

CART Platform Integration Process

Project Preparation & Funding

Define project components, identify & apply for project funding

1

Setup

Project Setup

Contracting & IRB

2

Project Details

Confirm all project logistics & materials in place

3

Site Training

On-site training on tech setup and maintenance

4

Enrollment

Home Installation Review

Review initial data/installation per home until proper setup achieved

7

Home Installations

Site installation of participant home

6

Participant Recruitment

Additional Consent as needed

5

Data Collection

Two Weeks

Two Weeks

8

9

Data Collection Complete

10

11

Ongoing Data Review

Site-level & home-level frequent data review to ensure ongoing high quality data collection

Transfer of Data

Scheduled (TBD, e.g., Quarterly/Annual) data transfer to collaborator (if not with API)

Final Data Analysis

Data Cleaning and Final Analysis

Publication

Joint production of scholarly articles



- **Components:**

- Define the overarching goals of the project and project timeline
- Define the digital technology to be used in the project
- Define which group will own which deliverables (IRB documentation and submission, installation, data review, analysis, publications, etc)
- Find and apply for appropriate project funding.

Project Preparation

1

- **Components:**

- OHSU identifies correct contracting group for approvals
- OHSU works with collaborator on needed documents and language for IRB documents regarding digital components
- Submission of IRB through all required IRB Boards

Project Setup

2

- **Time:** 2-4 weeks
- **Components:**
 - OHSU & collaborator work out timelines and logistical details such as shipping, schedule of digital device delivery, etc.
 - OHSU orders and starts preparing digital devices for collaborator

Project Details

3

- **Time:** 3 days per site
- **Components:**
 - OHSU to send sites training materials for review prior to site visit
 - OHSU staff will come to site for training on digital technologies
 - Group training for all sites @ one location
 - Individual site on-site training
 - Hybrid of group & individual site training
 - Review technologies
 - See one/do one technology setup

Site Training

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- **Time:** Ongoing
- **Components:**
 - All enrolling sites begin recruitment and enrollment of participants
 - Sites work together on what is and isn't working for recruitment

Study Enrollment

- **Time:** Ongoing during study recruitment
- **Components:**
 - Participant consent into in-home monitoring portion of the study (30 minutes) *or* entire study
 - OHSU team to provide training about Consent and technology FAQ

Participant Recruitment

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- **Time:** 1-4 hours per home depending on technology within 1-2 weeks of consent
- **Components:**
 - As each participant is consented, site staff schedule home-installation visit ideally within 1-2 weeks of consent
 - Site staff complete in-home digital technology installation with remote-support from OHSU
 - Site staff to submit installation recap to OHSU for use during home install review

Home Installations

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- **Time:** 1 hour per home allotted, 3-14 days after home-installation
- **Components:**
 - Study staff confirm via control panel that technologies are still working 1-2 days after setup
 - OHSU data team will review data to confirm installation has occurred properly and all data is being collected
 - If any issues are detected, study staff will be notified and will go to remedy the issue
 - This step will repeat until the in-home digital technology is all working properly

Home Installation Review

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- **Components:**
 - Once in-home digital technology is installed and confirmed working the participant can be randomized if required by study
 - Randomization completed by study staff if required

Data Collection

- **Time:** 5-20 minutes per home every 1-2 weeks
- **Components:**
 - Study staff review home data integrity on a frequent basis (every 1-2 weeks)
 - If any issues are detected, study staff will go to remedy the issue (10 min – 2 hours)

Ongoing Data Review

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- **Time:** At specified timepoints
- **Components:**
 - OHSU to provide data to study staff on a pre-determined timeline
 - Data can also be pulled via API access by study staff; OHSU can provide support

Transfer of Data

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- **Components:**

- All study activities complete
- Participant homes have had digital technology removed

**Data
Collection
Complete**

- **Time:** 1-3 months
- **Components:**
 - Data cleaning and final data analysis to be completed
 - Define what components of this will be done by OHSU/study staff or jointly

Final Data Analysis

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- **Time:** 2-6 months
- **Components:**
 - Determine which publications are worth pursuing
 - Determine who will be the point person for each publication
 - What about abstracts for posters/presentations at conferences?

