Treatment of Chronic Pain with Cannabidiol (CBD) and Tetrahydrocannabinol (THC)

Dr. Deborah Yurgelun-Todd, Ph.D. (PI)

Dr. Perry Renshaw, M.D., Ph.D. (Co-PI)

University of Utah

Time Line of Regulatory Approvals

IND Approval

- September 6th, 2017

IRB Approval

- September 18th, 2017

Certificate of Confidentiality Approval

- October 3rd, 2017

Schedule I Registration Approval

- January 12th, 2018

Study Drug Received

- January 11th, 2019

IRB Post IND Compliance Audit

- May 9th, 2019

Study Design

Baseline

Follow-up

Screen	Day 1 (Monday)	Day 2	Day 3	Day 4	Day5	Day 7 (Monday)

Testing

Bio-specimens

fMRI & MRS Scans

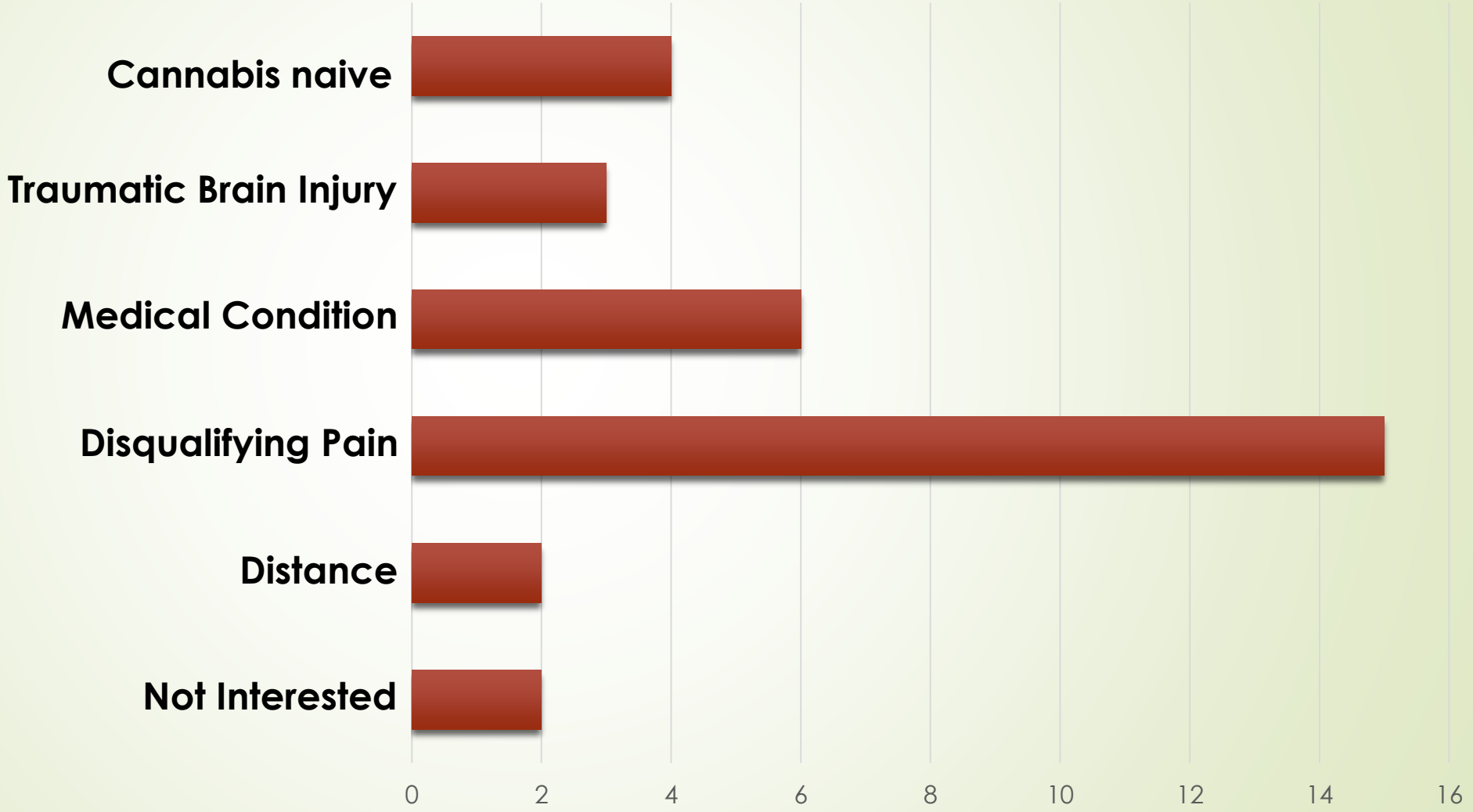
Recruitment Approaches

Efforts

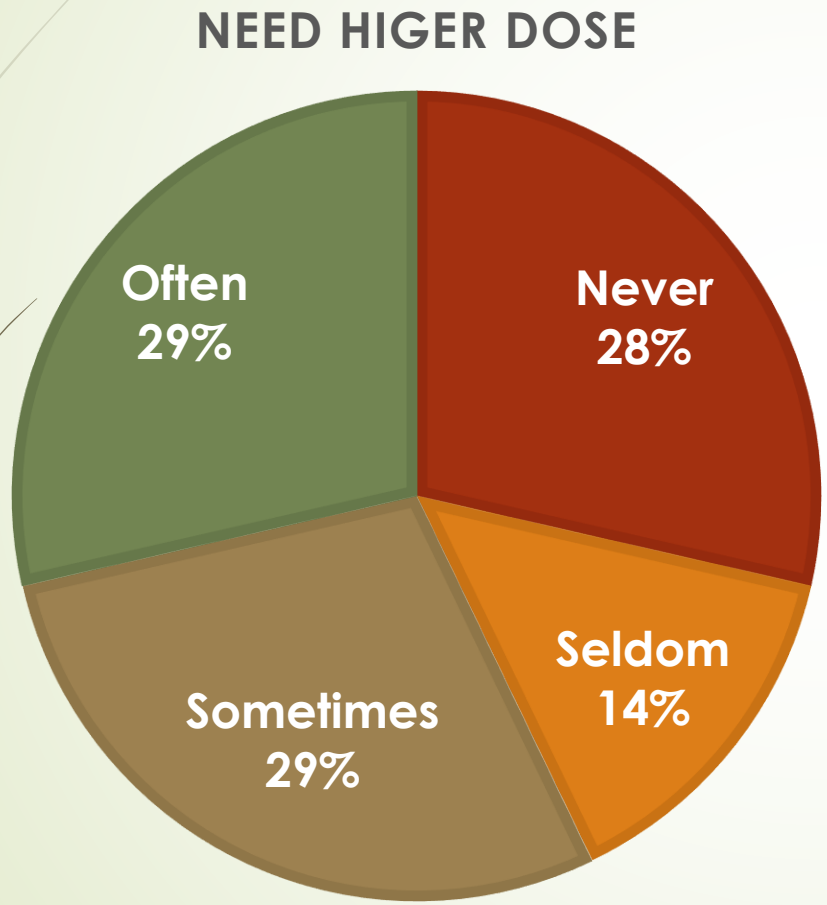
- **Clinicaltrials.gov** → **171 Inquires** → **32 Phone Screened**
- **Advertising (Fliers & Radio)** → **16 Inquires** → **10 Phone Screened**
  - **Start: 5/1/19**

