

Lessons from a Systematic Review of Existing Research: Recommendations for the Design and Reporting of Research on Behavioral Interventions to Change Diet

Introduction

Inconsistencies in the design and reporting of research studies is a major impediment to efforts to synthesize research addressing a common topic. In conducting a systematic review commissioned by AHRQ and NCI, investigators at RTI /UNC identified a variety of issues that limited their ability to synthesize the evidence of effectiveness of existing interventions to promote dietary change.

The following recommendations regarding the design and reporting of such trials parallel advice to researchers about design and reporting of other areas of research. The specific recommendations are aimed at improving the ability of future researchers to compare studies, synthesize results, and answer important questions about the efficacy of behavioral dietary interventions. Diversity is inevitable and useful in behavioral research, but greater attention to the specific issues will improve our ability to draw broader conclusions from this diverse research. Studies that ignore these criteria run the risk of being excluded from systematic reviews.

Background for Recommendations

To clarify what is known about the efficacy and effectiveness of behavioral interventions in promoting dietary change, a systematic review was undertaken to synthesize the findings of 92 studies that report the impact of behavioral interventions on dietary outcomes considered to be relevant to cancer risk: dietary fat intake and consumption of fruits and vegetables.

The review also provides recommendations for future research. A summary of the analysis can be found at <http://www.ahrq.gov/clinic/dietsumm.htm>. The full report can be accessed by visiting <http://www.ahrq.gov/clinic/evrptfiles.htm> and scrolling to “Modifying Dietary Behavior Related to Cancer Risk.” Click on the link to open the zipped file. AHRQ soon will provide a PDF of the document on its Web site.

Study Design and Analysis

Attention to a number of basic study design and analysis issues would greatly improve the available literature in the field of behavioral dietary change that serves as the basis for evidence reviews. A certain amount of flexibility in these areas is important to facilitate inclusion of a broader variety of intervention strategies, but most of the recommendations below should be achievable with nearly any intervention approach.

- **Include a control or at least a comparison group** in all intervention evaluation studies.
- **Group assignment** should be random when possible.
- **Both baseline and follow-up data** should be collected for intervention and control/ comparison groups.
- **Maintain good follow-up** response rates in the control group by keeping them adequately invested in the study through:
 - close communication with participants
 - incentives to stay involved
 - delayed intervention and interim non-diet intervention for control group
- **Analyze and report data** based on the “intention to treat” assumption to account for loss to follow-up.

Measure

Ideally, all dietary assessment measures should be standardized as much as possible to facilitate comparisons across studies.

- **The dietary measurement technique** should be clearly described and available reliability/validity information should be reported.
- **Fruit and vegetable intake** should be assessed and reported as total servings per day.
- **Dietary fat intake** should be assessed and reported as grams of total fat and saturated fat, and as a percentage of total calories.
- **One set of follow-up measurements** should be obtained immediately after the intervention is complete. For cross-study comparison purposes, subsequent follow-up measurements should be obtained at standardized time periods such as three months, six months, one year, and two years.

Reporting

Ideally, all reports should:

- Include the statistics needed for meta-analysis. These include the mean and standard error or standard deviation for all outcome measures as well as actual p values (not just significance cut-points) for both significant and non-significant findings.
- Include complete information about sample size and loss to follow-up at each measurement period.
- Include a detailed description of the intervention, such as:
 - Participant recruitment and sampling procedures (e.g., the recruitment pool)
 - Response rates for individuals and sites (e.g., schools, work sites)
 - Elements of intervention intensity (number of contacts or exposures, delivery channels, length of active intervention period, environmental exposures or manipulations of availability or access to certain foods)
 - Title and training of individuals involved with intervention delivery (such as dietitian, Registered Nurse, etc.)
 - Specific behavioral theories used and how they were applied to the intervention
 - Existence and extent of ongoing reinforcement or maintenance interventions.