Strategies to facilitate recruitment and screening for Alzheimer’s clinical trials

HHS NAPA Advisory Council for Research, Care and Services
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Rachel L. Nosheny, Ph.D.
UCSF Department of Radiology and Biomedical Imaging
Co-investigator

UCSF
University of California
San Francisco

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The National Patient-Centered Clinical Research Network

A collaboration between:
Mayo Clinic
UF University of Florida
US Against Alzheimer’s
BrainHealth Registry

Leadership:
- Principal Investigator: Ron Petersen, Mayo Clinic
- Co Investigators:
  - Meryl Comer, Geoffrey Beene Foundation
  - Michael Weiner, UCSF, Brain health Registry
  - Glenn Smith, University of Florida
  - Alex Alexander, Mayo Clinic
AD-PCPRN Goal and Specific Aims

**Overall goal:** To accelerate development of effective treatments for Alzheimer’s disease and related dementias

**Specific Aims**

- **Connect** patients, caregivers, and researchers focused on developing, conducting, and disseminating patient-centered dementia research
- **Recruit, engage, and educate** individuals at risk for or with Alzheimer’s Disease and related dementias and caregivers in a patient-centered network
- **Screen, refer, and enroll** individuals in Alzheimer’s trials and observational studies
- **Increase diversity** in Alzheimer’s trials through outreach to minority populations, especially African Americans and Latinos
BrainHealthRegistry.org:
Web portal for recruitment, engagement & longitudinal monitoring

ANSWER QUESTIONS & TAKE TESTS
When you complete online brain tests, we get “snapshots” of your health and brain performance. With many snapshots, from you and others, we can make a huge difference.

It’s safe, easy and free.

Sign up

Tell us about yourself

Take some tests

Invite a study partner

Come back…and come back again

Register, consent online
13 questionnaires (health history, family history, medications, memory problems, mood, lifestyle)
3 Online cognitive tests

Study Partner can separately register and answer questions about participant and self

Participants and study partners return every 6 months to complete follow-up tasks
AD-PCPRN participants in the Brain Health Registry

- Total of 30,944 participants enrolled
  - Age 55+
  - Interested in learning about future research opportunities

- Longitudinal data collected from 12,975
  - Retention rate of ~40% over 2 years of follow up
  - 31% complete all tasks
  - 64% provide enough information to assess whether they are likely to be eligible for AD trials

Geographic distribution of participants
Demographics

Age Distribution

Gender

Race & Ethnicity
- 4% African American
- 2.1% Asian
- 86.7% Caucasian
- 1.2% Declined To State
- 2.8% Mixed
- 0.3% Native American
- 2.3% Other
- 0.1% Pacific Islander

Educational Attainment
- 2.2% Grammar School
- 5.8% High School
- 18.3% Some College
- 9.5% 2 Year Degree
- 28.8% 4 Year Degree
- 25.1% Masters Degree
- 6.1% Doctoral Degree
- 6.8% Professional Degree
Alzheimer’s risk factors

Family History of Alzheimer’s
- Unknown: 64%
- Yes: 33%
- No: 2%

Memory Concern
- Unknown: 45%
- Yes: 2%
- No: 52%

How does the AD-PCPRN facilitate AD clinical study recruitment?

- Trackable PR sources (email, online ads, social media)
- Other PR (organic search, TV, radio, print, brochures)
- AD-PCPRN outreach and engagement (diversity focus)
- Co-enrollment of existing research cohorts, with data sharing

Brain Health Registry homepage or custom landing page
- Brain Health Registry Cohort
- Prescreen
- Clinical Site
Prescreening participants for AD clinical trials

Entire AD-PCPRN (30,944)

Cognitive test scores

Self-report memory problems or concerns
Common exclusion criteria (medical conditions, medications, etc.)
Risk factors: family history, age, etc.

Eligible participants

ADPCPRN participants likely to be eligible for Alzheimer’s trials

Prescreened Ineligible
21,344
- Age
- Medical exclusion
- Not enough info.

Cognitively-normal
7082
22.9%

Possible cognitive impairment
2071
6.7%

Self-reported dementia
447
1.4%

69.0%
Referral of AD-PCPRN participants to clinical studies

- **10,001 participants have been referred to 10 Alzheimer’s and aging clinical studies**
  - Large, observational studies (late life depression, healthy aging, olfaction)
  - Randomized treatment trials
  - Validation study of online tests

- **757 participants have been enrolled in studies**
  - Vast majority are enrolled in observational or validation studies
  - A major challenge has been to successfully enroll in treatment trials

New strategies to maximize enrollment in trials

- Trackable PR sources (email, online ads, social media)
- Other PR (organic search, TV, radio, print, brochures)
- AD-PCPRN outreach and engagement (diversity focus)
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New strategies to maximize enrollment in trials

**Trackable PR sources (email, online ads, social media)**

**Other PR (organic search, TV, radio, print, brochures)**

**AD-PCPRN outreach and engagement (diversity focus)**

**Co-enrollment of existing research cohorts, with data sharing**

**Brain Health Registry homepage or custom landing page**

**Brain Health Registry Cohort**

**Prescreen**

**Direct Clinic Site Referral Cohort**

**Clinical Site**

**Controlled distribution**
Facilitating recruitment through study partner engagement: The Brain Health Registry Caregiver & Study Partner Portal

Study Partner Portal

Welcome to the Study Partner Portal of the Brain Health Registry. This exciting new initiative allows you and your study partner to work as a team to advance brain health research and the search for new treatments.

