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TRANSFORMING DEMENTIA CARE

Challenges conducting pragmatic trials of interventions for care partners of people living with dementia

Robert Penfold, PhD

Leah Hanson, PhD

Richard Fortinsky, PhD

Housekeeping

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- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Associated podcast released about 2 weeks after Grand Rounds
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Approaches to Identify and Collect Outcomes from Care Partners in Embedded Pragmatic Clinical Trials:

Evidence from the STAR Caregivers - Virtual Training and Follow-up Study

Rob Penfold, PhD

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November 18, 2021

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Introduction

- Care Partner burden
- Review of original STAR-Caregivers trials
- Brief overview of our intervention and protocol
- Issues
    - Automated identification
    - Assessing eligibility
    - Consent
    - Pragmatic collection of measures and outcomes

Motivation for the STAR-VTF study

- Alzheimer’s Disease and related dementias (ADRD) are associated with behavioral and psychological symptoms

- Persons living with dementia (PLWD) are often prescribed antipsychotic medications for these symptoms

Choosing Wisely

An initiative of the ABIM Foundation

American Geriatrics Society

AGS Geriatrics Healthcare Professionals

Leading Change. Improving Care for Older Adults.

Five Things Physicians and Patients Should Question

Choosing Wisely

An initiative of the ABIM Foundation

American Psychiatric Association

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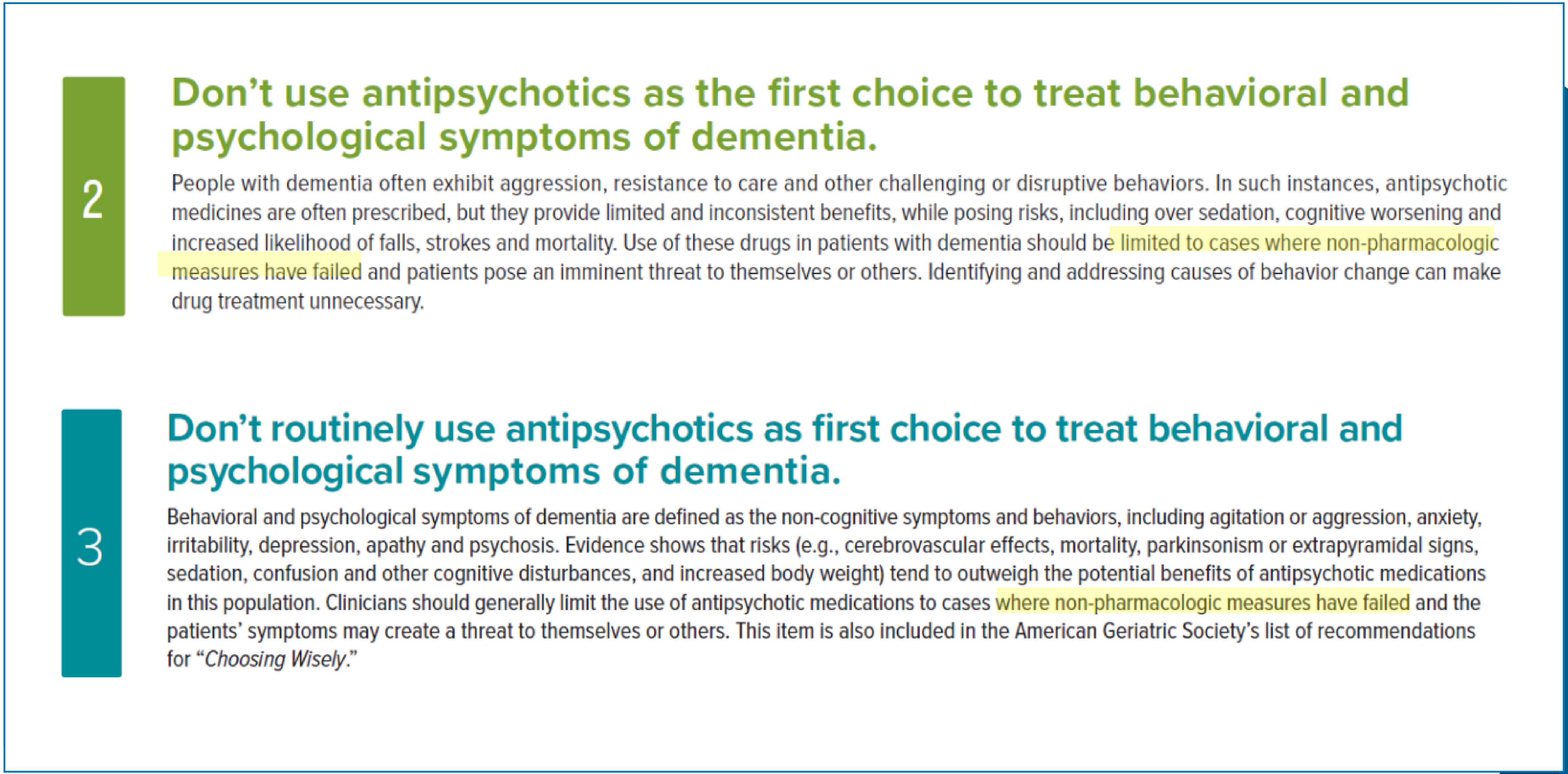
Five Things Physicians and Patients Should Question



2

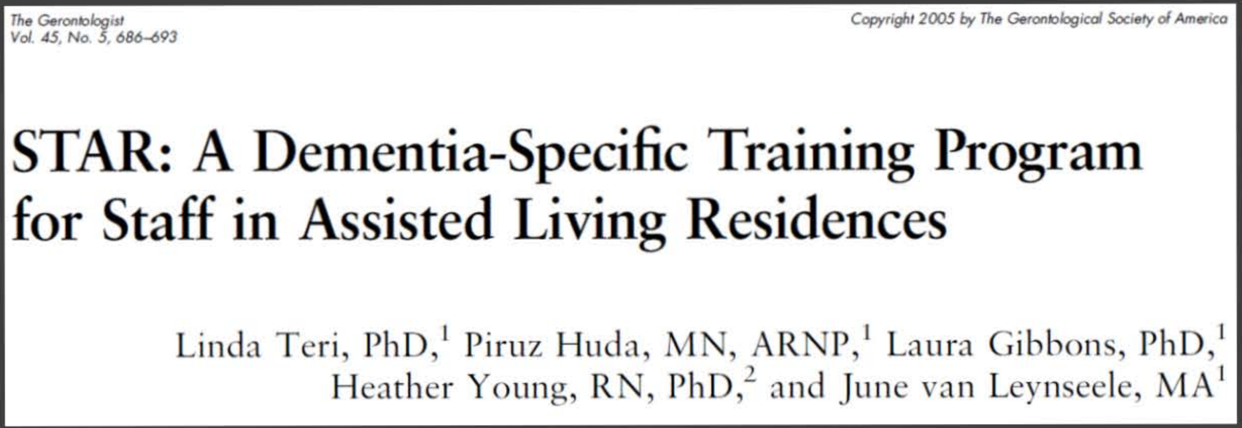
Don’t use antipsychotics as the first choice to treat behavioral and psychological symptoms of dementia.

