Early Detection via Mobile Apps: Data from the MyCog and MyCog Mobile Validation

I. Background

Pathological cognitive decline in older adulthood is a serious global health crisis and differs from normal cognitive aging (1). Cognitive impairments may result from Alzheimer's Disease and Related Dementias (AD/ADRD) (2–5), neurological disorders (6), or reversible causes such as infections or medications (7). Early detection of cognitive impairment is important to identify potentially reversible causes, manage symptoms and comorbidities, determine appropriate clinical care and caregiver involvement, and help families plan for the future (8,9). Neuropsychological measures play a critical role in the prediction and diagnosis of AD/ADRD (10–12), and are strongly linked to genetic risk factors and biomarkers of the disease (13,14). As such, large shareable datasets of neuropsychological assessments have enormous potential to identify cognitive profiles in aging and advancing early detection of AD/ADRD.

Cognitive screening tests are an inexpensive and efficient way to both capture performance-based neuropsychological data for research and detect early cognitive decline in clinical settings. Using brief, performance-based neuropsychological measures can promote higher rates of detection of cognitive impairment in older adults compared to informal observation alone, and facilitates appropriate referrals for comprehensive neuropsychological evaluations, laboratory tests, and brain imaging (15). Primary care visits offer an important opportunity to screen for and detect cognitive decline early in adults over age 65 (16). However, primary care clinics face significant barriers to routine screening, such as lack of time to conduct screenings as well as limited training and resources for dementia care (17). Moreover, data from these screeners are rarely shared with the research community(18).

We propose the creation of an open, shareable data set that can support innovative machine learning approaches for early prediction of AD/ADRD using data from the validation of two novel cognitive screening systems designed to overcome the barriers to early detection of AD/ADRD in primary care settings, MyCog and MyCog Mobile. MyCog is a tablet-based app that can be self-administered during the rooming process of a primary care visit (19). MyCog Mobile is a mobile app that allows for self-administration of MyCog on a personal smartphone remotely prior to a primary care visit (20), further increasing the flexibility of screening options. Scores from both apps can be automatically sent to the patient's Electronic Health Record (EHR) and trigger appropriate clinical decision-making support recommendations (20). These tools have demonstrated preliminary evidence of reliability and validity in pilot studies (21,22), supporting the proposed construct and clinical validation of the tools. ***The resulting dataset will include item-level data from gold-standard neuropsychological measures, novel cognitive screeners, demographic data, and documented diagnosis of AD/ADRD or MCI.***

This dataset offers the potential to identify neurocognitive measures and specific measure items that best predict diagnostic outcomes via machine learning approaches. Moreover, this dataset has the unique advantage of offering data from both common neuropsychological measures and novel cognitive screening apps. The use of common measures ensures our dataset can be combined with others to create even larger, multi-site datasets for both supervised and unsupervised approaches to machine learning. The introduction of novel measures (MyCog and MyCog Mobile) provides evidence to support accessible, low-cost measures that can predict cognitive decline and can be used by both researchers and clinicians.

II. Basic Information

The data collection efforts proposed in this application serve the existing aims of the Development and Validation of a Telehealth Strategy for Routine Detection of Cognitive Impairment in Primary Care: The MyCog Mobile Assessment (R01AG074245-01) grant funded by the National Institute of Aging. The Institutional Review Board at Northwestern University approved all study procedures (STU00214921). The primary goals of the study are: 1) examine the construct validity of the MyCog and MyCog Mobile screeners by comparing scores to

established measures; and 2) examine the ability of the screeners to accurately predict cognitive impairment.

Sample. We will recruit a sample of 300 participants in total, with 200 healthy controls and 100 participants with cognitive impairments documented in their EHR. We will stratify the sample by gender, race, ethnicity, and education levels. We will overrecruit participants from backgrounds that are disproportionately impacted by AD/ADRD, ensuring the sample includes 20% Black or African American participants (23), 20% Hispanic or Latino participants (24), and 45% participants with only a high school diploma or lower (25). Our sample will include a maximum of 60% non-Hispanic White participants to ensure the sample is not overly skewed towards the dominant population (26).The sample was determined by a power analysis that assumed 70% of the data will be randomly selected into a training set and 30% of the data will be subset into a testing set with the splitting process stratified by clinical/control groups.

