NIH Collaboratory

Health Care Systems Research Collaboratory

# Time to Reduce Mortality in End-Stage Renal Disease (TiME)

## Study Snapshot

**Principal Investigator:** Laura Dember, MD

**Sponsoring Institution:** University of Pennsylvania

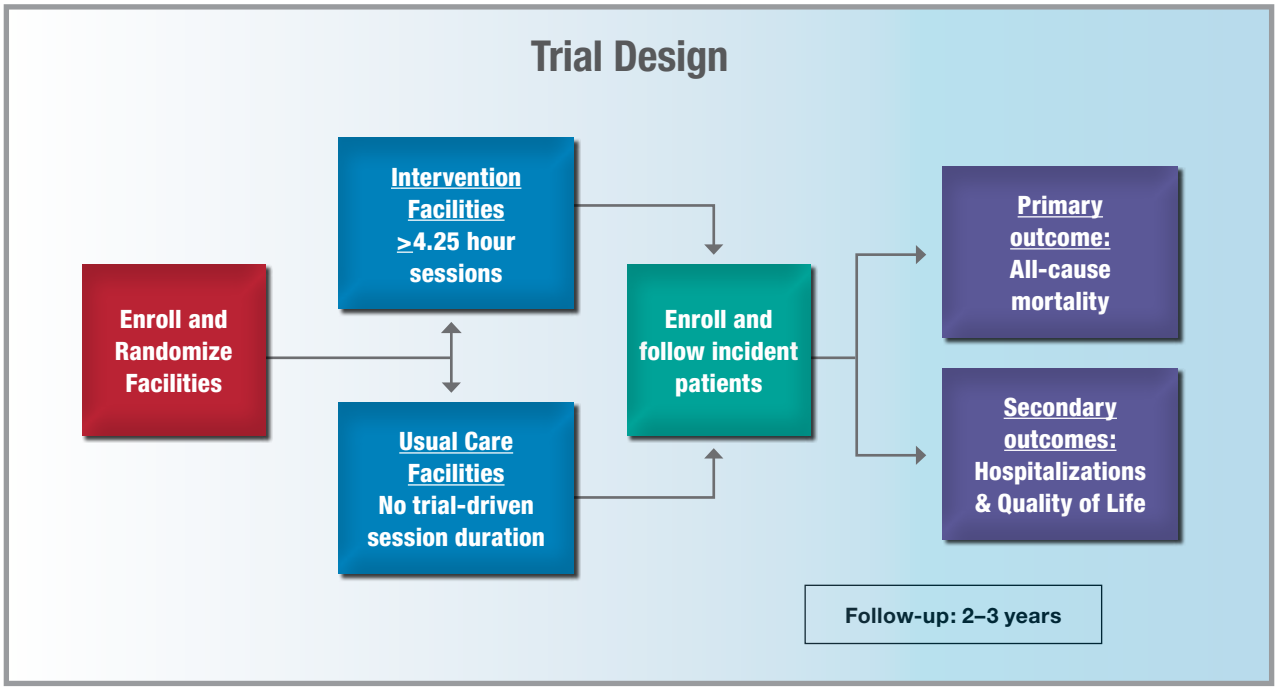
**ClinicalTrials.gov:** NCT02019225

**Collaborating Healthcare Systems:** Fresenius Medical Care North America, DaVita Clinical Research

**NIH Institute Oversight:** National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

**Abstract:** TiME is a large pragmatic, cluster-randomized clinical trial testing a simple intervention to improve survival and quality of life for patients with kidney failure who require chronic treatment with dialysis. The trial evaluates a minimum hemodialysis session duration of 4.25 hours compared with usual care for patients with end-stage renal disease initiating treatment with thrice weekly maintenance hemodialysis.

The TiME trial is conducted through a partnership between academic investigators and 2 large dialysis provider organizations in approximately 320 dialysis facilities. The pragmatic design of the trial, the use of multiple electronic health record systems for trial implementation, and the partnership between academia and industry will establish a framework for conducting research within health care delivery systems that will be relevant to a broad range of diseases and research questions.



# What We've Learned So Far

| Current Barriers | Level of Difficulty | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 |
| Enrollment and engagement of patients/ subjects | | | X | | |
| Engagement of clinicians and health systems | | | X | | |
| Data collection and merging datasets | | X | | | |
| Regulatory issues (IRBs and consent) | | X | | | |
| Stability of control intervention | | | | X | |
| Implementing/delivering intervention across healthcare organizations | | | | X | |

1 = little difficulty
5 = extreme difficulty

| Challenge | Solution |
|---|---|
| Because observational data suggest better outcomes with longer dialysis sessions, dialysis units, including some of those randomized to usual care, have increased session durations for their patients | In many PCTs, the control group is usual care and is "not controlled." This may require larger sample sizes and a design that allows for rapid completion of the trial. |
| A small change to workflow or the IT system was often viewed as a large change by health system personnel | More activity than expected was required at the local level and with individual practitioners and administrators to engage the personnel at the facilities. |
| There were fundamental questions about minimal risk that arose for this trial, which enrolls a high-risk population (patients with end-stage renal disease) and has an outcome of mortality | The incremental risk of the research was considered minimal both from a medical standpoint and because treating physicians and patients maintain autonomy with respect to intervention implementation. |

| Selected Publications & Presentations | |
|---|---|
| September 2017 | PCT Grand Rounds Presentation: Who To Include in a Pragmatic Trial? It Depends |
| October 2016 | Pragmatic Trials in Maintenance Dialysis: Perspectives from the Kidney Health Initiative, *J Am Soc Nephrol*, Dember et al. |
| February 2015 | PCT Grand Rounds Presentation: The TiME Trial: From Planning to Implementation |