

# Alzheimer's and Cognition Center

"Healthy Brain Aging Starts Here"

#### December 2021

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### **Boot Camp Complete**

In June 2021, the CU Alzheimer's and Cognition Center invited 16 men and women from the Denver metro Hispanic/ Latino community to participate in a program called Boot Camp Translation (BCT). Participants spent four months meeting regularly to discuss Alzheimer's disease in the Hispanic/Latino community, and officially completed the program in October!

BCT is an outreach initiative whereby a partnership is developed between the research team and community members to co-learn and co-create messaging related to a health topic, which in this case is Alzheimer's disease. Participants combine the knowledge generated in BCT meetings with their expert understanding of their community to develop messaging specific to Alzheimer's disease and tailored to the members of the Hispanic/Latino community.

Dr. Rebecca Mullen, a physician in the department of Family Medicine, and CUACC Administrator Polly Serrano facilitated the program. While the program has officially ended, the BCT participants are still working together with Dr. Mullen and Ms. Serrano to complete the products generated from their discussions during the BCT program. The CUACC looks forward to seeing the materials they have created to help spread awareness of Alzheimer's disease to members of the Hispanic/ Latino community.

This BCT program was completed as part of the Engaging Communities of Hispanics/Latinos for Aging Research

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# **Investigator Spotlight:** Samantha Holden, MD



Samantha Holden, MD, is a behavioral and movement disorders neurologist for the CU Alzheimer's and Cognition Center and the Memory Disorders Clinic. She specializes in neurological conditions that present with symptoms affecting both cognition and movement, such as Parkinson's disease dementia and dementia with Lewy bodies.

Dr. Holden knew early on in high school that she was interested in the brain, and more specifically, what makes humans tick. This led her to New York University for her undergraduate degree, where she majored in Neural Science, followed by medical school at Stony Brook University School of Medicine, to specialize in Neurology. Throughout her experiences as an undergraduate and medical student, she realized that she especially valued talking with patients, learning about their lives, and using their lived experiences to better understand their minds.

She also enjoyed being able to

see patients over time and having the opportunity to build a long-term relationship with them, something that not all providers can do, such as those who work in the emergency room. This led her to pursue Neurology residency training at Rush University followed by subspecialty fellowship training in Behavioral Neurology and Movement Disorders at CU Anschutz.

During her residency, Dr. Holden worked in the Rush Movement Disorders Clinic with Parkinson's disease and Lewy body dementia patients. Being able to spend time with them, learn about their lives and relationships, and see them back multiple times solidified for her that this was the patient population she wanted to work with. While there, she was also exposed to clinical research, and she began developing her research interests as well.

When it comes to research, Dr. Holden's main interests revolve around the problems she sees in clinic, identifying the gap connected to that problem that is preventing patients from getting the care they need, and working to solve that problem. For example, in the clinic, it can be difficult to determine whether the trouble with daily life that a person with Parkinson's disease is experiencing is due to motor impairment or to cognitive impairment. Therefore, one of Dr. Holden's research



## **Ins and Outs: Clinical Trials and Their Phases**

Research generally fits into one of three categories: laboratory research, clinical observational research, and clinical trials. Laboratory Research is research that is conducted in a controlled environment, such as searching for new drugs and treatments using cells and animal models to test them, or analyzing blood samples from clinical research studies, and does not involve directly interacting with participants. Clinical observational studies do not involve an intervention (i.e., testing a possible new drug or treatment). Instead, participants volunteer their time to let researchers observe and study certain processes and collect biological samples such as blood samples, brain images through MRI or PET scans, and cerebrospinal fluid (CSF) samples. Clinical trials involve an intervention, where researchers are studying a potential treatment or intervention, such as a drug or a medical device, that could produce a potential change in the way a disease or medical condition is detected, prevented, managed, or treated.

Clinical trials are an important part of Alzheimer's disease and related dementia research, and the CUACC has been a site for multiple clinical trials. Trials are the next step after an intervention has been identified and tested in the laboratory, and they are conducted to study the safety and/or effectiveness of the intervention. Clinical drug trials are overseen by the Food and Drug Administration (FDA) in the United States, and have four phases that begin with Phase 1 and end with Phase 4.

#### Phase 1

#### Main purpose: Determining drug properties

Phase 1 trials are generally conducted to determine basic properties of a proposed intervention or treatment, such as dose and tolerance (how the body responds to the drug). They are usually conducted with a very small number of participants, and do not require a comparison group of participants who do not receive the treatment. Results from the Phase 1 trial provide guidance for whether and how the treatment should move to a Phase 2 trial.

#### Phase 3

## Main purpose: Demonstrating effectiveness of intervention

Phase 3 trials are generally conducted to confirm that the treatment has the expected effect based on the laboratory research and prior phases, such as slowing down the progression of a disease or stopping it altogether. Researchers also continue to monitor for the safety of the drug. Phase 3 trials are conducted in a much larger number of participants than Phase 2 trials, and they are placebo-controlled and double-blind. If results from a Phase 3 trial are promising, it will be submitted to the FDA for approval to be used in the general public.

#### Phase 2

## Main purpose: Demonstrating safety of intervention

Phase 2 trials are generally conducted to continue testing the safety of the intervention. They are conducted with a larger number of participants, and for a longer period of time. They are placebocontrolled, which means they include a control group that receives a placebo, which is a pill or liquid that looks similar to the study treatment but is not real, and they are double-blind, which means that during the study, neither the participant nor the study staff know whether a participant is receiving the study treatment or the placebo. While the main purpose is safety, Phase 2 trials may begin to also look at the effectiveness of the drug based on specific outcomes. The results of a Phase 2 trial will indicate whether or not the drug should continue on to a Phase 3 trial.

#### Phase 4

## Main purpose: Investigation of drug in general public

Phase 4 trials are conducted after a drug has been approved by the FDA and is available on the market. They generally last many years, and results from these trials can lead to restrictions on the use of the drug, changes to side effects and labeling, or even removal of the drug from the market.





## **Community Engagement: BCT**

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(ECHAR) Network, of which the CUACC is a member. *Echar*, a Spanish verb, has several definitions including "to cast/throw", "to put", "to oust", and "to lay" and is fitting, given that the Network's goals are to establish a plan for better health communications and to oust health disparities.

The ECHAR Network was established in 2020 by Dr. Luis D. Medina at the University of Houston (UH), to engage Hispanic/Latino community members in aging research, with a focus on Alzheimer's disease and related dementias. It is funded by a National Institute on Aging grant (R24AG065170), and it brings together a diverse team of researchers, clinicians, and community members from Houston, Texas, Denver, Colorado, and Las Vegas, Nevada. The CUACC is very proud to be a member of the ECHAR Network.

There are many projects and opportunities for community engagement that have developed from the network, not limited to the BCT. For example, the ECHAR Network was recently featured in an article in the Houston Chronicle about another exciting outreach program through which they work to develop telenovelas that raise awareness about Alzheimer's disease in the Hispanic/Latino community. You can read the article at <a href="https://bit.ly/30YK8k2">https://bit.ly/30YK8k2</a>, and learn more about the ECHAR Network at echarnetwork.com.

## **Holden Spotlight**

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studies is focused on identifying ways to separate out these impairments using standardized assessments of functional ability, instead of relying on patient and caregiver informants or cognitive assessments originally designed for Alzheimer's disease.

Over the last year, Dr. Holden has not only pursued research to improve patient lives, but also taken on multiple leadership roles within both the CU Alzheimer's and Cognition Center and the Department of Neurology to help propel her work towards that goal. She is the Medical Director of our Memory Disorders Clinic, the Co-Director of our Lewy Body Dementia Association Research Center of Excellence, and the Clinical Director of Outpatient Neurology for UCHealth, while continuing to see patients in the Memory Disorders Clinic two days a week.

Dr. Holden is using her "seats at the tables" to be sure the patient's voice and lived experiences don't get lost in shuffle of bureaucracy, while using her experiences in clinic to inform her decisions and improve the clinic processes to advocate for patients in the most effective way.

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# Interested in a Research Study?

Contact Neurology Research Partners at 303-724-4644 or fill out a research inquiry form at <u>www.cumemoryresearch.org</u> to learn more!

## **Give to Research**

If you are interested in making a donation to the CU Alzheimer's and Cognition Center, please contact Carrie Radant Flynn at 303-724-9146.

