TUFTS MEDICAL CENTER
TUFTS UNIVERSITY
Occupational Therapy/ Nephrology

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

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

Principal Investigator: Keren Ladin, PhD, MSc
Co-Investigators: Daniel Weiner, MD; Vaidyanathapuram Balakrishnan, MD
Study team telephone number: 617-627-5931

INTRODUCTION

You are being invited to take part in a research study involving an interactive web-based decision-aid (Decision-Aid for Renal Therapy, or DART) that can help patients with advanced chronic kidney disease and their caregivers select the treatment option that best reflects preferences important to them. This study will examine how patients and caregivers use DART and whether DART improves patients' satisfaction with decision-making and with treatment. You are being invited to participate because you are a caregiver for a patient who receives treatment for advanced chronic kidney disease at Tufts Medical Center or St. Elizabeth's Medical Center.

Voluntary Participation

Taking part in this research study is entirely your choice. You can decide to refuse to participate in this study. If you decide to participate in this study, you can then choose to stop taking part in the study at any time for any reason. If you refuse to participate in the study or stop being in this study, it will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

Please read all of the following information carefully. Ask Dr. Ladin, or her representative, to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

New things might be learned during this study that you should know about. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you are eligible to participate and decide to be in the study, the Principal Investigator may still choose to stop your participation in this study if she thinks it is in your best medical interest. You may also choose to stop participating in this study.

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

As a participant in this study, your identity, medical records, and data relating to this study will be kept confidential, except as required by law. The study sponsor may also look at records that identify you if applicable to the study.

If you have question about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

PURPOSE OF STUDY

Successful communication between patients, caregivers, and physicians can improve how patients feel about their treatment. Our recent studies of older dialysis patients find, however, that many patients do not engage in this type of communication about treatment options. This study aims to determine whether the Decision-Aid for Renal Therapy (DART) can improve shared decision-making (decisions where patients are actively engaged) among patients, caregivers, and physicians, and improve certainty and satisfaction in treatment decisions.

The study will be conducted at Tufts Medical Center Nephrology Department and St. Elizabeth's Medical Center Nephrology Department.

The project described is being supported by the National Center for Advancing Translational Sciences, National Institutes of Health.

This study will enroll 62 subjects at Tufts Medical Center and St. Elizabeth's Medical Center.

PROCEDURES TO BE FOLLOWED

If you agree to participate in this study, you and your loved one will then be randomly assigned (meaning you have a 50% chance) to one of two study groups: one group will receive usual care, and the other group will receive usual care plus DART. Participants in both study groups will complete three visits to the clinic:

Visit 1 (90 minutes)
A research team member will ask you questions about your experiences helping your loved one make decisions about kidney disease and treatment. Participants who are assigned to receive usual care will receive a printed educational pamphlet, "Choosing a Treatment for Kidney Failure," published by the National Kidney Foundation. Participants who are assigned to DART will receive the educational pamphlet and will also have the opportunity to complete DART in the clinic setting. A research assistant will help participants access and navigate DART on a tablet or desktop computer in the clinic. Patients and caregivers can complete DART together or separately. Participants will also receive an email link to DART if they wish to access it from home.

Visit 2 (30 minutes). This visit will take place three months after visit 1.
Both sets of participants (those who receive usual care, and those who receive usual care plus DART) will be asked questions about their experiences making decisions regarding kidney disease treatment, their goals of medical care, and views about their health.

Visit 3 (30 minutes). This visit will take place six months after visit 1.
Both sets of participants will be asked questions about their experiences making decisions regarding kidney disease treatment, their goals of medical care, and views about their health.

Interviews will be conducted in-person at the clinic if you are accompanying the patient, or will be done by mail or phone. You will be given an addressed, stamped envelope in which to mail the survey back. You may also choose to complete the surveys at the Research on Ethics, Aging, and Community Health Lab (REACH Lab) at 574 Boston Avenue in Medford.

Subjects are expected to participate in this study for six months.

RISKS

The risks in participating in this study are minimal and involve no medical risks to you or the person you care for. We will be asking questions about your knowledge and experiences helping your loved one make decisions about his/her kidney disease treatment. You may feel uncomfortable discussing challenges related to kidney disease and treatment, but we will keep your data confidential and de-identify it in any presentations or publications. Every effort will be

made to keep your information confidential; however, this cannot be guaranteed. Participation in this study does not influence standard clinical care.

BENEFITS

There are no direct benefits to participating in this study. Participants randomized to DART may benefit from access to DART. Participants in both study groups may gain a sense of satisfaction in knowing that the information they provide will hopefully help older adults living with kidney disease and their care partners make informed decisions about their treatment options.

ALTERNATIVES

If you and your loved one are randomly assigned to the group that does not receive DART, your loved one will receive usual care for his/her chronic kidney disease. You and your loved one will also receive both printed and e-mailed electronic versions of "Choosing a Treatment For Kidney Failure", an educational pamphlet written and published by the National Kidney Foundation, and commonly provided in current practice. Alternatively, you may also choose not to participate in the study.

COSTS

There are no costs associated with participation in this study.

PAYMENT

Participants in both study groups will be compensated $25 after completing the first visit, $15 after completing the second visit, and $15 after completing the third visit, for a total of $55 for completing the entire study. Payments will be made using a gift card for each visit.

In the case that you prefer to complete the survey outside the clinic at our research lab at 574 Boston Avenue in Medford, we will provide a $5 gift card as a transportation stipend.

Due to federal tax law, you are required to provide us your name, social security number, and address in order to process your payments. Your information will not be used for any other purposes and will not be given or sold to anyone.
If you receive over $600 from Tufts Medical Center or Tufts University Health Sciences in a single calendar year (either in a single study or multiple studies), you will be issued an IRS 1099 form. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food and other expenses are not included in this IRS disclosure.

PRIVACY AND CONFIDENTIALITY

If you agree to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing. It will only be given if the law requires it. It will also only be given for regular hospital treatment, payment, and hospital management activities.

We will make every effort to keep your information private, but it cannot be completely guaranteed. Certain government agencies (Office for Human Research Protections, and the Institutional Review Board of St. Elizabeth's Medical Center, Tufts Medical Center and Tufts University Health Sciences) may check records that identify you. This might include your medical or research records and the informed consent form you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

WHOM TO CONTACT

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Documentation of Consent

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

_____ _____

Date Participant's Signature

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature