Transforming Brain Health for Better, For All, Now!

Early Detection for Cognitive Problems in Primary Care.

5-Cog 2.0 Pragmatic Trial

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MARCH 20, 2025

DISCLOSURES: Malaz Boustani

- Equity Ownership in
  - RestUp, LLC (Sold)
  - Preferred Population Health Management, LLC (Sold)
  - Blue Agilis, LLC (Active)
  - DigiCare Realized, Inc (Folded)
  - Mozyne Health, Inc (Active)
- Advisory board member in the past 12 months for :
  - NeuroX, Biogen, Genentech, Lilly, Merck & Eisai
- Author with royalty for the following books
  - Agile Implementation; Agile Network, Agile Diffusion
- Teacher of
  - IU Graduate Certificate in Innovation and Implementation Science
- Scientist who receive funding from Federal agencies
  - NIH, AHRQ, CMS
- **NIH funding relevant directly to today presentation (NINDS and NIA):**
  - **U01NS105565, R01AG069765**
- Others funded the journey.
  - NIA, AHRQ, CMS, Merck Pharmaceutical

Objectives

1. Why early detection of cognitive problems in primary care
    1. Need versus demand
    2. 0 minutes $1 dollar strategies
2. Review 5 COG 1.0 results
3. Overview of 5 COG 2.0 study design and flow
4. Current status of the 5 Cog 2.0 study
5. Agile science and its derivatives.

The Real World of Primary Care

Need is NOT Demand

PCP Patient Panel

1,500 patients

- > 65: 300
  - 3 chronic conditions: 150
  - Musculoskeletal pain: 195
  - Feeling anxious: 93
  - Hospitalized every year: 63
  - Prevalent Dementia: **18 to 36**
    - Recognized: **7 to 14**
  - Screened Positive for Cognitive Impairment: 8% to 12%.
  - Accept undergoing dementia assessment after positive screening test ranges from 33% to 52%.

Kulshreshtha et al, 2024; Fowler et al, JAGS 2020; Boustani & Callahan CM, et al, JGIM 2005; Callahan & Boustani, et al, JAMA 2006; Sha & Callahan et al, Am J of Med 2005; Schubert & Boustani et al, JAGS 2006.

The Daily Life of Primary Care Provider (PCP)

Older patient with 3 chronic conditions

- Receives 12 medications
- Pay $400 per month
- Adhere to numerous complex non-pharmacological regimens

PCP pay attention to

- conflicting recommendations
- drug interaction

PCP needs (per day)

- **10 hrs** for chronic care management
- additional **7 hrs** for preventive services

Boyd et al, JAMA 2005; Ostbye et al, *Ann Fam Med* 2005

The Three Breakthroughs in cognitive care

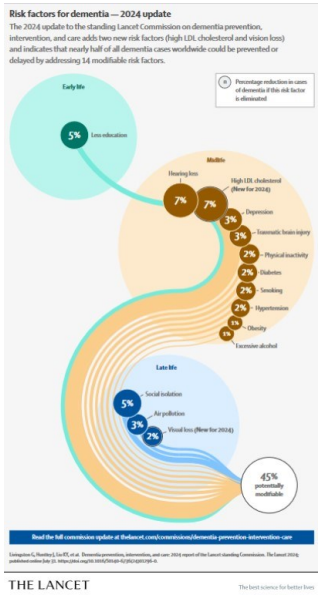
- ✓Prevention bundle of cognitive decline and dementia
- ✓Amyloid lowering therapy for Alzheimer Disease
- ✓The collaborative dementia care model

CMS Announces New Payment Model for Dementia Care Management

Georgia Green, Senior Manager, Health Care Consulting Practice

AUGUST 18, 2023

The Centers for Medicare & Medicaid Services (CMS) unveiled the Guiding an Improved Dementia Experience (GUIDE) Model - a new, voluntary nationwide program – on July 21, 2023. According to CMS, this model aims to provide support to people living with dementia and their unpaid caregivers.



JAMA Network | Open

Original Investigation | Geriatrics

Prevalence of Unrecognized Cognitive Impairment in Federally Qualified Health Centers

Ambar Kulshreshtha, MD, PhD; Erik S. Parker, PhD; Nicole R. Fowler, PhD; Diana Summanwar, MD; Zina Ben Miled, PhD; Arthur H. Owora, PhD; James E. Galvin, MD; Malaz A. Boustani, MD, MPH

204 participants (no recognized dementia or MCI) completed comprehensive cognitive assessment

- 62% of patients met the diagnostic criteria for MCI,
- 12% had dementia, and
- 26% had no cognitive impairment.