Publication

11

PwAD – Digital and Functional Outcome Measures, Sensors/Devices Used & Conventional Comparators

Core Functions - Digital Measures	Outcome Measures	Sensors or Devices	Conventional Assessments
Health & Life Events: <i>Weekly on-line 13 item report (care partner) , customized queries or standard scales (medical visits, med. changes, falls, AEs)</i>	AE Tracking (<i>on-line query checklist</i>) Quality Control (<i>tracking non-study med. changes wkly</i>) Secondary Outcome - <i>health status (non-study clinic visits)</i>	Personal computer, tablet, smartphone (on-line reporting)	Mood: Geriatric Depression Scale and NPI-Q; Self-report of health events (versions may be more frequently done online). AE Reports
Physiologic Health: <i>Daily BMI, pulse</i>	AE Tracking Secondary outcomes	Biofunction scale, pressure mat	Vital signs (height, weight, pulse)
Medication Adherence: <i>% of doses missed in a week relative to prescribed schedule</i>	Quality Control	MedTracker electronic pillbox	Self-report of adherence to medication regimen; pill counts
Cognitive Function: <i>Time & accuracy when completes on-line tasks wkly or biwkly (e.g., SMART assessment with CP)</i>	Primary Outcome - <i>trajectory of test scores over trial</i> Secondary Outcome - <i>trajectory of time to complete test over trial</i>	Personal computer or tablet	ADAS-cog, MMSE, Telephone Interview for Cognitive Status (TICS)
Physical Capacity/Mobility: <i>Total daily activity (steps), number of room transitions, time in bathroom, time out of home</i>	Primary Outcome - <i>total daily activity trajectory during trial</i> Secondary Outcomes - <i>trajectory of time to complete test, time in locations</i>	Motion sensors; contact sensors; watch actigraph	Walking speed (with stopwatch). Self-report of activity (e.g., Paffenbarger scale; PASE)
Sleep/Nighttime behavior: <i>Time awakening, time in bed, times up at night, sleep latency</i>	Secondary Outcomes	Motion sensors; watch actigraph, bed pressure mats	Pittsburgh Sleep Quality Index and Sleep Disturb. Symptom Questionnaire
Socialization/Engagement: <i>Time out of home, time alone or with spouse; # visitors to home</i>	Secondary Outcomes	Motion sensors, contact sensors, actigraphy, on-line reports	Self-report of 8 social activities (e.g., how often do you have visitors)

Care Partner - Digital and Functional Outcome Measures, Sensors/Devices Used & Conventional Comparators

Core Functions - Digital Measures	Outcome Measures	Sensors or Devices	Conventional Assessments
Health & Life Events: <i>Weekly On-line self-reports, customized queries and standard scales (mood, pain scale, medical visits, visitors)</i>	Secondary Outcome - <i>health status (non-study clinic visits), mood, etc.</i>	Personal computer, tablet, smartphone (On-line reporting)	Mood: Geriatric Depression Scale; Self-report of health events; QoL scale
Physical Capacity/Personal Mobility: <i>Total daily activity (steps), number of room transitions, daily steps, time out of home</i>	Secondary Outcomes	Motion sensors; contact sensors; watch actigraph	Walking speed (with stopwatch). Self-report of activity (Paffenbarger scale)
Community Mobility: <i>Driving time, distance driving, hard braking, hard accelerations, frequent locations out of home</i>	Secondary Outcomes	Home sensors (exit door contact sensors); Vehicle data port sensor	FAQ rating of ability: Traveling out of neighborhood, driving, public transport
Physiologic Health: <i>Daily BMI, pulse</i>	Secondary Outcomes	Biofunction scale, pressure mat	Vital signs (height, weight, pulse)
Sleep/Nighttime behavior: <i>Time of awakening, time in bed, times up at night, sleep latency</i>	Secondary Outcomes	Motion sensors; actigraphy, bed pressure mats	Pittsburgh Sleep Quality Index and Sleep Disturbance Symptom Questionnaire
Socialization/Engagement: <i>Time out of home, time alone or with spouse, on-line computer activity (email, social network sites), on-line wkly reports via loneliness scale, visitors</i>	Secondary Outcomes	Motion sensors, contact sensors, watch actigraph, computer monitoring software	Self-report of 8 social activities (e.g., how often do you have visitors)
Care Partner Experience: <i>Time alone, time with PwD</i>	Secondary Outcomes	Motion, contact sensors, watch actigraph	Zarit Caregiver Burden scale - ZBI-12