

Study: Decision-Aid for Renal Therapy Pilot Trial (DART Pilot Trial)

NCT Number: not yet assigned

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Primary Outcomes:

1. Completion of advance directives.

The primary outcome of this pilot trial is completion of advance directives at 3 months, which will be the first study visit after administration of the educational instrument.

2. Decisional conflict

The other primary outcome of this pilot trial is the difference in the decisional conflict scale score at 3 months, which will be the first study visit after administration of the educational instrument.

Statistical Analysis Plan:

Co-primary outcomes in this pilot trial include completion of advance directives at three months and changes in decisional conflict score at three months. For completion of advance directives, we will use logistic regression, dichotomizing advance directives as completed or not completed at the three month visit. There will be two secondary analyses of advance directives; the first will exclude anyone with completed advance directives at baseline from analyses while the second will look at any completion versus non-completion prior to death or a terminal hospitalization, extending beyond the initial three month follow-up. Advance directives can include DNR/DNI forms as well as completion of the Massachusetts Orders for Life-Sustaining Treatment (MOLST), a local Physician Orders for Life-Sustaining Treatment (POLST) equivalent.

The primary analysis for DCS will be a comparison between study arms at 3 months, using linear regression to adjust for baseline DCS. In secondary analyses, leveraging longer term data, all post-baseline measurements of DCS over time will be analyzed together in a single linear mixed effects model to account for within patient correlation.

Secondary outcomes will be analyzed similar to advance directives if dichotomous or similar to the DCS if continuous and are hypothesis generating for future trials. Critically, this pilot trial is not sufficiently powered to conclude efficacy of the DART survey instrument but rather is designed for feasibility assessment.