African Americans had higher odds of MCI or dementia compared with Whites

- OR =2.73, 95% CI = 1.38, 5.53, (p-value 0.019).

5 Cog is Funded by NINDS / NIH
2U01NS105565

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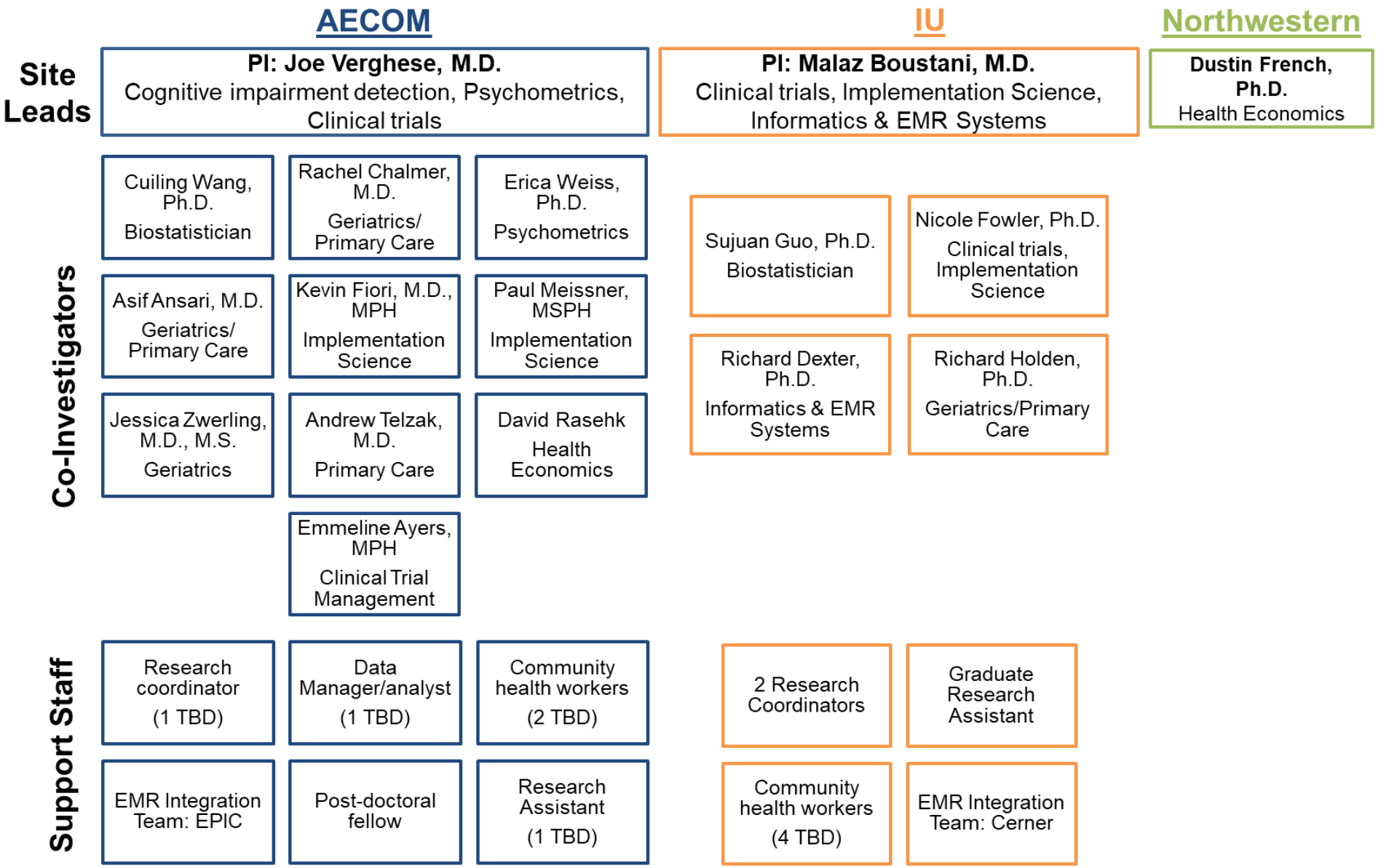
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Community health workers
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EMR Integration Team: Cerner

5-Cog 1.0 Efficacy Trial

nature medicine

Article

https://doi.org/10.1038/s41591-024-03012-8

Non-literacy biased, culturally fair cognitive detection tool in primary care patients with cognitive concerns: a randomized controlled trial

