420)

Impact of Event Scores by health behavior factors

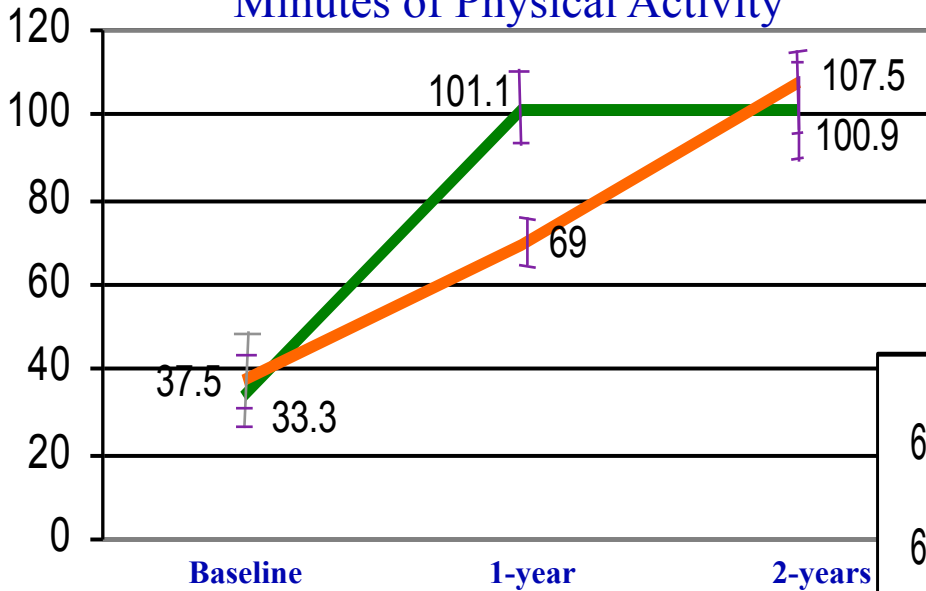


 Breast Cancer Survivors (n=500)

 Prostate Cancer Survivors (n=420)

Changes in Lifestyle Behaviors

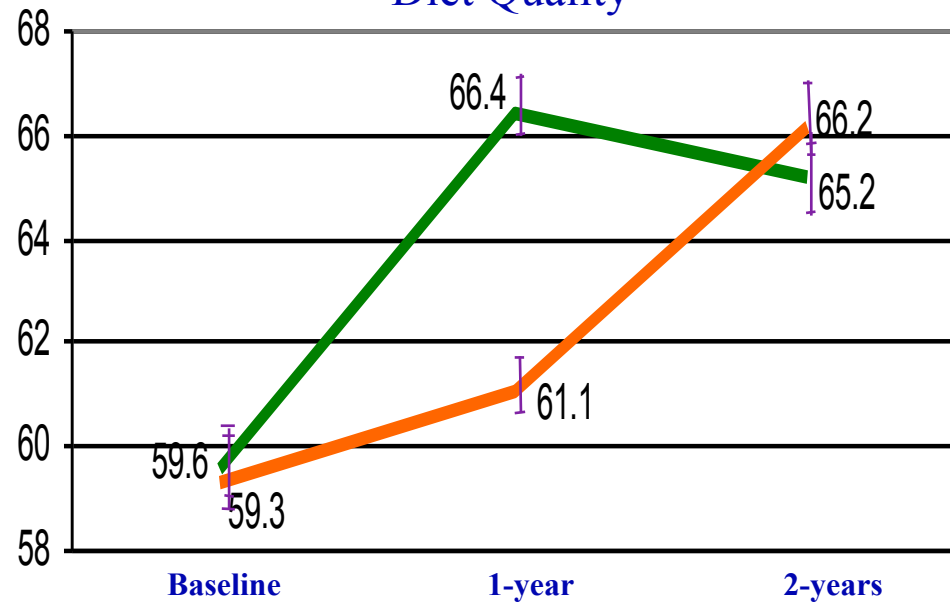
Minutes of Physical Activity



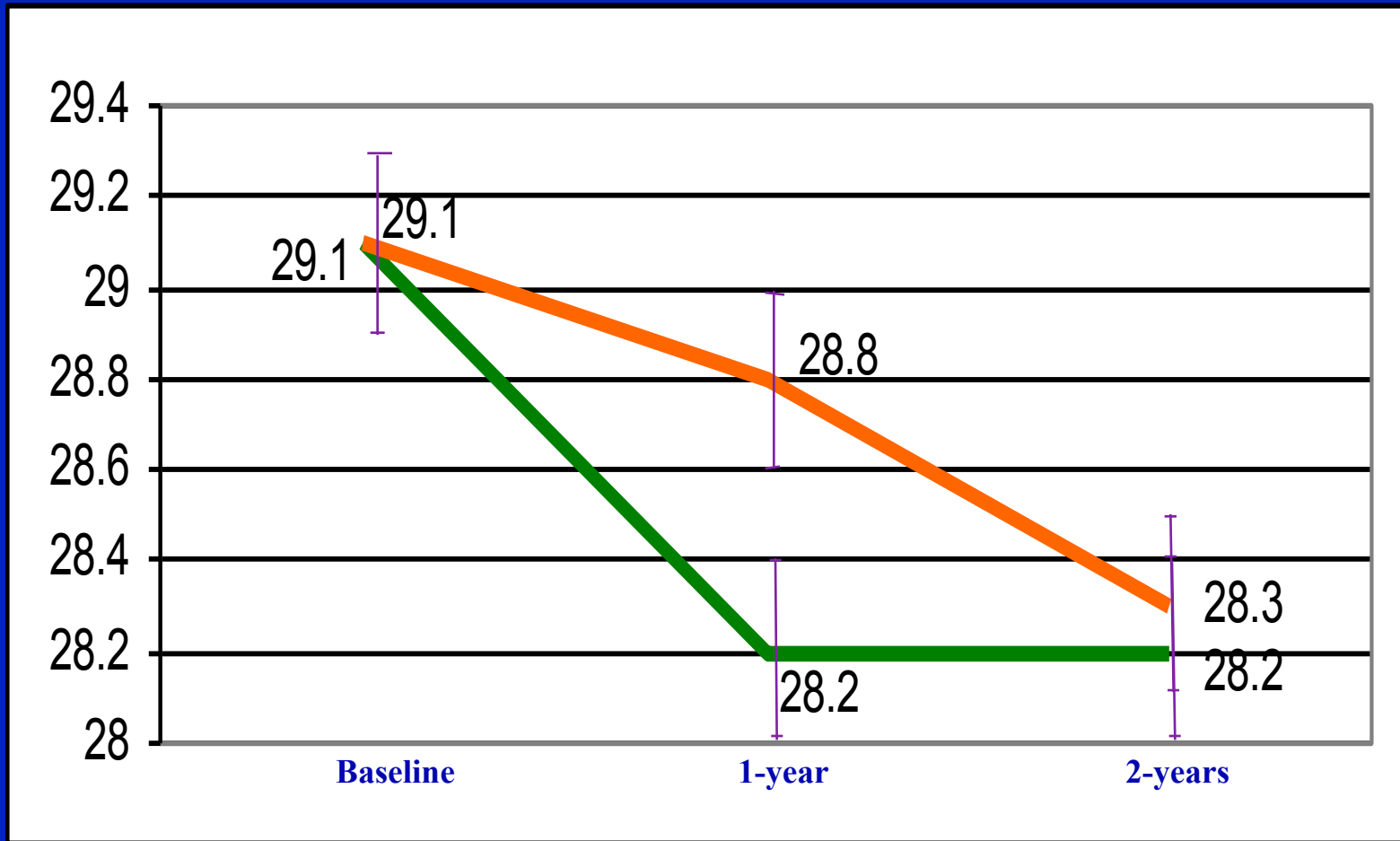
 Immediate **RENEW** Intervention

 Delayed Intervention

Diet Quality

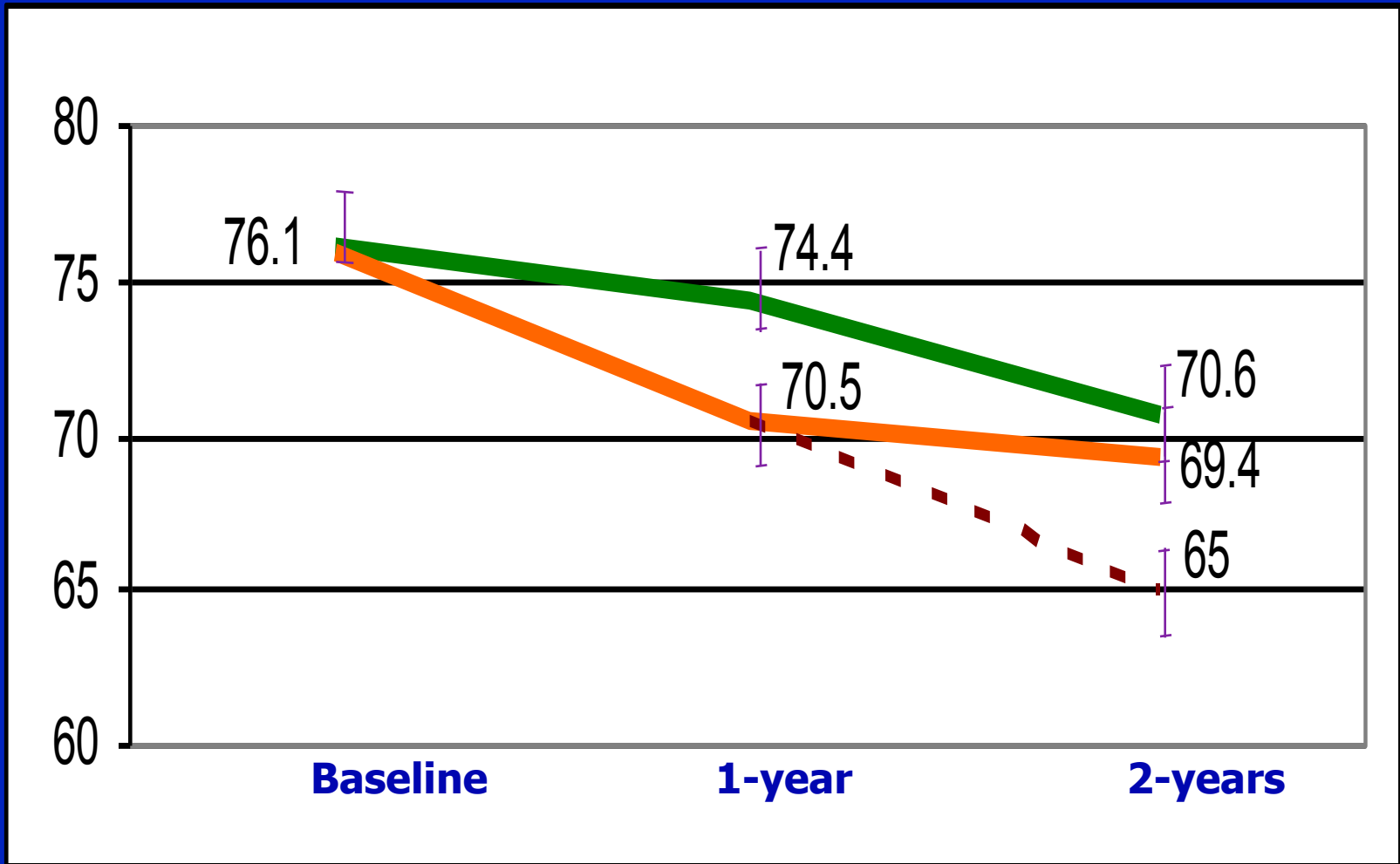


Change in BMI



■ Immediate RENEW Intervention ■ Delayed Intervention

Change in Physical Function (SF-36)



