



# DESCRIBING CHINESE HERBAL MEDICINE TELEHEALTH CARE FOR SYMPTOMS RELATED TO COVID-19: A TALE OF TWO STUDIES

LISA J. TAYLOR-SWANSON, PHD, MACOM, LAC

# ACKNOWLEDGEMENTS

- I acknowledge that I live, work, and **recreate on the traditional and ancestral homeland** of the Shoshone, Paiute, Goshute, and Ute Tribes.
- I honor and appreciate the **many teachers**, on whose shoulders I humbly stand, and offer to carry these traditions forward.

# CONFLICTS OF INTEREST

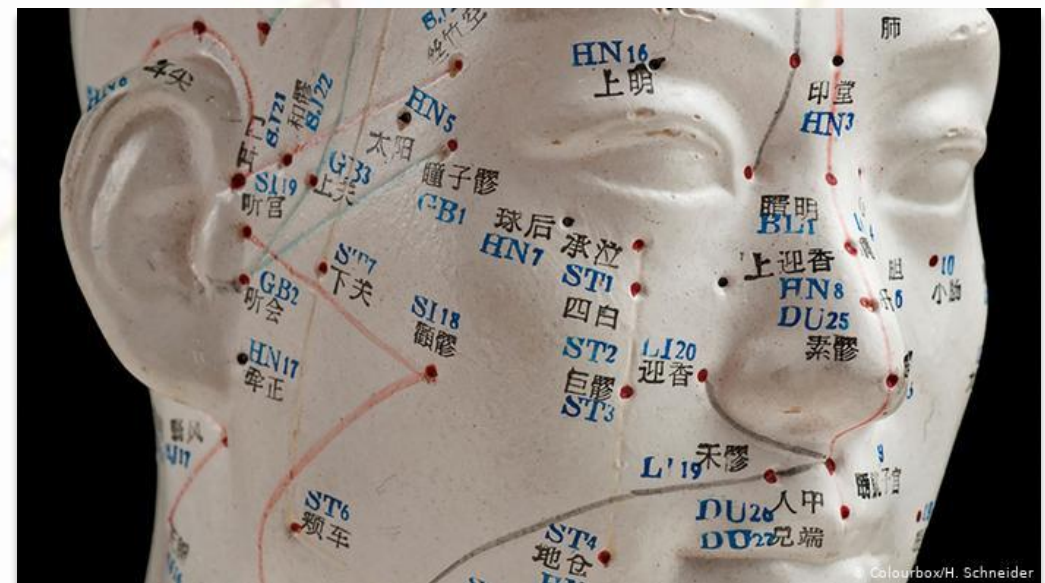
- **Dr. Lisa Taylor-Swanson** has no conflicts to declare.

# IMAGINE RESEARCH IN ALIGNMENT WITH THE 5 ELEMENTS

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# Seattle Institute of East

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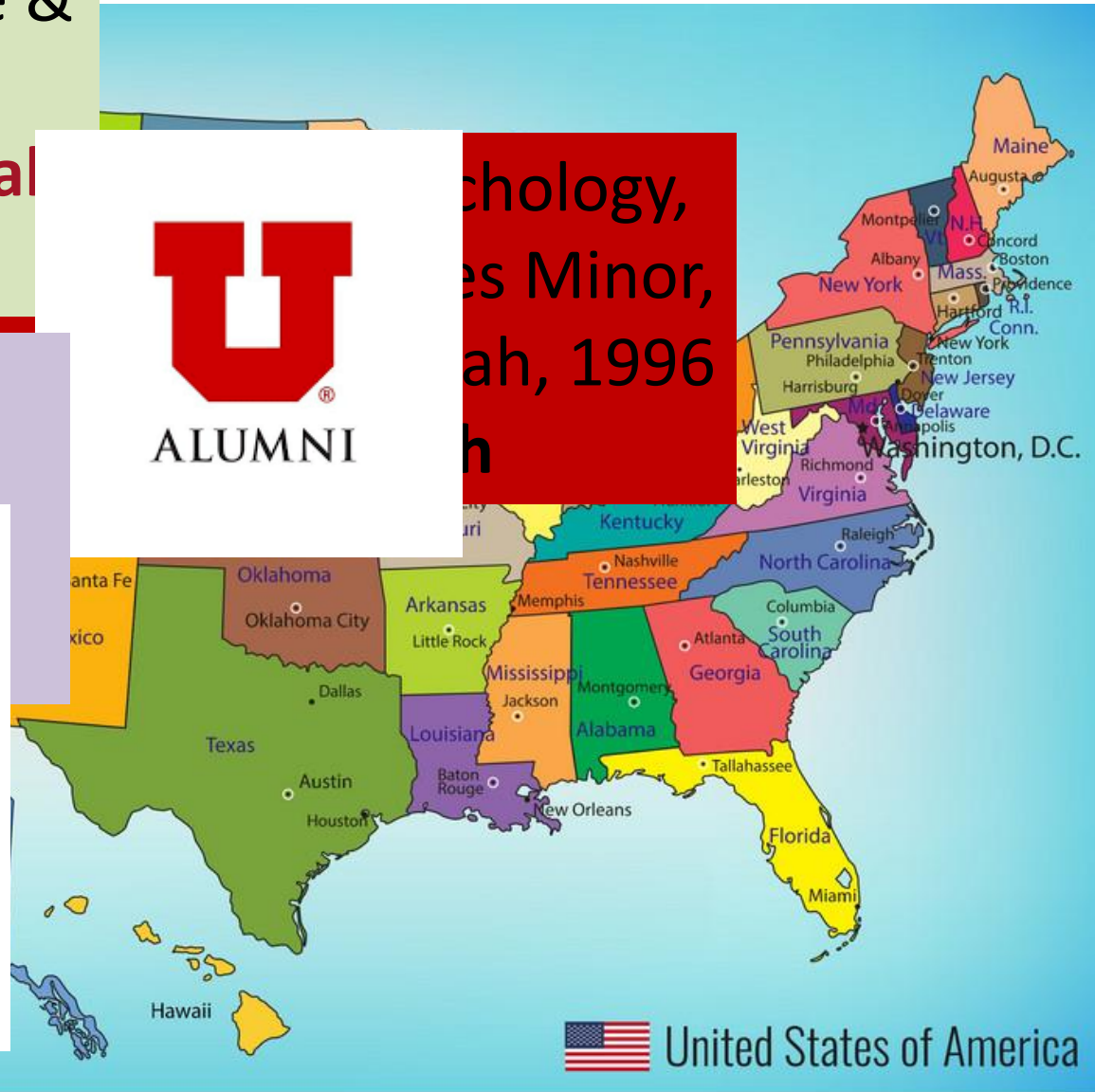
SCHOOL OF NURSING