People with dementia often exhibit aggression, resistance to care and other challenging or disruptive behaviors. In such instances, antipsychotic medicines are often prescribed, but they provide limited and inconsistent benefits, while posing risks, including over sedation, cognitive worsening and increased likelihood of falls, strokes and mortality. Use of these drugs in patients with dementia should be limited to cases where non-pharmacologic measures have failed and patients pose an imminent threat to themselves or others. Identifying and addressing causes of behavior change can make drug treatment unnecessary.

3

Don’t routinely use antipsychotics as first choice to treat behavioral and psychological symptoms of dementia.

Behavioral and psychological symptoms of dementia are defined as the non-cognitive symptoms and behaviors, including agitation or aggression, anxiety, irritability, depression, apathy and psychosis. Evidence shows that risks (e.g., cerebrovascular effects, mortality, parkinsonism or extrapyramidal signs, sedation, confusion and other cognitive disturbances, and increased body weight) tend to outweigh the potential benefits of antipsychotic medications in this population. Clinicians should generally limit the use of antipsychotic medications to cases where non-pharmacologic measures have failed and the patients’ symptoms may create a threat to themselves or others. This item is also included in the American Geriatric Society’s list of recommendations for “*Choosing Wisely*.”



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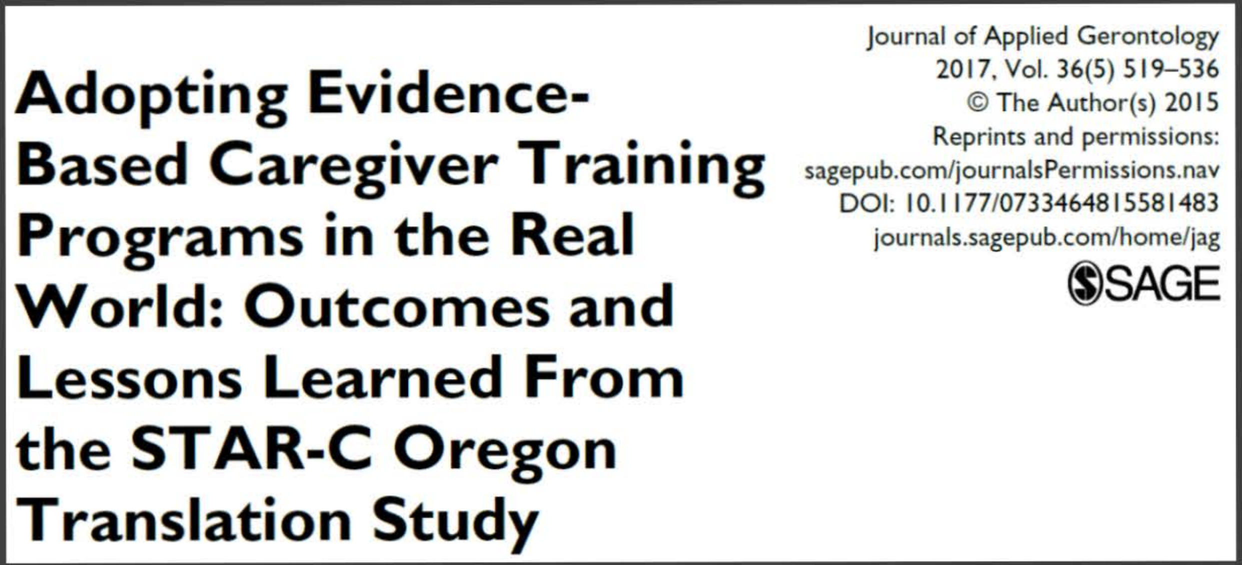
STAR: A Dementia-Specific Training Program for Staff in Assisted Living Residences

Linda Teri, PhD,[1] Piruz Huda, MN, ARNP,[1] Laura Gibbons, PhD,[1]
Heather Young, RN, PhD,[2] and June van Leynseele, MA[1]



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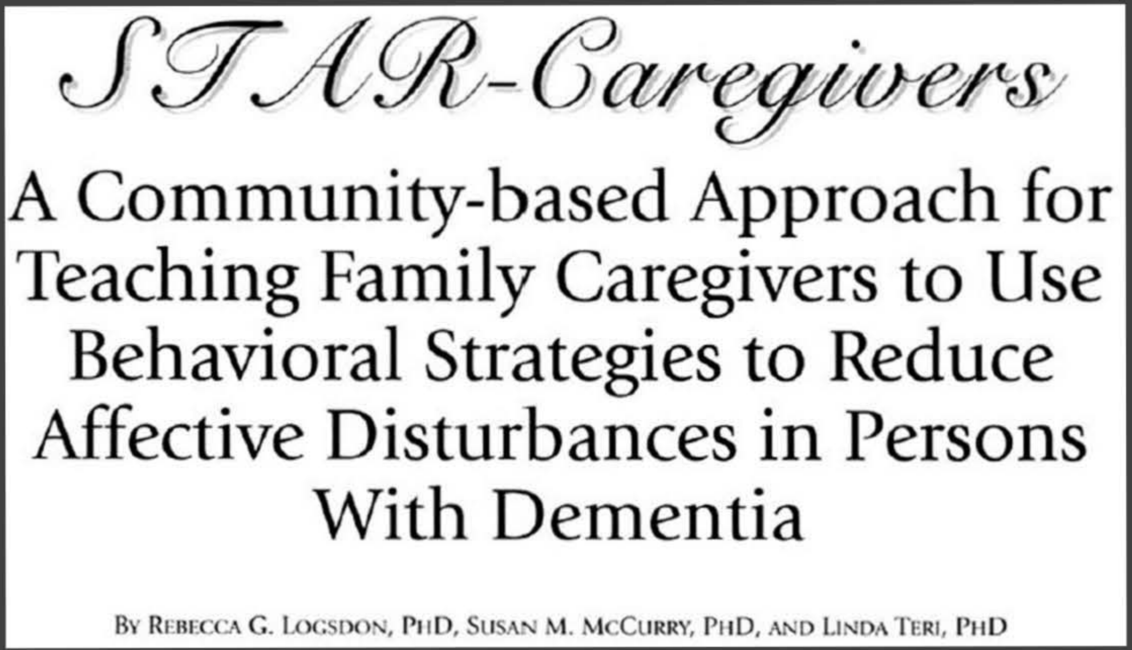
Adopting Evidence-Based Caregiver Training Programs in the Real World: Outcomes and Lessons Learned From the STAR-C Oregon Translation Study



STAR-Caregivers

A Community-based Approach for Teaching Family Caregivers to Use Behavioral Strategies to Reduce Affective Disturbances in Persons With Dementia

BY REBECCA G. LOGSDON, PHD, SUSAN M. MCCURRY, PHD, AND LINDA TERI, PHD

Compared to routine medical care, care partners experienced reduced

- Depression
- Reactivity to PLWD behaviors
- Frequency and severity of target behaviors

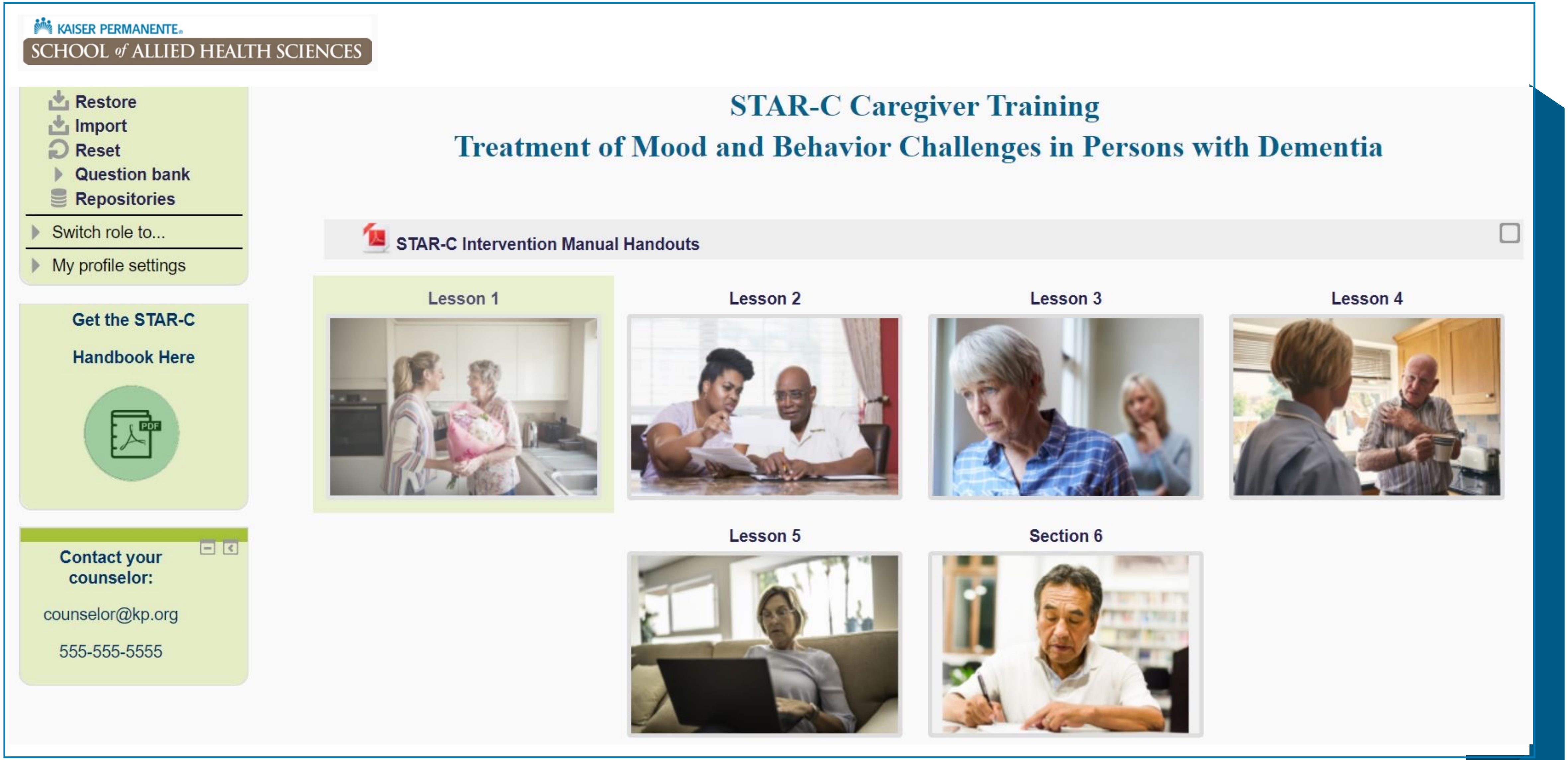
and improved quality of life.

STAR Caregivers Components

- Realistic Expectations
- Practical, effective communication
- Activators, Behaviors, Consequences
  - ABCs
- Pleasant events
- Caregiver self-care

STAR-VTF
Virtual Training & Follow-up

- Scale-up:
- Intervention
  - Online self-learning – 6 modules
  - 6 x 30 min calls with a coach
  - Secure message support – 6 months
- Control
  - Mailed materials
  - Links to Alzheimer’s Association video tutorials
  - No coach



STAR-C Caregiver Training

Treatment of Mood and Behavior Challenges in Persons with Dementia

STAR-C Intervention Manual Handouts

Lesson 1

Lesson 2

Lesson 3

Lesson 4

Lesson 5

Section 6

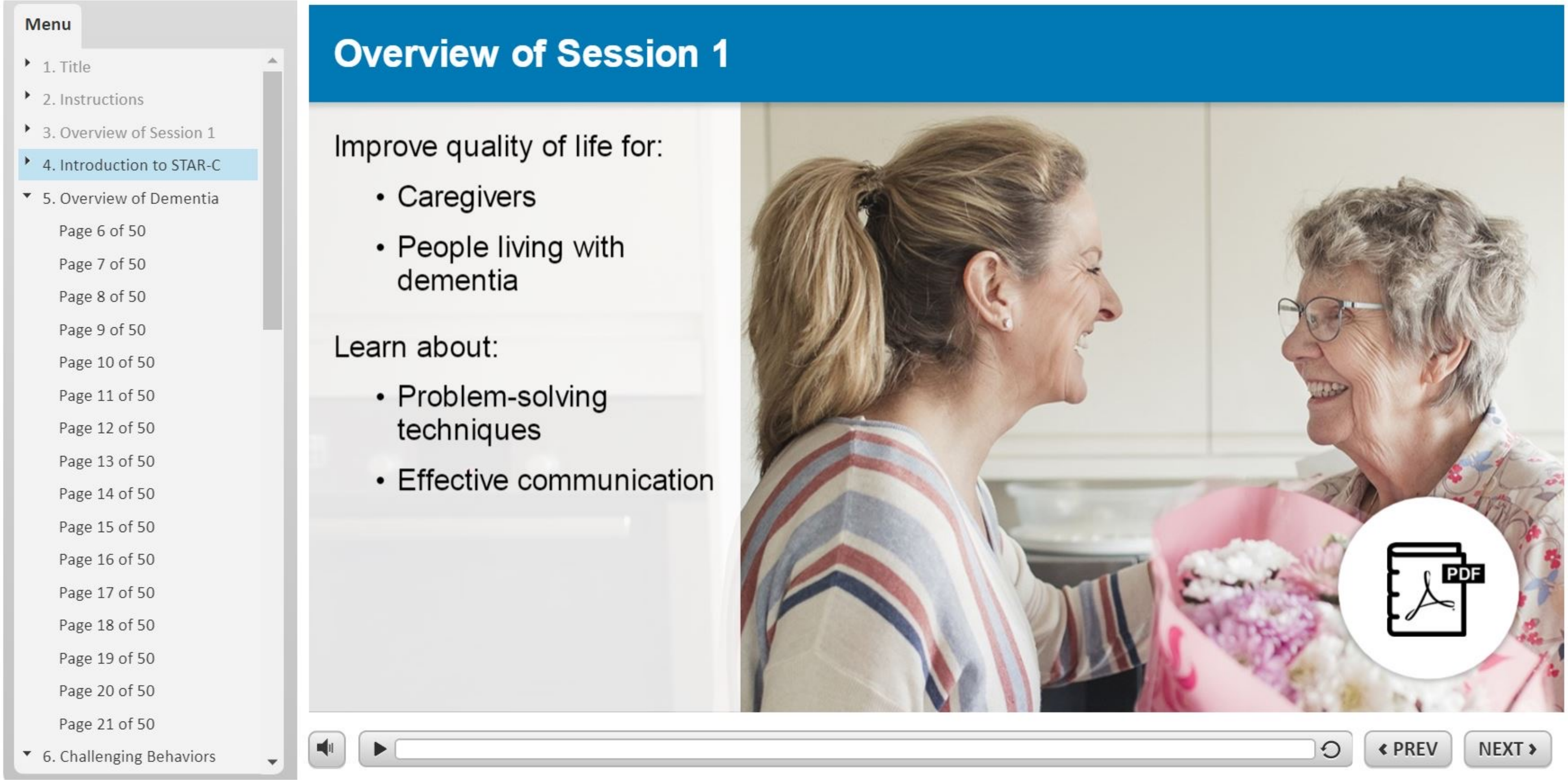
Get the STAR-C

Handbook Here

Contact your counselor:

counselor@kp.org

555-555-5555



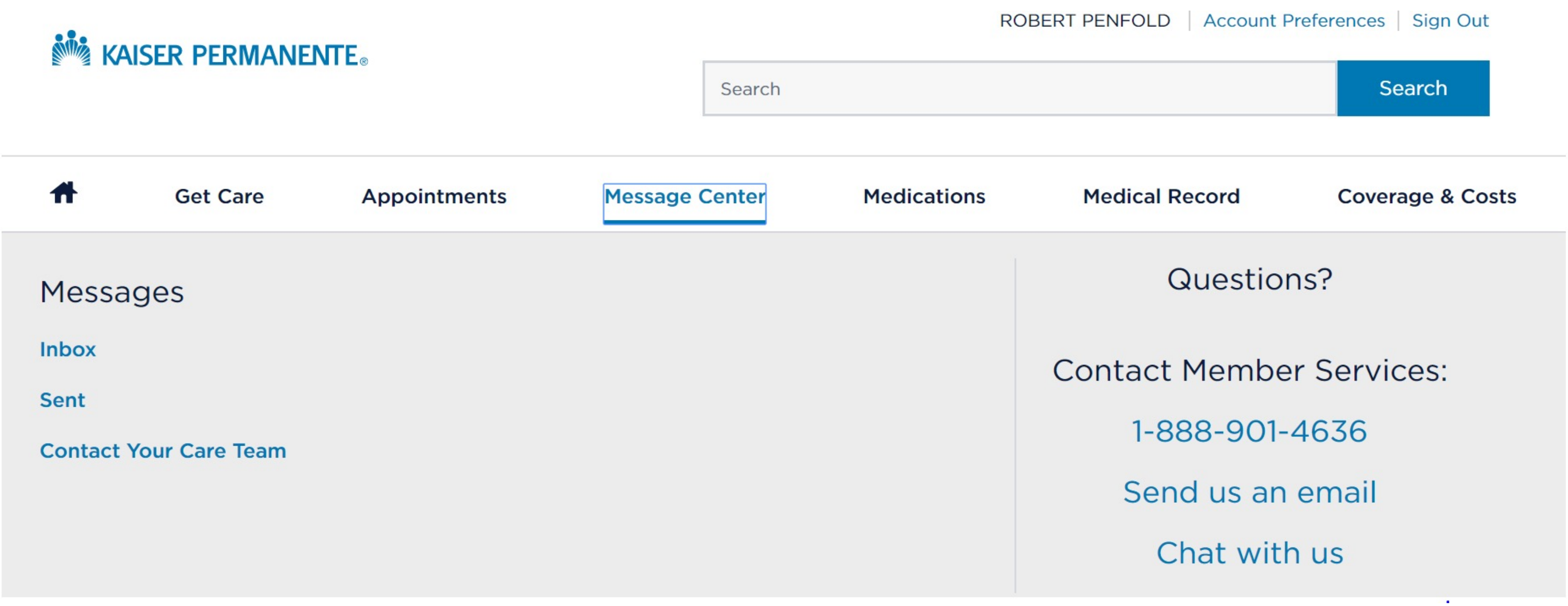
Overview of Session 1

Improve quality of life for:

- Caregivers
- People living with dementia

Learn about:

- Problem-solving techniques
- Effective communication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Account Preferences
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Search
Search
Get Care
Appointments
Message Center
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Medical Record
Coverage & Costs
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Questions?
Contact Member Services:
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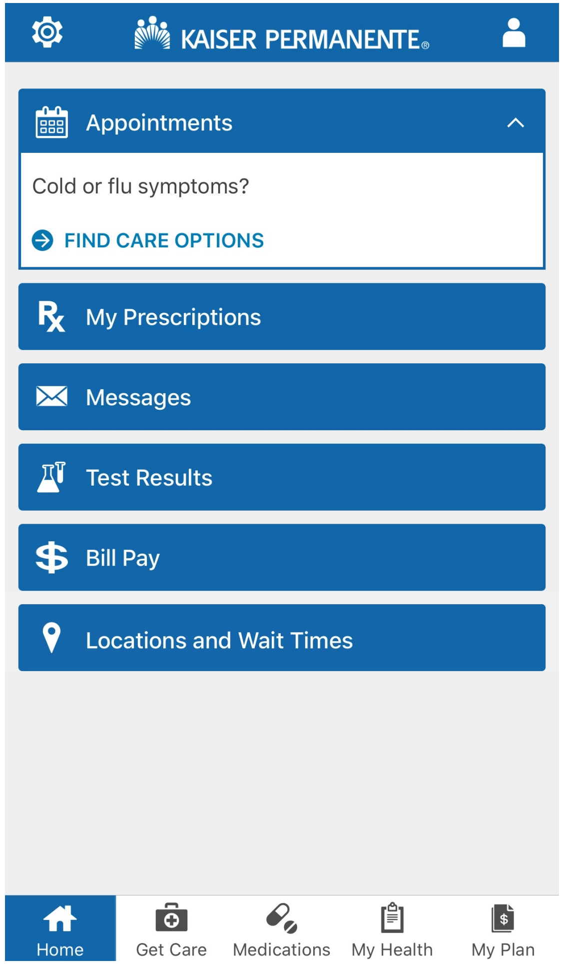
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Appointments
Cold or flu symptoms?
FIND CARE OPTIONS
My Prescriptions
Messages
Test Results
Bill Pay
Locations and Wait Times
Home
Get Care
Medications
My Health
My Plan

Recruitment of 100 dyads

- Automatic PLWD identification
  - Age >= 65
  - Diagnosis of ADRD
  - Recent visit with ADRD Dx code
  - Enrolled for >= 180 days prior
  - Expected to live >= 6 months
  - No psychosis, bipolar disorder Dx

- Caregiver
  - Age >= 21
  - Provides at least 8 hours of care
  - No ADRD diagnosis

Outcomes

- Caregiver
  - Caregiver burden (RMPBC)
  - Kingston Caregiver Stress Scale
  - Caregiver Mastery Scale
  - Depression (PHQ-8) ***

- Person living with dementia (PLWD)
  - Antipsychotic medication fills/refills

- Response rates to measure completion
- Training completion
- Time in motion for coaches (costs)

Pragmatic Trial Issues: Recruitment

- Automated identification
- Virtual Data Warehouse
    - Age, sex, race/ethnicity, Dx, enrollment, exclusion Dx
    - Recent encounter
- Not so automated (chart review, staff message):
    - What is the residential situation?
    - Care partner vs. emergency contact?
    - Who is the DPOA?
    - Hospice
    - Can PLWD Consent for themselves?
    - Other reason(s) to exclude

Pragmatic Trial Issues: Care Partner Outreach

- Warm-up letter addressed to care partner and PLWD
- Telephone screening questions
    - Are you the right care partner?
    - Are you the DPOA?
    - At least 8 hours of care?
    - Telephone dementia screen
- About 50% of care partners are not interested in completing the screening questions when we reach out.

STAR-VTF Experience

Criterion	Percent Excluded
Deceased	1.0
Hospice	2.2
No Dementia Dx	1.3
No care partner	0.6
MD advises to exclude	2.6
Not expected to live >6m	5.1
Refuses eligibility screen	51.0

Pragmatic Trial Issues: Consent

- Need consent/assent from the PLWD because using medical records downstream
- Can the PLWD consent on “good days”?
- What if care partner is not the DPOA?
  - First consent the DPOA on behalf of the PWD

Pragmatic Trial Issues: Outcomes

- Ideally collected in EHR
    - Spent months trying to implement
    - Ultimately created a REDCap survey

- “Standard of care” is to note care partner issues in the PLWD chart.
    - Cannot do this in research
    - Privacy
    - Legal disputes (e.g., adult children)
    - Treatment confusion
        - e.g., PLWD vs CG PHQ-9

Pragmatic Trial Issues: EHR Governance

- What about a caregiver Epic profile?
  - About 50% of caregivers are not KPWA members
- Need to develop a solution for documenting caregiver issues
  - Making all the decisions for PLWD
  - Caregiver functioning directly impacts PWD medically, QOL
  - Caregiver module?

Conclusion – Lessons Learned on STAR-VTF So Far

Need to Act

Scalable, family-centered programs like STAR-C need legal and informatics support for pragmatic implementation

Antipsychotics Still Common

Despite the Choosing Wisely Guidelines, prescribing of antipsychotics is surprisingly common

(7-10 new starts per week at KPWA)

Elders are Going Virtual

Care partners are increasingly using patient portals and becoming facile in internet-based learning and digital communication with clinicians.

Pragmatic Recruitment

Difficult to accurately identify caregivers with existing automated data.

"Pragmatic" Consent

Diminished capacity and divided responsibility make consent difficult from a pragmatic point of view.

Pragmatic Measurement

Until governance issues are resolved, pragmatic outcomes collection is not possible. We are stuck with parallel data collection platforms.

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THANK YOU!!

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Mindfulness-Based Dementia Care Pilot: *A New Approach to Collect Care Partner Outcomes in an ePCT*

Leah R. Hanson, PhD
Senior Research Investigator
HealthPartners Institute

Background

- Care Partners (CPs) experience:
- High rates of anxiety and depression
- Increased incidence of chronic conditions (e.g. heart disease, hypertension)

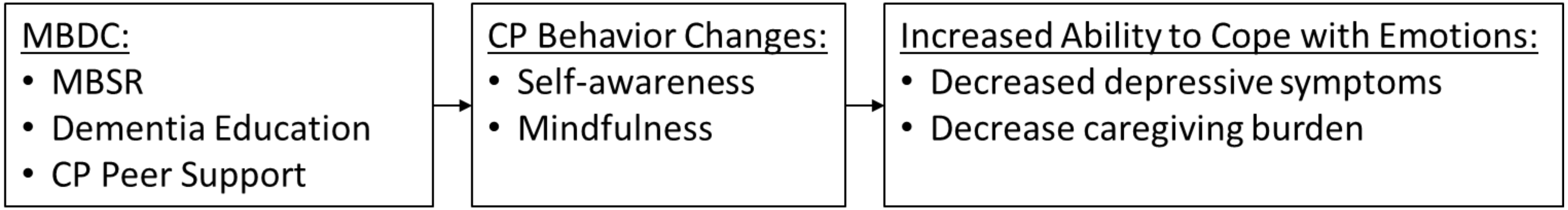
- CPs also have:
- Higher utilization of healthcare services
- Increased depressive symptoms are associated with higher healthcare utilization

Mindfulness Based Stress Reduction (MBSR)

- Group-based program that is both education and skills-based
- Uses mindfulness meditation practices to help people better cope with their emotions
- Studied in a wide range of conditions including chronic pain, fibromyalgia, cancer, anxiety and depression
- Three RCTs in CPs demonstrated lower level of depressive symptoms in MBSR groups compared to active control groups
- Some evidence for improvements in anxiety, stress, and overall wellbeing

Mindfulness Based Dementia Care (MBDC)

- Developed by a community-based non-profit called The Presence Care Project (www.presencecareproject.com)
- A version of MBSR designed specifically for CPs of PLWD
- Participants learn how to incorporate mindfulness practices into day-to-day life as a CP to help cope with the challenges and stresses of dementia care



MBDC:
- MBSR
- Dementia Education
- CP Peer Support

CP Behavior Changes:
- Self-awareness
- Mindfulness

Increased Ability to Cope with Emotions:
- Decreased depressive symptoms
- Decrease caregiving burden

MBDC – Current Landscape

- The Presence Care Project trains and certifies instructors
- Courses are offered at four memory care clinics in the US and >150 CPs have completed the program
- Health care settings have typically supported the cost of instruction through clinic operational funds or philanthropy (~$4k)
- A limited amount of preliminary pre-post data shows a promising trend of decreased depressive symptoms and caregiver burden
- CPs have provided overwhelmingly positive feedback
- No reported adverse events related to participation

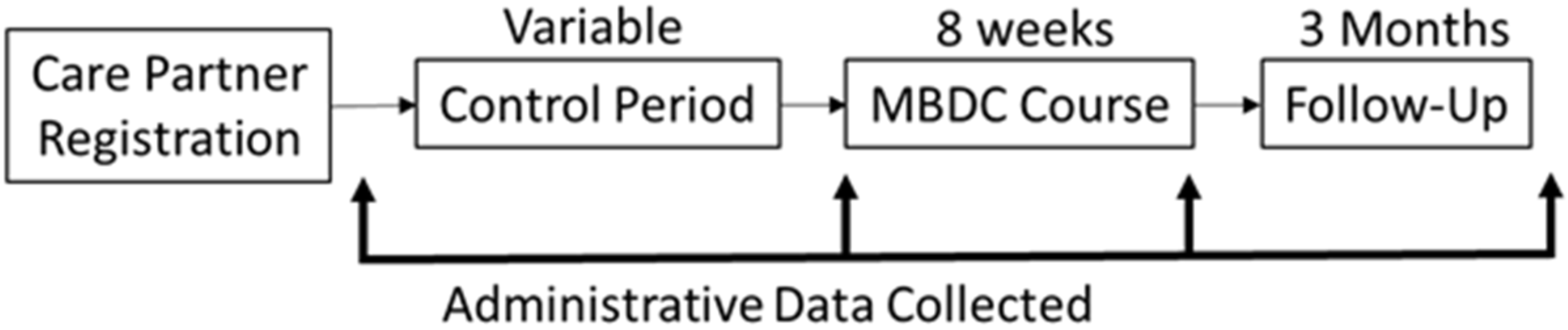
Study Aims

Overall goal is to test the feasibility of implementing MBDC to guide subsequent evaluation of effectiveness of the MBDC intervention in a full-scale ePCT

- Aim 1: To assess the feasibility, acceptability, and fidelity of implementation of the MBDC program
- Aim 2: To determine the feasibility of obtaining clinical outcome measures (symptoms of depression and burden)
- Aim 3: To explore the feasibility of obtaining online consent for research access to CP and PLWD healthcare utilization records

Study Design

- Stepped wedge design
- At enrollment CPs will select two class options (days/times) and be randomly enrolled in one of the two selected
- Administrative data collected will be used as pragmatic outcomes



Recruitment

- CPs will be recruited from 3 health care settings:
  - HealthPartners Center for Memory & Aging in St. Paul, MN
  - Ray Dolby Brain Health Center at California Pacific Medical Center, a Sutter Health affiliate in San Francisco, CA
  - University of Michigan – Alzheimer’s Disease Research Center in Ann Arbor, MI
- MBDC courses are ongoing, with systems in place at each site for recruitment, and classes being held virtually due to the COVID-19 pandemic
- Pilot of targeted mailing to PLWD of diverse backgrounds from HealthPartners electronic health records and healthcare claims data

Intervention

- MBDC courses will be taught in groups via web-based video calls by Presence Care certified instructors
- Eight courses will be taught over 9 months
- With 15 participants anticipated per course, a total of up to 120 CPs will be enrolled

MBDC Class Topics	
CLASS	TOPIC
1	
2	
3	Living Grief & Self-Compassion
4	Coming to Our Senses
5	Every Day Communication
6	Being with Difficulty
7	Caring for Yourself
8	

Pragmatic Outcomes

- KEY = Develop and implement a permanent centralized process for MBDC class registration on the Presence Care website
- Enable the collection of common administrative data across all sites for long-term use
  - Questionnaires with clinical outcomes
- REDCap (a secure web-based system) will be used for data collection

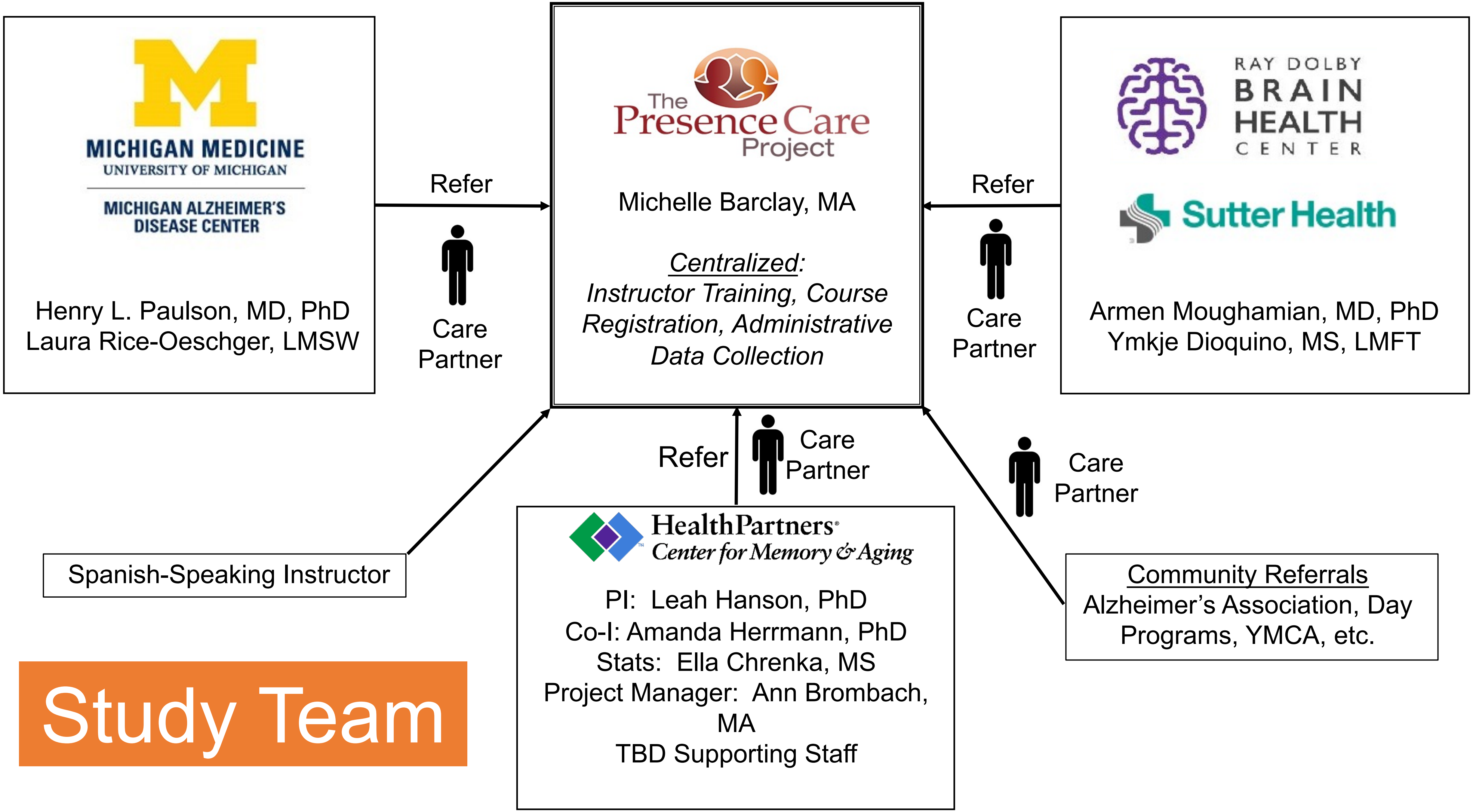
Data Forms	Time Point Collected	Entered By	Detailed Data Elements
Class Registration		CP	Name, Address, Date of Birth, Phone Number, Referral Source, Race, Ethnicity, Language, Education, Length of Caregiving, Relationship to PLWD, Preferred Classes
		CP (about PLWD)	Name, Type of Residence, Date of Birth, Dementia Diagnosis
Questionnaire 1,2, 3,4		CP	Clinical Outcome Scales: Depressive Symptoms (CES-D-10) and Caregiver Burden (6-item Zarit Burden Interview, ZBI-6)
			CP Behavior Change Measures (only for pilot): Self-Compassion (The State Self-Compassion Scale Short Form, SSCS-S) and Mindfulness (The 5-Item Mindful Attention Awareness Scale – State)

Data Forms	Time Point Collected	Entered By	Detailed Data Elements
Questionnaire 3 only	Week after MBDC	CP	Course Satisfaction, Willingness to offer consent to access healthcare claims for research (CP and PLWD, pilot only)
Presence Care	Throughout MDBC sessions	Instructor	Class assigned, dates of classes, attendance, mode of attendance (video/phone), make up class completed, instructor name
Automated Information	Throughout MBDC sessions	REDCap	Date of Registration, Date of Questionnaires Completion, Mode of Registration and Collection of Data
Post-Implementation Data	Following completion of all MBDC sessions	Clinic Directors	Healthcare Setting Stakeholder Interviews of Memory Clinic Directors

Overcoming Challenges

- Centralize data collection through the non-profit community organization that trains and certifies MBDC instructors across the nation
- The upgraded infrastructure will enable the collection of common administrative data, including questionnaires with clinical outcomes, for long-term use in evaluation of the program
- Leverages an existing and trusted partnership between PI and instructors at three health care settings

Study Team



The Presence Care Project

Michelle Barclay, MA

Centralized:
Instructor Training, Course Registration, Administrative Data Collection

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN
MICHIGAN ALZHEIMER'S DISEASE CENTER

Henry L. Paulson, MD, PhD
Laura Rice-Oeschger, LMSW

RAY DOLBY BRAIN HEALTH CENTER
Sutter Health

Armen Moughamian, MD, PhD
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HealthPartners®
Center for Memory & Aging

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Project Manager: Ann Brombach, MA
TBD Supporting Staff

Spanish-Speaking Instructor

Community Referrals
Alzheimer's Association, Day Programs, YMCA, etc.

