

Annual Meeting of the National Institute of Aging Roybal Centers for Translational Research in Aging

October 22, 2020

Virtual Meeting

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Executive Summary

On October 22, 2020, the National Institute on Aging (NIA) convened the annual conference for the Roybal Centers for Translational Research in Aging. The Roybal Program aims to use the National Institutes of Health (NIH) Stage Model to translate and integrate basic behavioral and social research findings into interventions aimed at innovatively improving both the lives of older adults and the capacity of institutions to adopt to societal aging. The Roybal Program currently consists of 15 centers across nine states and 23 primary investigators. The goal of the Annual Roybal Conference is to convene representatives of the 15 Roybal Centers, share updates and accomplishments from each Roybal Center, and hear presentations on the Roybal Program, successful Roybal Center-funded projects, and the NIA IMbedded Pragmatic Alzheimer’s Disease (AD) and AD-Related Dementias (ADRD) Clinical Trials (IMPACT) Collaboratory.

Overview of the NIA Roybal Program and the NIH Stage Model

Drs. Lisbeth Nielson and Lisa Onken, NIA

The NIA Division of Behavioral and Social Research (BSR) launched the Roybal Program in 1993, and since then the program has grown substantially in terms of both funding and research programs initiated. More recently, the Roybal Program adopted the NIH Stage Model, which is a conceptual framework whereby potent and scalable interventions are defined by their governing principles. An intervention’s principles define how an intervention works and how the intervention could be improved. The NIH Stage Model highlights the importance of delivering an intervention with fidelity, which involves delivering an intervention in line with the intervention’s principles.

The NIH Stage Model is non-prescriptive and allows investigators to use any methodology or research design that is needed to advance the behavioral intervention of research. The Stage model is well-suited for any type of behavioral intervention development whether the intervention is simple or complex. Although an overall goal of the Stage Model is to define and understand the mechanisms of action of an intervention, it is not a requirement that the mechanisms of an intervention are tested in every study. The NIH Stage Model acknowledges that it may not always be possible to use a linear approach to intervention development. It offers a common language to define specific activities necessary for the development of behavioral interventions.

Keynote: From Development to Dissemination—The Stage Model and Cognitive Behavioral Therapy for Substance Use Disorders

Dr. Kathleen Carroll, Psychotherapy Development Center for Drug Abuse, Yale University

The Yale Psychotherapy Development Center (PDC) has launched 26 independent research programs, including pilot studies and randomized controlled trials (RCTs). One major PDC success is the CBT4CBT program, an intervention for individuals with substance use disorder (SUD). In the context of SUD, cognitive-behavioral therapy (CBT) is used to enhance learning

and implementation of skills to reduce cravings and improve pattern identification, refusal, and problem-solving skills through practice. During a Stage II study, Dr. Carroll and colleagues found that cocaine users receiving CBT exhibited less cocaine-related problems by the 1-year follow-up visit, compared to subjects receiving treatment as usual (TAU). They then initiated a Stage III RCT in which clinicians were divided into groups receiving different CBT training materials and were rated according to their adherence and skills in delivering the intervention. Only clinicians with access to the 3-day training seminar, supervision, and feedback achieved sufficient adherence to the CBT principles; reading a manual or reviewing an informational website were not sufficient. Dr. Carroll and her team followed up with a study of volunteer clinicians from 11 community-based clinics and found that all were performing CBT but not as intended.

Dr. Carroll and colleagues developed a computerized SUD intervention, called CBT4CBT, which allows investigators to systematically assess behavioral outcomes and standardize intervention delivery. CBT4CBT includes seven video-based, self-guided modules and a True/False quiz following each module. CBT4CBT was first assessed in 87 outpatients with SUD. After receiving CBT4CBT, subjects were 20 percent less likely to be using drugs (determined via urine test) than subjects receiving TAU, and the positive effect size increased by the 20-week follow-up visit. CBT4CBT was then advanced into a large-scale clinical trial with a homogenous SUD population (i.e., cocaine users enrolled in methadone treatment); this study replicated the findings that CBT4CBT reduced SUD-related behavior. In comparison to clinician-based CBT, CBT4CBT subjects answered more post-module True/False questions correctly and exhibited less SUD-related behaviors. CBT4CBT was later adapted for alcohol use disorder and for SUD in Spanish. Both versions were tested and displayed similar benefits to previous studies.