UNIVERSITY of WASHINGTON



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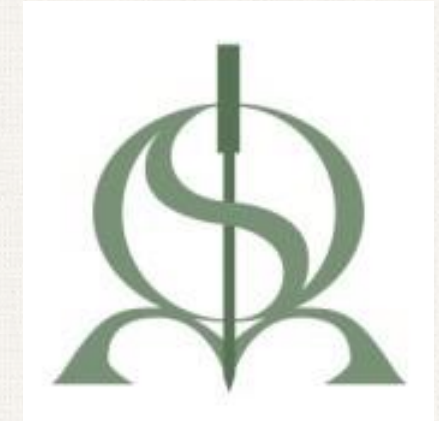


Seattle-Based **E**ast **A**sian Medicine  
**R**esearch of **C**hinese **H**erbs for  
Symptoms Possibly Related to COVID-  
19  
**(SEARCH Study)**



## SEARCH STUDY

### Seattle Institute of East Asian Medicine (SIEAM)



- Craig **Mitchell**, PhD;  
Katherine **Taromina**, DACM
- Currently **providing telehealth consultations to participants & collecting data**





# REGULATORY CONSIDERATIONS

- Documentation to support a **regulatory filing** with the FDA
- **60 single herbs**
- Botanical Drug Investigational New Drug (**IND**) Application





# RESEARCH DESIGN COMPONENTS

- **Prospective** study, **observational** in nature
- “*Why **observational** and not **controlled**?*”
- **Rigorous** and collecting data that can inform future RCT designs
- Two worlds: FDA/ NIH and CHM
- **Internal validity** and **external validity** can be accomplished

# NOVEL DESIGN ASPECTS

- **Ethics review** (IRB) at SIEAM and Utah
- Novel
  - NOT otherwise being studied in the USA!
  - No study design template to follow
- **Unfunded** at present



## **BACKGROUND**

The Coronavirus Disease 2019 (**COVID-19**) is caused by SARS-CoV-2, can lead to Acute Respiratory Distress Syndrome (ARDS)

– highly infections and widespread

**No known cure, but self-limiting in 80% of patients.**

## BACKGROUND



- Fever or chills, non-productive cough, dyspnea, myalgia, fatigue, headache, nausea or vomiting, diarrhea, new loss of taste or smell, sore throat, congestion or runny nose, normal or decreased leukocyte counts, and pneumonia
- **List changes, weekly in the beginning**



## BACKGROUND

Chinese herbs are a therapy within the whole system of East Asian Medicine

Historical record of treating epidemics/pandemics

Evidence is limited and generally poor in quality



There is a **gap** in our understanding of the clinical application of CHM in a community sample of individuals experiencing symptoms that may be related to COVID-19. We had no pragmatic clinic data about the use of CHM for coronaviruses when we launched this study.

## STUDY PURPOSE AND AIMS

### Purpose

To design and execute a prospective, longitudinal, descriptive cohort study in a pragmatic clinical practice for adults with symptoms that may be related to COVID-19

### Aim 1

Conduct quantitative analyses of the collected data and disseminate findings to CHM clinicians and to the scientific community.