Immediate RENEW Intervention

Delayed Intervention

DAMES Against Breast Cancer

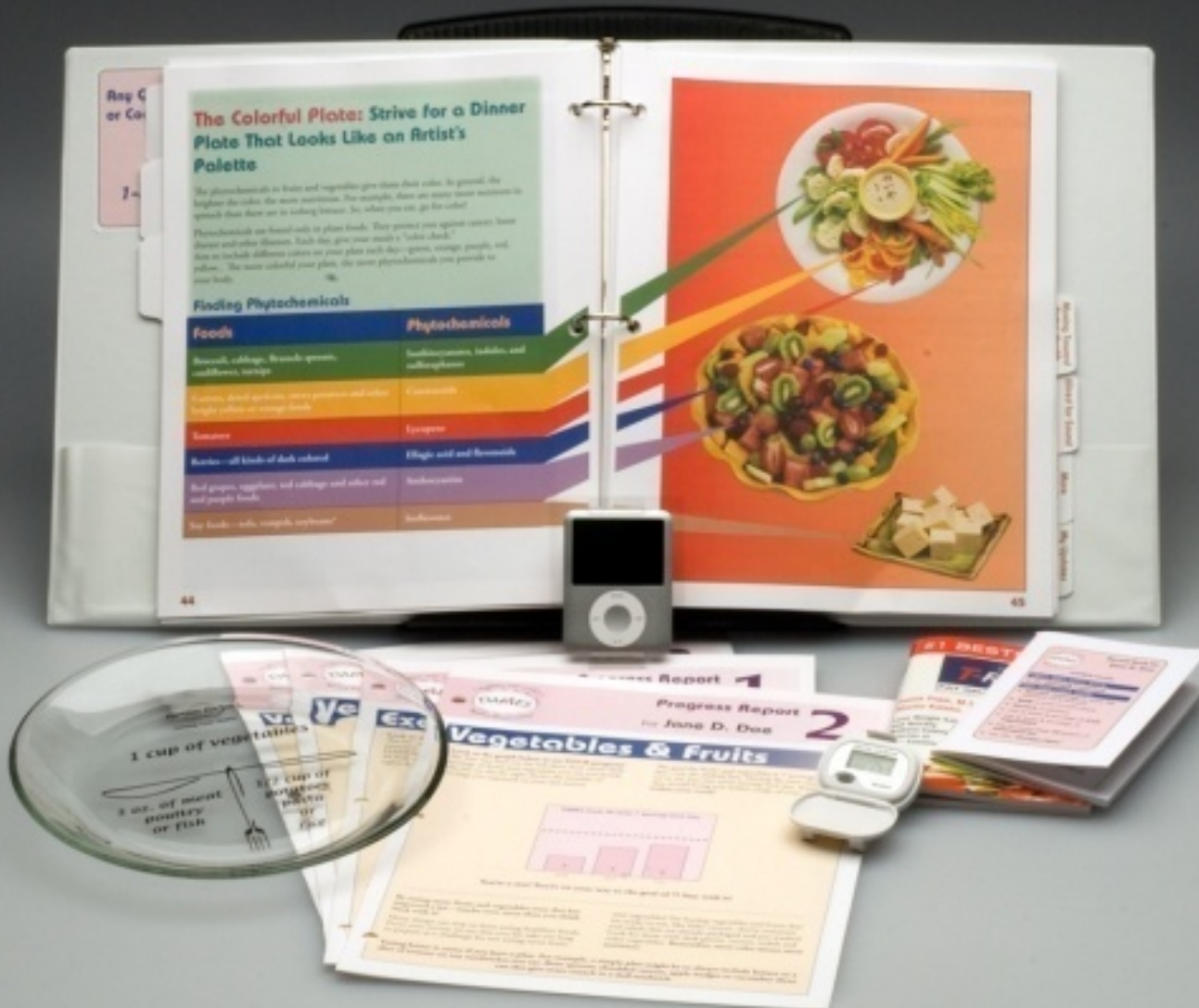
(R21-122413)



