Transplant Regimen Adherence for Kidney Recipients by Engaging Information Technologies: The TAKE IT Trial

NCT03104868

Informed Consent Form
12/10/2019

Permission to Take Part in a Human Research Study

Title of Research Study: ***Transplant Regimen Adherence for Kidney Recipients by Engaging Information Technologies: The TAKE IT Trial***

Investigator: ***Michael Wolf, PhD MPH***

Supported By: National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you received a kidney transplant between 5 weeks and 24 months ago.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study is being done to evaluate various ways technology can be used to help patients take their medicine safely and appropriately.

How long will the research last and what will I need to do?

We expect that you will be in this research study for about 2 years.

You will be asked to complete two in-person study visits, and four visits via phone.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

There is no physical risk from taking part in the other portions of this study.
There is a small potential for loss of private information; however, there are procedures in place to minimize this risk. The questions may make you feel uncomfortable or remind you of unpleasant aspects of your condition. You may skip any question you do not want to answer.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

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Will being in this study help me any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include better understating of prescription medications.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at (312) 503-3117.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 300 people here will be in this research study out of 600 people in the entire study nationally.

What happens if I say "*Yes, I want to be in this research*"?
If you participate in this research study, you will be randomized to be in 1 of 2 groups. Randomization means you will be randomly assigned to a group based on chance, like flipping a coin. Neither you nor the study team will choose what group you get. You will have an equal 1 in 2 chance of being in each group. The groups are:

1. Usual care group. Patients in the usual care group will receive the normal standard of care.
2. TAKE IT group. Patients randomized to the TAKE IT group will receive tools to help simplify your role in managing complex, multi-drug regimens and moniter use over time. This approach includes the following 2 components
    - **Monthly Questionnaire.** You will be asked to complete a monthly online questionnaire about your medications and any concerns or problems that you may have taking your medicines. Any concerns will be flagged to your doctor or nurse, and they may contact you to follow up.

- **Mobile application**. You will be given the opportunity to download the 'Transplant Hero' mobile app if you have a smartphone. If you decide to download the app, you will receive daily notifications reminding you to take your medicines. If at any point you do not want to get the reminders anymore, you will be able to stop them.

Interviews

Regardless of which of the groups you are assigned to, you will be asked to complete two in-person interviews and four interviews over the phone.

1. The first interview will take place in person and will take about 45 minutes to complete. During this interview, you will be asked questions about your health, the medications you take, how you understand health information, and a few other basic background questions.
2. The second interview will be 6 weeks after your first interview, and the third will be 6 months after your first interview. They will be completed over the phone and will take about 20-30 minutes. We'll ask you about how you are taking your medicines and your understanding of what they do, as well as some questions about your satisfaction with any materials you may have received (monthly questionnaire, mobile application, etc).
3. The fourth interview will take place 12 months after the first interview and it will take place in-person. It will take about 45 minutes to complete. We will ask you similar questions about your medications and health, as well as more questions about any materials you may have received.
4. The final interviews will take place at 18 and 24 months. They will be completed over the phone and will take about 20-30 minutes. We will ask similar questions about your medications and health, as well as questions about your experience participating in the study.

Medical Record Review

In addition to the interviews, we will also collect some health information from your medical record. We will collect information about your prescription medicines, chronic conditions, and clinical values. We will get this information directly from your clinic, so you won't need to do anything. Signing this form today will let us access your record.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given either treatment.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to participate in two in-person and four phone interviews for the study, as well make a decision to complete the optional blood draw.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can ensure that you will not be contacted again regarding the research study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not

to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?

There is no physical risk from taking part in this study.

Psychological risks: The questions make may you feel uncomfortable or remind you of unpleasant aspects of your condition. You may skip any question you do not want to answer.

Privacy risks: This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study? Taking part In this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to participants from taking part in this research. However, possible benefits include better understating of prescription medications.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the National Institutes of Health (NIH), US Department of Health and Human Services (DHHS) and US Office for the Protection of Human Research Protections (OHRP).

After the study is finished, a dataset that does not contain any identifying information will be kept indefinitely for future analysis. Only authorized research personnel will have access to these data.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web stie will not include information that can identify you. At most, the Web site will include a summary of the results. You can serach this Web site at any time.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific

standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you agree to take part in this research study, we will pay you $140 total for your time and effort. You will receive $30 after the first,6 month and 12 month interviews. You will receive $50 after the 18 month interview.. Payment will come in form of cash at the end of the in-person interviews. For phone interviews, payment will be mailed in the form of a money order.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about medication or drugs

During this study you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

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- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited the Rehabilitation Institute of Chicago (RIC), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The National Institute of Diabetes and Digestive and Kidney Diseases, who is sponsoring the study, and that company's contractors and partners.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

At the end of the research study, when all analyses have been completed, all protected health information (PHI) will be deleted.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Michael Wolf
Northwestern University
750 N. Lakeshore Drive
10th Floor
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any tests or procedures done may be included in your medical records and may be seen by your insurance company.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Your signature documents your permission to take part in this research.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent