Title

Addressing COVID-19 Barriers to Clinical Trial Enrollment and Implementation in the PHARM-DC Study

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We partnered with a national for-profit nursing home (NH) organization to test the acceptability and use of an advance care planning (ACP) website for people living with dementia using a randomized controlled trial (RCT) design. Concurrently, the COVID-19 pandemic disproportionately impacted NHs and halted in-person research. We will present challenges, opportunities, and adaptations in site engagement, recruitment, and data collection. Initially, NHs were overwhelmed by pandemic efforts and research staff were unable to enter sites. We capitalized on time and available resources by beta-testing the website in a comparable population and designing surveys to elicit COVID-19's impact on ACP. Once able, NH staff took on recruitment and data collection efforts intended for research staff. We supported NHs by pivoting to remote data collection, providing technology on site, and offering flexible communication. Flexibility is key in supporting site engagement, recruitment, and data collection and has implications for designing pragmatic RCTs.

INNOVATION IN TIMES OF UNCERTAINTY: CLINICAL TRIALS IN NURSING HOMES DURING SARS-COV-2

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In March 2020 the Centers for Medicare & Medicaid Services (CMS) announced restrictions on visitors and nonessential personnel in nursing homes to protect residents and facilities from SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) outbreaks. At the time, these measures were "temporary" but they continued well into 2021 resulting in a prolonged pause on in-person study activities in a palliative care clinical trial in 12 nursing homes. This session will address the impact of this pause and decisions made to overcome the potential failure of the trial. Of utmost importance was respecting nursing homes rapidly changing context, continued communication with the site leadership, transitioning to phone and video-conference study activities, and designing a retrospective study using existing data to answer a different but similar research question. As clinical researchers move forward implementing trials and complex interventions in nursing homes, we must use the lessons learned to design flexible trial protocols.

CONDUCTING A CLUSTER RCT ON MEDICATION SAFETY IN NURSING UNITS OVERTAXED BY THE COVID-19 PANDEMIC

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Medication errors continue to harm many hospitalized patients. In other high-risk industries, voluntary incident reporting is widely used to improve safety. Reporting is widely used in hospitals, but not as effectively. This AHRQ-funded cluster RCT will assess the effects of the SAFE Loop, which includes five enhancements in incident reporting implemented on hospital nursing units. Analyses will compare changes in nurses' attitudes toward reporting, event reporting rates, report quality, and medication event rates between intervention and control arms. The COVID-19 pandemic has created both obstacles and opportunities. The intervention requires study staff to engage nursing unit directors, attend daily nursing "huddles", and train overtaxed front-line nurses in a geographic area greatly impacted by COVID-19 surges. This created uncertainty around the best time to start the trial. Conversely, we have collected unique data on the implications of COVID-19 for medication safety while testing our instruments during the trial preparation phase.

ADDRESSING COVID-19 BARRIERS TO CLINICAL TRIAL ENROLLMENT AND IMPLEMENTATION IN THE PHARM-DC STUDY

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Recent hospitalization puts older adults at higher risk of experiencing adverse drug events (ADEs) that are a common cause of hospital readmission. Yet, most ADEs are preventable. The PHARMacist Discharge Care (PHARM-DC) study is a multi-site randomized controlled trial that seeks to evaluate the effect of pharmacist-led peri- and post-discharge interventions on 30-day hospital readmissions among older adults taking ≥10 medications or ≥3 high-risk medications. The PHARM-DC intervention includes pharmacist-led patient counseling, medication reconciliation at discharge, and a follow-up phone call post-discharge. We will highlight study protocol adaptations undertaken during the COVID-19 pandemic to address challenges to enrollment and to minimize risk of COVID-19 exposure for study participants and research personnel. Additionally, we will share insights from focus groups and semi-structured interviews with pharmacist interventionists and pharmacy leaders on barriers and facilitators to implementation due to the pandemic and strategies for future clinical trials to overcome barriers.

CAN WE DO BETTER FOR OLDER ADULT RESEARCH PARTICIPANTS? CLINICAL TRIAL IMPROVEMENTS PROMPTED BY A GLOBAL PANDEMIC

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Retaining older adults in clinical trials has often been a challenge for researchers. Clinical trial procedures, aimed at improving fidelity, often offer barriers to frail older adults who have challenges traveling to medical centers and enduring long clinical assessment visits. During the COVID-19 pandemic, we modified the procedures of two randomized controlled trials. COMPASS: A novel transition program to reduce disability after stroke is a clinical trial examining the efficacy of a transition home program that provides home modifications and self-management strategies compared to stroke education. HARP: Removing home hazards for older adults living in affordable housing is a pragmatic trial examining the effectiveness of a home hazard removal program