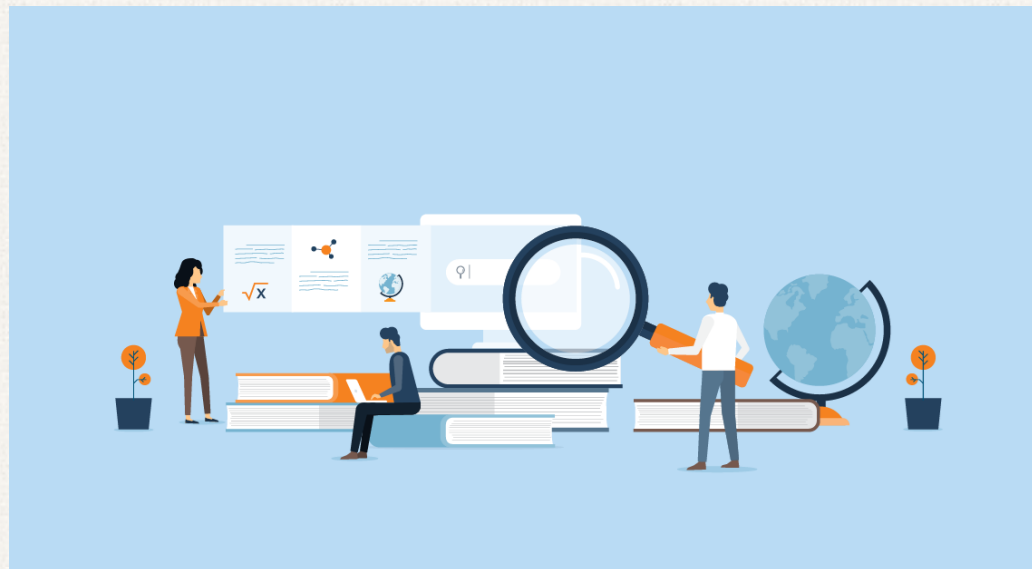
### Aim 2

Conduct qualitative analyses of the collected data and disseminate findings to CHM clinicians and to the scientific community.



# STUDY DESIGN

- **Pragmatic** - clinicians determine # consults, individualized Chinese herbal medicine (CHM) by differential dx
- **Descriptive, longitudinal cohort** study
- **Telehealth** consult via Zoom
- **No-contact** herb pick up / delivery



# INCLUSION CRITERIA

- **Experienced 1+ symptoms in the last 28 days:**  
Fever or chills, non-productive cough, dyspnea, myalgia, fatigue, headache, nausea or vomiting, diarrhea, new loss of taste or smell, sore throat, congestion or runny nose, normal or decreased leukocyte counts, and pneumonia.  
*(CDC list)* <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>
- OR at a **high risk of exposure**
- **18+ years old**
- Have a **Primary Care Provider**



## EXCLUSION CRITERIA

- **Anticoagulants, immunosuppressants, antiseizure Rx, antipsychotic Rx, active cancer** treatment
- Medications with **potential interaction** with herbal medicine
- **Discretion of practitioner or screener**
- Ineligible to receive **telehealth** for any reason
- **Breastfeeding, pregnant**
- Unable to communicate in **English**
- Have an open **legal case** about their health

# INDIVIDUALIZED TREATMENTS

- Patient **screening** appointment
- **Initial consult** same day as screening, if possible
- **Follow up consults:** timing, frequency determined by clinicians
- **Follow-up:** 24, 48 hours after each consult
- **Follow-up:** 3, 6, 12 months

	Day 1	Day 2	Day 3	Day 4-6	Day 7	Day 8-13	Day 14	Day 90	Day 180	Day 365
<i>Screening</i>	X									
<i>Initial consult</i>	X									
<i>Follow up consult</i>		X	X	PRN		PRN				
<i>Patient Check in</i>					X		X			
<i>Follow up questionnaires</i>								X	X	X



# HERB-DRUG INTERACTIONS

- Simultaneous cross-reference of drug/herb interactions using **Natural Medicines Database**
  - By SIEAM Student

Level of Significance: Stop-Light Rating System Occurrence/Severity

	Likely	Probable	Possible	Unlikely
High	Red	Red	Yellow	Yellow
Moderate	Red	Yellow	Yellow	Green
Mild	Yellow	Yellow	Green	Green
Insignificant	Green	Green	Green	Green

**Major** = Do not use combination; contraindicated; strongly discourage patients from using this combination; a serious adverse outcome could occur.

**Moderate** = Use cautiously or avoid combination; warn patients that a significant interaction or adverse outcome could occur.

**Minor** = Be aware that there is a chance of an interaction; advise patients to watch for warning signs of a potential interaction.

# INTERVENTIONS

SIEAM faculty: licensed herbalists -**15+ years' experience**

- Daniel Altschuler, Dan Bensky, Christina Jackson, Shouchun Ma, Craig Mitchell

**Assessment:** Pattern differentiation TEAM

- **Individualized Chinese herbal medicine (CHM) formula** (granules, raw herbs; pills)



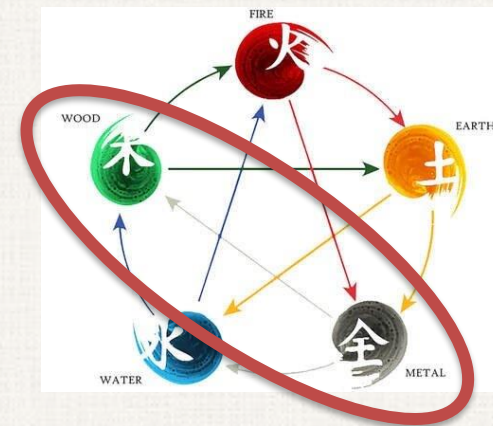
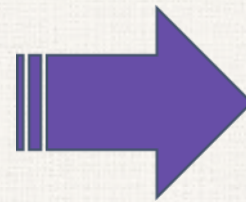
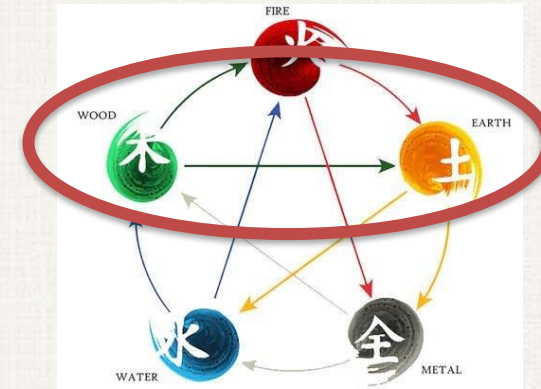
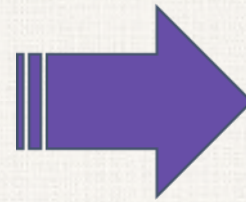


