

Investigators incorporate randomized trial within dialysis care delivery

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A recent clinical trial fully embedded into the routine delivery of care at dialysis facilities sought to determine if hemodialysis sessions that are longer than many patients in the United States currently receive can improve patients' health. Although the trial accomplished most of its objectives, uptake of the intervention was insufficient to determine whether longer sessions are beneficial. The findings, which appear in an upcoming issue of *JASN*, indicate that embedding trials into dialysis care will require more effective strategies for engaging clinicians and patients.

The trial's investigators had 2 goals: to develop approaches for embedding large randomized trials into the routine delivery of clinical care, and to determine whether patients benefit from hemodialysis sessions that are longer than usual. In the Time to Reduce Mortality in ESRD (TiME) trial, 266 dialysis facilities randomized to the intervention adopted a default hemodialysis session duration of at least 4.25 hours for new dialysis patients; those randomized to usual care had no trial-specified approach to duration. Trial implementation was highly centralized, with no on-site research personnel and complete reliance on clinically acquired data.

The team demonstrated that a trial embedded into clinical care delivery with no on-site research personnel could efficiently enroll a large number of participants using an opt-out approach to informed consent. (The trial enrolled 7,035 patients.) The trial was also able to obtain useful treatment and outcomes data from hundreds of [medical facilities](#)

and monitor trial conduct and safety through a centralized approach.

The trial was discontinued at a median follow-up of 1.1 years because of an inadequate between-group difference in session duration. Average session duration was 216 minutes for the intervention group and 207 minutes for the usual care group. Investigators found no reduction in [mortality](#) or hospitalization rates for the intervention vs. usual care.

"There is a pressing need for data from randomized trials to guide [clinical practice](#) in dialysis," said lead author Laura M. Dember, MD (University of Pennsylvania Perelman School of Medicine). "Pragmatic trials embedded in clinical care delivery have tremendous potential for efficiently producing evidence that is highly generalizable to the non-research setting; however, experience with this approach is limited. The TiME trial provides an important foundation for future pragmatic [trials](#) in [dialysis](#) as well as in other settings."

More information: JASN, [DOI: 10.1681/ASN.2018090945](https://doi.org/10.1681/ASN.2018090945)

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