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TRANSFORMING DEMENTIA CARE

IMBEDDED PRAGMATIC AD/ADRD
CLINICAL TRIALS (IMPACT)

IMPACT Collaboratory Projects

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Pilot Grants Program

Implementation of Care Ecosystem Training Model for Individuals with Dementia in a High Risk, Integrated Care Management Program (CRESCENT)

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ClinicalTrials.gov Identifier: NCT04556097



OBJECTIVE: To conduct a pilot study for an ePCT to evaluate feasibility of implementing and measuring outcomes of an adapted Care Ecosystem training model for primary care nurse managers serving a diverse panel of people living with dementia (PLWD) and care partners in a large healthcare system.



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, randomized pilot study
- Primary care practices participating in the Mass General Brigham Integrated Care Management Program in Boston, MA
- 30 nurse care managers caring for PLWD and care partners



INTERVENTION AND IMPLEMENTATION:

- Nurse care managers engaged in adaptation of the Care Ecosystem protocol to align with nurse manager scope of practice, knowledge, and skills
- Provide training, protocols, and checklists for CareEco intervention execution
- Offer regular office hours to discuss patient challenges and address knowledge gaps



RELEVANCE: This pilot study will set the foundation for a full-scale multi-site Stage IV ePCT evaluating the effectiveness of the adapted CareEcosystem training model to reduce ED visits and improve health outcomes for PLWD when integrated into primary care practices. This work has the potential to reduce unnecessary health care use while improving quality of care for PLWD.



MEASURES:

Implementation evaluation endpoints:

- % of nurses completing training
- % of nurse managers using protocols
- % of nurse managers attending office hours

Primary clinical outcome:

- Change in emergency department (ED) visits per member per month from 12 months prior to 6 months after the adapted Care Ecosystem training



RESULTS:

- Fidelity analysis: Intervention nurses more likely to address topics covered by training, document caregiver well-being, provide community resources, and identify behavioral/safety issues.
- Intent-to-treat analysis: Non-significant 39% rate reduction in ED visits for intervention patients relative to controls (difference-in-differences rate ratio: 0.61, $p=0.15$)

Pathway to Detection & Differentiation of Delirium & Dementia in Emergency Department

Ula Hwang, MD, MPH | Yale University School of Medicine

ClinicalTrials.gov Identifier: NCT04846322



OBJECTIVE: To conduct a pilot study for an ePCT to evaluate feasibility of an intervention that embeds cognitive impairment (CI) screening into routine delirium assessments to identify and refer emergency department (ED) patients with suspected (undiagnosed) dementia.



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- ED and outpatient setting (geriatric assessment center or clinic) in New Haven and Chicago
- 100 community-dwelling patients age ≥ 65 , referred from ED for outpatient evaluation



INTERVENTION AND IMPLEMENTATION:

- 3-step embedded intervention consisting of:
 - Screening for memory or thinking problems paired to routine ED delirium screening in electronic health records
 - Referral process for outpatient assessment for discharged ED patients suspected of undiagnosed CI or dementia
 - Training of ED clinicians on delirium and CI screening and referral process



RELEVANCE: This pilot study will set the foundation for a full-scale Stage IV ePCT evaluating the effectiveness of embedding cognitive impairment screening and into routine delirium assessments and referral for outpatient assessment in EDs. Findings demonstrate the ED is a feasible setting for accurate screening, identification of older patients with suspected CI, and referral for subsequent evaluation.



MEASURES:

Implementation evaluation endpoints:

- % of patient referral based on screens vs. clinician gestalt
- % of outpatient appointments scheduled
- % of outpatient appointments completed

Primary clinical outcome:

- ED patients suspected of CI referred for outpatient evaluation



RESULTS:

- 100 patients referred from ED for outpatient evaluation
- Mean age 82.0 years (SD 7.8), 63% female, 29% Black, 9% Hispanic
- 21% presented to ED with chief complaint of altered mental status; 20% had previously known diagnoses of dementia
 - 26 (26%) scheduled outpatient appointments.
 - 19 (19%) completed outpatient evaluations
 - 15 (79%) had outpatient diagnoses confirming dementia, cognitive impairment, memory loss, Alzheimer's, probable dementia, or mild cognitive impairment

Implementation of a Telehealth Palliative Care Model for Persons Living with Dementia

Joan Carpenter, PhD, CRNP, ACHPN | University of Maryland School of Nursing



OBJECTIVE: To conduct a study in preparation for pilot ePCT to assess the implementation outcomes including acceptability, appropriateness, and fidelity of the telehealth palliative care consultation in post-acute care (PCC-PAC) intervention in people living with dementia (PLWD) and their care partners.



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, preparatory pilot study
- 1 nursing home (NH) in the mid-Atlantic US
- ~30 NH residents living with dementia and their care partners admitted for post-acute care after recent hospitalization
- ~10 stakeholders



INTERVENTION AND IMPLEMENTATION:

- PCC-PAC is a multi-component non-pharmacologic, palliative specialist-delivered intervention designed to meet the needs of PLWD receiving post-acute care in NHs
- Specialty palliative care providers and NH clinicians will be oriented to deliver PCC-PAC to eligible residents/care partners



MEASURES:

Implementation evaluation endpoints:

- Delivery of PPC-PAC to 30 eligible residents/care partners
 - Treatment delivery fidelity
 - Intervention implementation fidelity
- Acceptability and appropriateness of PCC-PAC from semi-structured interviews and focus groups with stakeholders

Primary clinical outcome:

- 30-day hospitalization



RELEVANCE: Embedding complex interventions in NHs is challenging and requires addressing barriers to adopting new practices as well as effective implementation. Findings from this study will inform refinements of telehealth PCC-PAC and prepare the team for testing the PCC-PAC in a large-scale ePCT. This work has the potential to lead to adoption of telehealth delivered palliative care to provide high-quality care for NH residents with dementia.

Pilot Pragmatic Clinical Trial to Embed Tele-Savvy into Health Care Systems

Richard Fortinsky, PhD | University of Connecticut Health Center



OBJECTIVE: To determine feasibility of conducting an ePCT of Tele-Savvy care partner intervention in health care systems; assess implementation of electronic health record (EHR)-based care partner identification and invitation strategy; and determine viability of collecting and storing care partner outcome data in EHR patient portals.



DESIGN, SETTING, AND PARTICIPANTS:

- Pilot study using an individual caregiver-level randomized design
- 2 geriatrics and dementia care outpatient clinics in health care systems in Connecticut and Georgia
- Care partners of older adults living at home with dementia who are patients in the two outpatient care settings



INTERVENTION AND IMPLEMENTATION:

- Interventions: Tele-Savvy and Caregiving During Crisis
- Train clinic-based licensed clinical social workers (LCSW) to facilitate Tele-Savvy synchronous weekly sessions and guide care partners to asynchronous materials between weekly sessions
- Embed care partner identification and invitation strategy into daily clinic workflow



MEASURES:

Implementation evaluation endpoints:

- % complete Tele-Savvy program with fidelity to 3 successive care partner cohorts at each health care system
- Clinic staff acceptability of willingness to adopt Tele-Savvy as a routinely-offered care partner dementia care program
- Successful build-out of EHR system to accommodate care partner-clinic communication and collection and storage of clinically-relevant care partner-reported outcome data

Primary clinical outcome:

- Self-reported care partner mastery

Secondary clinical outcomes:

- Self-reported care partner reactions to memory and behavior problems
- Self-reported care partner perceived stress



RELEVANCE: This pilot study will inform design of a full-scale ePCT evaluating capacity of geriatrics and dementia care outpatient clinics to offer Tele-Savvy to care partners, and to routinely store care partner outcome data in EHR systems. This work has the potential to make Tele-Savvy and other educational and skill-building programs widely available to care partners of older adults living with dementia.

Using Telemedicine to Improve Engagement in Advance Care Planning in Patients with Cognitive Impairment or Unrecognized Dementia

Jennifer Gabbard, MD | Wake Forest University School of Medicine

ClinicalTrials.gov Identifier: NCT04912245



OBJECTIVE: To conduct a pilot study for an ePCT to evaluate the reach and adoption of Tele-Voice, a pragmatic telemedicine advance care planning (ACP) intervention embedded in outpatient primary care for people living with cognitive impairment (PLCI).



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- 7 primary care practices in North Carolina
- Community-dwelling PLCI age ≥ 65 with decision-making capacity and their care partners



INTERVENTION AND IMPLEMENTATION:

- Tele-Voice is a telemedicine ACP intervention to assist PLCI to discuss current goals, values, medical preferences, appoint a surrogate, review disease understanding, and document wishes within the EHR
- Conducted via video or telephone (per patient preference) in outpatient primary care
- ACP is documented in EHR using ACPWise



RELEVANCE: This pilot study will set the foundation for a full-scale Stage IV ePCT evaluating the effectiveness of Tele-Voice to promote ACP discussions and documentation for PLCI in diverse primary care settings. This work has the potential to enhance primary care providers ability to sustainably deliver high-quality, patient-centered care.



MEASURES:

Implementation evaluation endpoints:

- % of patients and care partners who agreed to participate
- % of patients and care partners who completed ACP telehealth intervention
- Satisfaction, acceptability, and appropriateness

Primary clinical outcome:

- Number of ACP discussions documented within EHR



RESULTS:

- 152 (71%) of 213 eligible patients and care partners opted in; 72% female, 17% non-white, and 5% Hispanic
- 111 (73%) of enrolled patients and care partners completed the intervention
- 100% had documented ACP and 96% had high-quality ACP

ALIGN: Aligning Medications with What Matters Most

Ariel Green, MD, MPH, PhD | Johns Hopkins University School of Medicine

ClinicalTrials.gov Identifier: NCT04938648



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate an intervention (ALIGN) in which an embedded clinical pharmacist makes deprescribing recommendations to the primary care provider (PCP) for people living with dementia (PLWD).



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, randomized pilot study
- Primary care practices in 2 health care systems in Maryland and Colorado
- PLWD and care partner dyads. PLWD on ≥ 5 medications and ≥ 1 clinic in past year identified in electronic health records (EHR)



INTERVENTION AND IMPLEMENTATION:

- ALIGN is a telehealth visit with pharmacist to discuss benefits/harms of medications with dyads in context with goals of care
- Deprescribing educational materials to activate care partner
- Pharmacist provides tailored deprescribing recommendations to PCP



RELEVANCE: This pilot study will set the foundation for a full-scale Stage IV ePCT evaluating the effectiveness of ALIGN to reduce medication regimen complexity for PLWD diverse primary care settings. This work has the potential to optimize prescribing and improve outcomes for PLWD and their caregivers in the primary care setting.



