ICE BREAKER ACTIVITY

3 words that describe you
It’s a Collaborative Effort

This project is partly funded through a Patient-Centered Outcomes Research Institute (PCORI) Pipeline-to-Proposal Award (2-46600-124), administered on behalf of PCORI by MPHI. Funding is also provided by the Central Illinois MS Clinic Fund.
Project Purpose

• Mission
  – Develop a Patient-Led Multiple Sclerosis Research Community -- a dynamic, diverse, patient-led group that is driving the research agenda based on what is important to them.

• Vision
  – Patients and the public have information they can use to make decisions that reflect their desired health outcomes.
Some Ideas for Research

• Dietary/nutrition benefits for MS?
  – Possibly research on the “gut” and probiotics
  – The “Wahl’s protocol” which includes:
    • Diet
    • Exercise
    • Meditation

• Effects of hormones/gender on MS?
  – Why do more women than men get MS?
  – Does inadequate hormone production lead to MS?
  – Is there a relationship between hormone imbalance, diet, and MS?

• Effects of chemical exposure on MS?
  – Mercury (from canned fish, used as a preservative in some contact lens solutions, etc.)
A multimodal intervention for patients with secondary progressive multiple sclerosis: feasibility and effect on fatigue.
PMID: 24476345  Free PMC Article

The seventy percent solution.
Wahls TL.
PMID: 21253878  Free PMC Article

Wahls TL, Reese D, Kaplan D, Darling WG.
PMID: 21138391
Similar articles
<table>
<thead>
<tr>
<th>Rank</th>
<th>Status</th>
<th>Study</th>
<th>Condition</th>
<th>Interventions</th>
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<tbody>
<tr>
<td>1</td>
<td>Active, not recruiting</td>
<td><strong>Wahls Paleo Diet and Progressive Multiple Sclerosis</strong></td>
<td>Multiple Sclerosis</td>
<td>Other: Wahls Paleo Plus; Other: Wahls Diet</td>
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<tr>
<td>2</td>
<td>Active, not recruiting</td>
<td><strong>Nutrition, Neuromuscular Electrical Stimulation (NMES) and Secondary Progressive Multiple Sclerosis (SPMS)</strong></td>
<td>Multiple Sclerosis</td>
<td>Other: Progressive exercise; Device: Neuromuscular electrical stimulation delivered using the electrical therapy device EMPI 300 PV; Other: Modified paleolithic diet; Dietary Supplement: Omega-3 fatty acids; Dietary Supplement: Full Spectrum vitamin;</td>
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Key Project Milestones

• **Conference-style event**
  – bring a variety of patients, researchers, and other stakeholders together
  – build relationships & discuss forming a patient-led multiple sclerosis research community in central IL
  – Provide “level-set” training on evidence-based decision making, patient engagement, & patient centered outcomes research

• **Adapt based on participant feedback (iterative)**
  – Document community vision, needs, priorities, communication and meeting preferences, updated team charter, and next steps.
Partnership Team

• Initial project partnership team is a subset of the MS Advisory Committee

• During the project, the partnership team will be expanded and adapted to become the patient-led multiple sclerosis research community ➔ This is YOU & the structure we are creating for continued involvement

• Today is a start of an ongoing conversation
Project Timeline

- September 2015-November 2015
  - Partnership Team strategic plan development – an Iterative process of seeking community guidance and adjusting the composition and structure of the partnership team
    - The partnership team charter will be updated
    - The partnership team membership will be expanded to include additional community members living with multiple sclerosis
    - The communication plan will be revised to address communication preferences shared at the event
    - Additional in-person meeting events may be conducted
Project Timeline

• December 2015-January 2016
  – Share strategic plan widely
  – Enact strategic plan (e.g., begin using the newly formed structure to develop a list of MS research priorities)
  – Project close-out/sustain community
Partnership Team Membership

• Volunteer group based on involvement and interest in the Patient-Led Multiple Sclerosis Research Community.
• The project manager maintains an updated roster with contact information.
• Members may join or leave the group at any time, and attendance at meetings is not required to be considered part of the Patient-Led Multiple Sclerosis Research Community.
Commitment of a Member

• I will share my experiences, expertise, and insight to support the Patient-Led Multiple Sclerosis Research Community in driving the research agenda on Multiple Sclerosis.

• I recognize that multiple sclerosis affects the life of each person differently and value each person’s perspective.
Including Different Perspectives

• Currently, there are 4 main types of multiple sclerosis, each with different treatment options and prognoses.
• Due to the progressive nature of the disease, a person who is newly diagnosed may have a different perspective than a person who has been living with the condition for decades.
• Due to health status or for other reasons, some people are not able to attend in-person meetings. The value of a person’s contribution to the Partnership Team is not related to the format in which the person participates.
What is the best way for you to meet?

- In-person
- By e-mail
- By Skype or webinar (over the computer)
- By phone
- By postal mail
How often should we meet?

- Every month
- Every 3 months
- Every 6 months
- Once per year
- Other - Please describe:
Other Questions?
Group Stretching Exercise

- Kim Cooley
- Kim Haddock
SEATED SHOULDER ROLLS

- Move shoulders up and around in a circle, forward and then backward. You may be seated or standing.

- Repeat 10–12 times.
- Complete 3–5 times throughout the day or as needed when you notice yourself having poor posture.
CHIN TUCKS

You may be seated or standing. The goal is to pull your chin toward the back of your head/toward your spine. You may use gentle over-pressure on your chin with your hand.

- Hold for 3–5 seconds and repeat 10 times.
- Complete 3–5 times throughout the day or as needed when you notice yourself having poor posture.
Shoulder Blade Squeezes

Rotate shoulders back, then squeeze shoulder blades together. Return to start position and repeat.

