

INFORMATION SHEET

Title of Research: Improving diagnosis of heart failure with preserved ejection fraction in primary care

UAB IRB Protocol #: IRB-300010946

Principal Investigator Yulia Khodneva, MD, PhD

Sponsor: National Heart Lung Blood Institute

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to gain primary care provider perspective on diagnosis and management of heart failure with preserved ejection fraction (HFpEF) in primary care.
Duration & Visits	You will be in this study for an online survey.
Overview of Procedures	This study will consist of 1 survey
Risks	The most common risks include time burden and stress, resulted from discussing potentially sensitive topics about practicing medicine and difficult patient cases.
Benefits	You may or may not benefit directly from this study, but the scientist will obtain invaluable information from primary care physicians on how to improve care for patients with HFpEF.
Alternatives	If you do not want to take part in the study you can decline to participate

Purpose of the Research

In this proposal we aim to develop and pilot test a clinical diagnostic decision support aide (CDDSA), embedded in the electronic health records and specifically designed for primary care providers (PCP) to diagnose HFpEF. This project will include identification of provider barriers to HFpEF diagnosis among PCPs via a survey and a stakeholder-engaged process to design an educational session and CDDSA to optimize HFpEF diagnosis in primary care. Prior research suggests that CDDSA that are designed with physician input lead to an increase of physician medical knowledge regarding heart failure, reduce time burden, improve adherence to guidelines and improve patient outcomes.

Explanation of Procedures

If you agree to participate in this voluntary research study, you will be asked to participate in a remote video-facilitated interview and answer a brief questionnaire. If you agree to participate in our study, a research staff member will ask you about your current practice with patients with HFpEF. The interview will take about 30 minutes to complete. The interview will be recorded using Zoom platform. Then, a written record of the recording will be typed. The written reports from the recording will give researchers helpful facts to understand the challenges you face in treating patients with HFpEF and your suggestions for developing an intervention to help diagnose patients with HFpEF. When we receive the interview and survey data from you we will draft the intervention protocol for HFpEF intervention in primary care and will reach out to you to participate in a follow up focus group to discuss the draft of the intervention. The focus group will take place via Zoom and will be about 35 minutes long. The group meeting will be recorded.

No names or any other information that could identify you will be put in the written record. At any time, you can refuse to answer any question that causes you discomfort. We will conduct all interviews and measurements in a respectful and non-judgmental manner.

No names or any other information that could identify you will be put in the written record. At any time, you can refuse to answer any question or to complete any measurement that causes you discomfort. We will conduct all interviews and measurements in a respectful and non-judgmental manner. Overall we plan to enroll 30 PCPs for interviews, 200 pcps for survey completion and 50 PCP for focus groups.

Risks and Discomforts

- You may feel anxious talking about your experiences as a primary care physician, however with this type of study it is extremely rare. You can skip any question(s) that takes uncomfortable or stop the survey at any point.

Benefits

- You may not directly benefit from participation in this study. However, on the aggregate level this study will collect important data in preparation of developing CDDSA.

Payment for Participation:

You will be paid \$25 (twenty-five dollars) in the form of a check or Visa gift card for your participation in the interview and \$25 in the follow-up focus group.

Cost of Participation

There is no cost associated with participation in this study.

Confidentiality

The information gathered during this study will be kept confidential to the extent permitted by the law. Research information that identifies you may be shared with the University of Alabama at Birmingham's Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including the UAB Office for Human Research Protections (OHRP). However, your name will not appear on any of the transcripts. Information from your participation will be used for the purposes of instruction and scientific publication only. If you would like, you can receive a copy of the results of this investigation and/or discuss the study with a staff person. Just call Dr. Khodneva's at (205) 937-3027 and we will be happy to answer all your questions and furnish you with a copy of the results.

By agreeing to participate in an interview and a follow-up focus groups you are consenting to allow your response to be used in this research study.

Voluntary Participation and Withdrawal

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Legal Rights

You are not waiving any of your legal rights by agreeing to participate.

Questions

If you have any questions, concerns, or complaints about the research, please contact Dr. Yulia Khodneva. She will be glad to answer any of your questions. Dr. Khodneva number is (205) 937-3027.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.