- **Pilot-Feasibility Trial to promote weight loss in overweight breast cancer patients and their overweight adult daughters**
- **Enroll 67 Mother-Daughter Dyads**
- **Home-based diet-exercise intervention aimed at weight loss:**
 - 1) **Standardized Materials;**
 - 2) **Tailored Materials (Independent Approach)**
 - 3) **Tailored Materials (Team-Based Approach)**



DAMES Tailored Intervention Materials



STUDY
FLOW

31 Self-Referrals

2516 Cancer Registry Cases

211 MD Denies Contact

2336 Breast Cancer Cases Mailed Study Invitation

56 Unusable address; 6 Deceased

2274 Total Potential Contactable Pool

141 Eligible Moms Notified
Daughters Sent Study Invitation

1385 No response
332 No eligible daughter
209 Not interested
93 BMI <25
48 Medical Exclusions
35 Exercise >150 min/week
15 BMI 40+
12 Enrolled in wt loss program
4 Non-English speaking

84 Mother-Daughter Dyads Identified
Sent Full Study Consent

5 No response
6 Not eligible
23 Not interested
4 Medical Exclusions
5 Exercise >150 min/week
9 BMI <25
3 BMI 40+
2 Enrolled in wt loss program

9 Consents received after study closure
5 Lost interest

70 Mother-Daughter Dyads –
Consented

2 Dyads Incomplete Baseline Assessment

68 Dyads Randomized

18 Attention
Control

25 Individually Tailored

25 Team Tailored

6M Follow-Up Assessments

18 Drop-outs (13.2% Attrition)

12M Follow-Up Assessments (58 Dyads)

Unadjusted BMI Change Scores (Baseline to 1-year)