MEASURES:

Implementation evaluation endpoints:

- % of dyads that opt out
- % of pharmacist messages to PCP that receive a response
- % of dyads who complete 2/2 pharmacist phone calls

Primary clinical outcome:

- Change in Patient-level Medication Regimen Complexity Index over 3 months ascertained from EHR



RESULTS:

- 69 dyads (138 participants) enrolled; 48% female, 45% non-White and 12% Hispanic
- 31% of dyads approached opted out; 79% randomized to intervention and 80% randomized to control group received the intervention
- PCPs responded to 82% of pharmacists' recommendations on first outreach and agreed with 84% of their recommendations



Cognitive Stimulation Therapy for Dementia: A Two-Armed Pragmatic Trial

Michael Lepore, PhD | University of Maryland School of Nursing



OBJECTIVE: To determine the feasibility of conducting an ePCT of physician referral for Virtual Cognitive Stimulation Therapy (V-CST) delivered by a community-based organization to people living with dementia, and to assess the feasibility of collecting outcome measures from electronic health records (EHR).



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, pilot trial
- Physicians at two academic health care systems in Connecticut refer patients with dementia to one community-based organization that delivers V-CST
- 168 people with mild to moderate dementia who are patients at an academic health care system



INTERVENTION AND IMPLEMENTATION:

- Physician referral for V-CST
- V-CST is a group therapy delivered by a community-based organization over 14 core sessions on virtual meeting platform



MEASURES:

Implementation evaluation endpoints:

- Pre V-CST Data Screening: identify eligible patients from EHR
- V-CST Enrollment: determine which referred patients enroll
- V-CST Sessions: assess attendance, attrition, adverse events
- Post V-CST Data Screening: collect cognitive screening scores from EHR

Primary clinical outcome:

- Change in cognition from pre to post V-CST per EHR



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating the effectiveness of V-CST for reducing cognitive decline in real-life routine practice conditions. This work has the potential to lead to the adoption of V-CST referral by physicians as an approach to providing therapy to reduce cognitive decline among people living with mild to moderate dementia.

Deprescribing of Diabetes Treatment Regimens in Long Term Care Residents with ADRD

Medha Munshi, MD | Joslin Diabetes Center, Harvard Medical School



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate the implementation of a clinician-focused diabetic management educational intervention for diabetic residents with dementia in long-term care (LTC) facilities, and to assess collection of clinical outcomes. This pilot study will also validate the clinical outcomes obtained from the electronic health record (EHR) against direct continuous glucose monitoring.



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- 6 LTC facilities in Michigan and Ohio
- LTC facility clinicians will receive intervention
- Subset of LTC residents with diabetes and dementia will wear continuous glucose monitor to validate outcomes from EHR



INTERVENTION AND IMPLEMENTATION:

- STRIDE (Simplification of Treatment Regimen and Individualized Diabetes Education) is directed toward LTC clinicians
 - Consists of webinars, a tool-kit with deprescribing algorithms and educational materials, and monthly tele-mentoring sessions



MEASURES:

Implementation evaluation endpoints:

- Using Acceptability of Intervention Measure (AIM) to assess:
 - Acceptability: extent to which the program is agreeable to LTC staff
 - Appropriateness: extent to which the program is suitable for a particular purpose (i.e., to improve the frequency at which LTC staff attempt diabetes medication regimen deprescribing)
- Using Feasibility of Intervention Measure (FIM) to assess:
 - Extent to which the program is practical at the LTC facility level

Primary clinical outcome:

- Change in proportion of LTC residents with diabetes and dementia prescribed high risk diabetes medications (e.g., sulfonylureas) from before to 6 months after educational intervention



RELEVANCE: This pilot study will set the foundation for a large-scale ePCT of the STRIDE intervention to improve management of LTC residents with diabetes and dementia. This work has the potential to promote the reduction of common but preventable medication-related adverse events among high-risk LTC residents with diabetes and dementia.



Patient Priorities Care for Hispanics with Dementia (PPC-HD)

Aanand Naik, MD & Rafael Samper-Ternent, MD, PhD | University of Texas School of Public Health



OBJECTIVE: To conduct a study to adapt the Patient Priorities Care (PPC) approach for older Hispanics with multiple chronic conditions (MCC) and dementia and pilot test its implementation in an outpatient clinic setting in preparation for an ePCT to evaluate the effectiveness of PPC in this population.



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, preparatory pilot study
- Community-based, geriatric outpatient clinic serving older adults in Galveston, Texas
- Community-dwelling Hispanic adults living with MCC and dementia and their family care partners



INTERVENTION AND IMPLEMENTATION:

- The PPC approach helps older adults with MCC identify their health priorities and work with their primary care providers (PCP) to align the care they received with what matters most to them
- PPC has been culturally tailored for Hispanics and consists of two steps: 1) a health priorities identification step, conducted by anyone trained in PPC; and 2) a care alignment step, conducted by a PCP



MEASURES:

Implementation evaluation endpoints:

- Completion of both steps of the PPC approach in > 80% of study participants
- Documentation of patients' health priorities in electronic health records (EHR) of 100% of participants
- Acceptability and ease of use of the PPC approach reported by Hispanic patients and their care partners and PCP

Primary clinical outcome:

- Documentation of care alignment attempts in EHR by PCPs in > 80% of EHR



RELEVANCE: This study will set the foundation for a full-scale ePCT evaluating the impact of PPC in reducing treatment burden and improving communication between Hispanic patients and their PCP. This work has the potential to reduce care burden and improve satisfaction with care received by Hispanics with MCC and their care partners.

ADVANCE-PC: Testing Critical Components for a Trial of Advance Care Planning in Primary Care for Dementia

Annette M. Totten, PhD, MPA | Oregon Health & Science University



OBJECTIVE: To determine the feasibility of two key potential components for an ePCT by evaluating the effectiveness of a technology-based tele-mentoring model, the ADVANCE-PC program, to improve advance care planning (ACP) in primary care clinics for people living with dementia (PLWD).



