Care Ecosystem: Navigating Patients and Families Through Stages of Care
NCT02213458
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Care Ecosystem Study Protocol

Pre-screening procedures:
Potential patient participants will be identified by providers at the various recruitment sites. Potential patient or caregiver participants may also self-refer within or outside of the targeted recruitment sites. The Research Coordinator (RC) will conduct a preliminary chart review to confirm patient subject's eligibility and to determine if the patient meets the inclusion criteria (a request for a "waiver for consent for screening" is attached). If the patient is outside of the UCSF medical record system, appropriate medical release will be obtained by the Research Coordinator in order to obtain medical records for determining eligibility.

Initial Encounter:
The RC contacts the potential subject and their caregiver to discuss the study and to assess their interest in participating. The RC meets with the potential subject and caregiver in-person or by phone. If by phone, consent forms will be provided to the potential subject and caregiver, and HIPAA form for the patient will be sent in advance along with the Quick Dementia Rating System (QDRS) form for the caregiver to complete. The primary purpose of this encounter is to determine eligibility and to sign the consent forms, one for the patient and one for the caregiver, and to obtain dementia stage through the QDRS form if patient and caregiver consent.

Consent:
Consent will be completed once the patient and caregiver have demonstrated understanding of the study, have had their questions answered, and agree to participate. Additionally, the Capacity Assessment Record will be used for each patient participant during the consent process and the caregiver (surrogate consent) will be involved as needed.

Baseline Outcome Assessment:
A Baseline Outcome Assessment will be performed following the consent. This includes all baseline measures, the National Institute of Neurological Disorders and Stroke-Canadian Stroke Network (NINSD-CSN) Vascular Cognitive Impairment Harmonization Standards 5-Minute Protocol for the patient, and demographic data and baseline characteristics for the patient and the caregiver. If the patient has a personal medication list, the RC will obtain a copy. Baseline Outcome Assessment will be completed over the phone at a later date. A list of the survey response scales will be provided in advance to assist with answering questions over the phone.

Randomization:
Patient subjects will be randomized with their caregiver (2:1) to Navigated Care or to Survey of Care. We will randomize participants to one of the two arms of the trial in a 2:1 ratio in Navigated Care vs. Survey of Care treatment arms. Allocation concealment will be ensured, as the randomization code will not be released until the participants are recruited into the trial and all baseline measures, including diagnostic evaluation, are taken. Following randomization, the subject and their caregiver will be informed of the next steps (when they will be contacted by study staff).

Outcome Measures:

Outcome measures will be completed at different stages during the study. These stages are selected to both provide important information regarding the Care Ecosystem and patient/caregiver concerns while minimizing subject burden. There are 4 categories of outcome measures: Baseline, Agile (Navigated Care only, at month 3 and 9 post baseline annually), Short (every 6 months), and Full (annually). All subjects (patients and caregivers), regardless of randomization assignment receive Baseline, Short and Full measures. Outcome survey questions will be answered by patients on themselves (if they have capacity to respond), by caregivers on behalf of the patient, and caregivers on themselves. Specifically, we will be asking caregivers about their experience with the patient's care, their needs regarding care, how prepared they are for changes in the patient's health, their mood (depression, anxiety), and how they are feeling overall about their health. Subjects in Navigated Care complete the Agile measures that rate their satisfaction with the program so that improvements can be made in a responsive and efficient manner. Outcome measures will be administered by a research coordinator who is not involved with the provision of care. Names will not be linked to the questionnaires when results are presented to the care team unless requested by the caregiver.

Contact initiated by study staff:
Care Team Navigators (CTNs) will contact subjects (patients and caregivers) who are enrolled in Navigated Care on a monthly basis to help guide and support the caregiver and patient with their dementia care. CTNs will not require a formal medical background but likely have a relevant BA or successful experience working with this population. CTNs will inquire about new problems, medication changes, experience with care, needs regarding care, how prepared the caregiver and the patient are for future changes in their health, how the patient and caregiver are feeling, and caregiver well-being. See the sample script in the appendix. CTNs will also provide help with dementia care education, planning for the future, managing stress, and dealing with medications. Patients and caregivers can contact their CTN at any time for questions, problems, and concerns, and clinic staff will be providing after-hours coverage for calls from patients and caregivers. The CTN will refer to a member of the clinical team as appropriate. If pertinent, the CTN will generate a message (fax, email, phone call) to the patient's provider describing the outcome of the contact. We estimate the caseload for each CTN to be approximately 80-90 patients with monthly touchpoints lasting 15 minutes on average. Detailed models of CTN activity were developed on our experience as health care professionals interacting with patients and their families throughout the course of disease.

CTNs will mail a letter to primary care providers informing that their patient was enrolled into the intervention along with graphic of the intervention model. Additionally, the CTN will include a preferred contact sheet for the provider to complete and return.

RCs will contact Navigated Care (intervention group) and Survey of Care (control group) participants at scheduled intervals (Baseline, 6 months, and annually) in order to complete outcome measures. If the RC identifies a risk or concern, they will contact the patient or caregiver's provider so that the provider can follow-up.

Focus Groups with Primary Care Providers:

Eligible PCPs will be invited to attend the Focus Group via: email invitation and group announcement via the primary care practice site medical director. PCPs will sign up ("first come first served" until the maximum Focus Group number is reached, with one back-up spot available to accommodate for cancellations or no-shows). The Focus Group will run 60-90min depending on how many participants attend. Each participant will receive and review a copy of the Focus Group participation info sheet and provide their verbal consent. Focus Group will comprise of an orientation to/overview of the DCE and then the Survey. Focus Group will be led by a geriatrician/primary care liaison member of the study. Survey answers and discussion will be documented in-time by a scribe. All transcripts will be reviewed by the geriatrician/primary care liaisons and core themes summarized for the study Leadership and care team navigators.