Control

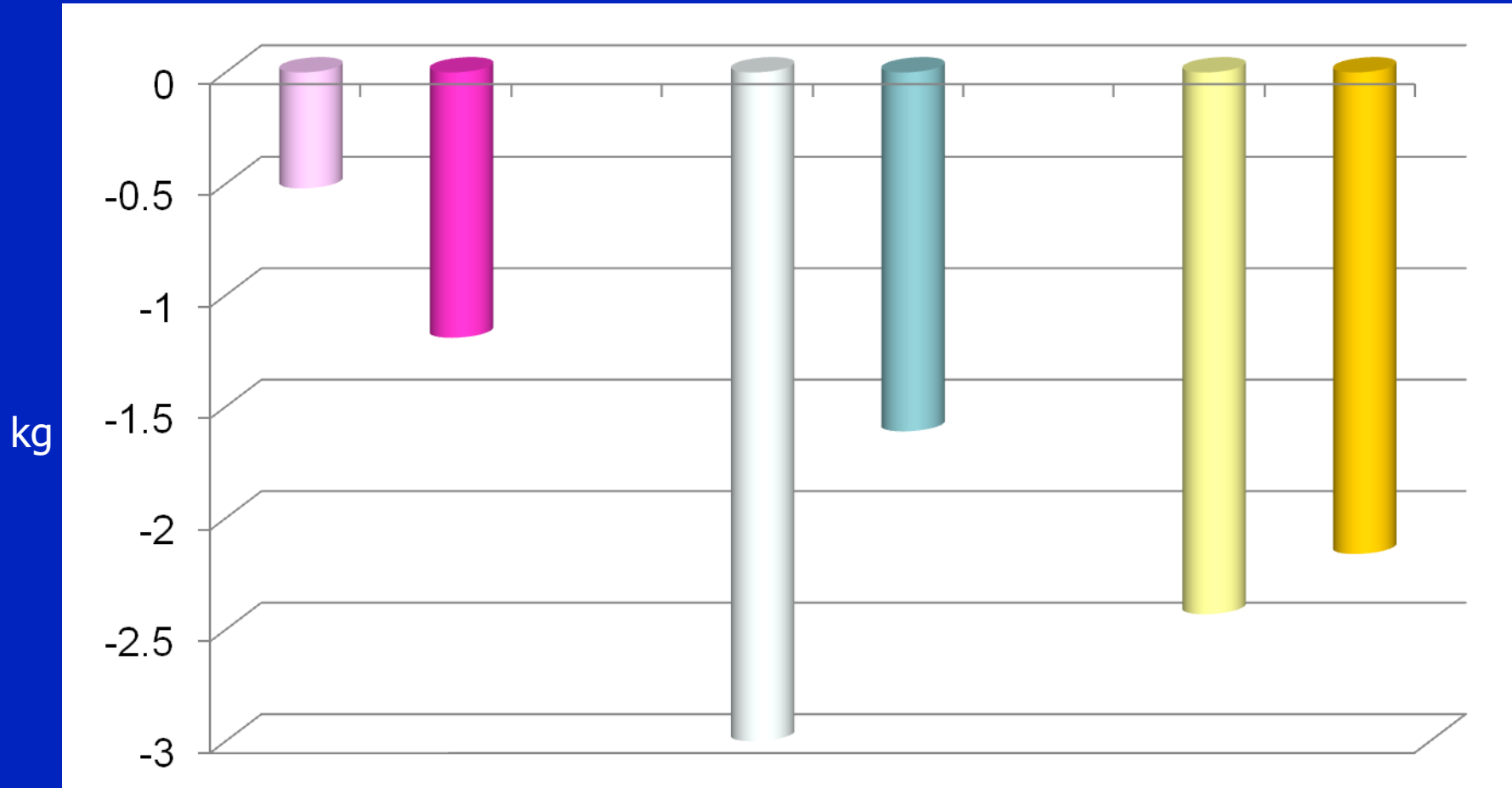
Moms Daughters

Independent

Moms Daughters

Team

Moms Daughters



Summary

- Behavioral intervention trials subject to self-selection (Intervention vs. Sample)
- Self-referred subjects differ significantly from those ascertained through cancer registry in terms of baseline characteristics and intervention response
- The most opportune time to intervene is close to diagnosis
- Diet and exercise interventions in cancer survivors can result in many clinical benefits, including functional status
- If you are ever considering doing a mother-daughter intervention – think again.

Interventions can result in Unforeseen Benefit



Daughter
lost 10
pounds

Mom
lost 23
pounds

Dog "Rocky"
lost 11 pounds

Areas for Future Research

- To determine optimal timing of interventions
- To determine optimal channels and modes of delivery for interventions
- To determine the optimal target (survivors alone or survivors and family/friends)
- To determine optimal means of addressing content in multi-component interventions
- To determine means by which effective interventions are sustainable



Harvest for Health Pilot Study

PURPOSE: To assess the feasibility of a F&V gardening intervention that pairs master gardeners with cancer survivors

