Executive Summary
National Cancer Institute Breast Cancer Steering Committee
Clinical Trial Planning Meeting

Lifestyle Intervention for Improving Disease-Free Survival (DFS)
in Early Stage Invasive Breast Cancer
February 10 – 11, 2014

Meeting Co-chairs: Nancy Davidson, M.D. and Rachel Ballard-Barbash, M.D., M.P.H.

Meeting Description

The National Cancer Institute (NCI) Breast Cancer Steering Committee (BCSC) convened a Clinical Trial Planning Meeting for Lifestyle Intervention for Improving Disease-Free Survival (DFS) in Early Stage Invasive Breast Cancer on February 10 - 11, 2014 in Rockville, MD. The goal of the meeting was to develop design recommendations for a feasible randomized clinical trial to determine the efficacy of a lifestyle intervention in improving DFS in women with invasive breast cancer. The meeting attendees included BCSC members, breast cancer clinicians, behavioral scientists, biostatisticians, a patient advocate, subject matter experts in weight loss, nutrition, physical activity, and lifestyle technologies, and NCI staff.

Background

Obesity, an important public health issue, has reached epidemic proportions in the United States with rates of at least 20% in all states.[1] Studies have shown that obesity is associated with an increased risk of mortality from breast cancer in women, and that women who gain weight after breast cancer diagnosis during treatment also have an adverse prognosis.[2] There are several hypotheses that provide a mechanism of action that may explain the observed increase in mortality in epidemiologic studies.[3] Observational studies have not shown a role for dietary intervention alone in decreasing mortality from breast cancer.[4] The Women's Intervention Nutrition Study (WINS), a randomized study of dietary intervention in post-menopausal women, reported that the intervention group lost weight, resulting in a between group difference of 2.3 kg in year 1. Additionally, a 2.6% difference in breast cancer events was observed between the intervention and control groups. When subtypes of breast cancer were considered, the benefit was most striking in the ER-negative subset.[5] There is a need to determine the role of lifestyle modification as an adjunct to conventional therapies in improving DFS in women with early stage breast cancer. Evidence obtained from a randomized clinical trial is needed to develop evidence-based guidelines for physicians and their patients. Trial data is also needed to provide evidence to third party payers to provide coverage for appropriate lifestyle interventions in breast cancer patients.

Recommendations

A randomized clinical trial to determine the efficacy of weight loss in improving DFS in women with invasive breast cancer should be conducted through the National Clinical Trials Network

(NCTN). The study design and statistical plan should address potential for interaction between hormonal therapy and weight loss intervention.

This Executive Summary presents the consensus arising from the Clinical Trial Planning Meeting. These recommendations are not meant to address all clinical contexts, but rather represent priorities for publicly funded clinical research.

Anticipated Actions

A Working Group consisting of representatives from each of the NCTN Groups, biostatisticians and subject matter experts will design a randomized clinical trial to be reviewed by the NCI Breast Cancer Steering Committee.

References

1. http://www.cdc.gov/obesity/
2. Protani M, et al. BCRT. 2010;123:627-635
3. Gunter MJ, Leitzman F. J Nutr Biochem. 2006 Mar;17(3):145-56
4. Women's Healthy Eating and Living (WHEL) Study, Pierce JP, et al. JAMA: 2007;298(3):289–298
5. Chlebowski R, et al. J Natl Cancer Inst. 2006;98(24):1767–1776

AGENDA

NCI Breast Cancer Steering Committee (BCSC)
Clinical Trial Planning Meeting (CTPM) for
Lifestyle Intervention for Improving Disease Free Survival (DFS) in Early Stage Invasive Breast Cancer
February 10 – 11, 2014
The NIH Neuroscience Center Building, 6001 Executive Boulevard
Rockville, MD 20852

DAY 1: MONDAY, FEBRUARY 10, 2014

6:00 PM **Welcome and introductions**
Nancy Davidson and Rachel Ballard-Barbash, Meeting Co-chairs