Received: 20 November 2023

Accepted: 22 April 2024

Published online: 04 June 2024

Joe Verghese[1,2], Rachel Chalmer[2], Marnina Stimmel[1], Erica Weiss[1], Jessica Zwerling[1], Rubina Malik[2], David Rasekh[3], Asif Ansari[2,3], Roderick A. Corriveau[4], Amy R. Ehrlich[2], Cuiling Wang[3,4] & Emmeline Ayers[1]

1. Primary care patients with Cognitive Complaints
2. Pictured based Memory Impairment Screen (PMIS)
3. Symbol Match
4. Subjective Motoric Cognitive Risk: a 5-item questionnaire
5. Computerized Decision Support

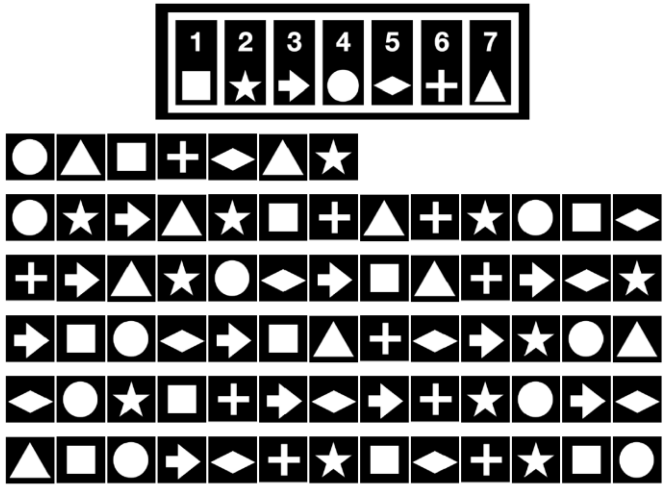

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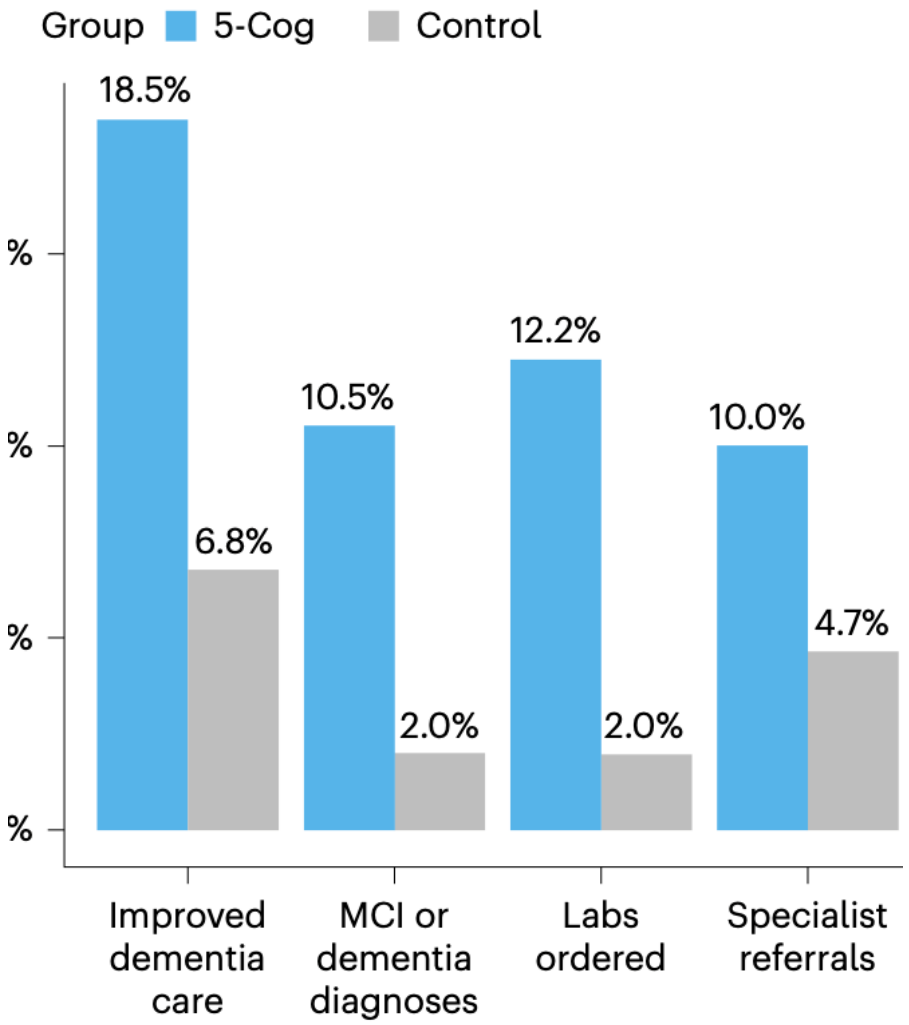
Table 2 | Improved dementia care actions related to diagnosis, investigation and treatment