# KEY POINTS ABOUT THE **DESIGN**

- **Which CHM to use** – by differential dx
- **Clinicians decided** interval of treatment
  - According to participant presentation
- **Dense, descriptive data**
  - “Standard” statistical analyses
  - Nonlinear analyses – require big N
  - Allows for **novel phenomenon discovery** (“**emergence**”)



# COMPLEXITY-INFORMED RESEARCH DESIGN

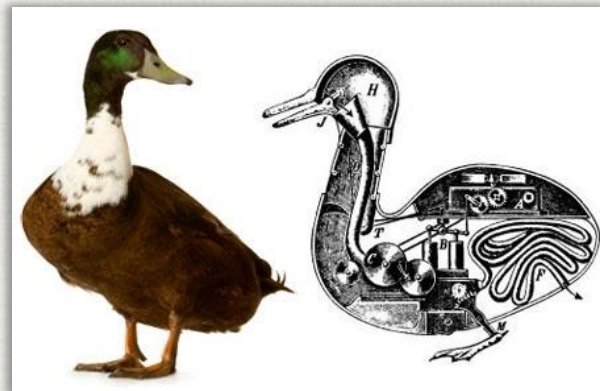


# INTRODUCTION TO COMPLEXITY SCIENCE

## Complexity Science

“When we try to pick out anything by itself, we find it hitched to everything else in the universe.”

- John Muir



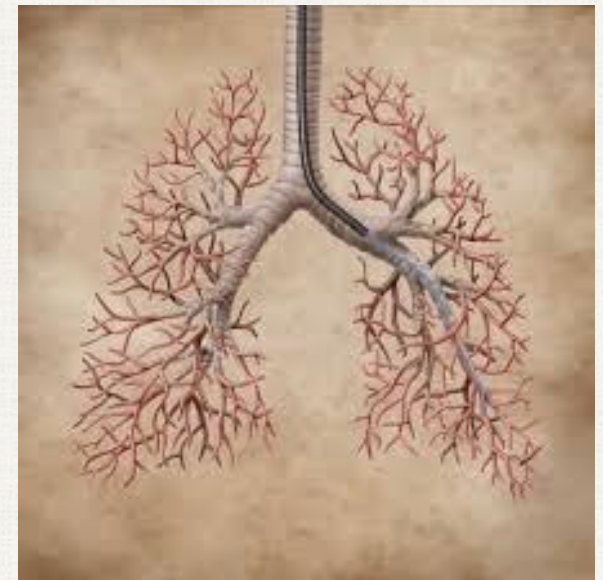
## Reductionism

“Human science fragments everything in order to understand it, kills everything in order to examine it”

- Leo Tolstoy

# INTRODUCTION TO COMPLEXITY SCIENCE

- **We are complex systems:**
  - Cells / organs / body: different emergent properties at each level
- **Emergent properties** at each level
- Self-similar patterns appear at different levels (e.g., fractals)



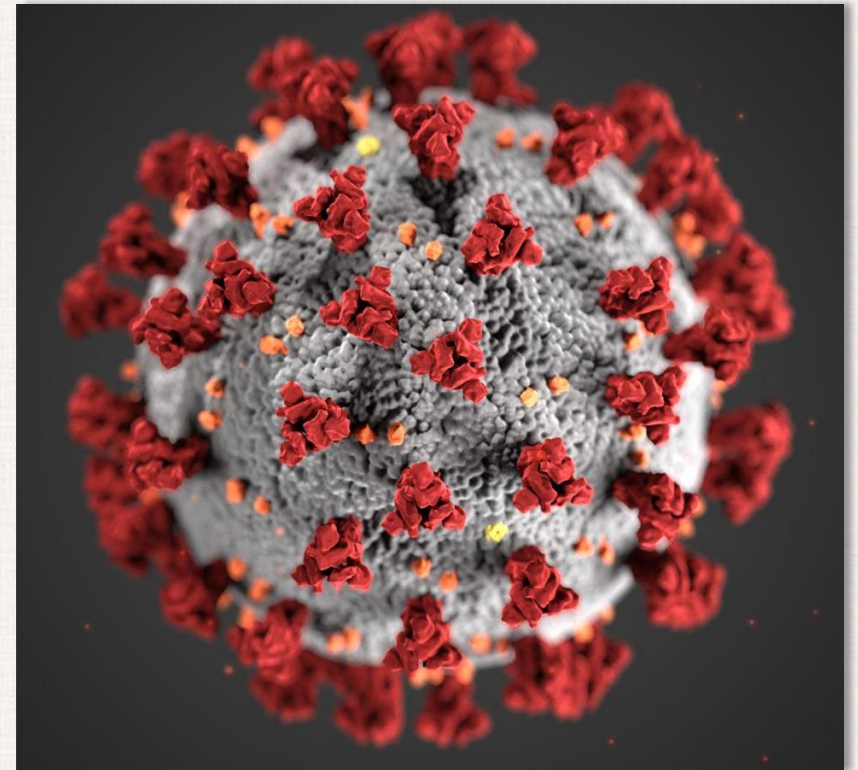


# INTRODUCTION TO COMPLEXITY SCIENCE

- **Perturbation:** alteration of the function by external or internal means (systems biology)
  - Acupuncture treatment perturbs the system so it can reconfigure (ideally, to a more healthy state!)
- **Nonlinear effects** – small changes in initial conditions (could be a perturbation) can cause a disproportionately large effect (Dore, 2009)