6:10 PM **Meeting goals/intended outcomes of meeting**
Nancy Davidson and Rachel Ballard-Barbash

6:15 PM **NCI coordination of trial and resources**
Lori Minasian

6:20 PM **State of the science on weight loss trials in people without cancer**
Tom Wadden

6:40 PM **State of the science on the effect of intentional weight loss in people with cancer and the feasibility of intervention approaches in the NCI clinical trials system**
Jennifer Ligibel

7:10 PM **Adaptations using remote technologies and other innovations to enroll and maintain high risk and hard to reach population participants**
Gary Bennett

7:30 PM **Panel and group discussion**
Moderator: Pam Goodwin
Panel Members: Tom Wadden, Jennifer Ligibel, Gary Bennett, Worta McCaskill-Stevens

7:55 PM **Issues to consider in trial design related to insurance companies covering clinical care provided for weight loss interventions among cancer patients (should the trial prove successful)**
Moderator: Catherine Alfano
Panel Members: Cay Loria, Kate Wolin, Gary Bennett

8:15 PM **Trial monitoring, evaluation and breast cancer–specific endpoints**
Garnet Anderson

8:35 PM **Group discussion**
Moderator: Rachel Ballard-Barbash

8:45 PM **Closing remarks**
Nancy Davidson and Rachel Ballard-Barbash

8:50 PM **ADJOURN**

DAY 2: TUESDAY, FEBRUARY 11, 2014

8:00 AM **Welcome and overview of day 2**
Nancy Davidson and Rachel Ballard-Barbash

8:05 AM **TRIAL DESIGN: What are the different types of overall design to consider for weight loss trials?**
Mary Evans

8:20 AM **TRIAL DESIGN: INTERVENTION: Weight loss**
Pam Goodwin

8:35 AM **TRIAL DESIGN: INTERVENTION: Physical activity**
Kate Wolin

8:50 AM **TRIAL DESIGN: INTERVENTION: Diet**
Marian Neuhouser

9:05 AM **Panel discussion: Behavioral counseling**
Catherine Alfano, Gary Bennett, Pam Goodwin, Tom Wadden

9:20 AM **Panel discussion**
Moderator: Garnet Anderson
Panel Members: Tom Wadden, Cay Loria, Pam Goodwin, Kate Wolin, Marian Neuhouser, Catherine Alfano

9:50 AM **Group discussion**
Moderator: Garnet Anderson

10:05 AM **BREAK**

10:15 AM **Intermediate Outcomes, Cost/Utilization, and Influence of Work/Productivity**
Kate Wolin

10:30 AM **Group discussion**
Moderator: Garnet Anderson

10:45 AM **TRIAL DESIGN: Eligibility**
Dawn Hershman

11:00 AM **TRIAL DESIGN: Statistical considerations**
Mark Espeland

11:30 AM **Panel discussion**
Moderator: Dawn Hershman
Panel Members: Tiffany Powell-Wiley, Mary Evans, Mark Espeland, Jennifer Ligibel

11:50 AM **Group discussion**
Moderator: Dawn Hershman

12:35 PM **BREAK**

1:35 PM **Summation of proposed trial design and group discussion**
Nancy Davidson

2:15 PM **Final thoughts on the data that insurance companies are seeking related to decisions to cover clinical care provided for weight loss interventions among cancer patients**
Moderator: Rachel Ballard-Barbash

2:25 PM **Meeting summary and action plan**
Nancy Davidson and Rachel Ballard-Barbash

2:45 PM **ADJOURN**

NCI-Breast Cancer Steering Committee (BCSC) Clinical Trial Planning Meeting (CTPM) for Lifestyle Intervention for Improving Disease Free Survival (DFS) in Early Stage Invasive Breast Cancer

February 10-11, 2014 • Rockville MD

NIH Neuroscience Center Building, 6001 Executive Boulevard

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