

Official Title:	Feasibility of a Family-oriented mHealth Intervention for Chinese Americans With Type 2 Diabetes
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Telephone Consent

Hello, my name is _____. I am a *student/faculty member/staff member*) from the New York University Grossman School of Medicine conducting research titled Feasibility of a Family-oriented mHealth Intervention for Chinese Americans with Type 2 Diabetes. I am contacting you because [Dr. _____ (enter name of treating physician) or your spouse/parents (enter patient name) informed me that you were willing to be contacted.]

I would like to tell you more about what you would be doing in the study and the risks and benefits before you decide to join the study. Your participation is very important to us because it will help us further improve our education program and improve diabetes care for Chinese Americans.

If you feel you have been contacted for this study in error, please let me know. If you feel you have been contacted for this study in error, please let me know. If you would like to remove your name from our contact list for future research studies, please call (1-855-777-7858) or email (research-contact-optout@nyumc.org).

I'd like to emphasize that your participation is completely voluntary. This means that you do not have to participate in this study unless you want to. Your decision whether or not to participate in this study will not affect your relationship with your medical providers or NYU Langone Health. There are no costs to you for participating in this study.

Would you be willing to hear more information about this study?

If yes: I would like to let you know that this phone call will be audio recorded. This recording will be labeled with a code number that will not identify you. It is important that we audiotape today's call, so that we have a record of exactly what was discussed and answered.

Is this ok with you?

(If yes, continue with below. If interested, but busy at this time, ask to schedule a time to talk within the next few days. If no, thank them for their time and end the call.)

Yes ☐

No ☐

Thank you, I appreciate your time. The purpose of this study is for us to learn whether our family-based diabetes education program can help Chinese Americans diabetes patients to lower their blood sugar.



If you agree to participate,

For patients: You will be asked to *answer a series of questions* on how you are currently managing your diabetes.

For family/friend: You will be asked to answer a series of questions on how you are currently supporting your family/friend to control their diabetes.

We estimate that approximately 60 participants will enroll in this study, including 30 T2D Chinese patients and 30 corresponding family members. Each participant pair will be randomly assigned to two different groups. **Group 1** is the intervention group where participants will receive 2 diabetes education videos every week over a 12-week period, and we will follow-up every 2 weeks. We will also host focus group discussion at the end of 3-month intervention to understand your experience with our study. The focus group will be video/audio recorded. **Group 2** is the control group where participants will continue their routine care at their own doctor and receive all videos at the end of the study.

You may find some questions difficult or sensitive in nature and do not wish to answer, just tell me and we will go on to the next question.

Your participation will take approximately 30-45 minutes each time for 3 times, including today, 3 months and 6 months later. Each session will include audio/Video recordings.

These recordings will be labeled only with a code number, which will be kept in the Investigator's locked files. The tapes will be used to help us understand your experience with our study intervention. Understanding this information will help us to make improvements to our study, so that we can better help Chinese Americans to manage their diabetes in future.

If you agree to participate in this study, your verbal consent gives the researchers permission to make and retain the audio/video recordings for this study. You have the right to review the recordings and to request that all or any portion of the recording be erased. Once the recordings are transcribed (typed-up), the audio/video tape will be destroyed by the research team.

The risks in participating in this study are minimal including some discomfort to answer some questions. You can skip those questions that makes you feel uncomfortable. Although this study may not benefit you personally, we hope that our results will add to the knowledge about how to best help Chinese Americans to control their diabetes.

Would you like me to continue describing the study?

(If yes, continue with below. If no, thank them for their time and end the call.)



You will be compensated \$30 each time for completing the surveys. If you are in the intervention video group, you will receive \$5 each week if you finish watching both videos for that week. For a total of 12 weeks' videos, you can receive \$60. If you are in the control group, we will also provide you with \$60 at 3-month follow up. You will receive in total of \$150 if you can complete the study with us. You will not have to pay for any research related expenses.

