Roybal Center for Therapeutic Optimization using Behavioral Science

Center PI: Niteesh Choudhry, MD, PhD

Study Title: Leveraging Social Networks to Control Hypertension after Ischemic Stroke

Study PI: Amar Dhand, MD, DPhil

NCT05258890

Consent Form Valid Date: December 20, 2023

Mass General Brigham

Research Consent Form
Certificate of Confidentiality
Version Date: February 2021

Subject Identification

Protocol Title: TEAMS-BP" (The Enhancement of social networks to Augment Management of Stroke-Blood Pressure): A Randomized Control Trial

Principal Investigator: Amar Dhand, MD, DPhil

Site Principal Investigator: N/A

Description of Subject Population: Adults with hypertension who are hospitalized at Mass General Brigham following a stroke.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about how to help stroke survivors achieve the best possible blood pressure control. We hope to understand whether the involvement of family, friends and other members of individual's social network can help achieve better health outcomes after experiencing a stroke.

How long will you take part in this research study?

If you decide to join this research study, it will take you about **3 months** to complete the study. During this time, we will ask you to make **3 virtual** study visits via Zoom or phone.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen:

1) The study team will ask you basic information about yourself. This will include demographic information and a questionnaire about how you are feeling. They will also gather information about your stroke from your electronic health record.
2) The study team will ask you about the people with whom you are connected on a regular basis and their health habits.
3) You will be provided with a blood pressure cuff and instructions for weekly home blood pressure monitoring.
4) You will be randomized to receive either personal or team counseling with a MGB study nurse.
5) People assigned to personal counselling will be asked to attend three 30 to 45-minute counseling sessions using the MGB-approved secure Zoom platform. During the first two sessions, the study nurse will educate you and help make a plan for your stroke recovery and blood pressure control. During the third virtual visit with the study nurse the nurse will see how you are doing physically and mentally. In between these sessions, you will also receive text messages about counseling sessions and blood pressure control.
6) In team counselling, the network members who you chose will be invited to participate in the study along with you. You and the network members who agree to participate will all attend the virtual visits together. These sessions will be similar to the individual coaching sessions except you will also learn about how teams can work together to assist in stroke recovery. You and your network members will also communicate as a group via text message.
7) After your participation in the study, the study team may contact you to invite you to participate in a brief survey or interview to ask your opinions about the study.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include increased knowledge and help with your stroke recovery and managing your blood pressure. Other stroke patients may benefit in the future from what we learn in this study. We hope to identify effective methods for improving network cohesion and participation during stroke recovery.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include accidental disclosure of the confidential information that you mention about you or others. As with any group interaction there is the possibility of uncomfortable interactions, tensions or embarrassment. We will use our best efforts to keep this information secure, and we think the risk of accidental disclosure is very small.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are the requirement of a smart phone, computer, or tablet to attend counseling sessions. This study will also request that you participate in 3 separate 30 to 45-minute Zoom sessions over the course of 3 months.

What other treatments or procedures are available for your condition?

Your provider is currently prescribing medication to control your blood pressure and offering appropriate treatment for your condition. You should continue to take these medications and do not require any additional clinical treatment or medical procedures to participate.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Amar Dhand, MD, DPhil, is the person in charge of this research study. You can call him/her at **617-732-5330 Monday-Friday 9AM-5PM**.

You can also call **Niteesh Choudhry, MD, PhD, Co-Investigator** at **617-278-0930** or **Katie Crum, Research Assistant**, at **617-264-3094 Monday-Friday 9AM-5PM** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Katie Crum** at **617-264-3094 Monday-Friday 9AM-5PM**.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. 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.

Why is this research study being done?

In this research study we want to learn more about how to help stroke survivors achieve the best possible blood pressure control. We hope to understand whether participation of friends and family members in the recovery process leads to different physical and mental outcomes than those patients with less network involvement.

Who will take part in this research?

We are asking you to take part in this research study because you are at least 21 and have a history of hypertension or have newly been prescribed blood pressure medications during your hospitalization. About 60 people who are hospitalized at a Mass General Brigham (MGB) hospital for their stroke will take part in this research study. The National Institutes on Aging (NIA) is paying for this research to be done.

What will happen in this research study?

If you decide to join this research study, the following things will happen:

You should continue all medication and treatments as prescribed by your treating physician. This study does not involve changes to your medical treatment. A notation that you are taking part in this research study may be made in your electronic medical record.

Study enrollment

If you agree to participate in this study, the study staff will help you to complete surveys while you are still in the hospital. These surveys will include information about your demographics, how you are feeling, and information about the people with whom you are connected with on a regular basis and their health habits. If you agree to participate in both this study and one of Dr. Dhand's other research studies ("SocialBit: Establishing the accuracy of a wearable sensor to detect social interactions after stroke" or Time is Brain: Social Networks and Risk of Delayed Arrival to the Hospital During Stroke), we will not have you repeat surveys collected by both

studies. Instead, information about how you are feeling and the people with whom you are connected with on a regular basis will be shared between research studies.

You will be provided with a blood pressure cuff and instructions for weekly home blood pressure monitoring. You will then be randomly assigned to one of the study groups. You may also work with study staff to call friends and family (network) members about participating in this study with you. This enrollment visit should take about 30-45 minutes.

Text messages
Prior to your first counseling session and in between counseling visits, you will receive text messages. You may also receive group text messages between study staff and your network members about blood pressure education.