# INTRODUCTION TO COMPLEXITY SCIENCE

- **COVID-19 as a perturbation** to the complex system that is our planet
  - **Economic** changes
  - **Social** changes
  - **Biologic / health** changes
  - **Governmental** changes



# A TALE OF TWO WORLDS - EMBEDDED DESIGN

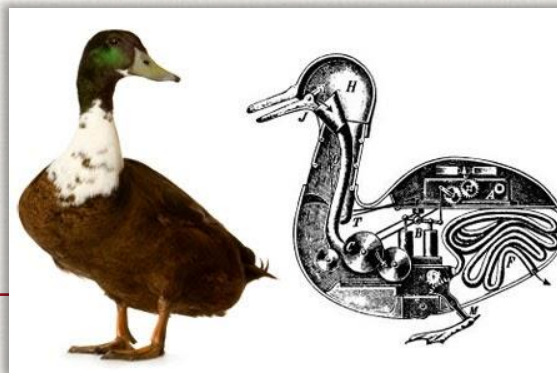
## Complexity design adds:

- Collecting data across body systems
- Emergent phenomena/outcomes
- Biopsychosocial outcomes

Dense data collection allows for cusp catastrophe & other non-linear analyses

## Design based on reductionism:

- Baseline
- Follow ups
- Data collected on primary outcomes (COVID-19 related symptoms)
- Adverse Events (AEs) and Serious AEs





# A TALE OF TWO WORLDS - EMBEDDED DESIGN

## Complexity-informed design:

- **Collecting data across bodily systems - 'whole person' perspective**
  - Lung, heart, diabetes, digestion, emotional symptoms, EENT, pain, digestion, urination, sleep, energy, gynecologic, self-care, protection from viral exposure
- **142 questions**
- Feeling **well**  $\leftrightarrow$  **unwell**
- **Tongue** body & coat

# A TALE OF TWO WORLDS - EMBEDDED DESIGN

## Complexity-informed design:

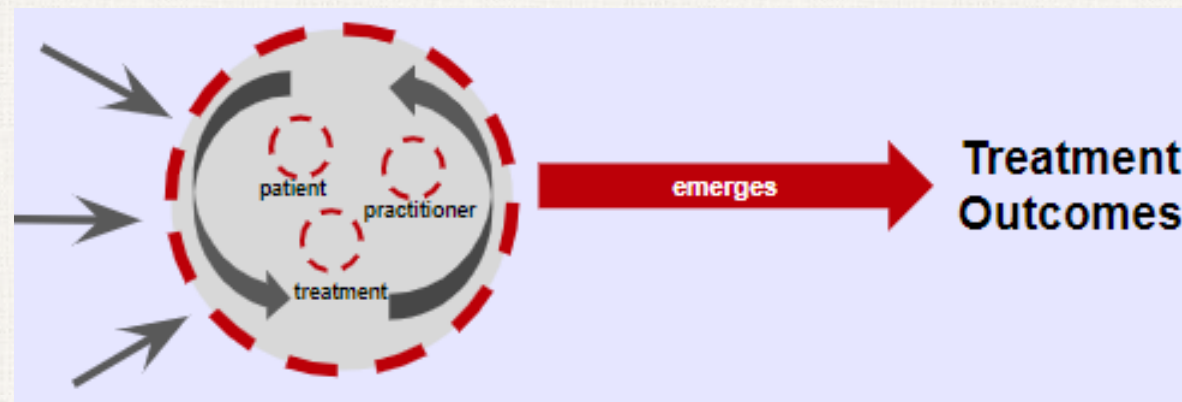
- **Biopsychosocial** outcomes - another '**whole person**' term, including social outcomes
- **Emergent phenomena/outcomes**
  - people's unanticipated improvement
  - asking clinicians what's relevant
- Dense data collection will allow for **cusp catastrophe & other non-linear analyses**
- Dense CHM data including base formula, modifications (*jià jiàn*) and *pào zhì*

