C3FIT (Coordinated, Collaborative, Comprehensive, Family-based, Integrated, and Technology-enabled Care): A Pragmatic Randomized Trial for Stroke Delivery to Improve Patient, Caregiver, and Family Care

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Presented by: Renee Crawley, Izzy Neel, Rylee Bledsoe, and Cole McCarson

**BACKGROUND**

- Patients recovering from stroke pass through four nodes of care:
  - Acute care
  - Post-acute in-hospital care
  - Subacute care (inpatient rehab, extended stay, etc.)
  - Chronic care

- **Current Standard of Care:** Joint-Commission-certified Comprehensive and Primary Stroke Care focused on acute and in-hospital care

- **Overarching goal of C3FIT:** To assess if the Integrated Stroke Practice Unit (ISPU), a novel, technology-enabled, coordination of care spanning all four nodes of care can improve outcomes at one year

**METHODS**

**Design:**
- A cluster randomized trial of 18 CSC/PSC-certified clinical sites
  - 9 sites randomized to manage patients using standard CPC care
  - 9 sites randomize to manage patients using coordinated ISPU care
- Randomization of sites stratified by geographic region and size
- Each site to recruit/follow: ~100 stroke patients
- Total sample size: ~1,800 stroke patients

**Comparator Arm Differences**

<table>
<thead>
<tr>
<th>Item</th>
<th>Comprehensive Stroke Center (CSC) Model</th>
<th>Integrated Stroke Practice Unit (ISPU) Model</th>
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</thead>
<tbody>
<tr>
<td>Time Focus</td>
<td>Acute care</td>
<td>Continuum of care for 1 year</td>
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<tr>
<td>Collaboration Mechanism</td>
<td>Monthly Stroke Committee</td>
<td>Stroke Central Daily interdisciplinary rounds</td>
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<tr>
<td>Goals</td>
<td>Process compliance</td>
<td>Patient-centered QOL, Patient-centered functional outcome</td>
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<tr>
<td>Measurement</td>
<td>Performance measures</td>
<td>Functional outcome</td>
</tr>
<tr>
<td>Geography</td>
<td>Hospital-based Post hospital clinic Home Health Agency</td>
<td>Stroke Mobile Hospital and home based care delivery</td>
</tr>
<tr>
<td>Focus Of Modification</td>
<td>Care providers</td>
<td>Engagement of patient and family &amp; caregiver</td>
</tr>
<tr>
<td>Key Post-Hospital Follow-Up Mechanism</td>
<td>Clinic</td>
<td>Home</td>
</tr>
<tr>
<td>Patient-centered Outcomes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Family/Home-based Care</td>
<td>No</td>
<td>Yes</td>
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</tbody>
</table>

**INCLUSION/EXCLUSION CRITERIA**

**Inclusion Criteria:**
- Age 18+
- Clinical diagnosis as ischemic or hemorrhagic stroke
- English- or Spanish-speaking subjects
- Patient admitted within seven days of their index stroke event
- Patient discharged alive – not to hospice care
- Patient living at discharge within the geography of recruitment for that C3FIT site
- Pre-morbid mRS score of 0-1
- Patient and/or surrogates give informed consent to participate
- Patients who go to rehabilitation inpatient therapy (excludes hospice and outside geographic area of recruitment)
- Pre-geographic proximity to hospital
- Pre-geographic mRS of 0 or 1

**Exclusion Criteria:**
- Patients not surviving to discharge
- TIA (even with demonstrable lesion on CT/MRI)
- Discharge admission to hospice
- Comorbidities anticipated to limit survival to less than 1 year

**OVERVIEW**

**Outcomes**

<table>
<thead>
<tr>
<th>Type</th>
<th>Measure</th>
<th>Duration</th>
<th>Purpose</th>
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<tbody>
<tr>
<td>Primary</td>
<td>Stroke Impact Scale (SIS)</td>
<td>12 months</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>Secondary</td>
<td>Modified Rankin Score (mRS)</td>
<td>3 &amp; 6 months</td>
<td>Short-Term Function</td>
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<tr>
<td></td>
<td>mRS</td>
<td>24 months</td>
<td>Durability of Intervention</td>
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<tr>
<td></td>
<td>Stroke Risk Factors</td>
<td>3, 6, &amp; 12 months</td>
<td>Blood Pressure, Lipids, HBAIC, Smoking Status, BMI, Diet, Exercise</td>
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<td></td>
<td>Mortality, Recurrence, Readmission, Time at Home</td>
<td>3, 6, &amp; 12 months</td>
<td>Mortality, Stroke Recurrence, Hospital Readmission, Time at Home</td>
</tr>
<tr>
<td></td>
<td>Patient Depression and Caregiver Strain</td>
<td>3, 6, &amp; 12 months</td>
<td>Severity of patient depression, strain on caregiver</td>
</tr>
</tbody>
</table>

**Potential Benefits for Patients, Caregivers, & Organizational Stakeholders**

- Patients and Caregivers: Information gained through a comprehensive, integrated, family-focused delivery system.
  - Access to results of C3FIT to inform their choices in health care.
  - Potential for home care management in the ISPU arm, avoiding the stress, time, and travel costs for outpatient clinic visits.
  - Having a team that monitors caregivers’ stress levels and offers support.

- Organizational Stakeholders: Access to high quality data to inform decisions regarding design and implementation of the most efficient and effective stroke delivery system.

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All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

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