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Overcoming Regulatory Hurdles

Richard H. Fortinsky, PhD
Professor and Health Net, Inc. Endowed Chair in Geriatrics and Gerontology
UConn Center on Aging | UConn Health

Learning Objectives

Upon completion of this presentation, you should be able to:

- Explain how issues involving consent and HIPAA authorization could be addressed and resolved during the IRB approval process in pragmatic trials compared to more conventional clinical trials.
- Discuss how institutional IRB policies might have to be addressed and resolved when the institutional IRB is not the IRB of record.
- Explain regulatory issues that might arise when using electronic health records to identify and communicate with care partners of patients treated in outpatient settings.

Acknowledgments and Disclosures

- Pilot study funded by the NIA IMPACT Collaboratory
- No financial conflicts to disclose.
- Expert guidance provided by Julie Lima, MPH, PhD, at Brown University School of Public Health, on behalf of the IMPACT Collaboratory, is gratefully acknowledged.
- Additional guidance by Ab Brody, PhD, RN, FAAN, at NYU Rory College of Nursing, on behalf of the IMPACT Collaboratory, is also gratefully acknowledged.

Rationale/Objectives of Pilot Study

- **Rationale:** Efficacious interventions offering meaningful benefits to care partners of older adults with ADRD would be attractive to office-based practitioners if a pragmatic linkage could be made between these interventions and outpatient health care settings.
- **Objectives:**
  - Embed a pragmatic care partner identification and invitation strategy into the daily workflow of outpatient centers, enabling care partners to participate in online dementia care education programs, specifically Tele-Savvy and Caregiving During Crisis.
  - Evaluate Tele-Savvy effectiveness, compared to Caregiving During Crisis, when offered pragmatically.
  - Determine viability of routinely collecting and storing care partner outcomes data into electronic health record systems.
  - Evaluate implementation of all the above.

Setting/Population

- **Setting:** Geriatric medicine and dementia care outpatient centers in two health care systems:
  - UConn Health: Geriatrics Associates
  - Emory Healthcare: Integrated Memory Care Clinic

- **Population:** 100 care partners of older adults living with ADRD who are patients in one of the two outpatient care settings.

Interventions

Tele-Savvy:

- 7-week synchronous and asynchronous program for care partners
- Care partners join an on-line class for weekly educational sessions and access Tele-Savvy website resources to help them learn more.
- Topics include dementia symptom management, environmental changes to enhance quality of life for care partner and person living with ADRD, and self-care for the care partner.

Caregiving During Crisis:

- Online, asynchronous, self-guided education course designed to help care partners ensure safety of persons with dementia and themselves during COVID-19 pandemic.
- Topics include strategies for creating safe home space, safely leaving and re-entering the home, safely allowing service personnel into the home, and risk management beyond COVID-19 restrictions.

Outcomes

- **Primary outcome** is self-reported caregiving mastery.
- **Secondary outcomes** are self-reported care partner reactions to memory and behavior problems, and self-reported perceived stress.
- All outcomes used in Tele-Savvy efficacy clinical trial.

Consent and HIPAA Authorization Issues

- In conventional clinical trials, written informed consent for research purposes under the Common Rule and written HIPAA Authorization expected by governing regulatory bodies, whether single IRBs for multi-site trials or institutional IRBs for single-site trials.
- In pragmatic trials embedded within health care systems (HCS), these regulatory expectations could present barriers to successful and efficient recruitment efforts and could lead to diminished enthusiasm among HCS partners.
- In our pilot study, we faced hurdles in having single IRB understand and ultimately approve our request for waiver of consent and full waiver of HIPAA Authorization for care partner at both study sites.

Consent and HIPAA Authorization Issues

- Initially, written informed consent was to be required, then waiver of documentation of consent, and finally waiver of consent was approved.
- We were asked to submit a robust rationale in which we specified:
  - Inclusion of consent would affect the scientific validity of studying a new process for engaging care partners within an HCS setting
  - The proposed interventions for care partners are similar to health education offerings that might be routinely offered by an HCS.
  - These points addressed the critically important regulatory issue of “practicability”: why the research could not be practicably carried out without waiver of consent.

Consent and HIPAA Authorization Issues

- To satisfy other consent waiver-related criteria, we also explained that:
  - the research was no more than minimal risk
  - care partner PHI were collected solely to ensure their outcome data were stored in correct EHR system record
  - care partners would be provided with synopsis of study results in lay language
  - study information sheet would be used in lieu of consent form, with an opt-in or opt-out feature, written without reference to “research” but instead that interventions were offered as programs by the outpatient clinics.

Consent and HIPAA Authorization Issues

- Key features of our request for full HIPAA Waiver of Authorization
  - plan to protect PHI from improper use or disclosure (e.g., identities of care partners who "opt out" will not be known to researchers; clinic staff and providers would invite care partners to join)
  - plan to destroy research identifiers at earliest possible opportunity
  - research identifiers will not be disclosed or used unless required by law or for authorized oversight of study.

Institutional IRB Policies Beyond Single IRBs

- Institutional/Local IRB policies governing use of local EHRs might require additional regulatory considerations when studying care partners of patients registered with the HCS.
- Proxy records for care partners vs. proxy access to patient records by care partners and embedding care partner data within patient's record; there are no uniform policies for these issues across all HCS.
- Degree to which EHR programmers must interface with the local office of human subjects protection during process of enhancing systems to enable electronic communication with care partners and capture of care partner data likely varies across HCS.

Regulatory Issues Regarding Care Partners When Using Electronic Health Records

- Regulatory issues that might arise when planning pragmatic trials with care partners of persons with ADRD:
  - At what point can members of the research team initiate contact with care partners who are initially identified via EHRs?
  - To what extent and how can care partner data stored in EHRs be safely and confidentially extracted for purposes of using these data for research purposes?
  - To what extent can care partner data stored in patient or proxy records be shared among health care providers?
  - What rights do care partners have regarding their data stored in EHRs?
  - Do any special regulatory issues arise if care partners are also patients at the HCS?

Study Team Members

- University of Connecticut
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  - Tori Pascoe, BS
  - Lisa Kenyon-Pesce, MPH
  - Alis Ohlheiser, MS

- Emory University
  - Kenneth Hepburn, PhD
  - Carolyn Clevenger, DNP, RN, GNP-BC
  - Melinda Higgins, PhD
  - Laura Medders, LCSW

Thank you for your attention

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Questions?

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