# A TALE OF TWO WORLDS - EMBEDDED DESIGN

**Patient-level measurement:** quantitative re: symptoms & qualitative re: experience

**Practitioner-level measurement:** qualitative re: experience and clinical reasoning

**Treatment-level measurement:** each herb, in grams and *pào zhì* from each telehealth consult





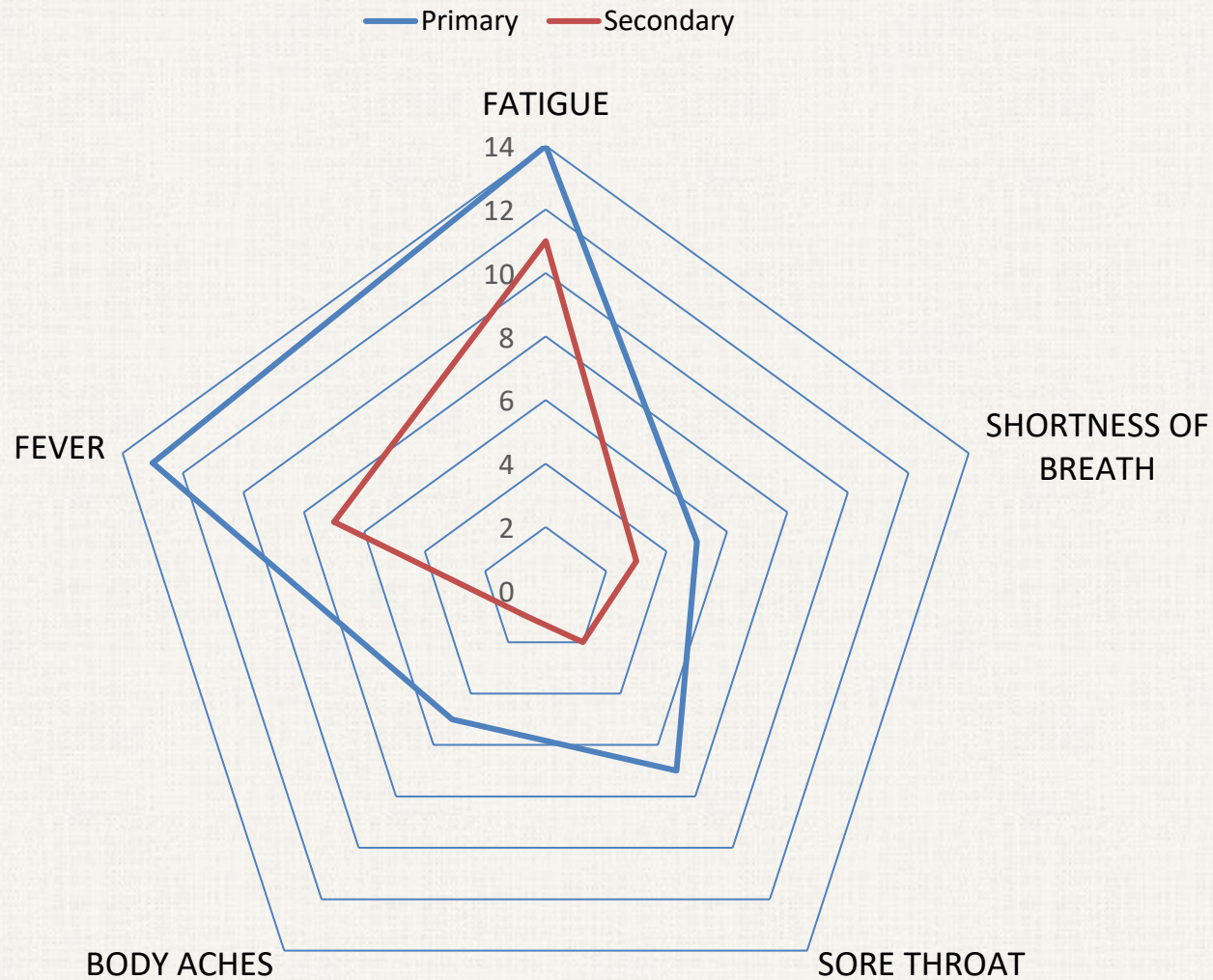
# RESULTS

- **Work in progress**
- **Preliminary data** presented today
- **Feasibility** – enroll, deliver telehealth sessions, F/U
- **Acceptability** – compliance with CHM
- **Safety** – no AEs
- ***Did we capture the complexity of clinic?***
  - REDCap has 142 sx questions
  - Loose / granules / pills
  - Herbal formulas - *Pao Zhi*

# SEARCH STUDY DATA – BASELINE

Demographics (n=57)	Details
Sex	Female = 35 (62%); Male = 22 (38%)
Age	Average = 45.73 years (Range 25-69)
Race	Caucasian = 33 Native American/Alaska Native = 1 Hispanic = 1 Black or African American = 1 Unknown = 21
Ethnicity	Non-Hispanic = 30 Hispanic = 5 Unknown = 22
Treatments	Total = 195      Average = 3.31 per participant      Range (1-9)
Long Hauler	N = 10

# PRIMARY & SECONDARY COMPLAINTS-BASELINE





# SEARCH STUDY DATA – RECOVERY & AES

Level of Recovery	Frequency (n=57)
Completely Recovered	49
Participant Improving (treatment in progress)	3
Incomplete recovery – referred for acupuncture	1
Lost to follow-up	1
Cancer- unrelated to study	1
Discontinued Treatment	2

Adverse Events (AEs)	Frequency
Serious AE	0
Minor AE	0

# AN EXTERIOR PATHOGEN & VARIOUS PRESENTATIONS

- Some formulas were **interior** (*Liu Jun Zi Tang*)
- Some formulas were **exterior** (*Gui Zhi Tang*)
- Some formulas were at the **pivot of interior and exterior** (*Xiao Chai Hu Tang*)

# REFLECTIONS

- We implemented a study that **the whole school could participate in:**
  - Faculty of all years' experience
  - Students
  - Administration
- **Students got direct experience of real-world, novel research**
  - CHM, filling formulas, creative problem solving
  - Data entry



