Research Matters!
How to Get Involved

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No disclosures
Learning Objectives for Today’s Webinar

After attending the webinar, attendees will be able to:

1) Write a research question and develop a hypothesis.

2) State the common elements included in a research proposal.

3) Explain what an Institutional Review Board (IRB) is and what types of research require IRB approval.
The “R” word: Research
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WHAT I USED TO THINK RESEARCH WAS...

WHAT NUTRITION RESEARCH IS...
Types of Research

Application

Basic

Applied
Research Hierarchy

Strength of evidence

- Systematic Reviews
- Meta-Analyses
- Randomized Controlled Trials
- Cohort studies
- Case Control studies
- Cross-sectional studies
- Animal or in vitro research
- Case reports
- Expert opinions
- Anecdotal evidence
Examples of Nutrition Research

Recent articles in the *Journal of the Academy of Nutrition and Dietetics*:

Dietary Intervention to Increase Fruit and Vegetable Consumption in Breastfeeding Women: A Pilot Randomized Trial Measuring Inflammatory Markers in Breast Milk (December 2018)


Caffeine Transiently Affects Food Intake at Breakfast (October 2018)
Why RDNs should conduct research

- Evaluate the success of different dietary interventions/approaches
- Identify best practices for patient care
- Track outcomes to justify the work of RDNs in various settings
- Elevate the dietetics profession
- Grow the evidence base for medical nutrition therapy
Nutrition-Related Research Options

<table>
<thead>
<tr>
<th>Translational&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Epidemiologic&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Practice-Based&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Quality Improvement&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Evidence Analysis&lt;sup&gt;e&lt;/sup&gt;</th>
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<tr>
<td>Academia</td>
<td>Academia</td>
<td>Academia</td>
<td>Implement solution across facility&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Identify question</td>
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<td>Identify question</td>
<td>Identify question</td>
<td>Apply in practice&lt;sup&gt;d&lt;/sup&gt;</td>
<td>Test more solutions if necessary</td>
<td>Identify question</td>
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<td>Investigate mechanism in lab</td>
<td>Investigate participants&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Analyze data with research experts&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Collect data to see if solution worked</td>
<td>Literature search</td>
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<td>Animal trials&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Track over time (prospective)</td>
<td>Conduct study in multiple practices</td>
<td>Test a solution</td>
<td>Combine and weigh data</td>
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<td>Clinical trials&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Gather lots of data (observational)</td>
<td>Work with research experts to design study</td>
<td>Engage stakeholders to identify solution</td>
<td>Determine answers and gaps&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>Application in large medical centers&lt;sup&gt;d&lt;/sup&gt;</td>
<td>Analyze relationships&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Identify pattern/ask a question&lt;sup&gt;e&lt;/sup&gt;</td>
<td>Collect data to find cause of problem</td>
<td>Create practice guidelines</td>
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<td>Application in small facilities&lt;sup&gt;d&lt;/sup&gt;</td>
<td>Test factor as intervention&lt;sup&gt;e&lt;/sup&gt;</td>
<td>Practitioner</td>
<td>Identify a problem</td>
<td>Guideline implementation&lt;sup&gt;cd&lt;/sup&gt;</td>
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Practitioner-Driven Research

- Includes Practice-Based Research & Quality Improvement

- Starts with a question related to practice
  - Used to evaluate effectiveness of interventions, patient care models, dietetics education, etc.

- Organized by practitioners in their work setting
  - Work with experienced researchers to develop study methods

- Partnering with other practitioners is often needed to obtain an adequate sample size
The Research Process

1. Identify a need or problem
2. Review existing literature
3. Formulate research question & hypothesis
4. Develop study plan
5. Collect the data
6. Analyze (and evaluate) data
Let’s Get Started!
Identify a Need or Problem

- Think about current trends in your practice area
- Check the Evidence Analysis Library for gaps in the research
  - Select a topic, and click “Grade Chart” from the left navigation tab
  - Click the Grade V (No evidence available) section of the pie chart
  - Select a question from the list for available information
- Look at recent nutrition journals for current topics
- Are there topics that keep surfacing?
- Focus on what interests you
Review Existing Literature

- Serves multiple purposes:
  - Informs you what has already been investigated related to the problem
  - Provides some ideas for study methods
- For more tips on how to conduct a literature search, visit the member section of the DIFM website (Resources → Archived Webinars) to watch “The How-To’s of Seeking Literature and Available Evidence”

- Check the EAL!
- Use the new Best Available Evidence Clinical Decision Tool from DIFM:
  - https://integrativerdtool.org
  - Instructional webinar on using this tool available on the DIFM member website
Next Steps: Formulating a Research Question

- Narrow down the initial problem

How?

