Official title: Investigation of cardiac function with ultrasound

NCT number: NCT06567106

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1. Background

Cardiovascular disease is one of the most common diseases worldwide and one of the leading causes of death. Common cardiovascular diseases include coronary artery disease, heart failure, and arrhythmias, etc. These diseases affect the structure and function of the heart, leading to issues with contraction and relaxation, blood supply, and oxygen transport. Therefore, the diagnosis and management of cardiovascular disease are particularly important. Recent advancements in medical technology have introduced ultrasound intervention as a promising new method for managing cardiovascular diseases, offering an innovative alternative to traditional interventions. Ultrasound intervention has the potential to affect the cardiac function. By integrating this technology into clinical practice, this technique can provide more personalized and effective management options for patients with various cardiovascular conditions, ultimately aiming to improve quality of life.

2. Study aims

The aim of this study is to investigate the cardiac function with ultrasound. We will investigate how ultrasound interventions affect cardiac function. This study will contribute to early diagnosis, monitoring, and treatment strategies for cardiovascular diseases.

3. Study plan

Have the participant lie flat and relaxed, maintaining a still position. Prepare the ECG equipment and attach the electrodes to the subject's body to record the heart's electrical signals. Collect the ECG signal before, during and after ultrasound intervention. Prepare the ultrasound equipment and place the ultrasound transducer on the participant's chest, adjusting the angle and position as needed. Set the ultrasound parameters and begin the cardiac ultrasound experiments. Conduct the experiments and analyze the data.

4. Statistical analysis plan

4.1 Outcome variables

4.1.1 Primary outcome

Variable: Heart rhythm.

Description: Monitor participants' electrocardiogram before, during and after ultrasound application. Calculate heart rate from the electrocardiogram signal. The change of heart rate is calculated as the rate of change relative to the baseline heart rate. Aggregate the data and do statistical analysis. Data will be presented as mean with standard deviations.

Measurement: Electrocardiogram.

4.1.2 Secondary primary outcome

Variable: Incidence of treatment-related adverse events.

Description: The incidence of treatment-related adverse events includes both minor (such as localized discomfort, transient arrhythmias, mild chest pain, short-term dizziness, nausea, and

temporary shortness of breath) and severe adverse events (including sustained arrhythmias, new-onset heart failure, significant myocardial injury, embolic events, or death).

Measurement: Electrocardiogram and observation.

4.2 Statistical methodology

To evaluate the influence of ultrasound intervention on cardiac function, analyze whether ultrasound intervention leads to significant differences in cardiac function. Participants will be randomly assigned to receive either ultrasound application or the control treatment. The differences between the two groups will be analyzed through statistical analysis. Use Shapiro-Wilk test to determine Gaussian distribution. For normally distributed data, use one-way ANOVA followed by Bonferroni multiple comparison tests to analyze the influence of ultrasound intervention.

5. Informed consent form

Title: Investigation of cardiac function with ultrasound

Principal investigator: Prof. Bingbing Cheng

You are invited to participate in a clinical study about the investigation of cardiac function with ultrasound. This informed consent form provides you with some information to help you decide whether to participate in this clinical study. Please read it carefully, and if you have any questions, please ask the researcher in charge of the study.

Your participation in this study is voluntary. This study has been reviewed and approved by the Research Ethics Committee of ShanghaiTech University.

The aim is to investigate the cardiac function with ultrasound, such as heart rate. Arrhythmias may affect cardiac systole and diastole, thus impacting the ejection fraction and shortening fraction. When the heart contracts in an uncoordinated manner or too rapidly, the ejection fraction may decrease because the left ventricle does not have enough time to expel the blood. Additionally, cardiac conditions such as myocardial infarction may also lead to decreased ejection fraction and shortening fraction. Therefore, these indicators of cardiac function are crucial for the diagnosis and management of cardiovascular diseases.

All equipment used is regularly maintained and inspected to ensure optimal working conditions. Before and after the experiment, we will thoroughly clean and disinfect the experimental environment. Throughout the experiment, professional personnel will monitor the process to promptly respond to any unexpected situations.

If you agree to participate in this study, we will communicate with you or your family in detail and introduce the study's relevant information. We will assign a number to each participant and establish a file.

The ultrasound application part of this study is expected to take no more than 120 minutes in total. This includes all necessary preparations, the duration of ultrasound application, and recovery time after the ultrasound intervention.

The experimental parameters used in this study are very safe. A small amount of gel will be applied to the skin over the heart, which may cause some discomfort for some individuals. All your information will be kept confidential.

We fully respect and protect the privacy rights of participants. All collected personal

information and experimental data will be kept strictly confidential and used only for the purposes of this study. Under no circumstances will we disclose participants' personal information to third parties without explicit consent from the participant. In the publication of experimental reports and papers, all participant information will be presented anonymously, ensuring that it cannot be traced back to individual identities.

Participants will receive free ECG and ultrasound application and will receive all examination results. Your participation will contribute valuable information to the research of cardiovascular diseases. Each participant will receive a fine souvenir.

As a research participant, you have the following responsibilities: to provide truthful information about your medical history and current physical condition; to inform the researchers of any discomfort experienced during the study; to avoid taking restricted medications, foods, etc.; and to inform the researchers if you have recently participated in other studies or are currently participating in other studies.

If you decide to participate in this study, your participation and personal data in the trial will be kept confidential. This information may include your name, address, phone number, medical history, and information obtained during your study visits. Identifiable information will not be disclosed to members outside the research team without your permission. All research members and sponsors are required to keep your identity confidential. When the results of this study are published, no personal information about you will be disclosed.

You may choose not to participate in this study or notify the researchers at any time to withdraw from the study. Your data will not be included in the study results, and you will not be discriminated against or treated unfairly.