In total, CBT4CBT has completed eight RCTs and is currently involved in Stage IV and Stage V clinical trials. CBT4CBT is now used in 26 states, Canada, and Spain. Next steps for the intervention include evaluating methods to adapt CBT4CBT into personalized treatment.

Forming Synergies between the NIA IMPACT Collaboratory and Roybal Centers

Dr. Susan Mitchell, Hebrew SeniorLife, Harvard Medical School

NIA launched the NIA Collaboratory in order to address common complications associated with embedded pragmatic clinical trials (ePCTs) for AD/ADRD. The NIA Collaboratory aims to transform the delivery, quality, and outcomes of care provided to people living with dementia (PLWD) and their caregivers by accelerating the testing and adoption of evidence-based interventions in health care systems. The NIA Collaboratory is focused on developing and disseminating ePCT best practices; enhancing research development through pilot study and ePCT support; building investigator capacity; catalyzing stakeholder engagement; and ensuring the inclusion of culturally tailored interventions and diverse populations.

Pilot studies are the main outcome of the NIA Collaboratory, and approximately eight pilot studies—funded at \$200,000 each—are selected per year. During the last funding cycle, the NIA Collaboratory received 39 letters of intent (LOIs), invited 10 of these applicants to submit proposals, and received 5 full proposals (many of which were focused on COVID-19-related and telehealth interventions). The study section for these proposals will occur on October 30, and funding will be distributed during February 2021.

The NIA Collaboratory is dedicated to training through its Career Development Awards (CDAs; which provide researchers with \$100,000 over 2 years), workshops (next retreat to be held in April 2021), and online training modules. It is now developing the IMPACT 101 training curriculum that will serve as a resource to educate researchers on ePCTs.

The NIA Collaboratory and the Roybal Program have many opportunities for synergy. The Roybal Program facilitates studies from NIH Stage Model's Stages I to IV, whereas the NIA Collaboratory facilitates only Stage IV studies. The Roybal Program could allow researchers to develop and test their interventions in preparation for entry into the NIA Collaboratory program. The NIA Collaboratory could also redirect applicants to the Roybal Program if their studies do not have sufficient preliminary data to enter a Stage IV study.

Treatment Fidelity on Complex Interventions

Dr. Melissa Riddle, Behavioral Social Sciences Research Program, National Institute of Dental and Craniofacial Research

Treatment fidelity consists of treatment integrity (i.e., the degree to which a treatment is implemented as intended) and treatment differentiation (i.e., the degree to which two or more study arms differ among critical dimensions).¹ Assessing the fidelity of an intervention allows researchers to understand how an intervention works in terms of the underlying mechanisms of behavior change. One concept that help defines the fidelity is optimal specificity.

Optimal specificity refers to the level of granularity given to the principles and goals of the intervention. Interventions can range from low (e.g., general guidelines) to high specificity (e.g., prescriptive instructions); however, general guidelines are often too general to convey the study's principles, and prescriptive instructions are too restrictive. Thus, interventions with intermediate specificity (e.g., goal-based principles or specific techniques) provide the optimal level of flexibility and potential for personalization.

In the NIH Stage Model, an intervention's principles must be integrated into the study's intervention manual, training materials, fidelity procedures, and study design. The main goal of these resources is to present the principles driving the intervention in order to ensure that the

¹ Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity In public health clinical trials. *J Public Health Dent.* 2011;71(s1):S52-63.

intervention is delivered correctly. Principles involved in clinical treatment interventions include contingency management, CBT, exposure, unified protocols, and system-level defaults. However, more research is needed to obtain that same level of progress for public health interventions. The public health interventions field rarely tests its theories; one metareview finding that only 70 percent of studies cited theories and 13 percent tested a theory.²

The NIH Science of Behavior Change (SOBC) Program was developed to identify gaps in behavior change research. One such gap was the lack of testing mechanisms of behavior change in alignment with principles and theories. The Agency for Health Research and Quality (AHRQ) recently published a report detailing that most studies exhibit low-strength evidence because the studies lacked attention to intervention fidelity and thus the mechanism of behavior change was limited.³ Attending to the fidelity of an intervention can help define the interventions capabilities, identify essential components of intervention training, facilitate standardization across sites and interventionists, facilitate theory testing, and allow for early detection of errors.

Introduction to Roybal Pilot Award Approval Process

Dr. Partha Bhattacharyya, National Institute on Aging

During the 2020 Roybal Program pilot review process, NIA staff observed many application errors that significantly delayed the review process. The Roybal Program aims to fund potent and scalable interventions, and many of the proposals received were not appropriate or lacked required materials. For example, many applications did not address the scope of the Roybal Program (i.e., to facilitate a clinical trials) or did not include study design components, such as the Data Safety Monitoring Plan (DSMP) or Clinical Trial Dissemination Plan.

To mitigate these common errors, NIA staff recommends that applicants consider the following approaches: (1) use available resources, such as the Roybal Coordinating Center Pilot Checklist Form ; (2) develop a master clinical trial dissemination plan and single institutional review board plan which can be reused for all pilots; (3) check conflicts of interest related to safety officer nominations; (4) use consistent naming conventions for pilot studies each year; (5) Roybal pilot staff consider using training sessions and other resources offered by the coordinating center. The Roybal Program also will soon develop educational videos that illustrate how to complete certain aspects of the annual progress and share with all Roybal centers.

² Glanz K, Bishop DB. The role of behavioral science theory in development and implementation of public health interventions. *Annu Rev Public Health* 2010;31(1):399-418.

³ Butler M, Gaugler JE, Talley KMC, Abdi HI, Desai PJ, Duval S, Forte ML, Nelson VA, Ng W, Ouellette JM, Ratner E, Saha J, Shippee T, Wagner BL, Wilt TJ, Yeshi L. Care interventions for people living with dementia and their caregivers. *AHRQ Comparative Effectiveness Review* No. 231. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2015-00008-I.) AHRQ Publication No. 20-EHC023.

Appendix 1: List of Roybal Centers for Translational Research in Aging

Cornell Roybal Center—Translational Research Institute on Pain in Later Life at Weill Medical College of Cornell University

Primary Investigators: Drs. Drs. Manney Carrington Reid, Karl Pillemer, and Elaine Wethington

The goal of the Cornell Roybal Center—Translational Research Institute on Pain in Later Life is to develop effective behavioral interventions to address the problem of later-life pain in order to increase the health and wellbeing of older adults with adversely affected pain.

Columbia Roybal Center for Fearless Behavior Change at Columbia University Health Sciences

Primary Investigators: Drs. Ian Kronish and Donald Edmondson

The goal of the Columbia Roybal Center for Fearless Behavior Change is to develop and test novel interventions for improving medication adherence and physical activity in distressed survivors of acute medical events.

Duke Roybal Center at Duke University

Primary Investigators: Drs. Janet Alexandria Pyru and Francis Keefe

The goals of the Duke Roybal Center are (1) to provide a research infrastructure with a novel experimental learning and team approach to enhance behavioral intervention development and implementation skills and (2) to stimulate, facilitate, and accelerate the science of behavioral interventions to optimize mobility and promote independent living for older adults.

Roybal Center for Personalized Trials: Physical Activity Promotion to Foster Healthy Aging at Feinstein Institutes for Medical Research

Primary Investigator: Dr. Karina Davidson

The goal of the Roybal Center for Personalized Trials: Physical Activity Promotion to Foster Healthy Aging is to generate intervention development research and in turn launch several independent programs of research to improve physical activity and thus contribute to successful aging.

