COVID-Related Challenges and Solutions: UM MRC

MPIs: Clauw & Hassett

NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.
SMART Design

PainGuide 4wk run in

PT/Exercise 8 weeks
- PGIC = 1
- PGIC ≥ 2
  - Long-term follow-up
  - Mindfulness CT (8 weeks)
  - Acupressure (8 weeks)
  - Duloxetine (8 weeks)

Mindfulness CT 8 weeks
- PGIC = 1
- PGIC ≥ 2
  - Long-term follow-up
  - PT/Exercise (8 weeks)
  - Acupressure (8 weeks)
  - Duloxetine (8 weeks)

Acupressure 8 weeks
- PGIC = 1
- PGIC ≥ 2
  - Long-term follow-up
  - Mindfulness CT (8 weeks)
  - PT/Exercise (8 weeks)
  - Duloxetine (8 weeks)

Duloxetine 8 weeks
- PGIC = 1
- PGIC ≥ 2
  - Long-term follow-up
  - Mindfulness CT (8 weeks)
  - Acupressure (8 weeks)
  - PT/Exercise (8 weeks)
SMART Operationalized

Pre-screening

Day-30 to Day 1

Week 1

Weeks 2-5 (4 week run-in)

Week 6

Weeks 7-14 (8 week intervention)

Week 15

Weeks 16-23 (8 week intervention)

Week 24

Weeks 25-35 (12 weeks follow-up)

Week 36

PT Exercise (n=100)

Mindfulness (n=100)

Acupressure (n=100)

Duloxetine (n=100)

PainGuide

EMA wk 1

EMA wk 6

EMA wk 15

EMA wk 24

EMA wk 36

Mini assessment at the end of week 3

Mini assessment at the end of week 8, 10, 12

Mini assessment at the end of week 17, 19, 21

Mini assessment at the end of week 26, 28, 30, 32, 34

EMA wk 36

EMA wk 24

EMA wk 15

EMA wk 6

EMA wk 1

Week 1

Deep Visit 1 (optional)

Deep Visit 2 (optional)

BACPAC

NIH HEAL INITIATIVE BACCPAC
COVID Adaptations

• **Hybrid visits:** reduce the amount of time participants are in clinic by completing a substantial component of the visit virtually.

  ✓ **Remote activities:** screening, consenting, survey completion, review of study documents and scheduling any follow-up appointments.

  ✓ **In-person visits:** physical exam and biospecimen collection, physical function test and provision of the PRO-Diary device and medication.
COVID Adaptations

- **Consenting** conducted via SignNow

- **Pro-diary devices** will be returned by mail, so participants do not have to come into the clinic.
  - Packaging materials are provided to participants along with the devices
  - Extensive cleaning protocols used – new wrist bands for all

- **Mini-assessments** (short assessments every 2 weeks) completed remotely through Qualtrics.

- **MBSR groups delivered online**: Groups will be conducted via Zoom using an already tested and manualized online delivery protocol.
COVID Precautions
Training, Screening and PPE

• **Staff training:** All have completed appropriate training emphasizing physical distancing, hand hygiene and disinfecting of the environment.

• **Screening:** Symptom and exposure screening of participants done twice prior to any in-person encounters.

• **Temperatures** of participants will be taken upon check in.

• **Alone:** Participants are asked to come to their visits unaccompanied whenever possible.

• **PPE:** Corresponding PPE is used by staff and participants (to be masked).
COVID Precautions

Patient Visits

• **Contact logs** for staff and participants are kept for contact tracing.

• **Rooming:** Visits are conducted in an assigned patient exam room. Signs at room entrance indicating room occupancy.
  ✓ Exam room chairs, furniture and equipment have been configured to maximize distance – marked with stickers

• **Hand Washing:** All individuals entering the research space will be asked to wash their hands with soap and water, or hand sanitizer upon entering and before leaving the suite.
COVID Precautions

Cleaning

- **Cleaning guidelines** are followed for disinfecting surfaces and high touch items in the lobby area, examination rooms, workstations and shared equipment.

- **Routine disinfecting** occurs twice daily (once at the start of the shift, before any participant visits occur, and again at the end of the day), as well as before and after each visit.
  - special attention paid to QST equipment and high-touch surfaces.

- **Cleaning log** is maintained and checked daily.