Why are we asking you to become a study partner?
Put simply, we are committed to advancing brain health research for all, and you are a powerful part of that plan. Click here to join, or if you’d like more details about why read on.

Brain Health Registry Caregiver and Study Partner Portal (CASPP)

- **Infrastructure & database within BHR for a study partner to separately register and consent online**
- **Study partners answer questions about the participant’s cognitive and daily functioning**
- **Unique advantages of study-partner reported information**
  - Associated with many disease-related outcomes
  - May sometimes be more accurate than self-report
  - Can identify change in function using a single data point
  - Focuses on outcomes that matter to patients & families
  - Can help overcome patient barriers to participation
  - May help recruit participants who are too impaired to join themselves
- **Study partners also report on their own health and caregiver experience**
  - Improve caregiver health
Demographics of AD-PCPRN Study Partners

Total: 1895 Study Partners

Age Distribution

Gender

55.4%

44.6%

Demographics of AD-PCPRN Study Partners

Relationship to participant

Caregiver status

Frequent caregiver for someone with disease/illness/disability

Infrequent caregiver for an older person

557

427
Characteristics of BHR Study Partners: Report of health/cognitive status

About the participant

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<th>Report of participant status</th>
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<td>Concern about participant memory</td>
<td>9.5%</td>
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<td>Participant cognitive change</td>
<td>15.6%</td>
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<tr>
<td>Participant IADL change</td>
<td>10.5%</td>
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<td>Participant MCI</td>
<td>2.0%</td>
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<tr>
<td>Participant AD</td>
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About the study partner him/herself

Self-report health

| Memory concern                        | 34.7%  |
| Positive stress screening question    | 6.3%   |
| Positive mood screening question      | 15.4%  |

Online study partner-reported data provides valid information about participant function

- Study partner-reported variables are significantly associated with:
  - self-reported subjective memory complaints
  - Self-reported recent changes in memory and daily functioning
  - Online memory test scores of the participant

Nosheny et al. CTAD 2016
Summary & Future Directions

- **Overall Goal** of the AD-PCPRN is to facilitate Alzheimer’s clinical research

- **To date**
  - Over 30,000 participants, 1800 study partners, and 800 caregivers are enrolled in AD-PCPRN through the Brain Health Registry
  - Over 700 participants have been enrolled in clinical research studies
  - Engagement efforts are reaching many more, with a focus on increasing diversity
  - Major challenges are successful enrollment into treatment trials and recruitment of minorities

- **In the future, the AD-PCPRN will aim to**
  - Increase enrollment and engagement of participants
  - Optimize referral to studies by analysis of success rates
  - Conduct research to advance recruitment science
February 3, 2017 -- Advisory Council Meeting #23

The meeting was held on Friday, February 3, 2017, in Washington, DC. The theme of this Advisory Council meeting was clinical trials for Alzheimer's disease and related dementias and recruitment challenges. Additional afternoon presentations included updates on progress towards a Care and Services Summit, federal workgroup updates, and preparation for the Advisory Council's 2017 Recommendations, due in April 2017. Material available from this meeting is listed below and is also available at https://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-meetings#Feb2017.

Comments and questions, or alerts to broken links, should be sent to napa@hhs.gov.

General Information

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Handouts

| Panelist Bios                  | [HTML Version] | [PDF Version] |

Presentation Slides

<p>| 2017 Recommendations            | [HTML Version] | [PDF Version] |
| Alzheimer's Association TrialMatch | [HTML Version] | [PDF Version] |
| Clinical Services Subcommittee Federal Update | [HTML Version] | [PDF Version] |
| Clinical Studies Recruitment Strategy | [HTML Version] | [PDF Version] |
| Development and Use of Registries to Accelerate Enrollment into Alzheimer's Trials | [HTML Version] | [PDF Version] |
| Long-Term Services and Supports Committee Update | [HTML Version] | [PDF Version] |
| National Recruitment Strategy   | [HTML Version] | [PDF Version] |</p>
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<td>Strategies to Facilitate Recruitment and Screening for Alzheimer's Clinical Trials</td>
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<td>Transforming AD Therapy Development</td>
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<td>Update National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers</td>
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**Videos**

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