# REFLECTIONS

- *The whole school attends these herb clinics* online! Faculty, too! **Everyone learning, and quickly.**
- Prescription styles:
  - Combining whole formulas
  - Taking parts from formulas – not whole recognizable formulas

# REFLECTIONS

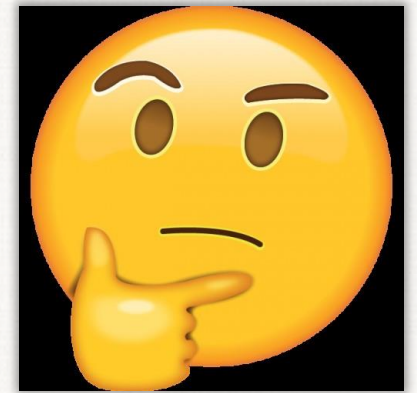
**Feasibility** – *Could we do what we thought?*

- Delivered a trial that utilized **multiple ways in which herbs are dispensed**: raw, granules, pills. Truly pragmatic & feasible
- **Retained** participants

**Acceptability** – *What did participants think?*

- High compliance with CHM – not an issue
- Positive feedback to clinicians, coordinator

# LESSONS LEARNED



- **Lessons learned:** students initially following up 24- 48-hours and then faculty had to do so because of the seriousness of COVID disease
- **48-hour was most significant;** sooner re-evaluation than may have done typically
  - **Not** an inexperienced clinician or RA



# LOOKING TO THE FUTURE

- **How do we envision conducting complexity-informed studies?**
- **Large datasets / computing power**
- **Collaboration – team science!**
- **RCT**
  - **Conversations and team building underway**
  - Application to NCCIH
  - Herbs + usual care vs. usual care
  - Nurse coordinator attention control

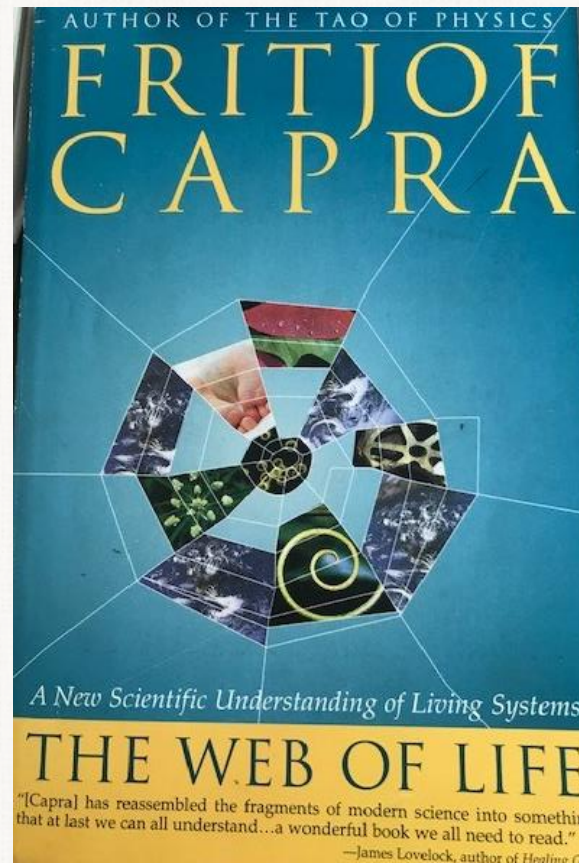
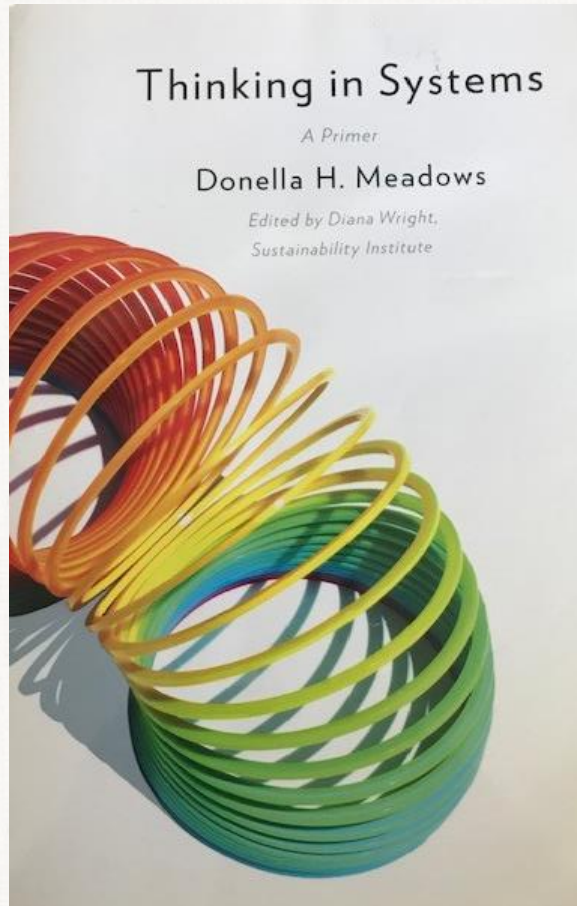
## LOOKING TO THE FUTURE

# Strategic Plan

- Future studies planned – opportunities
- **NCCIH new strategic plan**
  - **Objective 2: Advance Research on the Whole Person** and on the Integration of Complementary and
    - Conduct clinical and translational research on **multicomponent interventions**, and study the impact of these interventions on **multiple physiological systems** (e.g., nervous, gastrointestinal, and immune systems) and **domains** (e.g., biological, behavioral, social, environmental).