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- 6 primary care clinics in two Practice-Based Research Networks (PBRNs) within Meta-LARC consortium
- Primary care clinicians caring for PLWD and their families



INTERVENTION AND IMPLEMENTATION:

- Adapt the Serious Illness Care Program (SICP), an established ACP program, for use with PLWD and families by primary care practices
- Finalize ADVANCE-PC: a hybrid communications/technical assistance program to support implementation of SICP
- Deliver ADVANCE-PC using remote technology (ECHO) to primary care providers from different clinics and networks
- Supplement ECHO with practice facilitation



MEASURES:

Implementation evaluation endpoints:

- Creation of ECHO curriculum and practice facilitation structure
- Number of clinics recruited
- Number of clinicians enrolled
- % participating in ECHO and intersession activities

Primary clinical outcome:

- Clinicians report engaging PLWD/families in ACP

Secondary clinical outcomes:

- Clinics report of: Number of PWLD in panel; Number of PWLD and families engaged in ACP during pilot period



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating the effectiveness of ADVANCE-PC, a dementia specific approach to deliver ACP that uses ECHO to provide training and technical support to multiple clinics in different states/time zones. This work has the potential to assure that ACP becomes routine in primary care for PLWD and their families, thereby promoting alignment of care with their goals and preferences.

Mindfulness-Based Dementia Care Partner Program to Reduce Depressive Symptoms

Leah Hanson, PhD | HealthPartners Institute



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate the implementation of a mindfulness program to reduce stress and symptoms of depression in care partners of people living with dementia (PLWD).



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- 3 memory care clinics located in Minnesota, Michigan, and California
- 120 care partners of PLWD



INTERVENTION AND IMPLEMENTATION:

- 8-week Mindfulness-based Dementia Care (MBDC) Program including virtually-delivered weekly 2-hour classes and a retreat (4 hours)
- Collection of care partner outcomes through an administrative data set



MEASURES:

Implementation evaluation endpoints:

- Participation rate: % of participants who attend the first class
- Completion rate: % of participants attending at least 6 or 9 classes
- Questionnaire response rate: completeness of administrative data for care partner outcomes

Primary clinical outcome:

- Change in Symptoms of Depression (CES-D-10)

Secondary clinical outcomes:

- Change in care partner burden
- Change in self-compassion
- Change in mindful attention awareness



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating the effectiveness of MBDC. This work has the potential to improve the well-being of care partners.



Virtual Training for Latino Caregivers to Manage Symptoms of Dementia

Maggie Ramirez, PhD, MS, MS | University of Washington



OBJECTIVE: To conduct a study in preparation for pilot ePCT to integrate Latino cultural values, beliefs, concerns, and language preference into STAR caregivers virtual training and follow-up (STAR-VTF) intervention content and pilot test the adapted content among Latino care partners to manage behavioral and psychological symptoms of dementia.



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, preparatory pilot study
- Recruiting in community settings in Washington State
- Spanish- and English-speaking care partners of PLWD who self-identify as Hispanic or Latino/a/e/x



INTERVENTION AND IMPLEMENTATION:

- STAR-VTF provides training for care partners to learn how to manage behavioral & psychological symptoms of dementia
- For 6-8 weeks, care partners receive weekly STAR-VTF videos and a weekly check-in phone call from a STAR-VTF coach
- Care partners will receive the STAR-VTF videos with the culturally-adapted content (the coaching component will be part of a future pilot ePCT)



MEASURES:

Implementation evaluation endpoints:

- System usability scale
- STAR-VTF video completion rates
- Care partner satisfaction with cultural adaptations obtained via qualitative interviews

Primary clinical outcome:

- Revised Memory and Problem Behavior Checklist

Secondary clinical outcome:

- Preparedness for Caregiving Scale



RELEVANCE: This study will set the foundation for a pilot ePCT of the full STAR-VTF intervention (video content and coaching). This has the potential to address the important issue of a lack of evidence-based, culturally-competent support for Latino care partners of PLWD to learn to manage behavioral and psychological symptoms of dementia.

Implementation of MIND at Home Program in Primary Care for People Living with Dementia

Elizabeth Ciemins, PhD, MPH, MA | AMGA (American Medical Group Association)



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate the implementation of the MIND-at-Home program into primary care to improve the care of people living with dementia (PLWD).



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, non-randomized pilot study (usual care comparator)
- 3 primary care clinics in 2 geographically and demographically diverse health systems
- Community-residing PLWD and at least one care partner (dyad)
- PLWD receives care at study primary care clinic



INTERVENTION AND IMPLEMENTATION:

- Embed MIND-at-Home care coordination program into primary care
- Existing primary care clinic staff trained as memory care coordinators
- Monthly home visits to conduct needs assessment, develop and implement care plan, in coordination with primary care provider and care team
- Intervention period = 3 months



MEASURES:

Implementation evaluation endpoints:

- Identify 150 PLWD using electronic health record
- Enroll 150 PLWD + care partners (dyad) in MIND-at-Home
- % of enrolled dyads completing 3 home visits, needs assessments, and care plans with fidelity

Primary clinical outcome, assessed pre/post intervention:

- Number of hospital transfers (admissions, emergency department visits, observation stays)

Secondary clinical outcomes:

- Number of medications (Rx)
- Number of antipsychotic Rx; number of acetylcholinesterase inhibitor Rx; number of memantine Rx



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating the effectiveness of Mind-at-Home on avoidable health care utilization. This work has the potential to keep PLWD in their homes longer and empower care partners to successfully care for their loved ones at home.