- Consider the PICO framework
  - P: Participants/population
  - I: Intervention/Observation
  - C: Comparison
  - O: Outcome

- Need to concurrently think about the potential study design
Next Steps: Formulating a Research Question

Research questions should be:

- Clear – specifically explains the purpose of the study using key terms
- Focused – narrow in on the who/what/where/when
- Concise – written as succinctly as possible
- Relevant – advances the current knowledge in the area
Next Steps: Formulating a Research Question

Too narrow: What is the childhood obesity rate in Syracuse, NY?

Avoid questions that can be answered with a simple “yes” or “no”.

Less narrow: How does participation in the school lunch program impact childhood obesity rates in Syracuse, NY?

This question is specific and thought-provoking.

Adapted from: https://cirt.gcu.edu/research/developmentresources/tutorials/question
Examples of Nutrition Research Questions

- What effect does a fish oil supplement (containing EPA/DHA) have on triglyceride levels in hypertriglyceridemic patients when combined with MNT provided by a RDN?

- In overweight/obese children, does using foods or beverages with sucralose affect appetite?

- What amount of nutrition counseling is needed to reduce chronic disease risk factors in adult outpatients?
Next Steps: Generating a Hypothesis

- Traditionally, this is considered an “educated guess”
  - Your “guess” is based on the results from past research that was similar

- State what you think the outcome will be based on the intervention
  (or what you think the relationship will be for the variables being measured)

- A good hypothesis must be testable (and therefore, clearly written)
Examples of Hypotheses

- Taking a fish oil supplement in combination with MNT provided by a RDN will improve triglyceride levels in hypertriglyceridemic patients to a greater extent than taking a fish oil supplement alone.
- There will be no difference in triglyceride levels in hypertriglycemic patients taking a fish oil supplement in combination with MNT provided by a RDN compared to those taking a fish oil supplement alone.

- Consumption of foods or beverages containing sucralose will lead to increased appetite levels among overweight or obese children.
- Consumption of foods or beverages containing sucralose will have no effect on appetite levels among overweight or obese children.

- In adult outpatients, chronic disease risk factors will be reduced after four nutrition counseling sessions.
- In adult outpatients, there will be no change in chronic disease risk factors after one, two, three, or four nutrition counseling sessions.
Identifying a Research Team

Who will:

- Be responsible for the submission of materials related to the study?
  - Institutional Review Board application
  - Grant applications
  - Journal articles

- Recruit or identify participants?
- Collect the data?
- Analyze the data?
The Real Work: Developing a Study Plan

Research Design
- What data do you need to collect in order to answer your research question?
- Think about the main outcome variables as well as other factors that may influence them

Target Population
- Who will serve as participants? How many?
- How will they be identified? Will they be compensated?

Procedures
- When and where will the data be collected?
- How will you collect the data?
  - Think about equipment or instrumentation needed
  - Consider using AND’s Health Informatics Infrastructure (ANDHII)

Statistical Analysis: How will the data be analyzed?
Considerations for Human Subjects Research

- Most institutions require researchers to complete research ethics and compliance training
  - Collaborative Institutional Training Initiative (CITI): citiprogram.org
- Recruitment
- Informed Consent
- Compensation
Institutional Review Board (IRB)

A committee at research institutions who review research involving human subjects to ensure that the rights and welfare of human participants are adequately protected.

Why do we need IRB review?

- People underestimate the risks involved in things they are very familiar with
- People overestimate the benefit of things that are important to them

Your study will need an IRB approval if data:

- Is obtained from/about human subjects
- Collection relies on direct interaction with human subjects
- Includes identifiable private information about human subjects
Types of IRB Review

Full Board
- If your research involves “greater than minimal risk” to participants

Expedited
- Will only be sent to 1-2 members of the IRB committee
- Examples: analysis of saliva or hair samples; blood analysis (of healthy participants)

Exempt
- The research will be registered by the IRB
- Examples: anonymous surveys; passive observation; retrospective chart reviews; discarded specimen analysis (no patient identifiers)
IRB Application

1. Protocol Information
2. Funding Information
3. Study Rationale
4. Methods
5. Performance Site Information
6. Research Qualifications
7. Characteristics of Participants
8. Recruitment of Participants
9. Informed Consent Procedures
10. Potential Financial Conflict of Interest
11. Data Collection, Storage of Data, and/or Confidentiality
12. Risk to Participants
13. Benefits
Informed Consent

What needs to be included:

- A statement that the study involves research AND that participation is voluntary
- A description of the:
  - Purpose for the study
  - Procedures
  - Time commitment
  - Risks/Benefits
- How participant confidentiality/privacy will be protected
- Contact information for the PI/Researcher and IRB
- Depending on the study, will need to mention compensation
Results of IRB Review

- Approved (can start research)
- Modifications Required (need to modify application and re-submit)
- Not approved
- Re-categorize research
One More Item... $$$

