

# An overview of methodologies, proficiencies, and training resources for controlled feeding studies

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## ABSTRACT

Dietary intervention studies of human beings produce valuable information regarding dietary effects on biological processes and risk factors for chronic diseases. Using the well-controlled feeding approach, participants consume only foods that have been precisely prepared in a research kitchen, whereas in behavioral counseling studies, participants self-select their foods within guidelines. Because controlled feeding studies meticulously control experimental diets, they are intellectually and logistically challenging to conduct. They afford exciting opportunities for dietetic professionals in designing protocols, developing budgets, and collaborating in multidisciplinary research teams. Research dietitians use food composition data and chemical analysis of menus to prepare research diets with precision. They determine the energy requirements of subjects and adjust diets as required, most often for weight maintenance, throughout the study. All people involved in research must be attentive to the ethical treatment of the study participants while motivating them to adhere to the protocol requirements. Dietitians possess many of these skills, but may require training specific to well-controlled feeding studies. Information related to the conduct of controlled feeding studies has recently become more accessible. We provide an overview of well-controlled feeding study methodologies, proficiencies for planning and implementing these studies, and training resources. *J Am Diet Assoc.* 2003; 103:729-735.

Controlled feeding studies in human beings are valued for their precision in dietary manipulation that directly impacts physiologic processes and therefore establishes cause-and-effect relationships of diet and metabolism. These studies provide exciting opportunities for dietitians to contribute to the knowledge base in the area of human nutrition and to health promotion through diet. Dietitians in career tracks outside of research also have been interested in keeping abreast of research-based concepts and findings so that they can critically interpret study results and apply or translate new findings to their clientele (1).

Dietitians who conduct controlled feeding studies are challenged to manage complex and expensive studies. Major costs include staffing, purchasing, and subject- and laboratory-related expenses. Often these expenses are paid through grants, and as a consequence of scarce resources coupled with high costs, there are financial incentives to maximize efficiencies. Over the years, a body of knowledge related to the efficient and effective conduct of well-controlled feeding studies in human beings has evolved and, recently, this information has become more readily available through workshops and publications.

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This article highlights the elements and complexities that are unique to well-controlled feeding studies and that distinguish them from other types of human nutrition research. It addresses the concepts useful for planning and implementing dietary intervention studies. Finally, we indicate ways of obtaining appropriate didactic and hands-on practicum training and skill development for conducting well-controlled feeding studies.

### **A COMPARISON OF CONTROLLED FEEDING STUDIES AND BEHAVIORAL COUNSELING STUDIES**

In human nutrition research, distinction is made between behavioral counseling studies, in which dietary counseling is used to modulate self-selected dietary intake, and controlled feeding studies, in which participants are provided with and consume diets that are prepared to exact specifications. Controlled feeding studies, which exert optimal control of dietary interventions and study conditions with strict dietary adherence, are among the best research methods for investigating how dietary modifications affect metabolic parameters, risk factors, and health outcomes. They measure the true biological effect, or the efficacy of a dietary manipulation. In contrast, behavioral counseling studies evaluate the effectiveness or the application of a dietary intervention under more generalized, true living conditions. In these studies the biological effect of a dietary intervention is attenuated because of variations in food selections and discrepancies in dietary adherence (2).

To illustrate, the Dietary Approaches to Stop Hypertension (DASH) trial was a well-controlled feeding study designed to identify a dietary pattern that substantially and quickly lowers blood pressure (3). The DASH diet is low in total fat, saturated fat, and cholesterol; high in fruits, vegetables, and low-fat dairy products; and moderately high in protein. Because the study participants were provided with the prepared diet, it is not known to what extent people can adhere to the DASH diet on their own and in conjunction with other lifestyle recommendations for lowering blood pressure. Thus, the PREMIER study was designed to determine the effectiveness of the multicomponent lifestyle intervention programs, with and without the DASH diet, under real-world conditions, in adults who were at risk for hypertension and in those with stage 1 hypertension (4). A comparison of the study design and management elements for the DASH and PREMIER studies is given in Tables 1 and 2.

### **DISTINCTIVE ASPECTS OF CONTROLLED FEEDING STUDIES**

Dietetics professionals who conduct controlled feeding studies develop intellectual and practical skills specific to these studies (Table 3). Most of these stem from the nature of the dietary intervention, which requires a strict degree of control in the composition of the food provided and rigorous adherence of the study participant to the protocol.