A Patient-Facing Tool to Reduce Opioid, Psychotropic Polypharmacy in People Living with Dementia

Donovan Maust, MD, MS | University of Michigan



OBJECTIVE: To determine the feasibility of conducting an ePCT to adapt and evaluate the implementation of direct-to-patient education to use with people living with dementia (PLWD) and care partners to reduce central nervous system-active polypharmacy (CNS polyRx).



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, pilot study (usual care comparator)
- 4 primary care clinics at University of Michigan Health and Henry Ford Health systems (one intervention + one control clinic in each system)
- 120 primary care patients living with dementia experiencing CNS polyRx (concurrent exposure to ≥ 3 medications)



INTERVENTION AND IMPLEMENTATION:

- Direct-to-patient educational tool mailed to 60 participants in primary care clinics (with 60 patients in control clinics)
- Interviews with prescribing clinicians on perceived barriers and facilitators to intervention



MEASURES:

Implementation evaluation endpoints:

- Implementation feasibility: documented evidence of discussion of CNS polyRx between clinician and patient-caregiver in EHR
- Acceptability, feasibility, and appropriateness of this approach from clinicians' perspectives through semi-structured interviews in intervention clinics

Primary clinical outcome:

- Change in total standardized daily dosage of CNS polyRx from baseline to 4 months post-intervention

Secondary clinical outcome:

- Categorical change in CNS polyRx (i.e., does participant still have ≥ 3 CNS-active medications)



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating the effectiveness of an educational nudge intervention. This work has potential to reduce CNS polyRx among PLWD thru a light-touch intervention.



Deprescribing to Reduce Injurious Falls Among Older Adults with Dementia (STOP-FALLS-D)

Elizabeth A. Phelan, MD, MS | University of Washington



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate the implementation of STOP-FALLS, a patient-centered deprescribing intervention to reduce use of central nervous system (CNS)-active medications among people living with dementia (PLWD).



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- 4 primary care clinics in Kaiser Permanente Washington
- 120 community-dwelling older PLWD taking ≥ 1 CNS-active medications for ≥ 3 months, care partners, and their primary care providers (PCPs)



INTERVENTION AND IMPLEMENTATION:

- STOP-FALLS-D deprescribing intervention consisting of educational materials for patients plus provider decision support
- Direct mailing to patients
- Staff message to PCPs within electronic health record (EHR)



MEASURES:

Implementation evaluation endpoints:

- % of participants with evidence of medication taper plan for targeted CNS-active medication in EHR
- Feasibility: % of patient-mailings that reached PLWD and their care partners
- Acceptability: measured by Acceptability of Intervention (AIM) scale

Primary clinical outcome:

- Incidence of medically treated falls

Secondary clinical outcomes:

- All-cause emergency department visits and hospitalizations
- Nursing home placement



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating the effectiveness of STOP-FALLS adapted for PLWD. This work has the potential to improve the safety of medication regimens for PLWD and reduce their risk of falls. It may also benefit care partners by reducing stress of managing complex medication regimens and fall risk for their care recipient.



Embedded Clinical Trial of Patient Priorities Care among Persons Living with MCI and Dementia

Jennifer Carnahan, MD, MPH, MA | Indiana University School of Medicine



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate the implementation of Patient Priorities Care (PPC) by trained facilitators to identify health priorities and align care with their goals and priorities.



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- Outpatient geriatrics, neurology, and primary care clinics in 3 health systems in Indiana and Texas
- 160 community-dwelling people living with dementia (PLWD) or mild cognitive impairment and their care partners



INTERVENTION AND IMPLEMENTATION:

- Embed PPC intervention in outpatient clinics
- Facilitators (social workers, nurses, nursing assistants) trained to identify patient priorities
- Priorities communicated to providers → Care alignment with patient priorities



MEASURES:

Implementation evaluation endpoints:

- Identify 50% of care partners
- Documentation of PPC with $\geq 35\%$ participants
- Acceptability and feasibility assessment via semi-structured interviews with PLWD or mild cognitive impairment, care partners, clinicians and facilitators

Primary clinical outcome:

- Number of days at home pre-post intervention

Secondary clinical outcomes:

- Total medication prescriptions
- Specialist referrals



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating effectiveness of PPC with community-dwelling PLWD or mild cognitive impairment and their care partners. This work has the potential to improve care and quality of life by centering medical care on individual care preferences and values.

Reducing Inappropriate Medication use for Behavioral and Psychological Symptom of Dementia and Improving Health Outcomes in PLWD

Helen Kales, MD | University California, Davis



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate the implementation of delivering the DICE (Decide-Investigate-Create-Evaluate) model into primary care to manage behavioral and psychological symptoms of dementia (BPSD) among people living with dementia (PLWD).



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- 4 primary care practices in Primary Care Network at University of California, Davis
- 100 PLWD and care partner dyads (25 dyads per site) with upcoming appointments in primary care



INTERVENTION AND IMPLEMENTATION:

- 6-hour online modular training completed by clinic social workers (onsite DICE coordinators, or ODCs) with companion manual; coaching as needed
- Telephone call with care partner to assess BPSD and teach DICE approach
- Create plan and strategies for care partner to manage challenging behavior
- 2-week follow-up call to evaluate how strategies are working



MEASURES:

Implementation evaluation endpoints:

- Rate of subject enrollment (PLWD-care partner dyads)
- Number of contacts between ODCs and dyads
- Time requirements for ODCs implementing DICE
- Acceptance rate of ODC's recommendations of strategies for BPSD (generated by DICE)

Primary clinical outcome:

- Psychotropic medication use at 6 months (compared to historical controls)

Secondary clinical outcomes:

- Hospitalizations and emergency department visits
- Nursing home placement



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating the effectiveness of DICE approach to provide evidence-based care for managing BPSD. This work has the potential to ensure a systematic approach to provide evidence-based care for managing BPSD and reduce psychotropic medication use.