- Need to determine budget for proposed study
  - Supplies/materials
    - Participant compensation
    - Disposable equipment
    - Software (or cost of analysis)
  - Study-related travel
  - Research staff salary (and possibly benefits)
  - Indirect costs from your institution

- Identify potential sources of funding
  - Internal vs. External

Stay tuned to hear how DIFM may be able to help...
The Fun Part! Collecting Data

Have clear procedures in place from day 1
  ◦ Keep a record of methodology throughout data collection
  ◦ Determine how the data will be recorded and stored

Pre-test equipment & measurement procedures prior to data collection
  ◦ Make sure all research staff are trained appropriately
  ◦ Be consistent with measurement

Prepare any update reports, if required by funding agency or institution

Hope for smooth sailing, but plan for bumps in the road
Wrapping Up: Analyze (and Evaluate) Data

✓ Combine all data collected into one file
✓ Complete any calculations based on the data (i.e. BMI)
✓ Perform initial data “cleaning”
   - Remove incomplete data
   - Identify outliers
✓ Run statistical analysis
✓ Interpret results of analysis
   - Focus on what is meaningful, not just what is significant
✓ Decide on plan to publicly share results
Resources

Books
- Research: Successful Approaches (3rd Edition): AND Store
- Nutrition Research: Concepts & Applications: Jones & Bartlett

Nutrition Research Organizations:
- Nutrition Research Network (former Dietetics Practice-Based Research Network)
  - https://www.eatrightpro.org/research/projects-tools-and-initiatives/nutrition-research-network
- Research DPG
  - https://www.researchdpg.org/
- National Association for Research Nutrition
  - https://sites.google.com/site/narnresearch/
Introducing... the 2018-2019 DIFM Research Grant!
2018 – 2019 DIFM Research Grant!

Purpose:
- To financially support research conducted by DIFM DPG members and student members.
- To encourage research studies in integrative and functional nutrition.

DIFM DPG will provide one Member Research Grant for $5000 and two Student Research Grants, each for $1000. Funds will be used to cover research expenses including but not limited to equipment, incentives to participants, research assistant stipend/salary, and other supplies directly related to research activities. Grant money cannot be used for applicant (primary investigator) stipend/salary, to cover indirect costs, or for conference travel.
Selection Criteria

- Quality and feasibility of the proposed project
- Relevance to integrative and functional nutrition
- Extent to which the results can benefit DIFM DPG members
Requirements & Policies

- Must be a paid member of DIFM DPG for the 2018-2019 member year.
  - Members of the DIFM DPG Executive Committee are NOT eligible to apply for the DIFM DPG Research Grant
  - Members of the DIFM DPG Leadership Team are eligible to apply for the DIFM DPG Research Grant

- Student eligibility: Must be enrolled in an undergraduate or graduate program for the 2018-2019 year, with plans to continue in an educational program for 2019-2020. Members in a post-doctoral position are considered students.

- Appropriate approval from an Institutional Review Board (IRB) or Animal Care Committee (ACC) must be provided to info@integrativerd.org as soon as it is obtained.

- Recipients must provide a grant status update to info@integrativerd.org by December 31, 2019, indicating the following:
  - Current status of the study
  - Amount of grant funds used
  - Estimated timeline for completion of the study

- Research activities (i.e. data collection) must be completed by May 31, 2020.

- Within 3 months of study completion, recipients must submit a final report (e-mailed to info@integrativerd.org) including:
  - A 150-300 word abstract of the study
  - Summary of key findings
  - Plan for presentation or publication

- Recipients will be required to share the results of their research by writing an article for the DIFM DPG newsletter and/or presenting a poster at a national conference (i.e. FNCE®).

- Recipients will be required to disclose “DIFM DPG Research Grant” as a source of funding in any and all publications and presentations that include data collected with grant money.
Application Components

**Personal Statement** (two page maximum) addressing:
- How grant funds will benefit DIFM DPG and RDNs interested in integrative and functional medicine
- How receiving this grant will aid the career of the applicant
- How the applicant will have time to complete the proposed research

**Research Proposal including the following items:**
- Proposal Title
- **Introduction and Background** (one page maximum)
- **Study Justification** (two page maximum), **including:**
  - Research Question
  - Specific Aims and/or Hypothesis
- **Study Design and Methods** (two page maximum)
- **Timeline for Completion** (one page maximum)

**Detailed Budget with Justifications** (one page maximum), **including:**
- Existing sources of funding for this project
- Other sources of funding sought for this project

**Reference List** (Does not count toward any of the above page limits)

**Description of Expertise, Resources, and Environment** (one page maximum)

**STUDENTS ONLY:**
- Submit a signed letter of support from the faculty member overseeing your research project (primary research advisor).
- Include the CV of their primary research advisor
Grant Due Date: February 1, 2019
Questions?