Accurate formulation, production, and delivery of research diets are major components in assuring the scientific integrity of a controlled feeding study. The allowable variation in average daily nutrient content for research diets typically is small. When meals are prepared for research studies, the kitchen staff members precisely weigh each recipe ingredient and food on electronic balances for each study participant. But first, the research dietitian must construct menus that match specific nutrient goals defined by the study protocol. The nutrition requirements of the study participants also must be considered,

and whenever possible the diets should not oversupply or undersupply other nutrients, especially in lengthy studies. To avoid bias, many studies are blinded; that is, although the nutrient composition differs among dietary treatments, the meals appear similar. It is the research dietitian's task to determine the correct types and proportions of foods needed to achieve diets that attain these goals. Because food database values are only estimates, calculated nutrient composition of menus is typically validated by chemical analysis. Ideally, chemical analysis is conducted before feeding begins (allowing time for any corrections) and periodically throughout the study. Care is taken to ensure that foods used in diet composites are identical to the foods prepared, served, and consumed by the study participants and are handled in a manner to optimize subsequent assay of nutrients of interest.

Dietitians and other investigators must appreciate the role of study participants who tolerate inconveniences to comply with the demands of the study. Unlike people consuming self-selected diets who may choose not to finish a meal, participants of a well-controlled feeding study must eat all of the food provided (usually at predetermined times) and only the food provided. Their everyday routines are changed, and their travel may be restricted. The participants may need encouragement to continue with the study, especially for longer studies, in which adherence becomes more difficult. Yet according to professional ethics, they must feel free to leave the study for any reason. Although not common, one person can compromise the study not only through attenuated outcome measurements but also by dampening the motivation of others in the study. Dietitians who conduct feeding studies must master both firm and flexible management techniques and apply the proper mix that will encourage and motivate the participants to make their experience enjoyable while maintaining study integrity.

Although controlled feeding studies have distinctive elements that require specialized skills, the knowledge and proficiencies needed for conducting other types of clinical trials also are required, especially for advanced research dietitians and those who are principal investigators. In addition to designing a study that will test a hypothesis, they must know how to determine sample size using power calculations and effect size estimates. Research investigators must possess skills in writing succinct and thorough protocols for success in securing grant funds. All protocols are subjected to Institutional Review Board (IRB) requirements, and knowledge of the application process and operating procedures is a must. Additional understanding of data and safety monitoring boards that review the progress of a study may be important. Research investigators, especially those funded by the National Institutes of Health (NIH), are required to receive training in the protection of human research subjects in clinical trials. They also must adhere to the informed consent process, maintain participant confidentiality, and prevent conflicts of interest. At the end of the study, they participate in the interpretation, publication, and presentation of research findings.

### **ACQUIRING NECESSARY SKILLS AND BACKGROUND**

For a well-controlled feeding study to succeed, all members of the research team must orchestrate an array of skills and specialized knowledge. Training should be an integral part of the research plan (5). Although controlled feeding studies receive minimal, if any, attention as part of traditional dietetics training, those dietetics professionals with experi-