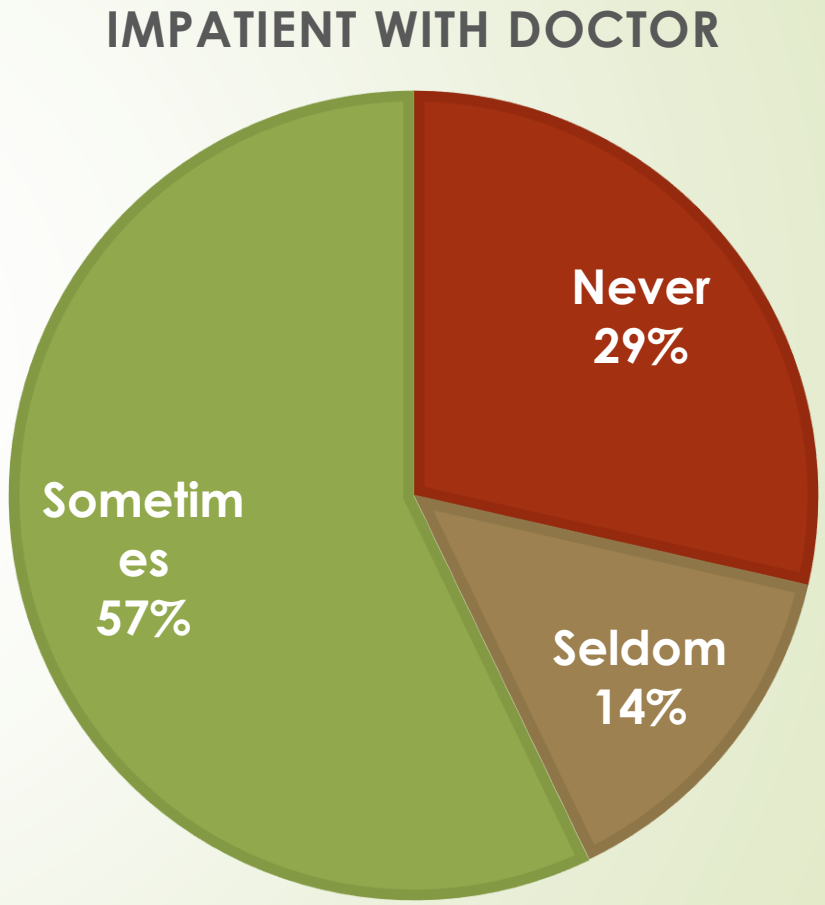
8 Enrolled → **15 in Screening**

Reasons for Ineligibility



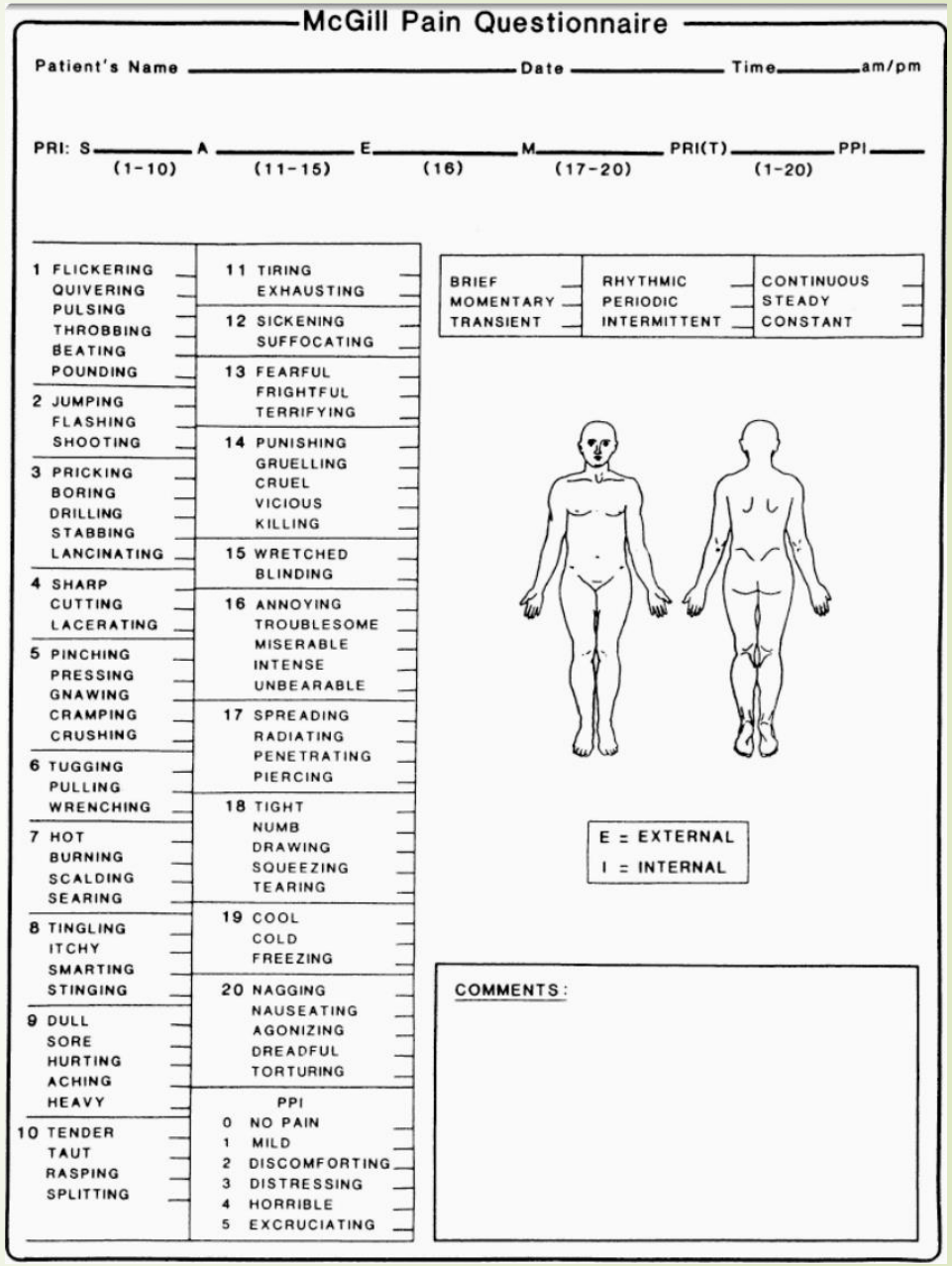
Opioid Use Factors





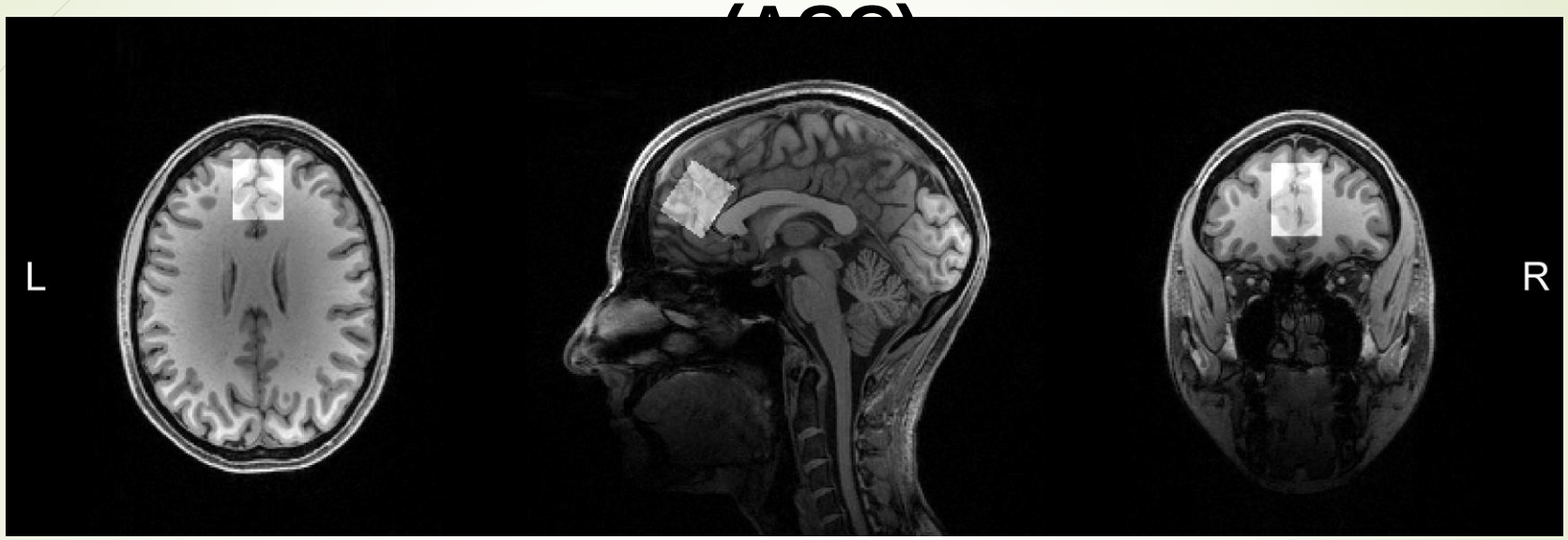
Pain Characteristics

- Average Pain Rating At 1st dosing visit = 4.1
  - Worst Pain on over past 24 hours = 4.5
  - Lowest Pain over past 24 hours = 2.3
- Average Duration of Pain in months = 90 (7.5yrs)
  - Range = 12 – 204 months (1 -17 yrs)
- Common Locations
  - Low Back
  - Hips & SI joints
  - Neck



Spectroscopy Methods

1H MRS Focused on Anterior Cingulate Cortex (ACC)

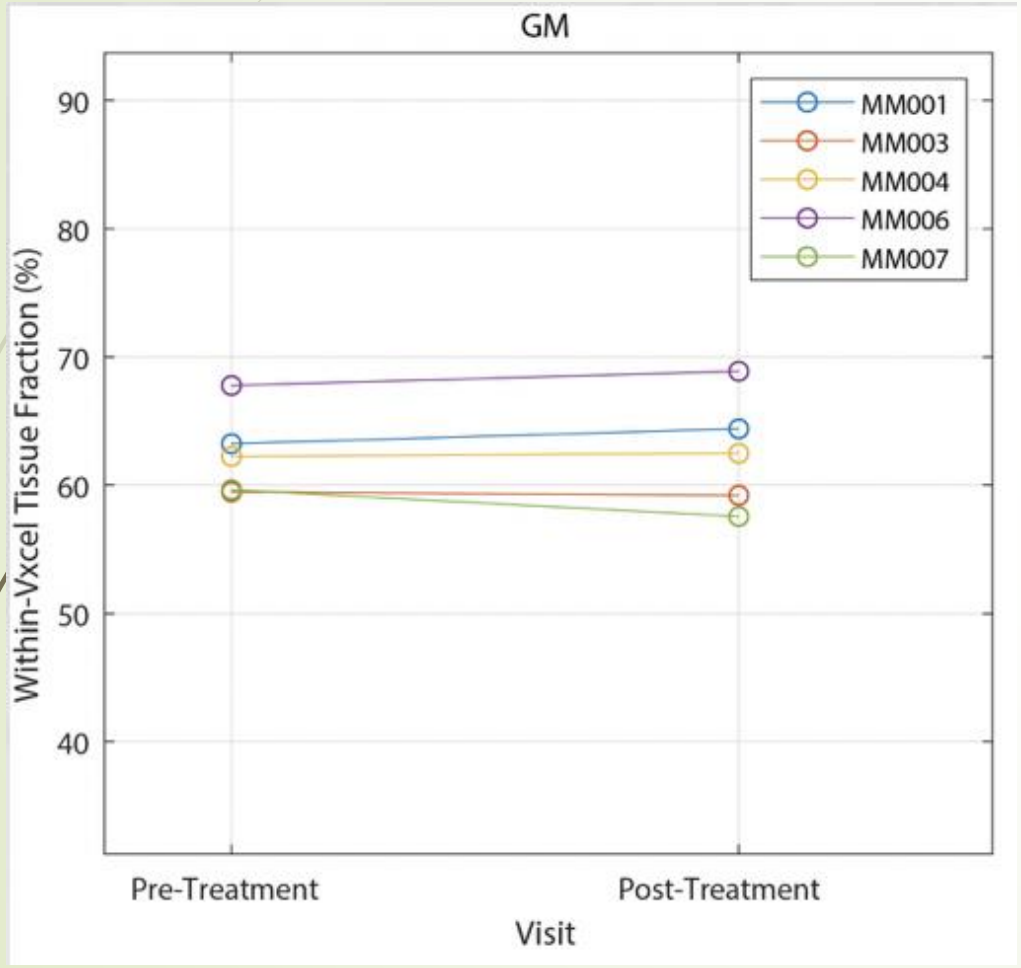


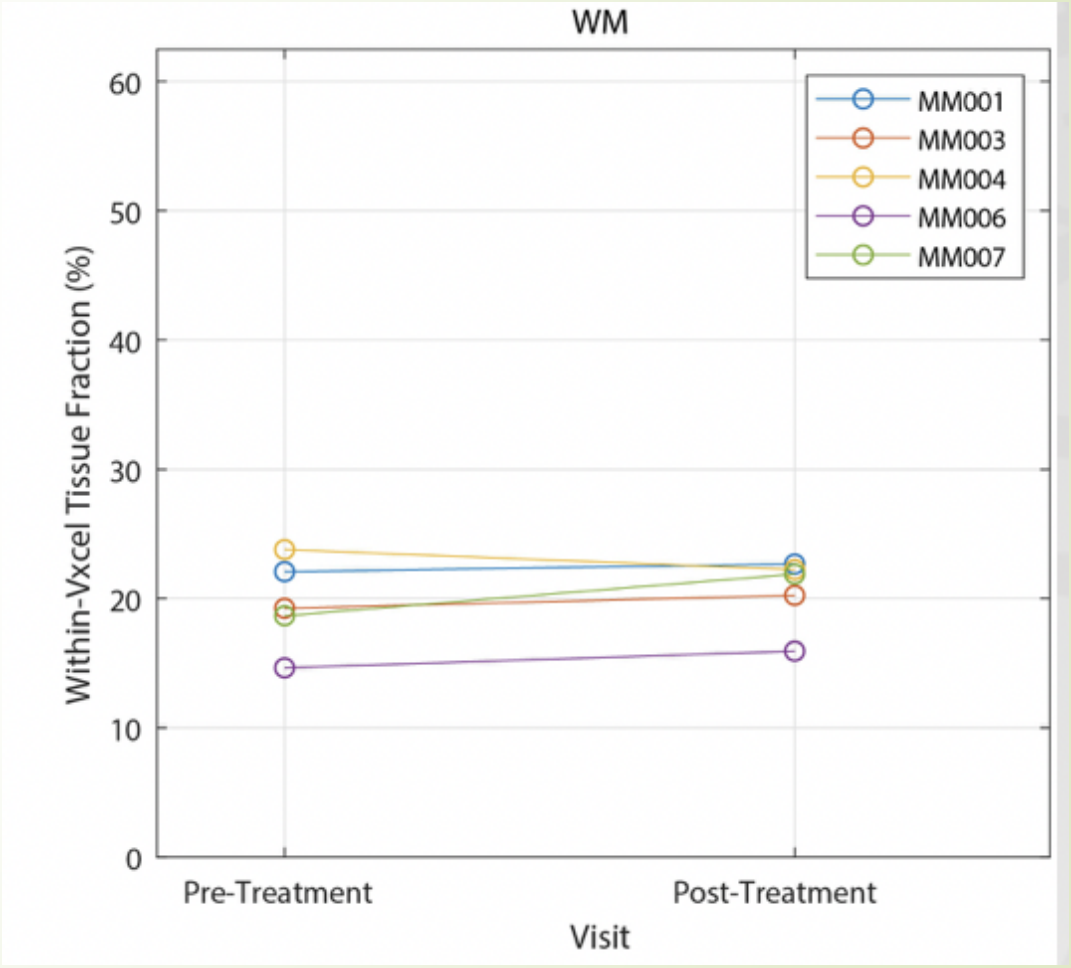
- **Two types of 1H MRS measurements performed:**

