

## **Decision-Aid for Renal Therapy Pilot Trial**

Principle Investigator: Keren Ladin, PhD, MSc; Tufts University

8/24/2017

Patient Informed Consent Form

### **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

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 receive care for your 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.

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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**

If you agree to participate in this study, you and your care partner will 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:

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### **Visit 1 (90 minutes)**

A research team member will ask you questions about your experiences make decisions about kidney disease and treatment. Participants who are assigned to receive regular 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.

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. We will be asking questions about your knowledge and experiences with kidney disease and treatment as well as your care partner's experiences. 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 your 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 care partner are randomly assigned to the group that does not receive DART, you will receive usual care for your chronic kidney disease. You and your care partner 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

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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.ClinicalTrials.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.

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### **AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION**

If you sign this document, you give permission to the Principal Investigators named above and research staff at St. Elizabeth's Medical Center, Tufts Medical Center, or Tufts University Health Sciences, as well as other individuals at St. Elizabeth's Medical Center, Tufts Medical Center, or Tufts University Health Sciences who may need to access your information to do their jobs (such as for treatment, payment (billing) or health care operations) to use or disclose (release) your health information that identifies you for the research study described above.

The parties listed in the preceding paragraph may disclose the health information described below to the following persons and organizations for their use in connection with the research study:

- Individuals or organizations working under the direction of the Principal Investigator(s) for the study,
- Outside individuals or entities that have a need to access this information to perform activities relating to the conduct of this research, such as analysis by outside laboratories on behalf of St. Elizabeth's Medical Center, Tufts Medical Center, or Tufts University Health Sciences,
- Other researchers and institutions that are conducting or participating in this study,
- The study sponsor (National Center for Advancing Translational Sciences, National Institutes of Health) and any companies that they use to oversee, manage, or conduct the research,
- The Office for Human Research Protections in the U.S. Department of Health and Human Services, the United States Food and Drug Administration (FDA) and other federal and state agencies that have the right to use the information as required by law, and
- The members and staff of any Institutional Review Board (IRB) that oversee this study.

The health information that we may use or disclose (release) for this research study includes all information in your medical record related to the diagnosis and management of your chronic kidney disease, including the record of your care, as well as any information collected or created during the course of this study.

St. Elizabeth's Medical Center, Tufts Medical Center, and Tufts University Health Sciences are required by law to protect your health information. By signing this document, you authorize St. Elizabeth's Medical Center, Tufts Medical Center, or Tufts University Health Sciences to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You may not be allowed to see or copy the information described on this form as long as the research is in progress, but you have a right to see and copy the information upon completion of the research in accordance with hospital policies.

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St. Elizabeth's Medical Center, Tufts Medical Center, or Tufts University Health Sciences may not withhold or refuse to provide you with clinical care based on whether or not you sign this form.

This authorization does not have an expiration date. You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, this site's clinical, administrative and research staff may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this authorization, you must write to HIPAA Privacy Officer for Research at One Kneeland Street, Room 334, Boston, MA 02111. For St. Elizabeth's Medical Center, contact Vaidyanathapuram Balakrishnan, MD, telephone: 617-789-3168. If you revoke this authorization, you may no longer be allowed to participate in the research described in this form.

### **WHOM TO CONTACT**

#### **Overall Principal Investigator**

Keren Ladin, PhD  
Telephone: 617-627-5931  
After-hours telephone: (617) 431-6467  
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#### **St. Elizabeth's Principal Investigator**

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#### **Study Coordinator**

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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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness' Signature

\_\_\_\_\_  
Witness Name