Testing the Feasibility of the Individualized Positive Psychosocial Intervention

Katherine Abbott, PhD, MGS | Scripps Gerontology Center, Miami University, OH



OBJECTIVE: To conduct a pilot study for an ePCT to evaluate feasibility of an intervention of an Individualized Positive Psychosocial Intervention (IPPI) embedded in nursing homes (NH) to improve the care of residents with dementia and distress and/or depression.



DESIGN, SETTING, AND PARTICIPANTS:

- Single-armed, pilot study
- 9 NHs managed by United Church Homes
- 120 NH residents with dementia and either communication of distress and/or depression identified using Minimum DataSet (MDS) (sections D or E)



INTERVENTION AND IMPLEMENTATION:

- IPPI guides direct care workers to engage residents with dementia in brief (10 min) 1:1 preference-based activities
- Certified nursing assistants (CNAs) will be trained to deliver IPPI to eligible NH residents over 6 months



MEASURES:

Implementation evaluation endpoints:

- Delivery of IPPI to 12-15 eligible residents/communities
- Training of CNAs with fidelity
- Engagement of eligible residents in at least 2 IPPIs/week
- Acceptability, feasibility, and appropriateness of IPPI from semi-structured interviews with the NH staff

Primary clinical outcome:

- Improvement, no change, or worsening of the residents' MDS distress or depression ascertained with MDS 3.0 data



RELEVANCE: This pilot study will set the foundation for a full-scale ePCT evaluating effectiveness of IPPI. This work has the potential to lead to adoption of IPPI as an approach to providing preference-based care to reduce distress and improve quality of life of NH residents with moderate to severe dementia.

Demonstration Projects Program

Collaborative Care Coordination Program for Alzheimer’s Disease and Related Dementias (Co-CARE-AD)

Xiaojuan Li, PhD & Richard Platt, MD, MSc | Harvard Pilgrim Health Care Institute, Harvard Medical School



OBJECTIVE: To conduct a randomized ePCT to evaluate the impact on health care utilization of a collaborative care-coordination program, the Dementia Care Consultation program, embedded in a health plan for people living with dementia (PLWD) and care partners.



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, randomized, open-label, ePCT (usual care comparator)
- Embedded in Tufts Health Plan in New England
- Community-dwelling Medicare Advantage beneficiaries with dementia and their care partners



INTERVENTION AND IMPLEMENTATION:

- Dementia Care Consultation program, personalized service for PLWD and their care partners
- Includes: comprehensive needs assessments; creation and implementation of personalized care plans; monitoring and revising care plans; disease education and support coaching; referrals to community-based organizations for service and support; and access to additional assistance
- Trained clinical social workers offer the above services over 6 months



MEASURES:

Implementation evaluation endpoints:

- % using service upon outreach
- % completing the full intervention
- Acceptability of intervention at 6 months
- Satisfaction with intervention at 6 months

Primary clinical outcome:

- Number of all-cause emergency department (ED) visits

Secondary clinical outcomes:

- Number of outpatient visits
- Number of potentially avoidable ED visits
- Admission to long-term care facilities



RELEVANCE: This ePCT will generate evidence on best practices for implementation and effectiveness of a comprehensive dementia care-coordination program that can be implemented at scale in Medicare Advantage plans. This work has the potential to open a new avenue for providing support to large segments of individuals and families affected by dementia.

Can Value Champions Reduce Inappropriate Prescribing for People with Dementia?

Michael L. Parchman, MD, MPH | Kaiser Permanente Washington Health Research Institute



OBJECTIVE: To conduct a cluster-randomized ePCT to evaluate the effectiveness of training a clinician to be a 'value champion' within clinical settings (vs. usual care) to decrease the use of 3 classes of potentially inappropriate medications (PIMs) among people living with dementia (PLWD).



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, cluster-randomized ePCT (usual care comparator)
- Randomize 60 primary care clinics across 2 accountable care organizations (ACO): 30 intervention clinics, 30 control clinics
- Medicare beneficiaries with dementia attributed to ACO



INTERVENTION AND IMPLEMENTATION:

- Recruit one value champion from each intervention clinic
- 6 months of training as a value champion followed by monthly check-ins to support champions in their work to support clinician colleagues in their clinic to de-prescribe 3 PIM classes: antipsychotics, benzodiazepines, or hypoglycemic medications (sulfonylureas and insulin).



MEASURES:

Implementation evaluation endpoints:

- Appropriateness, fidelity, feasibility, penetration, and equity will be assessed through qualitative interviews with 4 value champions from each ACO

Primary clinical outcome:

- Medication Possession Ratio for any medication in 3 PIM classes (antipsychotics, benzodiazepines, or hypoglycemic medications) over the 12 months following the completion of the value champion training program



RELEVANCE: This ePCT will allow health care systems to gain real-world experience integrating this pragmatic intervention in a manner that provides clear information on its effectiveness and will enable them to train others to be value champions to address other overused services across new clinical sites.

Mitigation of Postoperative Delirium in High-Risk Patients

Ira Hofer, MD & Susana Vacas, MD, PhD | Icahn School of Medicine & Massachusetts General Hospital



OBJECTIVE: To conduct a cluster-randomized ePCT to evaluate the effectiveness a clinical decision support system to promote adherence to best practices with the goal of decreasing postoperative delirium in patients with baseline cognitive impairment.



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, prospective, cluster randomized ePCT (usual care comparator)
- Perioperative setting at Mount Sinai Health System, an integrated health system that encompasses 130 operating rooms
- Patients with cognitive impairment undergoing surgery



INTERVENTION AND IMPLEMENTATION:

- Embed clinical decisions support alerts in electronic health records (EHR) directed at anesthesiologists caring for patients with preexisting cognitive impairment
- Patients meeting enrollment criteria will be screened by physician assistants (PA) postoperatively for delirium using the 4AT assessment



MEASURES:

Implementation evaluation endpoints:

- Integration of automated screening and alert deployment into the EHR
- Training of PAs for delirium screening
- Enrollment rates
- % of enrolled patients screened for delirium

Primary clinical outcome:

- Incidence of postoperative delirium while inpatient

Secondary clinical outcomes:

- Adherence of providers to clinical decisions support prompts
- Effectiveness of individual measures in preventing post-op delirium (POD)



RELEVANCE: This ePCT will generate evidence on the ability of intra-operative interventions to prevent POD and the effectiveness of clinical decisions support prompts in modifying anesthesiologist behavior. This work has the potential to create improved pathways for preventing POD in high-risk patients.

Improving How People Living with Dementia are Selected for Care Coordination: A Pragmatic Clinical Trial Embedded in an Accountable Care Organization

Lisa Kern, MD, MPH | Weill Cornell Medicine



OBJECTIVE: To conduct a randomized ePCT to evaluate the comparative effectiveness of assigning care coordinators to people living with dementia (PLWD) based on care partners' perceived need for care coordination vs. usual care, which involves assigning care coordinators after hospital discharge.



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, prospective randomized ePCT (usual care comparator)
- Embedded in NewYork Quality Care, an accountable care organization (ACO) that includes Weill Cornell Medicine, NewYork-Presbyterian Hospital, and ColumbiaDoctors
- Medicare beneficiaries age ≥ 65 years attributed to ACO who: have dementia, are community-dwelling, are not enrolled in hospice, and who have highly fragmented ambulatory care (risk factor for gaps in communication in outpatient care coordination)



INTERVENTION AND IMPLEMENTATION:

- Eligible participants in each group receive care coordination services from care managers already working with ACO
 - Intervention group: Participants whose care partners report on a telephone survey a perceived need for care coordination are eligible
 - Control group: Participants who are hospitalized are eligible



MEASURES:

Implementation evaluation endpoints:

- Acceptability: % engaged with care coordinators
- Appropriateness: % problems in scope for care coordinators
- Fidelity: % eligible who receive care coordination services
- Efficiency: number of care manager hours per group

Primary clinical outcome:

- Number of emergency department (ED) visits or hospital admissions over 12 months



RELEVANCE: This ePCT has the potential to show that an innovative, pragmatic, and patient-centered change in the way care coordinators are deployed can reduce ED visits and hospital admissions compared to usual care.

Supplements

Improved Vaccine Uptake in Skilled Nursing Facilities: IMPACT-C

Sarah Berry, MD, MPH & Vince Mor, PhD | Marcus Institute for Aging Research Hebrew SeniorLife & Brown University School of Public Health

ClinicalTrials.gov Identifier: NCT04732819



OBJECTIVE: To determine whether a multicomponent vaccine campaign would increase vaccine rates among residents and staff of skilled nursing facilities (SNF).



DESIGN, SETTING, AND PARTICIPANTS:

- Cluster randomized trial with a rapid timeline, December 2020-March 2021
- 133 SNFs in 4 health care systems across 16 states
- 63 facilities in intervention and 70 facilities in control arm (usual care)
- 7,496 long-stay residents (>100 days) and 17,963 staff



INTERVENTION AND IMPLEMENTATION:

- Multicomponent facility-level intervention, including:
 - Educational material and electronic messaging for staff
 - Town hall meetings with frontline staff; messaging from community leaders
 - Gifts with socially concerned messaging (e.g., T-shirts)
 - Use of specialist to facilitate consent with residents' proxies
 - Funds for additional COVID-19 testing of staff and residents



MEASURES:

Primary clinical outcome:

- % of residents receiving COVID-19 vaccine (from electronic medical records)
- % of staff receiving COVID-19 vaccine (from facility logs)



RESULTS:

- 71.4% of SNFs were for-profit, 26.3% of residents were Black
- Residents: 82.5% [95% confidence interval (CI), 81.2--83.7%] were vaccinated in intervention arm, compared to 79.8% [95% CI, 78.5--81.0%] in the usual care arm
 - Marginal difference: 0.8% [95% CI, -1.9 to 3.7%]
- Staff: 49.5% [95% CI, 48.4--50.6%] were vaccinated in intervention arm, compared to 47.9% [95% CI, 46.9--48.9%] in usual care arm
 - Marginal difference: -0.4% [95% CI, -4.2 to 3.1%]
- No observed association with race with vaccination among residents



RELEVANCE: A multicomponent vaccine campaign did not have a significant effect on vaccination rates among SNF residents or staff. Vaccination rates among residents were high. However, half the staff remained unvaccinated despite these efforts. Vaccination campaigns to target SNF staff will likely need to use additional approaches.

COVID-19 Serology Strategies in Skilled Nursing Facilities (CERO)

Joshua Chodosh, MD, MSHS | NYU Langone Health



OBJECTIVE: To determine the feasibility of conducting an ePCT to evaluate implementation of a novel cohorting strategy that leverages COVID-19 antibody and polymerase chain reaction (PCR) status to pair staff and residents of skilled nursing facilities (SNFs) to reduce COVID-19.