J-edited 1H MRS (HERMES) for ACC GABA measures

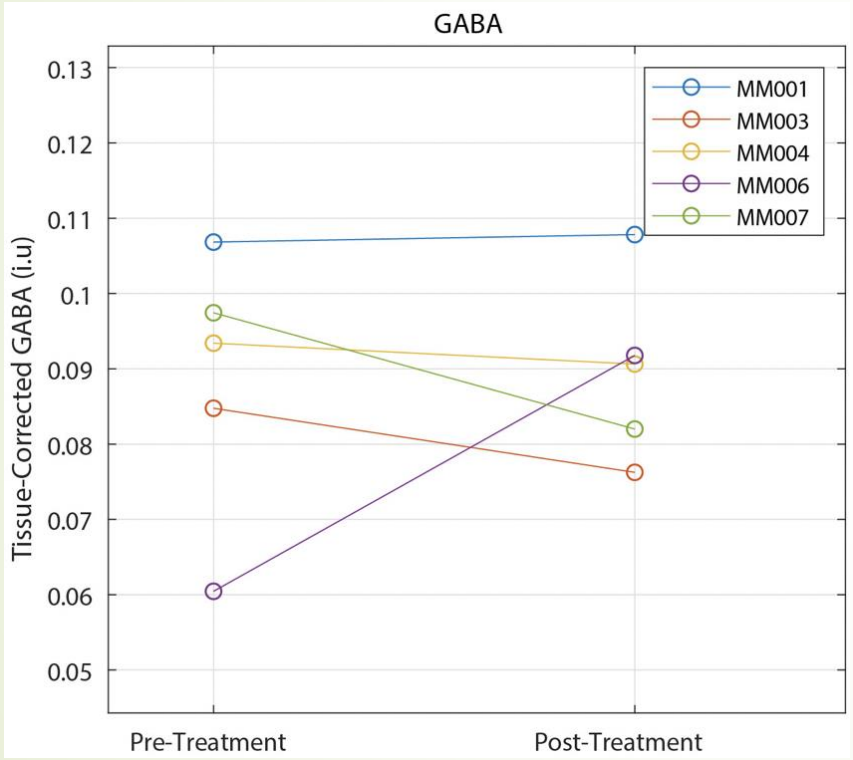
Two-dimensional (2D) J-resolved 1H MRS for measures of other ACC metabolites including glutamate, glutamine, NAA, *myo*-inositol, and choline-containing compounds