You may be seated or standing.

Repeat 10–12 times throughout the day (every 30–60 minutes) or as needed when you notice yourself having poor posture.
Seated Thoracic Extensions

Sit on a low firm-backed chair, hands behind head. Place a pillow on the back of chair or under low back if needed.

Elbows leading motion, lean back, arching upper body. Hold 3–5 seconds and exhale. Return to starting position and repeat 10–12 times.

Complete 3–5 times throughout the day or as needed when you notice yourself having poor posture.
SPINAL MOBILIZATION

- Cervico–Thoracic: Extension / Rotation


- Repeat 5 times.

- Do 3 times per day.
HAND – WRIST FLEXOR STRETCH

- Keeping elbow straight, grasp hand and slowly bend wrist back until stretch is felt.
- Hold 30 seconds. Relax
- Repeat 5 times per set.
- Do 3 sessions per day.
Calves/Heels/Feet

Sit with strap/towel around ball of foot.
Gently pull toward body.
Hold 30 seconds.
Repeat 5 times per session.
Do 3 sessions per day.
SEATED LEG STRETCHES – 2

- Hamstring

- Sit at edge of seat, spine straight, on leg extended. Put a hand on each thigh and bend forward from the hip, keeping spine straight.
- Allow hand on extended leg to reach toward toes.
- Support upper body with other arm.
- Hold 30 seconds.
BENEFITS FROM EXERCISE

- Improvement in aerobic or cardiovascular fitness
- Improvement in strength
- Reduction of risks for cardiovascular disease
- Reduction of the risk of falls through improvement of balance
- Enhancement of the overall quality of life
References


http://www.nationalmssociety.org/Symptoms—Diagnosis/MS—Symptoms/Spasticity#section-0
How Research Influences MS Care Today – A Panel Discussion

Kim Cooley, RN, CCRC
September 19, 2015
Panel Presenters:

1. **Kim Cooley, RN, BSN, CCRC** (RN Research Coordinator II at OSF Saint Francis Medical Center)

2. **Vicky Schwegmann, RN, MSCN** (Nurse at INI MS Clinic)

3. **Tonya Welch, BSW** (Social Worker at INI MS Clinic)

4. **Kim Haddock, RN, BSN, CPN, CCRC** (Research Associate II for UICOMP Department of Pediatrics)
Objectives for Kim C.’s presentation:

1. Understand what research is.
2. Be briefly introduced to the FDA Approval Process for drug trials.
3. Identify the benefits of continuing research after drugs are FDA approved.
4. Describe other topics that are important to research.
5. Continue to expand upon your small group discussions and brainstorm what is important to you about MS.
What is Research?

- Research is a study that is done to answer a question.
- Scientists do research because they don’t know for sure what works best to help you.
- Research is not the same as treatment.

Process involved in FDA approval of drugs

- **Clinical Trials** are an important step in the process of making a newly discovered treatment available to the general public.

- All trials are **regulated by the FDA** (Food and Drug Administration) to protect the safety of research volunteers.
Drug discovery continued:

- The process of drug/device discovery is quite long and involves many processes which include.
- This is why it takes many years for a drug to “reach the market”.
- Patient Safety is the FDA’s concern in this process.
Pre-Clinical Phase

- Scientists are working with the compound to determine if it is initially safe to use in humans.
- Ex. animal and lab experiments are done.
- EAE model (experimental autoimmune encephalomyelitis)
- 10+ years
New Drug Application

- Once the pre-clinical studies are completed, the “sponsor”, submits to the FDA for an Investigational New Drug Application.
- At this point the FDA will approve or disapprove the application based on the pre-clinical data.
Phase 1:

- First time the study drug is given to humans.
- Given to healthy volunteers or those who have the condition.
- Purpose is to find out how the drug should be given (oral or injection) and how much should be given (the dose).
- Shorter time frame
  (ex. 6mo-1 year)
Phase II trials:

- Started after phase I studies have been completed.
- Involve a small number of subjects. (Usually around 100-200).
- Only given to population with the disease.
- The purpose of phase II studies is to check the efficacy (how well the study drug works to treat the disease). Safety is also monitored.
- Placebo or comparator, or both used.
- Time: 1-2 years.
Phase III trials

- Begun after the data collected from phase I and II studies shows evidence of benefit and safety.
- Involve hundreds to thousands of volunteers nationwide or worldwide.
- Usually two Phase III trials need to be completed prior to FDA approval.
- Some exceptions are made by the FDA to fast track drugs which are intended for the treatment of serious or life-threatening conditions. In this case only one phase III trial is needed.
- Longer time frame (2-3 years)
New Drug Application

- After phase III trials are complete, the sponsor will submit a NDA (new drug application) to the FDA.
- This is a “formal request to be allowed to market a drug”.
- If approved by the FDA, the drug may be made available to the general public.
Phase IV Trials

- Phase IV trials are studies done on already approved drugs.
- Their purpose is to collect additional safety and benefit/risk information on the drug.
- Information collected in the “real world” setting.
- Benefit is that more patients can be followed over a longer period of time (5+ years).
Drug Trials vs. other research

- Research just doesn’t include drug trials.
- There are many other questions that need answered in addition to “What drug is the best?”
- Other examples that could be researched:
  - Testing (Imaging or labs)
  - Assessments (exam rating scales, questionnaires, cognitive tests)
  - Quality of Life
Important “take-a-way”

- Research is NOT just drug trials.
- We can apply the same scientific process in drug trials and design a research study around alternative therapies, testing, and other areas such as quality of life.
- Think outside of the box today.
- What is important to you? It may be important others.
My inspiration!
References


CARL’S Presentation
Tamara Lott’s Presentation