Outcome	5-Cog *n* (%) (*N*=599)	Active control *n* (%) (*N*=602)	OR (95% CI)[a]	*P* value
Improved dementia care	111 (18.5)	41 (6.8)	3.43 (2.32–5.07)	<0.001
New MCI or dementia diagnoses	63 (10.5)	12 (2.0)	6.48 (3.41–12.31)	<0.001
Imaging ordered	39 (6.5)	9 (1.5)	4.80 (2.29–10.06)	<0.001
Tests ordered	73 (12.2)	12 (2.0)	7.64 (4.05–14.39)	<0.001
New prescriptions	6 (1.0)	2 (0.3)	3.24 (0.63–16.65)	0.15
Specialist referral	60 (10.0)	28 (4.7)	2.38 (1.49–3.80)	<0.001

[a]Adjusted for age, sex and education. CI, confidence interval.



g. 2 | Outcome rates by study arm. Proportion of par
lue) and control (grey) study arms who met improvec
well as individual criterion by 90 days.

5-Cog 2.0
Pragmatic Trial

Protocol

Improving Early Dementia Detection Among Diverse Older Adults With Cognitive Concerns With the 5-Cog Paradigm: Protocol for a Hybrid Effectiveness-Implementation Clinical Trial

Rachel Beth Rosansky Chalmer[1], MD; Emmeline Ayers[2], MPH; Erica F Weiss[3], PhD; Nicole R Fowler[4,5], MHSA, PhD; Andrew Telzak[6], MSc, MD; Diana Summanwar[7], MD; Jessica Zwerling[3], MS, MD; Cuiling Wang[3,8], PhD; Huiping Xu[9], PhD; Richard J Holden[10], MS, PhD; Kevin Fiori[11], MPH, MD; Dustin D French[12], PhD; Celeste Nsubayi[3], BA; Asif Ansari[1], MD; Paul Dexter[4,5], MD; Anna Higbie[5], BS; Pratibha Yadav[3], MA; James M Walker[12], BA; Harrshavasan Congivaram[12], BS; Dristi Adhikari[3], MA; Mairim Melecio-Vazquez[3], MA; Malaz Boustani[4,5], MPH, MD; Joe Verghese[2], MBBS, MS

Specific aims

1. Evaluate, using a pragmatic cluster-randomized trial design, the clinical effectiveness of the 5-Cog paradigm to increase cognitive impairment detection (new MCI and dementia diagnoses) relative to enhanced usual care (clinician education).
2. Explore the implementation context, process, and outcomes of the 5-Cog paradigm in diverse primary care clinics using mixed methods guided by the Consolidated Framework for Implementation Research (CFIR).
3. Assess the cost effectiveness of the 5-Cog paradigm from a societal perspective.

Study design

A **hybrid Type 1 effectiveness-implementation *pragmatic trial*** to adapt and test the **5-Cog paradigm** to increase detection of cognitive impairment and improve cognitive care in older adults with **cognitive concerns** in real-world primary care settings.

6,600 older patients presenting with cognitive concerns

22 primary care clinics (16 in Indiana and 6 in NY) in Bronx, NY, and Indiana will be randomized to receive 5-Cog or 'enhanced usual care'

Effectiveness Outcomes

PRIMARY OUTCOME

New diagnosis of dementia (relevant ICD-10 codes) or MCI (331.83) by PCPs. For patients with a previous diagnosis of MCI in EMR, only a new diagnosis of dementia will be considered as an incident outcome.

SECONDARY OUTCOME

Any of the following:

1.Tests ordered for reversible causes of cognitive impairment as per published guidelines.

2. New cognitive enhancing medication prescriptions or deprescribing anti-cholinergic.

3. Referral for cognitive/dementia evaluation by specialists (Neurology, Neuropsychology, Geriatrics, Psychiatry).

4. Referral to social worker or community-based organizations.

Implementation Outcomes

- Acceptability of Intervention Measure (AIM)
- The Feasibility of Intervention Measure (FIM)
- The Intervention Appropriateness Measure (IAM)

Each is a 4-item self-report survey measure of implementation outcomes (acceptance, feasibility, and appropriateness) that are considered “leading indicators” of implementation success.