SAMPLE: 4 Breast, 4 Prostate & 4 Childhood Cancer Survivors

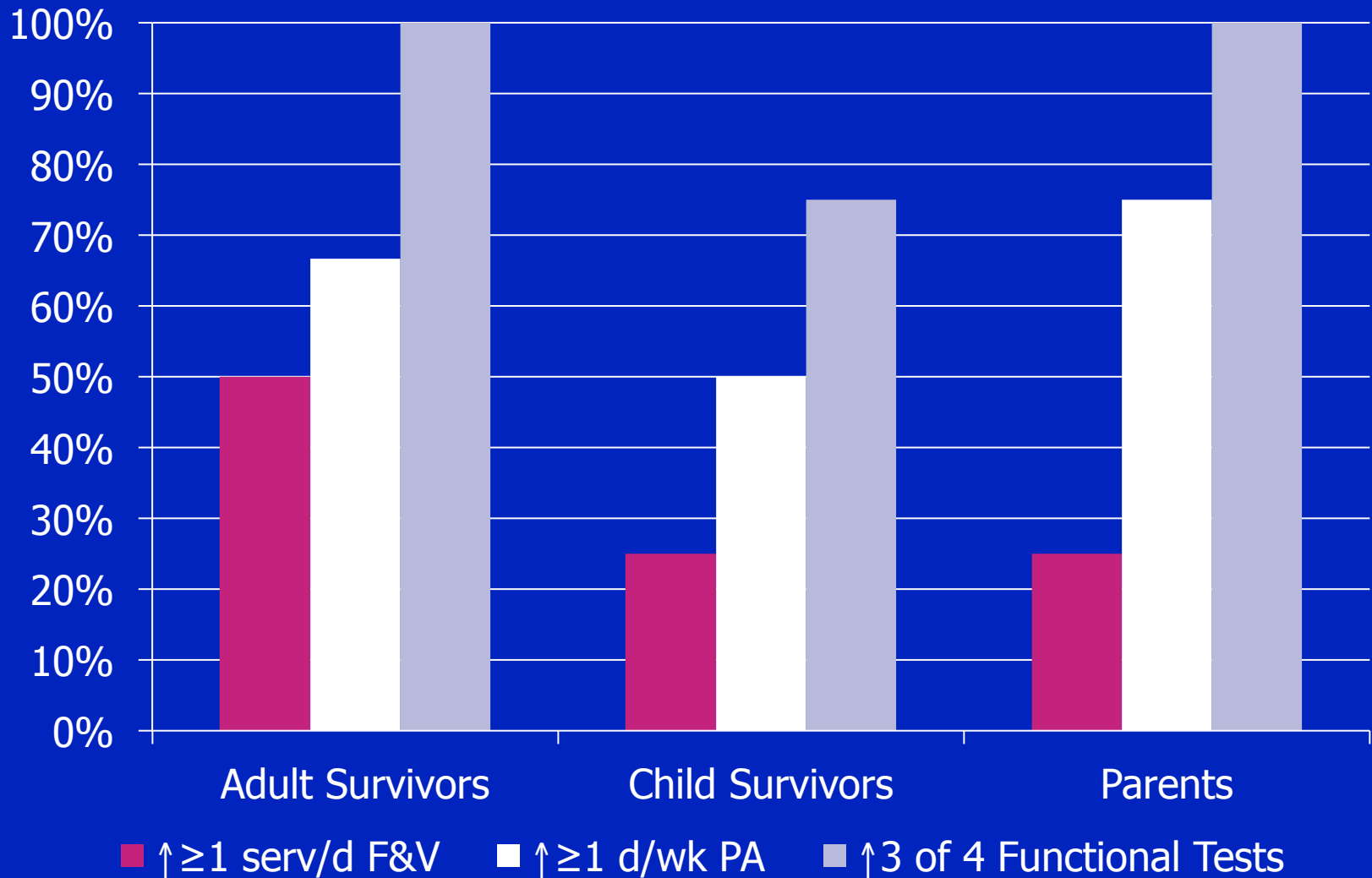
HYPOTHESIS: Intervention will improve F&V consumption

Measures: F&V screener (EATS), QoL (Peds QOL/SF-36), height, weight, Physical activity (Godin), 30 sec chair stand, grip strength, 6 minute walk, & 8' get-up & go (baseline, 3,6,9,12 M)



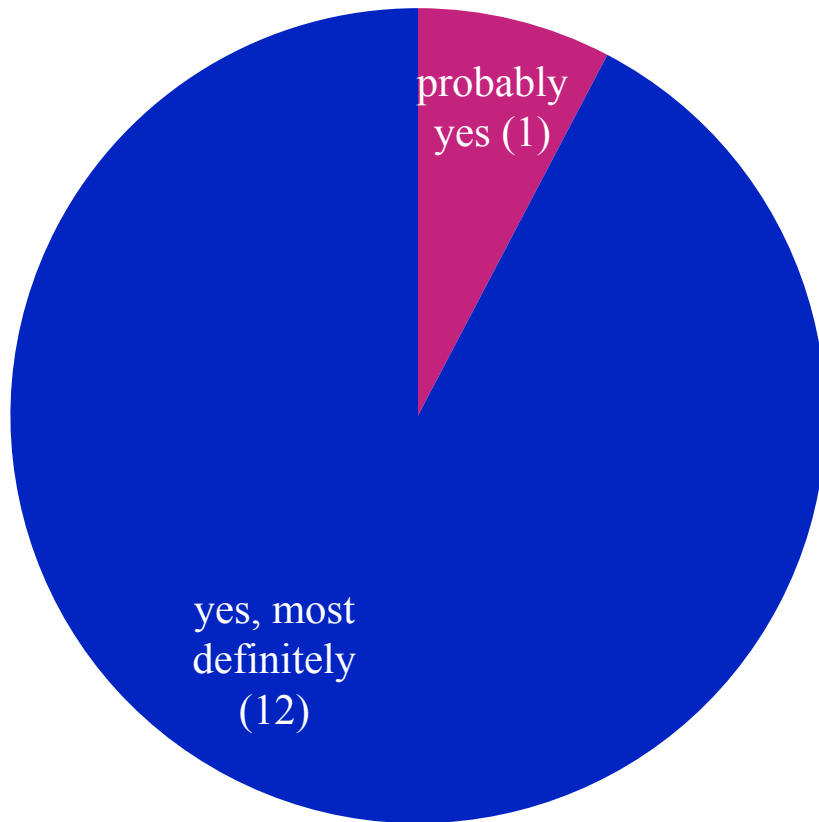
Results

Percentage achieving health goals

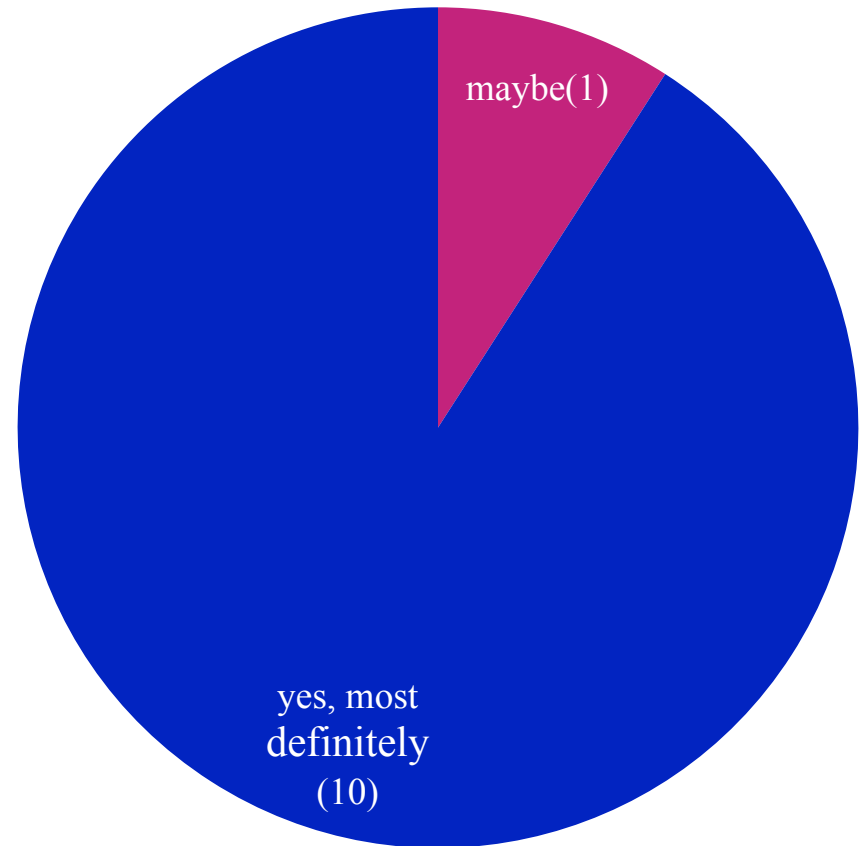


Future Gardening Plans

Plan to Continue the Garden



Plan to Expand the Garden



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