Boston Roybal Center for Active Lifestyle Interventions at Brandeis University

Primary Investigator: Dr. Margie Lachman

The goal of the Boston Roybal Center for Active Lifestyle Interventions is to develop and test behavior change strategies to promote healthy aging, especially among sedentary adults and others at high risk for poor health outcomes.

Penn Roybal Center on Behavioral Economics and Health at University of Pennsylvania

Primary Investigator: Dr. Kevin Volpp

The goal of the Penn Roybal Center on Behavioral Economics and Health is to conduct impactful research with the potential to significantly improve health in multiple therapeutic foci, such as behavioral economics, physical activity promotion, leveraging technology to promote healthy aging, and increasing sustainability and persistence of behavior change.

NBER Roybal Center for Behavioral Change in Health at National Bureau of Economic Research

Primary Investigators: Drs. Joseph Doyle and David Laibson

The goal of the NBER Roybal Center for Behavioral Change in Health is to translate research from basic science programs into applications that address real-world problems in order to improve population health directly, broadly, and cost-effectively.

MIT Roybal Center for Translational Research to Improve Healthcare for the Aging at Massachusetts Institute of Technology

Primary Investigator: Dr. Amy Finkelstein

The goal of the MIT Roybal Center for Translational Research to Improve Healthcare for the Aging is to develop and evaluate translational behavioral interventions to improve health and healthcare delivery for older people.

The Palliative and Advanced Illness Research Center at University of Pennsylvania

Primary Investigator: Dr. Scott Halpern

The goal of the Palliative and Advanced Illness Research Center is to develop, test, and implement novel interventions that bridge the dramatic gap between the supply of and need for palliative care services among PLWD in long-term services and support facilities, as well as family caregivers.

The Roybal Center for Therapeutic Optimization using Behavioral Science at Brigham and Women's Hospital

Primary Investigator: Dr. Nitesh Choudhry

The goal of the Roybal Center for Therapeutic Optimization using Behavioral Science is to develop principle-driven interventions to enhance the evidence-based use of prescription medications.

The Emory Roybal Center for Caregiving Mastery at Emory University

Primary Investigators: Drs. Ken Hepburn and Molly Perkins

The goal of the Emory Roybal Center for Caregiving Mastery is to provide support to investigators across the United States to conduct NIH Stage I to III intervention research that will enhance the context-specific role-mastery of informal caregivers of persons living with Alzheimer's disease and similar disease.

Midwest Roybal Center for Health Promotion and Translation at University of Illinois at Chicago

Primary Investigator: Dr. Susan Hughes

The goal of the Midwest Roybal Center for Health Promotion and Translation is to design scalable interventions for older racial/ethnic minority adults and expand the focus of interventions to include cognitive health.

Rochester Roybal Center for Social Ties and Aging Research at University of Rochester

Primary Investigators: Drs. Kathi Heffner and Kimberly Van Orden

The goal of the Rochester Roybal Center for Social Ties and Aging Research is to advance development of novel, principle-guided behavioral interventions that ensure vitality and wellbeing for healthy aging in middle-aged to older caregivers of a family member with AD or ADRD.

ORCASTRAIT Oregon Roybal Center for Care Support Translational Research Advantaged by Integrating Technology at Oregon Health & Science University

Primary Investigator: Dr. Jeffrey Kaye

The goal of the ORCASTRAIT Oregon Roybal Center for Care Support Translational Research Advantaged by Integrating Technology is to develop effective care support interventions facilitated by wise use of technologies that optimize health and quality of life for PWD and their caregivers.

Roybal Center for Behavioral Interventions in Aging at University of Southern California

Primary Investigators: Drs. Dana Goldman and Jason Doctor

The goal of the Roybal Center for Behavioral Interventions in Aging is to encourage safe and effective medical decisions through behavioral economic interventions.