Inclusion/Exclusion Criteria

Inclusion criteria:

1. >=65 years.
2. Presence of cognitive concerns.
3. English or Spanish speaking.

Exclusion criteria:

1. Prior dementia diagnosis (recorded in EMR or reported by primary care physicians).
2. Nursing facility residents.
3. Patient is blind/has difficulty reading even with the help of glasses or is deaf/ has hearing impairment that makes them unable to follow auditory cues

5 Cog Battery

Picture Memory Impairment Screen (PMIS): A 4-picture cued recall test. It discriminated cognitively normal older adults from those with dementia, regardless of age, sex, education or depression. It takes 4 minutes, which includes a 2-minute delay between picture presentation and recall.

Paper-based Symbol-Match test: Test of executive functions where patients are asked to match symbols to corresponding numbers. The 90-second Symbol-Match correlates highly with the Symbol Digit Modalities

Subjective Motoric Cognitive Risk (SMCR): MCR diagnosis requires eliciting cognitive complaints and measuring gait speed. MCR cases are twice as likely to develop dementia. MCR predicts dementia with greater accuracy than slow gait or cognitive complaints. SMCR substitutes slow gait with subjective motoric complaints. Subjective MCR definition predicted incident 'objective MCR' with *Hazard ratio adjusted for age, sex, education and medical illnesses of 3.88, 95%CI: 1.58-9.51, p=0.003*.

Study Flow

Day before appointment with PCP

CHW pre-screens scheduled patients for following day/week

CHW calls all potentially eligible patients and asks 3 questions about memory

If cognitive concerns endorsed and pt is scheduled to be seen at an INTERVENTION clinic they will be asked to come to their appt 15-30 mins early

If cognitive concern present and pt is seen at CONTROL site, CHW will document in chart

If no cognitive concern present and pt is seen at EITHER CONTROL OR INTERVENTION SITE, CHW will document responses to questionnaire in chart

Day of appointment with PCP

CHW meets pt at clinic prior to the patient and administers 5-Cog

CHW returns pt to waiting room with token to alert PCP to study participation

CHW posts 5-Cog result and corresponding decision menu in a clinical note in EMR

PCP receives token from patient, reviews 5-Cog results in EMR, performs usual clinical care

Token

EINSTEIN
Albert Einstein College of Medicine

Montefiore

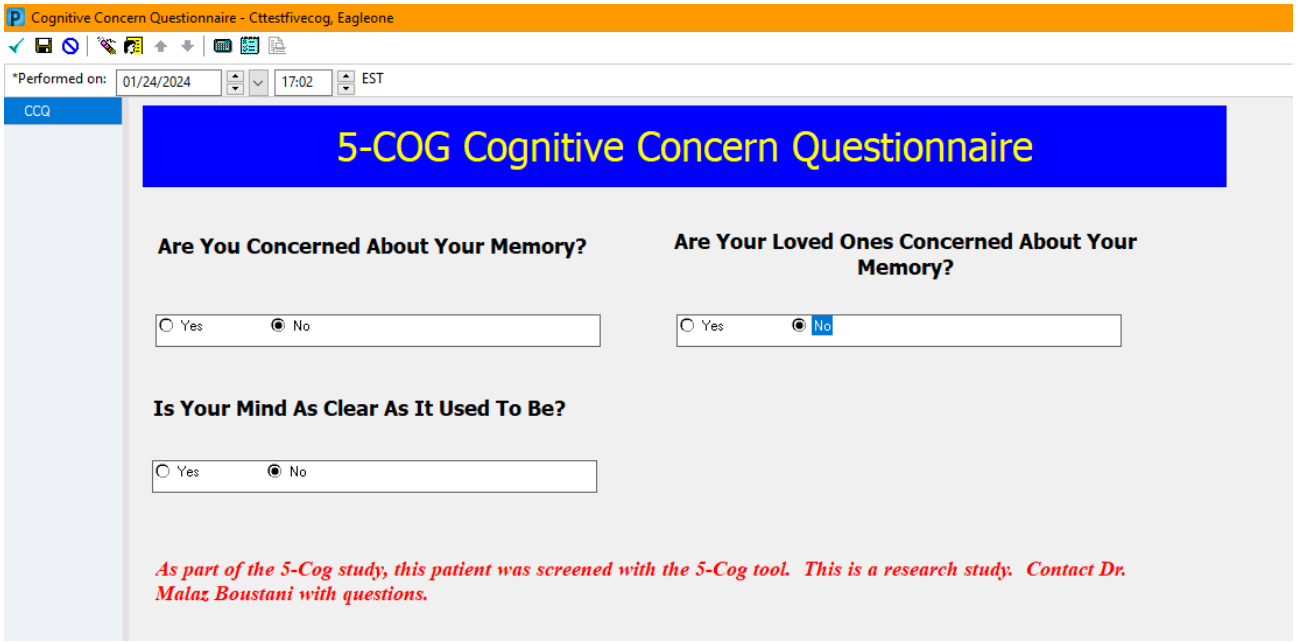
***Reminder to patient**: Please hand this to your doctor.*

Your patient completed the **5-Cog cognitive screening**. Please review the result in the **Research Note**. You can locate this through the Best Practice Advisory or through Chart Review in the Notes section.