Participants will be recruited through two sources. The healthy control sample will be recruited by a market research agency through their large, nationally representative database of research volunteers. Participants in the clinical sample will be recruited through specialty memory care clinics in the diverse Chicagoland area. All participants will provide informed consent prior to participation. Participants in the clinical sample will also be evaluated with the Decision-Making Audit Tool (27) to determine if they are able to consent to participation. All participants must be age 65 or older and speak English. Participants in the healthy control sample must have a Mini-Cog score of five or higher (28) and no history of a cognitive impairment diagnosis, while participants in the clinical sample must have a Mini-Cog score less than five and a documented diagnosis related to mild cognitive impairment, dementia, other cognitive deficits, or other memory loss (see below).

Procedure. Participants will first be administered the Mini-Cog to ensure they meet inclusion criteria. They will then self-administer MyCog Mobile on study-provided iPhones and be administered a battery of gold standard neuropsychological assessments by trained examiners (see below). Data collection will begin in May of 2024 and is expected to be completed by January of 2025. The primary challenge of this project is the recruitment of a clinical sample. However, our team has experience partnering with specialty care memory clinics within the Chicagoland area, and we expect to achieve the target sample within the study timeframe.

III. Utility and Rigor

Outcome Variable. Our primary outcome variable will be a diagnosis related to AD/ADRD. For the clinical subgroup (N=100), this will be measured via a diagnosis documented in the EHR by a qualified health professional. Inclusion diagnoses for the clinical sample will be related to dementia (ICD-10 codes F01.X, F10.97, F10.27, F19.17, F19.97, F19.27, F02.X, F03.X, or G31.83), mild cognitive impairment (ICD-10 codes G31.84), cognitive deficits (ICD-10 codes 69.91, R41.81, or R41.84), and other memory loss (R4.13). For the healthy control subgroup (N=200), diagnosis status will be determined by self-report of no previous diagnosis of cognitive impairment in a screening interview and a score of 5 or greater on the Mini-Cog.

Predictor Variables. Our predictor variables encompassed numerous commonly used performance-based measures, including brief cognitive screeners and well-established neuropsychological assessments. These measures have strong evidence of validity and as findings can generalize to insights about the overall constructs measured (e.g., memory, executive functioning, etc.). Our dataset will also include demographic variables such as age, gender, race, ethnicity, education, and diagnosis status. See supplemental materials for a list of all variables in the proposed dataset. Importantly, in addition to the gold standard assessments, ***we propose to collect neuropsychological data via an innovative, smartphone-based assessment system, MyCog Mobile, which has the potential to reduce data collection costs and increase accessibility compared to traditional neuropsychological assessment methods.***

MyCog Mobile. MyCog Mobile includes four cognitive measures adapted from well-established neuropsychological measures for use on a mobile phone. MyFaces is an associative memory test within MyCog Mobile originally developed by Rentz and colleagues and previous versions accurately predict cerebral amyloid beta burden (29). MySorting is a measure of executive function and cognitive flexibility adapted from the MyCog Dimensional Change Card Sorting (19) and Mobile Toolbox Shape-Color Sorting (30) test, and similar paradigms have been shown to predict conversion to AD (31). MySequences was adapted from the Mobile Toolbox Sequences test and measures working memory, which is known to be significantly impaired in AD/ADRD (32). MyPictures is a measure of episodic memory adapted from the Arranging Pictures task in the Mobile Toolbox (30) and the MyCog Picture Sequence Memory test (19) and which has been show to predict cognitive impairment (22). All measures have undergone user and pilot testing to ensure optimal usability and reliability in older adults.

MyCog. MyCog is a tablet-based cognitive screener intended to be self-administered during the rooming process of a primary care visit. MyCog contains two assessments of executive function and working memory: Dimensional Change Card Sorting (DCCS) and Picture Sequence Memory (PSM). Early studies suggest MyCog has .79 sensitivity and .82 specificity to detect cognitive impairment (22).

Mini-Cog. Mini-Cog screening scores may be used as both a predictor and outcome variable, as it is commonly used to identify early cognitive impairment. The Mini-Cog is a brief and widely used cognitive screening tool designed to assess memory and executive function (28), and has a 0.91 sensitivity and 0.86 specificity to detect cognitive impairment (33).

Gold Standard Cognitive Measures. We will administer four external cognitive measures as points of convergent validity for MyCog Mobile***.*** The Verbal Paired Associates Test is a subtest from the Wechsler Memory Scale, 4th edition (34) and assesses episodic memory. Verbal paired associates tests have been used extensively in AD/ADRD research (35). The Color Word Interference Test is a subtest from the Delis Kaplan Executive Functioning System (D-KEFS) and assesses inhibitory control and the ability to switch between tasks (36). Performance on this type of task has been shown to predict AD/ADRD status and severity (37). The Trail Making Test is a neuropsychological test commonly used to assess attention, mental flexibility and executive functions (36). The Trail Making Test has been shown to reflect inhibitory deficits in AD/ADRD patients (38). The Letter Number Sequencing subtest from the Wechsler Adult Intelligence Scale, Fourth Edition (WAIS-IV) assesses working memory and cognitive flexibility (39). Performance is associated with severity of cognitive decline (40).

IV. Innovation

An estimated 500,000 neuropsychological assessments are conducted in the United States each year resulting in a massive amount of data, yet the majority of these data are never shared with the larger research community (18). There is an urgent need to create open-access repositories of item-level neuropsychological data that can facilitate advanced analyses of large datasets (18). Even more pressing is the need to collect data from both healthy adults and adults diagnosed with cognitive impairment to more accurately differentiate neuropsychological profiles and trajectories (41). There are some existing datasets that include cognitive data on older adults, such as the Uniform Dataset (42,43), Alzheimer's Disease Neuroimaging Initiative (44), and National Alzheimer's Coordinating Center (45). However, ***our proposed dataset offers advancements over existing datasets as it provides item-level data from new app-based cognitive screeners that have the potential to improve cognitive screening rates and early detection, both in research and clinical contexts***. MyCog and MyCog Mobile are innovative cognitive screening systems that can eliminate many of the barriers to screening in primary care by saving clinicians time and providing appropriate clinical support (46). The batteries are self-administered, and scores are automatically sent to the EHR and trigger appropriate best practice alerts. This approach eliminates the need for staff to manually administer, score and enter assessment data, as well as avoids common human errors in test

administration and scoring (47,48). MyCog Mobile offers even further benefits as patients can complete the screener remotely and focus on other aspects of the primary care visit when they arrive in person. The MyCog and MyCog Mobile systems may also be used by primary researchers outside of clinical settings to remotely collect large datasets. Given these benefits, MyCog and MyCog Mobile have the potential to encourage broader cognitive screening in primary care and research, leading to earlier detection, diagnosis, and intervention.

Using our proposed dataset, researchers will be able to leverage a broad range of machine learning techniques to advance early prediction of AD/ADRD. These methods will include the capacity to construct empirically driven supervised and unsupervised models on a dataset with outcome variables that can be utilized for either predictive or classification analysis. Likewise, the proposed dataset will provide a broad range of variables (e.g., item level, user interactions, scores) that can be used in comprehensive feature selection, the creation of key composites that improve model fit, and implementation of granular hyperparameters or tuning parameters during a regular or non-regular grid search. Unlike other datasets often used for AD/ADRD research, our data collection will also oversample for clinical cases to improve the reliability and validity of the training and testing datasets. The collected data will be appropriate for any preferred prediction or classification algorithm, or development of stacked generalization or ensemble models. Models resulting from the original dataset can be validated on new independent datasets which include our commonly used cognitive measures to ensure generalizability.

V. Disproportionate Impact

Our dataset will be unique in that it does not use a convenience sample rather a sample that was intentionally recruited to reflect underrepresented populations, a major advantage for researchers interested in examining disparities in AD/ADRD. Our sample will be stratified by demographic groups, and we will ***overrecruit participants who are disproportionately impacted by AD/ADRD.*** All participants will provide informed consent and be compensated for their participation. The diversity of the sample will ensure that findings from the dataset will generalize to the U.S. population as well as represent groups most at-risk for AD/ADRD.

Our sample will also ***address biases by providing evidence of an accessible new smartphone-based screener that can help reach underrepresented populations****.* Smartphone ownership among older adults has risen from 10% in 2011 to 61% in 2021, (49), and this trend is expected to rise as the population ages. Low-income earners are more likely to own a smartphone than other electronic devices (50), and research suggests that low-income and minority groups are more likely to access their personal health records exclusively via smartphones (51). From a research participation perspective, the ability to complete measures at home on a personal smartphone benefits older adults who may have mobility issues or transportation concerns. Moreover, these tools help reduce research costs related to facilities, recruitment, and staffing, allowing researchers to collect larger and more diverse samples. Taken together, our data will provide evidence to support a smartphone-based assessment that can be used in research and clinical settings and serve as the foundation for future research using MyCog Mobile or other smartphone-based screeners with at-risk populations.

VI. Feasibility

Our team has extensive experience conducting large-scale validation studies with older adults in both clinical and healthy populations. Dr. Michael Wolf has strong relationships with specialty memory care clinics in the Chicagoland area and has previously conducted research using mobile apps with their AD/ADRD patient populations. Moreover, our market research partners have demonstrated success in recruiting diverse populations of older adults for validation studies for several of our department's mobile-app projects. We aim to mitigate known challenges in conducting research with AD/ADRD populations by leveraging established relationships with specialty memory care clinics, using experience study team experts to assess the clinical sample, and allotting an extended data collection timeline (9 months).

Team Introduction

We have an experienced team of aging researchers, clinicians, measurement scientists, and technical experts to ensure the same success we have previously realized in multiple prior large-scale data collection projects. We highlight select team members below.

Dr. Michael Wolf is a Professor of Medicine in General Internal Medicine and Geriatrics, Associate Division Chief of Research for the Division Chief of General Internal Medicine and Geriatrics, and Director of the Center for Applied Health Research on Aging (CAHRA) in Northwestern University's Feinberg School of Medicine. He is an expert in cognitive aging and currently an MPI on both the MyCog and MyCog Mobile grants. He is the PI of Northwestern's NIA-funded Claude D. Pepper Older Americans Independence Center that focuses on primary care management of older adults with multiple chronic conditions and is Director of the Center for Applied Health Research on Aging (CAHRA) within the Feinberg School of Medicine, and Associate Division Chief for General Internal Medicine & Geriatrics.

Dr. Cindy Nowinski is Research Professor in the Departments of Medical Social Sciences and Neurology, Northwestern University Feinberg School of Medicine. She is currently the MPI on both the MyCog and MyCog Mobile grants. She has extensive experience leading and managing large research networks and measure validation projects, including prior service as PI of "NIH Toolbox" Design Consulting for Research Domain (RDoC) Criteria Field Test Battery, Scientific Director of the original NIH Toolbox Contract; Scientific Director and Dissemination Core Lead for Mobile Toolbox, and Scientific Director of MyCog.

Dr. Stephanie Ruth Young is a licensed clinical psychologist Research Assistant Professor in the Department of Medical Social Sciences at the Northwestern University Feinberg School of Medicine. She is a co-investigator on MyCog, MyCog Mobile, and Mobile Toolbox, projects in which she has led the development and validation of app-based cognitive tests to monitor cognitive aging across the adult lifespan and detect AD/ADRD.

Dr. Lihua Yao Dr. Yao is a data scientist and Associate Professor in the Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine. She has considerable expertise in applying machine learning approaches to large datasets as well as item response theory (IRT), multidimensional item response theory (MIRT), computer adaptive testing (CAT), and multidimensional computer adaptive testing (MCAT).

Dr. Elizabeth Dworak is a data scientist and Research Assistant Professor in the Department of Medical Social Sciences at the Northwestern University Feinberg School of Medicine. She is a co-investigator on Mobile Toolbox and MyCog Mobile, and has extensive experience in analysis of large datasets and machine learning related to cognitive aging.

Dr. Sandra Weintraub is a Professor of Psychiatry and Behavioral Sciences, Neurology - Ken and Ruth Davee Department and Weinberg College of Arts and Sciences. Dr. Weintraub led the Work Group for the neuropsychological battery of the Uniform Dataset, a standard set of data collection procedures adopted by the NIA Alzheimer's Disease Centers program.

Dr. Richard Gershon is a Professor and Division Chief of Outcomes and Measurement Science in the Department of Medical Social Sciences, and Professor in the Department of Preventive Medicine-Health and Biomedical Informatics at Northwestern University Feinberg School of Medicine. His career has been characterized by his successful management of large organizations and multi-site neuropsychological assessment development and data collection projects related to cognitive aging.

Mr. Greg Byrne is a Project Manager in the Department of Medical Social Sciences at the Northwestern University Feinberg School of Medicine. He has served as the project manager for several technology-based assessment projects that require collection of large datasets, including MyCog and MyCog Mobile, which will be a strong advantage on the proposed project.

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