The Nuts and Bolts of Developing and Conducting Impactful Research Studies

PBNHC 2018
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Introduction

- PhD in Nutritional Epidemiology (Tufts) and MSPH in Human Nutrition and Public Health (Johns Hopkins)
- Director of the Lifestyle Medicine Economic Research Consortium from the American College of Lifestyle
- Co-investigator on the Adhering to Dietary Approaches for Personal Taste (ADAPT) Study (Tufts University)
- Adjunct Faculty for the University of New England Master’s Programs in Applied Nutrition and Global Public Health
- Author of *A Plant-Based Life* and a contributor to the New York Times bestseller *Forks Over Knives: The Plant-Based Way to Health*
- Founder of PlantBasedResearch.org, an online library of original, peer-reviewed research studies relevant to plant-based nutrition and SustainableDiet.com, a 3-month transition and support program
Workshop Goals

• Empower participants to:
  • Plan and conduct their own research studies
  • Participate in research as effective collaborators

• Provide template materials and networking opportunities

• Invite participants to participate in and recruit for research studies to advance the field of plant-based nutrition
Outline

• Welcome and Introductions (10 min)
• Audience goals, networking needs (10 minutes)
• Presentation on research collaboration, research gaps, policy goals, and considerations for RCTs (25 min)
• Questions (10 min)
• Workshop Materials Review (90 min)
• Study recruitment and collaboration invitations (10 min)
• Networking close (remaining time)
Approaches to Conducting Research

• Publish Case Histories
• Be the Principal Investigator
  • Develop and conduct intervention studies (our focus today)
• Collaborate with an academic researcher
• Do both!
Publishing Case Histories

• Valuable contribution to research to “generate hypotheses” in the field and generate public media attention, though limited impact among research community and policy

• Manageable workload for busy clinicians

• Journals:
  • Disease-specific journals often public case histories
  • Many case-history-specific journals
  • International Journal of Disease Reversal and Prevention (The Plantrician Project)

• Focus today is on small-scale or pilot RCTs, but information on scientific writing relevant for case histories
Developing and Conducting Intervention Studies

• Contribution:
  • Fill research gaps
  • Bring attention to plant-based diets
  • Help shape policy (gradually)

• Challenges
  • Need time and money to do the work and publish
  • Need skills in research methods and statistical analysis, or a collaborator
  • Need affiliation with a research institution to be approved by an Internal Review Board (IRB) to conduct human subjects research, or to use a private IRB
Challenges Are Not Insurmountable

• Money and time
  • Consider applying for grants
    • Internal grants
    • Local, community grants
    • Private foundations
  • Request research activity to be incorporated into scope of work within your workplace
  • Plan small-scale projects that can be worked into your typical activities
    • Small sample sizes
    • Interventions similar to treatment also prescribed
    • Data collection that overlaps with usual clinical assessments
Offer Yourself As a Collaborator

• Contact local university researchers
  • Nutrition
  • Medicine
  • Public health

• Describe typical improvements in patients for specific outcomes

• Suggest a research collaboration to assess effects of PBN interventions

• Offer yourself as an informed collaborator and co-author of grant applications for their research projects
  • Describe your interests and skills
  • Identify your available time
  • Send them an excited dose of inspiration about plant-based diets
    (Sometimes the people who have never heard of this get the most excited)
Research Gaps

**Methodological**
Randomized controlled trials that use plant-based diets as the intervention and that also use a control or comparison group (2 or more arms)

**Topical**
Studies that compare the performance of plant-based diets with conventional and/or Mediterranean diets for improving health outcomes and risk factors, such as body weight, weight status, blood lipids, blood glucose, and other symptoms of chronic disease
Conventional Hierarchy of Evidence

- Not without limitations

- Among those:
  - Certain research questions cannot readily be answered with RCTs
  - Mortality, longevity, cumulative lifetime effects of lifestyle

- However:
  - Short and medium-term conclusions can be drawn about specific dietary practices
  - Plant-based diets perform well in such conditions because effect is rapid and large
Plant-Based Diets in Policy

• Frustration on the part of the public and some clinicians that PBN is not more front and center in public policy
• Clinical experience, case histories, cross-sectional studies, and one-arm intervention trials (pre-post analyses with only one group) are not considered strong evidence by researchers
• Data from papers with those designs that is published is simply not read, and therefore not used when making policy (i.e. US Dietary Guidelines)
• Inherent bias due to hierarchy of evidence (but not necessarily deep-seated prejudice)
• Solution (that’s us!) is to conduct more plant-based intervention studies with a strong design
What does it look like to shift policy?