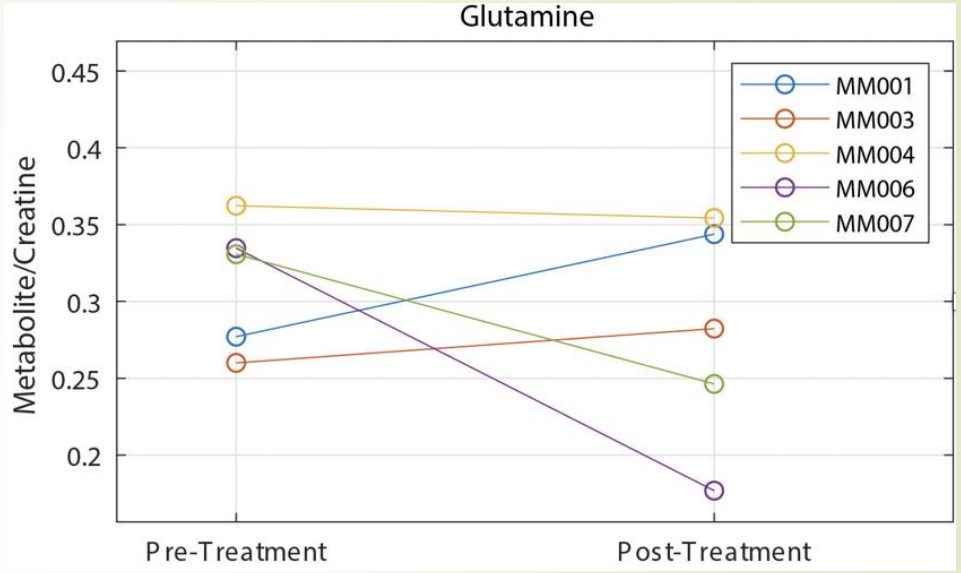
Stability of Tissue Composition

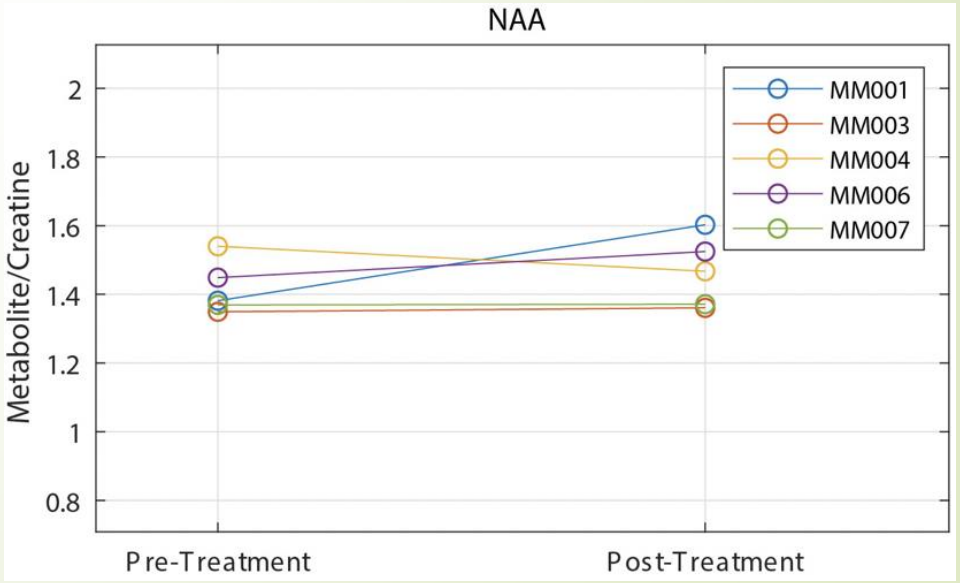




ACC Metabolite Measures: 2D J-resolved 1H MRS







Assessment of Pressure Algometry

- **Assessed Usability of Two Different Pressure Algometers**
  - **Digital – increasing pressure**
  - **Manual – steady pressure across time**
  - **Fifty-nine participants**
    - **Half female, ages 19-70**
    - **Found that manual algometer is ok for pain threshold, but has a ceiling effect when measuring tolerance**
    - **Participants tolerate objective pain measures in research protocols**

Objective Pain Measurement – Pressure Algometer in MJ Sample

- **Average Pre-Dose Pain Threshold = 10.03 (4.25) lbf**
  - **Range = 4.78 – 19.49 lbf of Pressure**
- **Average Post-Dose Pain Threshold = 10.57 (5.09) lbf**
  - **Range = 5.48 – 22.01lbf of Pressure**

- **Increase in Pain Threshold Post -Dose**