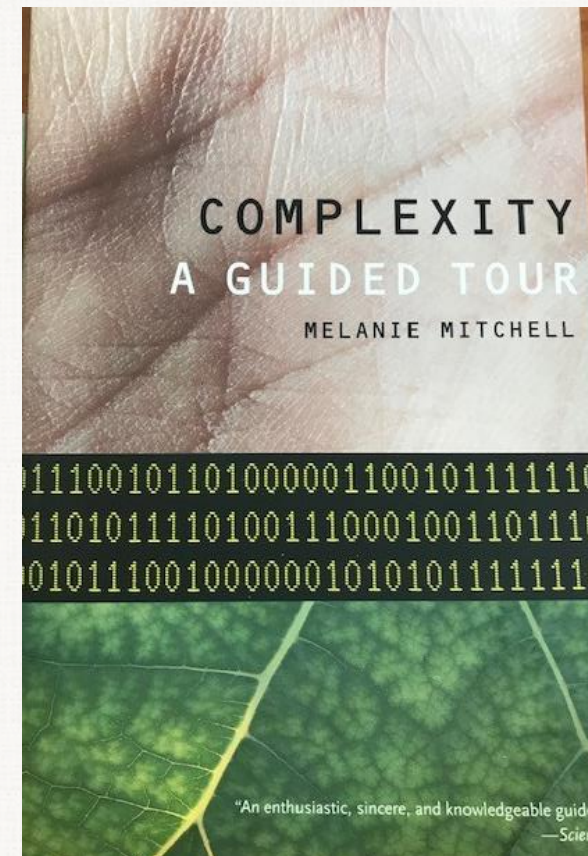


# RESOURCES



## Santa Fe Institute

**Complexity Explorer.org:**  
free MOOCs (Dr. Mitchell  
is the former director)





# RESOURCES



HOME: [News](#)

## Welcome to Complexity Explorer

Complexity Explorer delivers online courses, tutorials, and resources essential to the study of complex systems. Complexity Explorer is an education project of the [Santa Fe Institute](#).





Haven't registered?

[Register here](#) to enroll in courses and receive updates

Already registered?

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## Available Courses

 <p>COURSE</p> <p>ACTIVE</p> <h3>Fractals and Scaling</h3> <p>Always available</p> <p>ENROLL</p>	 <p>COURSE</p> <p>ACTIVE</p> <h3>Introduction to Complexity</h3> <p>Always available</p> <p>ENROLL</p>	 <p>COURSE</p> <p>ACTIVE</p> <h3>Introduction to Dynamical Systems and Chaos</h3> <p>Always available</p> <p>ENROLL</p>	 <p>COURSE</p> <p>ACTIVE PAYWALL</p> <h3>Computation in Complex Systems</h3> <p>15 Jul 2020 UTC - 07 Sep 2020 UTC</p> <p>ENROLL</p>
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# RESOURCES: UPCOMING PRESENTATION ON THIS STUDY



THE SOCIETY FOR  
**ACUPUNCTURE**  
RESEARCH

## SAR RESEARCH CONFERENCE

2021

Pandemics, Pain, & Public Health: Roles  
and Relevance of Traditional East  
Asian Medicine



*co-sponsored by the University of Michigan Department of  
Anesthesiology and Program in Integrative Medicine*

**JUNE 14 - 17, 2021 VIRTUAL CONFERENCE**

**CONFERENCE PROGRAM AT-A-GLANCE**



# SIEAM CLINICIANS – **SINCERE GRATITUDE!**

- Daniel **Altschuler**, LAc
- Dan **Bensky**, DO
- Christina **Jackson**, LAc
- Shouchun **Ma**, PhD
- Craig **Mitchell**, LAc, EAMP, PhD(China)
- Jason **Robertson**, DAHM, LAc



# SEARCH STUDY TEAM – SINCERE GRATITUDE!

- **Lisa Conboy, ScD,**  
MA, MS
- **Lee Hullender Rubin,**  
DAOM
- **Craig Mitchell, LAc,**  
PhD(China), EMP
- **Kathy Taromina,**  
DACM, EMP



# GROWING THE SEARCH STUDY TEAM – SINCERE GRATITUDE!

- **Belinda “Beau” Anderson, PhD, MA**
- **Claudia Citkovitz, PhD, LAc**
- **Helen Huang**
- **Iman Majd, MD, LAc**
- **Rosa Schnyer, DAOM, IFMCP, LAc**



# SHARING OUR EXPERIENCE

Check SIEAM's website for  
case reports

<https://sieam.edu/search-covid-19>





# CONTINUING THE CONVERSATION

[ComplexityinMedicine@gmail.com](mailto:ComplexityinMedicine@gmail.com)

Claudia Citkovitz, PhD, MS, LAc, Dept of Rehabilitation Medicine, NYU Medical School

Lisa Conboy, MA, MS, ScD, Instructor in Medicine BIDMC, Harvard Medical School &  
Director of Research New England School of Acupuncture

Lisa J. Taylor-Swanson, PhD, MAcOM, LAc College of Nursing, University of Utah

Tanuja Prasad, MS Elect. Engg, [ApplyComplexity](#) (Founder)

Rosa Schnyer, DAOM, IFMCP, LAc, Clinical Assistant Professor,  
School of Nursing, University of Texas at Austin