• Public health recommendations change
• Also don’t forget about changing the face of healthcare!
Evolution of the USDA Food & Nutrition Guides: Change Does Happen

- The USDA's "Basic 7" food groups from 1943 to 1956
- 7 groups, 2 of which are animal food
- "Butter and fortified margarine" is a food group!
- Key message at the bottom is to "Eat any other foods you want" in addition to the Basic 7
Today’s Infographic

Choose MyPlate
Lots to complain about, BUT:

• No more meat food groups
• “Protein” group refers to plant-based as well as animal-based foods
• Fruits, vegetables, and whole grains make up half the plate
• Dairy substitutes are included in “dairy” recommendations
Today’s Dietary Guidelines

- US Dietary Guidelines 2015-2020

### Table A5-1.

<table>
<thead>
<tr>
<th>Calorie Level of Patterna</th>
<th>1,000</th>
<th>1,200</th>
<th>1,400</th>
<th>1,600</th>
<th>1,800</th>
<th>2,000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food Group</strong> b</td>
<td>Daily Amountc of Food From Each Group (vegetable and protein foods subgroup amounts are per week)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Vegetables</td>
<td>1 c-eq</td>
<td>1½ c-eq</td>
<td>1¾ c-eq</td>
<td>2 c-eq</td>
<td>2¾ c-eq</td>
<td>3 c-eq</td>
</tr>
<tr>
<td>Dark-green vegetables (c-eq/wk)</td>
<td>½</td>
<td>1</td>
<td>1</td>
<td>1½</td>
<td>1½</td>
<td>1½</td>
</tr>
<tr>
<td>Red and orange vegetables (c-eq/wk)</td>
<td>2½</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>5½</td>
<td>5½</td>
</tr>
<tr>
<td>Legumes (beans and peas) (c-eq/wk)d</td>
<td>½</td>
<td>½</td>
<td>¾</td>
<td>1</td>
<td>1½</td>
<td>1½</td>
</tr>
<tr>
<td>Starchy vegetables (c-eq/wk)</td>
<td>2</td>
<td>3½</td>
<td>3½</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Other vegetables (c-eq/wk)</td>
<td>1½</td>
<td>2½</td>
<td>2½</td>
<td>3½</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Fruits</td>
<td>1 c-eq</td>
<td>1 c-eq</td>
<td>1½ c-eq</td>
<td>1½ c-eq</td>
<td>1½ c-eq</td>
<td>2 c-eq</td>
</tr>
<tr>
<td>Grains</td>
<td>3 oz-eq</td>
<td>4 oz-eq</td>
<td>5 oz-eq</td>
<td>5½ oz-eq</td>
<td>6½ oz-eq</td>
<td>6½ oz-eq</td>
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Workshop Materials Review
Workshop Materials

- Download page: https://plantbasedresearch.org/pbnhc-2018
- Outline:
  - Developing Research Questions and Getting Started
  - Planning and Design
  - Study Protocol
  - IRB Application
  - Recruitment and Consent
  - Data Collection
  - Data Analysis
  - Manuscript Write-Up
Use a Citation Manager (Endnote Recommended)
CITI Training

• Collaborative Institutional Training Initiative (CITI Program) training for human subjects research

• CITI Program is designed to be a cost-effective and easy to manage training solution for organizations. It is available through a base subscription fee that varies depending on the type of organization. Customization options can also be included for additional fees. See subscription details.

• Learners who are affiliated with a subscribing organization can take CITI Program courses assigned to them by their organization for free. Those who are not affiliated with a subscribing organization or need additional content not offered through their organization can purchase courses as an independent learner (learn more). Course fees for independent learners start at $50 USD. Download our independent learner course guide (.pdf) for discount and pricing information.

• https://about.citiprogram.org/en/homepage/
Ethical Principals for Human Subjects Research

- **Principle 1:** Trials should be conducted with ethical principles that come from the Declaration of Helsinki.

- **Principle 2:** Risks, benefits and alternative procedures need to be weighed prior to designing and beginning a trial. They should also be discussed in detail with the prospective research participant.

- **Principle 3:** The rights, safety and welfare of the research participant override the interests of the study, society and science. The advancement of medicine is never the most important factor in research; therefore investigators must never sacrifice the interests and rights of study subjects to ensure completion of a trial.

- **Principle 4:** The proposed study should be based on sound scientific data.

- **Principle 5:** Trials should be described in a clear and detailed protocol.

- **Principle 6:** Trials should be conducted in accordance with the protocol that has received prior approval by an Institutional Review Board or ethics committee.
Ethical Principals for Human Subjects Research

- **Principle 7**: Medical care within the context of a trial should be the responsibility of a qualified physician, dentist or other health care provider.

- **Principle 8**: Each individual on the study team should be qualified by education, training and experience to perform their designated study responsibilities.

- **Principle 9**: Freely given informed consent should be obtained from every participant prior to their participation. After completing this module, you will understand the International Conference on Harmonization’s (ICH) role in providing guidelines that are applied to social and behavioral research. You’ll also be familiar with ICH’s development of Good Clinical Practice (GCP) and how to interpret and apply it within the context of social and behavioral clinical trials.

- **Principle 10**: All trial information should be recorded, handled, and stored in a way that allows accurate reporting, interpretation and verification.

- **Principle 11**: The confidentiality of participants' records and their privacy should be protected in accordance with all applicable federal and local regulation.

- **Principle 12**: Systems with procedures that assure quality of every aspect of the trial should be considered and implemented.
Sample Size Calculations

• Need to find number of subjects at which expected difference between intervention group and control group will be less than 5% likely to occur due to chance
  • Can be based on prior research or clinical experience
• For a simple comparison pre/post (one arm) need:
  • Mean difference in outcome
  • Standard deviation
• Use PS sample size calculator to estimate sample size needed using t-test
• For difference in change between two groups, calculation is slightly more complicated
• See follow-up email invitation to share anonymous results for changes in weight, fasting blood glucose, HbA1c, LDL, TC
  • Sample size calculations will be shared back with the group for each outcome
Example: Weight Loss Among Vegan Group after 6 Months

Comparative effectiveness of plant-based diets for weight loss: a randomized controlled trial of five different diets.


Abstract

OBJECTIVE: The aim of this study was to determine the effect of plant-based diets on weight loss.

METHODS: Participants were enrolled in a 6-mo, five-arm, randomized controlled trial in 2013 in South Carolina. Participants attended weekly group meetings, with the exception of the omnivorous group, which served as the control and attended monthly meetings augmented with weekly e-mail lessons. All groups attended monthly meetings for the last 4 mo of the study. Diets did not emphasize caloric intake.

RESULTS: Overweight adults (body mass index 25-49.9 kg/m(2); age 18-65 y, 19% non-white, and 27% men) were randomized to a low-fat, low-glycemic index diet: vegan (n = 12), vegetarian (n = 13), pesco-vegetarian (n = 13), semi-vegetarian (n = 13), or omnivorous (n = 12). Fifty (79%) participants completed the study. In intention-to-treat analysis, the linear trend for weight loss across the five groups was significant at both 2 (P < 0.01) and 6 mo (P < 0.01). At 6 mo, the weight loss in the vegan group (-7.5% ± 4.5%) was significantly different from the omnivorous (-3.1% ± 3.6%; P = 0.03), semi-vegetarian (-3.2% ± 3.8%; P = 0.03), and pesco-vegetarian (-3.2% ± 3.4%; P = 0.03) groups. Vegan participants decreased their fat and saturated fat more than the pesco-vegetarian, semi-vegetarian, and omnivorous groups at both 2 and 6 mo (P < 0.05).

CONCLUSIONS: Vegan diets may result in greater weight loss than more modest recommendations.

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Recruitment

• Adhering to Dietary Approaches for Personal Taste (ADAPT) from Cornell University
  • Please participate and help us recruit!

• Multi-site intervention in development among adult diabetics
  • Plant-based diet intervention (3-month SustainableDiet.com program)
  • Comparison group using similar Med diet and ADA diet interventions
  • Please share your interest in potential collaboration!
First ADAPT Paper Published on Web-Based Methods