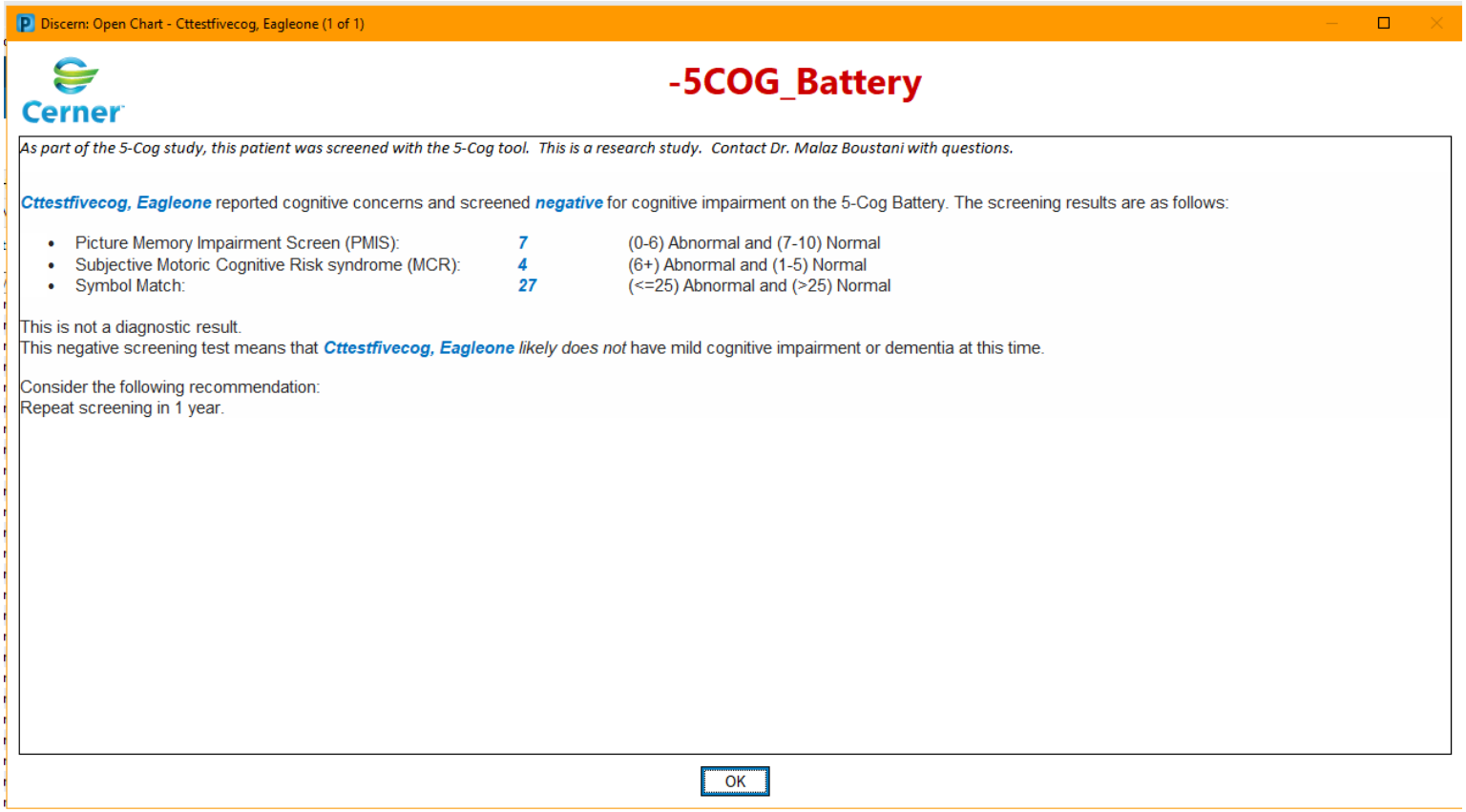
***Recordatorio al paciente:** Por favor entregue esto a su doctor(a).*

Su paciente completó la **evaluación cognitiva de 5-Cog**. Por favor revise el resultado en la **Nota de Investigación**. Puede localizar esto a través del Best Practice Advisory o a través de Chart Review en la sección de Notas.