We are committed to protecting your privacy and maintaining confidentiality, as comprised confidentiality is a risk during research studies. In order to lower this risk, you will be identified only by a study number and all study related information will be stored securely. If it is okay with you, I might want to use direct quotes from you, but these would only be cited as 'from a person'. We will not identify you by name or any other information that would make it possible for anyone to identify you in any presentation or written reports about this study. When this call is completed all the surveys, I will group all the answers together with the other participants in one report. Further, psychological risks and discomforts may arise from answering personal or sensitive questions. To minimize that risks and discomforts you can decline to answer any of the interview questions.

For patients only:

To do this research, we need to temporarily collect some health information that identifies you. We may temporarily collect your blood sugar results *from your medical record*. We will call your doctor's office to ask for your HbA1c blood test results at the beginning of the program, 3 months and 6 months later. We will only collect information that is needed for the research. For you to be in this research, we will need your permission to collect and share this information.

For both:

This study is expected to end after all participants have been enrolled and all information has been collected. To reiterate, your participation in this study is completely voluntary. If you decide to participate, you are free to leave the study at any time. If you agree to participate in this study, you are giving us permission to collect, use and share your health information. If you decide not to verbally agree to allow for us to use and disclose your protected health information, you cannot be in the research study. We cannot do the research if we cannot collect use and share your health information.

The following individuals would be granted access to your information for this research study: the principal investigator and all members of the research team, the study sponsor (National Institutes of Health), and governmental agencies responsible for



research oversight, health care providers who provide services to you in connection with this study.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it. You may withdraw your permission at any time. If you do, we will not be able to take back information that has already been shared with others.

How will you contact me during this study?

We will contact you mainly through phone calls from an NYU Langone Study Phone. WeChat will be only used to send you the health education videos. You should not respond to these WeChat message in a manner that provides or discloses any Protected Health Information. We will ask your permission to use WeChat platform. Please be advised that sending messages over an unsecured application like WeChat is an unsecure and unencrypted form of communication and there is a potential risk of disclosing information to an individual who is not authorized to receive it (unauthorized disclosure). If you do not wish to communicate in this manner, please let us know.

What will happen if I don't want to be contacted via WeChat?

We will not contact you via WeChat. We will contact you by phone calls. WeChat will only be used to send you the education videos. No other communication will occur via WeChat. If you have any questions, please call us at our study phone number. You can still participate in the study if you decline to receive the education videos on your WeChat. As an alternative, we will send the education videos as regular text messages to your phone.

Can I decline to the use of WeChat at any time on the study?

Yes, you can decline at any time during the study to receive the videos on WeChat and then we will switch to send you videos via regular text messages.

How will you protect my information and minimize the risks while using WeChat in this study?

As I mentioned above, we will communicate with you through phone calls. No communication will occur via WeChat. WeChat will only be used to send education videos to you. Also, we will remind you at the beginning of the study and during the bi-

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weekly phone calls about not sending any Protected Health Information via WeChat. In addition, our education videos do not contain any Protected Health Information and it will teach you about diet, exercise, and stress management in general. Based on our recent completed pilot study (a similar WeChat video study in 30 Chinese immigrants), we did not observe any breach of privacy or confidentiality. All of the study team members received sufficient training on protecting privacy and confidentiality and have extensive experience in working with Chinese immigrants.

Would you like to be contacted via WeChat?

Yes ☐

No ☐

NYU Langone Health would also like to store, use and share your health information from this study in research databases or registries for future research conducted by NYU Langone Health or its research partners. You may still participate in this study even if you do not give us this additional permission. NYU Langone Health will continue to protect the confidentiality and privacy of this information as required by law and our institutional policies. You have the right to take back this additional permission at any time. Would you be willing to allow us to store, use and share your health information from this study in research databases or future registries?

(Yes/No)

Yes ☐

No ☐

Your information may also be useful for other studies. We can only use your information again if a special committee in the hospital gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information private.

