Clinical Research Core (CRC)

Core Leaders:
Kristen Beavers, PhD  W. Jack Rejeski, PhD
Anthony Marsh, PhD  Jeff Williamson, MD, MHS

Administrator: Kimberly Kennedy, MS
CRC Offerings

• Provides institution-wide guidance on the design and conduct of clinical research consistent with the WF OAIC theme and involving older adults.

• Provides assistance to pilot study and research scholar applicants. Requests the core be involved prior to submitting an application so the core can help incorporate the most applicable measures and resources for the project.

• Turnkey operations for clinical studies:
  • Administrative and regulatory support
  • Recruitment and retention (VITAL newsletter and transportation)
  • Standard test battery & supplemental functional and self-report assessments
  • Expertise with design and monitoring of behavioral interventions
  • Promote study of interactions between cognitive & physical function
  • COVID protocols

• New state-of-the-art $5M/15,000 square foot CRU space, 1st floor Sticht Center
  • 28 exam beds, phlebotomy station, overnight observation suites, processing laboratories, all functional equipment and DXA
Core Assessment Battery

Physical Function Components:

- Anthropometry (Height, Body Mass, Abdominal Circumference)
- Grip strength (Jamar hand grip dynamometer)
- Lower extremity muscle power (Keiser knee extension, leg press)
- Short Physical Performance Battery (SPPB: three tests of physical function - standing balance, usual pace gait speed over 4 meters, time to rise from a chair and sit down five times)
- 400-meter walk test (400MWT: study specific protocols for either usual or fast pace gait speed)
- Pepper Assessment Tool for Disability (PAT-D: self-report instrument)
- Mobility Assessment Tool – short form (MAT-sf: 10 or 12-item computer based self-report assessment of mobility using animated video clips)
Core Assessment Battery, continued

Strength Components:

• Biodex isokinetic dynamometer
• Gait speed and spatiotemporal parameters of gait (GAITRite instrumented mat)
• Postural sway descriptors (AMTI portable force platform)

Cognition Components:

• Digit Symbol Substitution Test (DSST: validated cognitive assessment that is strongly correlated with walking speed)
• Montreal Cognitive Assessment© (MoCA: global cognitive assessment that aids in interpreting DSST performance)

Bio-Specimen Procurement Components:

• Muscle, Fat, Blood, Urine
CRC Utilization at Various Career Stages

- **Postdoctoral Project**
  - Administrative assistance
  - Recruitment efforts
  - Physical function components
    - Strength components
  - Biospecimen processing

- **Early Career Projects**
  - Industry Funded
    - Regulatory support
    - Cognitive components
    - Recruitment efforts
    - Accelerometry
  - K01
    - Parent study access
    - Behavioral-based intervention training platform
    - Recruitment efforts

- **Mid-Career Projects**
  - R21
    - IASDR mining
  - R01
    - Protocol review
    - Recruitment efforts

Success derived from synergy across OAIC cores.
CRC Innovations

- Bridging the brain and body connection
  - SPRINT-MIND: BP lowering benefits older adults with physical, but not cognitive, impairment (Pajewski, et.al 2020)
  - WF selected as coordinating center for PREVENTABLE trial (n=20,000) which will assess the effects of statin use on physical and cognitive function among older adults

- Refining recruitment process
  - Applying inclusion/exclusion criteria to recruit from WF EMR
  - Significant work developing eFI to EMR to target recruitment to fitness/frailty status (Callahan)

- Pooled data projects
  - Accelerometry development project validating patterns of movement across different site and devices (Fanning)
  - Determining predictors of variability in functional response to weight loss across OAIC RCTS (Beavers/Beavers)

- Incorporation of bone health outcomes into CRC supported studies
  - Flagship INVEST trial, assessing use of weighted vests to minimize bone loss with weight loss among older adults (Beavers)
  - Contributions to S10 to bring high resolution peripheral computed tomography to Wake Forest (with BRC)
CRC Future Directions

• Utilize social media to enhance recruitment and implementation of findings

• Partnership with Atrium Health (Charlotte, NC) which adds:
  • >50% of Charlotte market
  • >40 hospitals
  • Opportunity for scaling OAIC discovery and innovation to larger population
  • Opportunity to recruit more broadly into OAIC research with the Winston Salem campus remaining the scientific hub
  • Increased collaborative opportunity with the Center for Healthcare Innovation
  • Ability to incorporate function testing as a new “vital sign” in larger health system

• Expand mHealth platform into hospital and community settings and remote intervention options
Questions? Comments?