Cognitive Concern Questions



Physician receives alert upon chart entry



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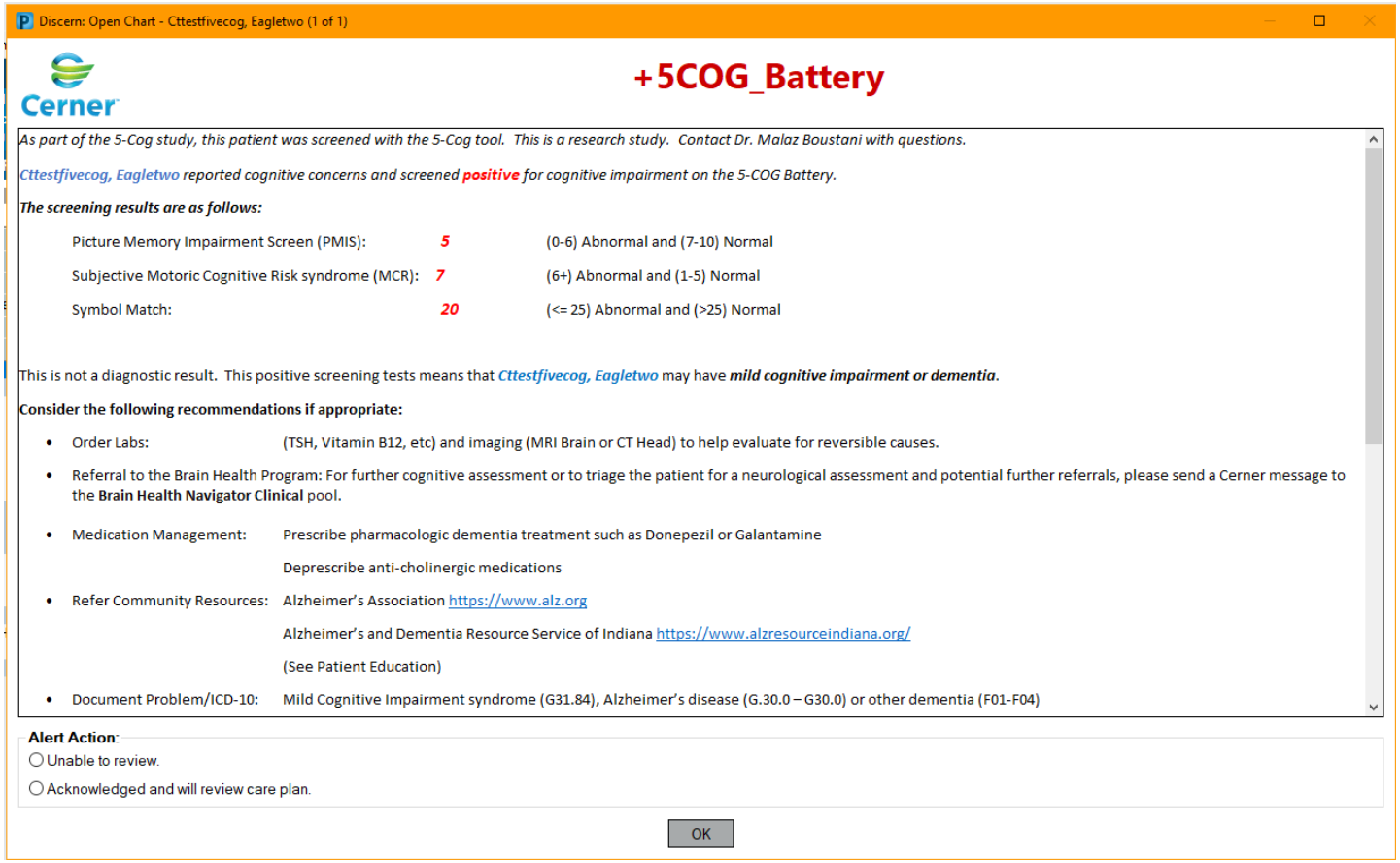
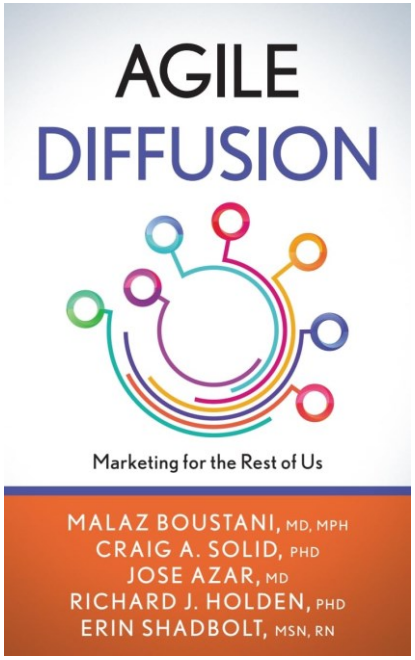
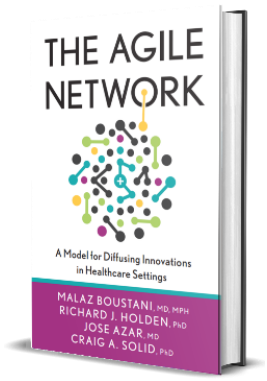