Once I gather the required information, I will delete any identifying information related to you, such as your name or medical record number. For you to be in this research, we will need your permission to collect this information. Only research personnel authorized for this study will have access to your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the Principal Investigator (*Lu Hu, PhD; 180 Madison Ave, 7th floor, New York, NY, 10016*). The letter needs to say that you have



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changed your mind and do not want the researcher to collect and share your health information. At that time, we will remove any information we have collected about you in regard to this study. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Do you have any questions at this time?

Would you like to participate in this research?

(If yes, continue with below. If no, thank them for their time and end the call.)

Yes ☐

No ☐

Thank you so much for your time. Before I let you go, I just want to tell you about the Institutional Review Board and give you some contact info in the event you have any questions or concerns. Please feel free to reach out to the study team at 347-380-2416 with any questions, concerns or complaints regarding your participation in this study. Finally, the IRB is a committee that reviews all human research studies, including this study, to ensure that the rights and welfare of all participants are protected and that the study risks are as minimal as possible. If you have any questions regarding your rights as a research subject, please contact the Institutional Review Board (IRB) at 212-263-4110.

I would like to send you via text message a form that provides a detailed overview of everything I've discussed with you today, including contact information. Is that ok?
(If 'yes', send them the Key Information Sheet by text and wait for them to review before beginning study interview. If 'no', tell them that they can request this information anytime and begin study interview.)

Yes ☐

No ☐



Research Subject Key Study Information Form

Title of Study: Feasibility of a Family-oriented mHealth Intervention for Chinese Americans with Type 2 Diabetes
s19-01275

Principal Investigator: Lu Hu, PhD
Department of Population Health
NYU School of Medicine
180 Madison Ave, New York, NY 10016
(646) 501-3438

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

Purpose of the Research Study

The purpose of this research study is to learn about whether our family-based diabetes education program can help Chinese Americans or Immigrants manage their diabetes. We are asking you to take part in this research study because you or your family/friend has type 2 diabetes.

Other Key Information

This study will last about 6 months and will involve about 3 telephone surveys. We will send you brief diabetes videos to help you with your diabetes management. If you are the patient participant, during each visit, we will obtain your HbA1c result from your health care provider and ask you to answer questions from our survey. If you are the family/friend participant, you will only be asked to answer questions from our survey. We will randomly select some of you to join a group discussion or interviews to understand your experience with our study.

Foreseeable Risk and Benefits

A comprehensive list of all possible risk and discomforts related to this research is included in the full consent, the most common risk experienced for both patient and family/friend participants include 1) feeling uncomfortable to answer some questions, 2) breach of confidentiality. For patient participants, our study is designed to enhance your adherence to standard diabetes care (e.g., adherence to the prescribed diabetes medication, healthy eating, and physical activity behaviors). If our intervention improves adherence to the medication regimen or if you make lifestyle changes (e.g., increased physical activity), more incidence of low blood sugar may result. We advise you to monitor your blood sugar as suggested by your doctors, and to contact your doctors as soon as you experience low blood sugar.

We will contact you mainly through phone calls from NYU Langone Study Phone. WeChat will be only used to send you the health education videos. You should not respond to these WeChat messages in a manner that provides or discloses any Protected Health Information. We will ask your permission to use WeChat platform. Please be advised that sending messages over an unsecured application like WeChat is an unsecure and unencrypted form of communication and there is a potential risk of disclosing information to an individual who is not authorized to receive it (unauthorized disclosure). Our study team will remind you at the beginning of the study and during the bi-weekly phone calls about not sending any Protected Health Information via WeChat. In addition, our health education videos do not contain any Protected Health Information and it will teach you about diet, exercise, and stress management in general. If you do not wish to communicate in this manner, please let us know.

You can still participate in the study if you decline to receive the health education videos on your WeChat. As an alternative, we will send the education videos as regular text messages to your phone. You can decline at any time during the study to receive the videos on WeChat and then we will switch to regular text messages.



You may not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because your participation in this study will help us to understand whether our program can help patients to control their diabetes and how we can make it better.

Alternatives to Participation

Should you choose not to participate, your medical care will not be affected.

For questions and concerns regarding any of this information, contact Dr. Lu Hu at 347-380-2416 or lu.hu@nyulangone.org.