DESIGN, SETTING, AND PARTICIPANTS:

- Two-armed, pilot study (usual care comparator)
- 2 racially and ethnically-diverse SNFs in New York City that care for high proportion of residents with dementia
- Up to 40 residents and 3-5 staff per unit and 4 units per facility



INTERVENTION AND IMPLEMENTATION:

- Convene stakeholders in group and one-on-one meetings
- Cohorting strategy: "pairing" serology-positive staff with serology-negative residents and serology-negative staff and serology-positive residents to the degree that penetration of serologic presumed immunity allows this pairing to be positive



MEASURES:

Implementation evaluation endpoints:

- Staff and residents' acceptance of cohorting strategy
- % of intended pairings

Primary clinical outcome:

- Incidence of COVID-19 infections in residents over 12 months

Secondary clinical outcomes:

- Incidence of COVID-19 infections in staff over 12 months
- Number of hospitalizations over 12 months



RELEVANCE: This study will set the foundation for a full-scale ePCT evaluating the effectiveness of staff-resident assignments in SNFs that minimize risk of acquiring COVID-19. This work has the potential to inform novel strategies that maximize the safety and quality of life for SNF residents with dementia and staff who care for them in future pandemics.

Evaluation of a State-wide Effort to Improve COVID-19 Infection Control in Massachusetts Nursing Homes

Lewis Lipsitz, MD | Marcus Institute for Aging Research Hebrew SeniorLife



OBJECTIVE: To conduct a multi-component infection control intervention in nursing homes (NHs) in Massachusetts (MA) from 4/1/2020-8/12/2020 to mitigate the spread of the 2020 SARS-CoV-2.



DESIGN, SETTING, AND PARTICIPANTS:

- State-wide intervention (neighboring states as comparator)
- 2,085 residents in 20 NHs in MA vs. 4,493 residents in 45 NHs in neighboring states



INTERVENTION AND IMPLEMENTATION:

- 28-item infection control checklist of best practices
- Incentive payments to NHs contingent on scoring ≥ 24 on checklist
- Onsite and virtual consultations for deficient NHs
- 6 weekly webinars
- Continuous communications with MA Department of Public Health
- Access to personal protective equipment, temp staff and, SARS-CoV-2 testing



RELEVANCE: This state-wide intervention was associated with a more rapid reduction in the rate of SARS-CoV-2 infection compared to similarly managed NH in neighboring states. This work provides an implementation model that may help reduce high rates of infection and prevent future COVID-19 surges in NHs.



MEASURES:

Primary clinical outcome:

- SARS-CoV-2 infection confirmed with polymerase chain reaction testing at the resident-week level

Covariates

- Resident-level: demographics, functional status, clinical conditions
- Facility-level indicators of quality: staffing rating, bed size
- Infection risk: facility type (post-acute care vs long term care), SARS-CoV-2 prevalence in surrounding community (county)



RESULTS:

- Adjusted risk of infection was higher in MA but declined more rapidly in NHs compared to similarly managed NHs in neighboring states
- Early intervention period, decline in infection risk was 53% greater in MA [interaction hazard ratio (HR) 0.47, 95% confidence interval (CI) 0.37-0.59]
- In late intervention period, infection risk continued to decline in both groups; change was marginally greater in MA [interaction HR 0.80, 95% CI 0.64-1.00]

Effect of a COVID-Specific Advance Care Planning Intervention on Documentation of Advance Directives and Goals of Care

Ellen McCreedy, PhD, MPH | Brown University School of Public Health

ClinicalTrials.gov Identifier: NCT04852055



OBJECTIVE: To conduct a cluster-randomized ePCT to test effects of a COVID-specific, advance care planning (ACP) intervention on documentation of care preferences in assisted living community (ALC) residents with dementia.



DESIGN, SETTING, AND PARTICIPANTS:

- Cluster randomized ePCT (usual care comparator): 210 ALCs randomized during study (3,126 patients enrolled)
- ACP Information sent to residents / families followed by structured call from their physician vs usual care (50 ALCs per arm)
- ACP information sent to residents / families vs usual care (80 ALCs per arm)
- ALCs served by common physician group in Florida, Minnesota, Wisconsin
- ALC residents with dementia who are full-code or missing code status



INTERVENTION AND IMPLEMENTATION:

- Intervention facilities received enhanced COVID-specific ACP intervention
- ACP information sent to residents/families, including video describing goals of care and instructions for completing advance directives or medical orders
- Structured conversation guides and training for physicians



RELEVANCE: A multicomponent ACP intervention did not have a significant effect on DNR documentation in EHR for ALC residents. However, despite low compliance, the more complex intervention, which combined information sent to families and a structured conversation with physicians, may have been more successful.



MEASURES:

Implementation evaluation endpoints

- % of residents or proxies mailed ACP materials
- % of completed physician ACP conversations

Primary clinical outcome:

- % of residents with do-not-resuscitate orders (DNR) documents in electronic health record over 4 months



RESULTS:

- Mean age of residents was 81 years, 30% were male, 88% white, and 94% had a dementia diagnosis
- 83% of residents or proxies mailed ACP materials; 29% of completed physician ACP conversations
- 15.5% of residents in Information + Physician Call arm had DNR orders compared to 12.9% in control (average marginal effect, AME: 2.8 [-1.6, 7.5])
- 12.0% of residents in Information Only arm intervention arm had DNR orders compared to 14.7% in control (AME: -2.7 [-6.1, 0.5])