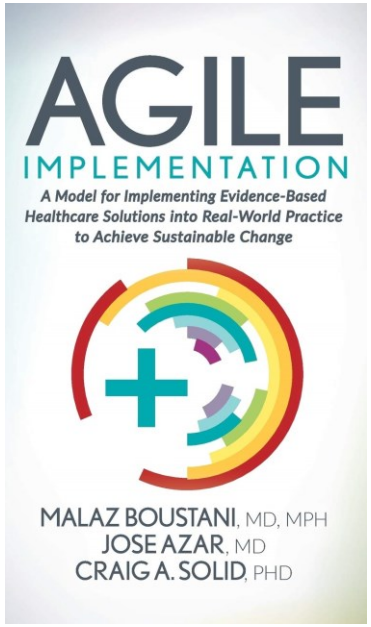
Progress Summary as of Feb 15th 2025

- First participant on August 2023 in NY and Feb 2024 in IN.
- Recruitment of clinics
  - Indiana: 7 active; 2 completed; 9 total
  - New York: 2 active; 4 completed; 6 total

- 8,309 participants from six clinics at **New York** have been screened in the EMR, 4,170 were screened for subjective cognitive complaints, 1661 reported subjective cognitive complaints, and **1,348 attended** their primary care appointment and were enrolled in the study.
- 9,208 participants from seven clinics at **Indiana** have been screened in the EMR, 4,904 were screened for cognitive complaints, 2021 reported subjective cognitive complaints and **1,654 attended** their primary care appointment and were enrolled in the study.







Agile Science

Definition: Agile science is a **rapidly evolving and adaptive process** for knowledge discovery and acquisition within the dynamic, constantly changing and evolving **real-world**.

Purpose: Agile science integrates insights from behavioral economics, complexity science, and network science to understand, predict, and steer the behaviors of both an individual human and a social organization.

Outcome: Agile science provides insights to design scalable and effective human-centered strategies, processes, and tools, implement them into routine care and subsequently diffuse them across various social networks.

THE Building Blocks of creating a New Social Norm

To spread an **evidence-based solution** in a targeted, **complex adaptive human network**, you need to become an **Agile Storyteller** and an **Engineer** capable of:

- Developing a **Minimally Viable STORY** about why people need to adopt the evidence-based solution.
- Designing a **Minimally Viable NUDGE** to change behaviors without taking away choice.
- **SPRINTING** to find out if you are making a difference.

STORY → NUDGE → SPRINT

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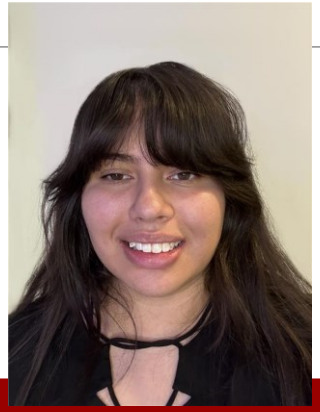

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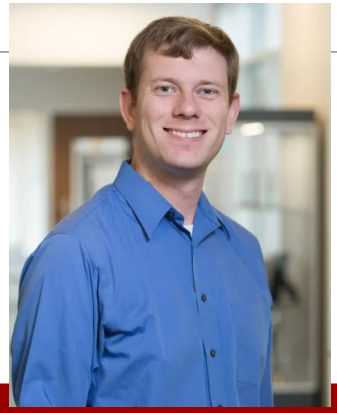

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For Relevant References

JMIR RESEARCH PROTOCOLS Chalmer et al

Protocol

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Open discussion / Questions