Virtual Counseling Visit #1
The first virtual counseling session will take place two weeks after your enrollment visit at the hospital. You and potentially some of your identified network members will meet with the study nurse for a remote counseling visit through Zoom, an MGB-approved secure video platform. The nurse will provide counseling about managing blood pressure. You will then be asked to collect a blood pressure measurement with the cuff provided by the study staff under supervision of the study nurse. This visit will last approximately 30-45 minutes.

Virtual Counseling Visit #2
The second virtual counseling session will take place six weeks after your enrollment visit at the hospital. You and potentially some of your identified network members will meet with the study nurse for a remote counseling visit through Zoom, an MGB-approved secure video platform. The study nurse will provide counseling about physical activity and exercise. You will again be asked to collect a blood pressure measurement with the cuff provided by the study staff under supervision of the study nurse. This visit will last approximately 30-45 minutes.

Final Virtual Visit
The final virtual visit will take place 12 weeks after the enrollment visit. In this session, you will be asked to collect a blood pressure measurement with the cuff provided by the study staff under supervision of the study nurse. You and potentially some of your identified network members will complete surveys and answer questions about how you are feeling and what has taken place during the study.

Post-study survey or interview
After you have finished your participation in this study, the study team may reach out to you to invite you to participate in a brief survey or interview to ask your opinions about the study. You

will be asked about the timing and appropriateness of the study, what you liked or disliked, and other questions that will help us to improve the study for future participants.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you consent to participate in both this study and one of Dr. Dhand's other research studies (SocialBit), we will share information about how you are feeling and the people with whom you are connected with on a regular basis with his study team. Additionally, if you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a steppingstone in understanding how social networks can be used in stroke recovery and blood pressure control. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. The results of the study will not be placed in your medical record.

We will publish what we learn in medical journals. In the future, when research results are published, they may show that certain groups (for example, racial or ethnic groups, or gender) are associated with increased risk of a disease. If this happens, you may learn that you are at increased risk of developing a disease or condition.

What are the risks and possible discomforts from being in this research study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include accidental disclosure of the confidential information that you mention about yourself or others. Some of your social network members (friends and family members) may be invited to participate in this study and will potentially receive text messages and participate in discussions regarding the management of your blood pressure. As with any group interaction there is the possibility of uncomfortable interactions, tensions, or embarrassment. By agreeing to participate in this study, you agree to include friends and family members in discussions about your post-stroke care and blood pressure control.

Other things to consider are the requirement of a smart phone, computer, or tablet to attend counseling sessions. This study will also request that you participate in 3 separate 30 to 45-minute Zoom sessions over the course of 3 months.

You will also receive text messages to remind you of your upcoming appointments and share general information about blood pressure control. Text messages by mobile/cell phones are a common form of communication. Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. We are minimizing this risk by only transmitting mostly educational information, task adherence, and social skill education. For example, text messages may be seen by unintended parties. This research study and Mass General Brigham cannot control these risks.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messages sent to the research team will only be read during regular business hours (Monday through Friday, 9AM – 5PM Eastern Time). Texts sent on nights, weekends or holidays will not be read until the following business day.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."

- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.

- You should not screen shot, forward or save any messages sent within the study-related group SMS thread in order to protect the privacy of yourself and other network members.

- We cannot guarantee that messages shared within the group SMS thread will be treated as confidential by everyone in the group and, therefore, you should not disclose any confidential or sensitive information.

- All participants should exercise both common sense and courtesy in the messages they transmit on the group SMS thread and may not use the group SMS thread to transmit defamatory, obscene, and otherwise offensive communications.

- Participants are prohibited from using the group SMS thread for any purposes that may be illegal.

There is a risk that the programs' servers could be compromised, either by hackers or other computer failures, and this data made public, resulting in the unwanted release of health information. Risks of this sort will be minimized by only uploading your phone number to the text messaging platform, so that these external platforms do not have access to information such as your name or location.

You may withdraw from this study at any time, and this will in no way affect the care you receive at Mass General Brigham.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include increased knowledge and help with your stroke recovery and managing your blood pressure. Other stroke patients may benefit in the future from what we learn in this study. We hope to identify effective methods for improving network cohesion and participation during stroke recovery.

What other treatments or procedures are available for your condition?

Your provider is currently prescribing medication to control your blood pressure and offering appropriate treatment for your condition. You should continue to take these medications and do not require any additional clinical treatment or medical procedures to participate. You do not have to take part in this study to be treated for your stroke or blood pressure.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will receive $100 for completing the entire research study. You will receive $25 for completion of the first virtual study session, $25 for completion of the second virtual study session, and $50 upon completion of the final virtual study session. You will receive these payments in a one-time, single payment upon your completion of study participation.

What will you have to pay for if you take part in this research study?

Study funds will pay for a blood pressure cuff which will be used for remote blood pressure monitoring during the study. This will be given to you before you leave the hospital. You will not be required to undergo any additional medical procedures to participate in this study.

Therefore, you will be responsible for payment of any deductibles and co-payments required by your insurer for routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

You will be responsible for all fees charged by your cell carrier's service plan for text messaging and phone calls. You are also responsible for any fees charged related to broadband and/or internet usage associated with Zoom video meetings. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records

- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the

hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.
- I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: 4; 11 December 2023