**Table 1**  
Comparison of study design features for controlled feeding and behavioral counseling studies

Study features	General design		Example	
	Controlled feeding	Behavioral counseling	DASH, <sup>a</sup> a controlled feeding study (3)	PREMIER, a behavioral counseling study (4)
Rationale/hypothesis	Estimate with high precision, because of the controlled conditions, the magnitude of the physiological response to diet	Establish that people can affect a physiologic measurement through behavioral changes involving food selection under relatively generalizable conditions	A diet with specific food patterns will lower blood pressure (in the absence of changes in body weight, sodium intake, or physical activity level)	People can be taught to consume diets with specific food patterns and thereby lower their blood pressures
Effect size	“Biologically true” effect; optimized estimate Biological response estimate maximized because of the high precision in producing the research diets and the high degree of confidence that the diets are consumed	Attenuated effect; “real life” estimate Attenuated difference between control and test diets and high variance in diet composition because of inaccuracies in achieving dietary target values	Statistical power sufficient to detect 2.0 mm Hg differences in diastolic blood pressure between control and test diets	Statistical power sufficient to detect 2.0 mm Hg differences in systolic blood pressure between intensive intervention and control arms
Intervention	Defined diets provided Parallel arm or crossover designs acceptable	Counseling for behavior change Parallel arm or crossover designs acceptable	Three different research diets prepared and provided by study centers: one control diet and two experimental diets Parallel-arm study (three arms)	Two intensive intervention programs (dietary and lifestyle counseling with or without the DASH dietary pattern); and an advice-only control program Parallel-arm study (three arms)
Diets	Research kitchen staff selects, prepares, and provides all food; other foods typically not allowed Nutrient content of menus estimated by computer analysis, assuming precise weights; confirmed by chemical analysis of diet composites	Participants modify habitual diet; obtain and prepare own foods Nutrient content of diets estimated by computer analysis, assuming standard household practices; gathered by recall techniques; ie, food diaries, 24-hour recalls, food frequency questionnaires	All foods provided at clinical site Chemical analysis of diet composites	Participants select foods based on education and behavioral counseling Three sets of two 24-h recalls conducted over 18 months (total of 6 days of intake data)
Duration	Short (usually days, weeks, or months) Allow sufficient time to establish biological response	Long (usually months or years) Allow sufficient time to establish biological response and/or stability of behavioral change	8 weeks	18 months
Sample size	Typically 5-25 participants per cohort; larger sample sizes may require multiple study sites and/or enrollment of successive cohorts	Larger sample sizes may require multiple study sites and/or enrollment of successive cohorts	456 participants Four study sites; 2-y duration; two cohorts/site/y; cohorts of 25-30 participants	800 participants Four study sites; 2-y duration; two cohorts/site/y; cohorts of 50 participants
Outcomes or measured endpoints	Laboratory values and other biological markers of response Physical measurements	Laboratory values and other biological markers of response Physical measurements Disease incidence or severity Category of disease risk	Change from baseline in diastolic and systolic blood pressure primary outcome Urinary electrolytes and blood lipids also measured Stable Weight measured every weekday for all participants and energy intake adjusted as needed	Change from baseline in systolic and diastolic blood pressure
Body weight	Typically maintained stable throughout study, unless specifically altered as part of study design	Typically not controlled Intervention may specifically target weight loss	Stable Weight measured every weekday for all participants and energy intake adjusted as needed	Intervention includes weight loss as one of the comprehensive lifestyle changes Weight measured periodically for all participants

<sup>a</sup> DASH=Dietary Approaches to Stop Hypertension.

**Table 2**  
Comparison of study management features for controlled feeding and behavioral counseling studies

Study features	General design		Example	
	Controlled feeding	Behavioral counseling	DASH, <sup>a</sup> a controlled feeding study (3)	PREMIER, a behavioral counseling study (4)
Focus of effort for the investigator and research dietitian	Emphasis on delivery of defined diet and attendance at clinic to ensure food is received and consumed	Emphasis on education and behavioral and motivational techniques to facilitate participants' selection of foods promoted by the study diet	Foods prepared and weighed according to exact specifications with intensive monitoring Participants' attendance and food consumption monitored	Participants counseled through behavioral and motivational techniques on how to select foods
Educational component	Typically minimal	Typically extensive	Orientation session before study to discuss expectations Some diet advice provided at the conclusion of the study	Continual intervention sessions and visits to adequately provide information needed to achieve intervention diet and/or lifestyle changes
Monitoring dietary adherence	Observation by staff; use of checklists Biological markers incorporated into test foods 24-h urine collections; blood draws	Interviews; ie, 24-h recalls, dietary records, food frequency questionnaires 24-h urine collections; blood draws	Urinary sodium, potassium, phosphorus, and urea nitrogen Daily checklist	Urinary sodium, potassium, phosphorus, and urea nitrogen Blood carotenoids, tocopherols, and folate
Location for meals and/or counseling	Meals consumed at clinical facility and/or picked up for off-site consumption as dictated by study protocol	Counseling performed in study office or by telephone	Weekday lunches or dinners consumed at clinical site; all other meals provided as take-out	Counseling sessions conducted at clinical sites Telephone contacts only if participant cannot visit clinic
Staffing pattern and skills emphasis	Food service workers Dietary staff Clinic staff	Counselors Educators Clinic staff	Food service workers Dietitians Study coordinators	Dietitians Study coordinators
Usual frequency of contact with research staff	Almost daily	Weekly or monthly	Daily on weekdays	Intensive intervention arms: 32 visits over 18 months Control arm: three visits over 18 months
Participant commitment	Temporary change and inconvenience in schedule; no extended out-of-town travel Convenience of no grocery shopping or cooking for self Dropouts usually within the first days of study; dropout rate then typically low	Long-term commitment to attempting changes in eating behavior Dropout rate typically increases over time	Participants commit to eating and picking up their food at the clinical site Participants also commit to consuming assigned research diets, which for some involve unaccustomed intakes of fruits, vegetables, nuts, and low-fat dairy products	Participants commit to attending the full set of intervention sessions associated with their treatment group Participants also commit to making comprehensive lifestyle changes, and for some, adopting the DASH diet
Motivation	Participants motivated for short-term adherence Participants often paid a stipend	Participants motivated for long-term adherence Participants often seek to improve health outcome Participants often paid a stipend	Stipend with occasional incentives Social interactions at meals At conclusion of study, receipt of individualized data on response to diet	Incentives (cash, gifts) provided at data collection visits Possibility of improved health because of participation

<sup>a</sup> DASH=Dietary Approaches to Stop Hypertension.

**Table 3**

Examples of knowledge and practical skills that are required by dietitians for conducting controlled feeding studies

**Designing controlled feeding studies**

Determine protocols and dietary modifications that will test hypotheses  
 Compare advantages and disadvantages of various study designs  
 Calculate costs and develop a budget for conducting controlled feeding studies  
 Analyze the benefits and limitations of outpatient feeding studies  
 Adhere to internal review board regulations for conducting research and maintaining confidentiality  
 Build effective, high-performance multidisciplinary research teams  
 Manage wisely staff and resources  
 Collaborate with others to achieve a well-planned and well-executed study

**Developing menus and determining nutrient intakes**

Know and use food composition data  
 Compare features, ease of use, and cost of nutrient calculation software  
 Evaluate nutrient databases provided by software applications for reliability of data  
 Select software for calculating research diets  
 Determine how recipe yields are computed  
 Compare results of diet calculations  
 Know various diet assessment tools, including food frequency questionnaires  
 Evaluate programs for food record analysis  
 Compare data from food frequency questionnaires and food records

**Providing research diets**

Evaluate the unique design and equipment needed for a research kitchen  
 Determine staff and resources needed for providing research diets  
 Understand the nutrient variability inherent in the food supply  
 Identify critical control points and apply HACCP<sup>a</sup> to the research kitchen  
 Establish quality assurance procedures during food production and delivery  
 Present tasty foods in an attractive manner  
 Develop plans for providing carry-out meals  
 Assure safety in carry-out foods, and apply HACCP in the process

**Preparing and delivering research diets**

Assess precision needed in food preparation to accurately provide nutrients  
 Know effects of food preparation methods on nutritional constituents  
 Compare portioning techniques such as weighing and measuring  
 Determine feasibility of using commercial portion-control foods  
 Compare raw and cooked yields of selected foods  
 Determine feasibility of serving fresh fruits and vegetables  
 Evaluate cook-chill-reheat procedures  
 Use seasonings that add flavor to meals without altering nutrient composition  
 Conduct taste testing of foods developed for a research diet  
 Train study participants in the safe handling of carry-out foods

**Estimating energy (caloric) requirements**

Know the major components of energy expenditure  
 Understand procedures for measuring energy expenditure  
 Assess methods for estimating physical activity  
 Determine the caloric cost of physical activity  
 Calculate energy requirements from standard prediction formulas  
 Estimate and compare energy requirements by using various procedures  
 Translate energy requirements into food and adjust as needed  
 Determine procedures for monitoring weight stability

**Measuring food composition**

Know introductory methods of nutrient chemical analysis  
 Compare costs of chemical analysis procedures  
 Evaluate food composition laboratories  
 Decide study-specific needs for nutrient analyses  
 Estimate frequency of food sample collection for chemical analyses  
 Collect, prepare, and store composite food samples  
 Know procedures required for shipping diet aliquots  
 Assess variability in nutrients and menus

**Working with study participants**

Implement techniques and considerations for recruiting participants  
 Practice the ethical treatment of study participants  
 Develop objective and subjective adherence measures  
 Encourage adherent behaviors, and create activities to motivate study participation  
 Evaluate ways of communicating with study participants  
 Define and practice successful counseling techniques  
 Determine how to deal with the difficult study participant  
 Know when and how to dismiss a noncompliant participant  
 Suggest ways to accommodate participants' emergencies

<sup>a</sup> HACCP=Hazardous Analysis Critical Control Point.

ence in other areas of nutrition may translate and refine their skills to the specialized work that is required to conduct these studies. For example, clinical dietitians with a background in patient care and skilled in counseling adherence to a self-selected therapeutic diet may effectively transfer their talents to address adherence to the strict dietary regime in a research study. Dietitians who already are engaged in feeding studies might need to refine particular skills or translate developed techniques to study protocols in new scientific fields. Furthermore, with the increasing concern regarding the use of human subjects in studies, all people conducting research must keep ethical considerations in the forefront of their activities. Various avenues are available for receiving training.

### Written Materials

For years, few resources on controlled feeding studies existed. *A Dietetic Manual for Metabolic Kitchen Units*, published in 1969 by the National Institutes of Health (NIH) Clinical Center, describes the procedures of research diets (6). Traditionally, research reports in journal articles have stressed study outcomes and minimized description of diet methodologies. Recently, a few journal articles devoted to the methodologies of well-controlled feeding studies have been published (for example, the Dietary Effects on Lipoproteins and Thrombogenic Activity [DELTA] study [7] and the DASH study [8]). Study-specific manuals of operations may be obtained by contacting the clinical site or study coordinating center (for example, DELTA [9]). A chapter in the American Dietetic Association's book, *Research: Successful Approaches*, outlines the design and management of a small clinical trial (10). Tailored to the research dietitian, *Well-Controlled Diet Studies in Humans: A Practical Guide to Design and Management* (11), offers a comprehensive description of controlled studies and was assembled through the cooperation of the National Heart, Lung, and Blood Institute (NHLBI), the General Clinical Research Centers Program of the National Center for Research Resources, and the American Dietetic Association. Unique applications of clinical nutrition studies and related information are available elsewhere (12). Although still limited, the current materials serve as excellent resources for conducting controlled feeding studies.

### Short Courses

Short courses, some with practicum modules, are a highly effective way of providing training in the methodologies for well-controlled feeding studies. However, formal organized training programs have been infrequent. In 1991, approximately 350 nutrition researchers from across the country attended two NHLBI-ADA workshops, "Well-Controlled Studies of Diet and Lipid Metabolism in Humans." A brief workshop report was published (13). Three training workshops conducted at the Pennington Biomedical Research Center, Baton Rouge, LA, provided didactic instruction about controlled diet studies and offered unique opportunities for practical hands-on laboratory experiences. The instructional setting also provided the attendees with opportunities to share ideas and successes with other people doing similar work and with those moving into this research field.

Academic courses and training sessions in dietary study methodologies can be established within a research or aca-

**Table 4**

Selected web sites for research-related information, resources and tutorials

#### Ethics and research involving human beings

- National Institutes of Health on-line tutorial and assessment for researchers involved in the design and conduct of research involving human participants  
<http://cme.nci.nih.gov>
- Informed consent tutorial developed by the University of Minnesota  
<http://www.research.umn.edu/consent>
- Exploration of ethical issues pertinent to research involving human participants  
<http://www.research.umn.edu/ethics>
- Food and Drug Administration Center for Drug Evaluation and Research information regarding the protection of human subjects from a regulatory perspective  
<http://www.fda.gov/cder/about/smallbiz/humans.htm>
- Links to web-based biomedical ethics resources  
<http://www.nih.gov/sigs/bioethics/casestudies.html>
- Links to biomedical research and ethics information  
<http://cpmcnet.columbia.edu/research/bio.htm>

#### Grant writing and study design

- Links for grant writing help  
<http://research.unc.edu/grantsource/grantwriting.html>
- Description and explanations of qualitative research and methodologies excerpted from the book *How to Read a Paper: The Basics of Evidence-Based Medicine*  
<http://www.bmj.com/collections/read.shtml>
- A collection of research design tutorials created by Cornell University graduate students  
<http://trochim.human.cornell.edu/tutorial/tutorial.htm>
- Information on National Institutes of Health grants and funding opportunities  
<http://grants.nih.gov/grants/index.cfm>

#### Research diets and assessments

- Workbooks from the Designing, Preparing and Delivering Research Diets Training Workshops held at Pennington Biomedical Research Center and sponsored by the National Heart, Lung, and Blood Institute  
<http://www.pbrc.edu/>
- Research diet information from the University of North Carolina General Clinical Research Center  
<http://verne.med.unc.edu/diet>
- Food service and food composition resource lists from the Food and Nutrition Information Center with a link to the United States Department of Agriculture/Agricultural Research Service Nutrient Data Laboratory  
<http://www.nal.usda.gov/fnic>
- Information on dietary assessment from the Dietary Assessment Calibration/Validation Registry  
<http://www-dacv.ims.nci.nih.gov>

dem institution and are offered periodically. Dietetic interns, students in coordinated undergraduate programs, and nutrition graduate students benefit from the experiences related by those who plan and direct controlled feeding studies. For example, the research staff at the Indiana University Medical Center's General Clinical Research Center in Indianapolis, IN, developed a 4½-day training seminar specific to their institution. The curriculum addressed general aspects of research diet methodology and management, and also reviewed the details of each controlled feeding protocol that was under active investigation. Plans for a new seminar geared toward beginning investigators and medical residents will encompass a range of nutrition research topics, including nutrition assessments, nutrient databases, and research diet topics. The training experience also could be used as a model for teaching other allied health care professionals. The sessions would encourage and enhance their learning experiences in nutrition research.

## Apprenticeships

Individuals who are interested in acquiring or enhancing those skills required for conducting well-controlled feeding studies often seek out information by visiting facilities that conduct controlled studies. To help dietetics interns make specialized career choices, for example, some internship programs arrange for enrichment experiences at research facilities. Informal programs for visiting dietitians may range from 1 day for answering questions to a 1-year-long sabbatical that allows full participation in the conduct of an ongoing study. Valuable experiences may be obtained in the day-to-day operations of subject management and in a research kitchen. Even experienced research dietitians find it useful to visit other institutions to learn new techniques.

## Online Education

Web-based instruction, now used as an effective educational tool (14), has promise for the study of controlled feeding methods. Learning may be customized to the student and to the individual research study. The ability to interact with experienced researchers allows students to gain knowledge that is unique to research techniques and topics in which they are interested (Marjorie Busby, personal communication, February 2001). Examples of educational modules for well-controlled feeding studies that are well suited to online education include exercises for designing experimental diets, calculation of energy needs, determining sample size using power calculations, and establishing a study budget. Website demonstration videos may show, for example, techniques required for food ingredient weighing, preparing meal composites, and participant counseling.

Computer-based training modules are available for receiving the NIH-required certification in the protection of human research subjects. Other useful research-related information currently is accessible through the internet (Table 4). Much of the information deals with the ethics of conducting research involving human participants, and some relates to broader research design issues.

## SUMMARY

Well-controlled feeding studies have a long history in nutrition research. They have provided much of the core knowledge pertaining to nutrient requirements and dietary recommendations for the public. Traditionally, dietitians learned how to conduct these studies through apprenticeship arrangements or by trial-and-error experience. More recently, methods-oriented workshops, tailored to the design and the logistical dimensions of human feeding studies, have proven to be valuable learning opportunities. They provide a highly effective way of stimulating intellectual exchange and furnish hands-on experiences to both novice and established research dietitians. These workshops have resulted in a readily accessible methodology literature that augments the useful, but less detailed and relatively diffuse, information published in traditional journal articles. Furthermore, academic and online educational opportunities are becoming available as researchers facilitate the exchange of tutorials and educational materials related to nutrition research study methodologies.

## APPLICATIONS

- The availability of methodology-oriented resources for well-controlled feeding studies allows research dietitians to better plan their research programs. Furthermore, staff training activities may be specifically integrated into the study schedule.
- The materials provide a venue for professional development for dietitians experienced in other subspecialties in the field. Now that training to acquire the advanced skills needed for conducting well-controlled feeding studies can be met more readily, dietetic professionals from a broad array of backgrounds can consider taking on this challenging line of work.
- Finally, training is useful not only for the novice research dietitian, but also for advanced research dietitians who are principal investigators wishing to upgrade to state-of-the-art concepts, techniques, and skills.

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