INFORMED CONSENT FORM

Effects of Stress Ball Use for Patients Undergoing Local Anesthesia in Ambulatory Surgery: A Randomized Controlled Trial

English Translation of the Original Chinese Version — Blank/Redacted Version for Public Posting

Official Study Title	Effects of Stress Ball Use for Patients Undergoing Local Anesthesia in Ambulatory Surgery: A Randomized Controlled Trial
Brief Title	Stress Ball Use During Outpatient Hand Surgery Under Local Anesthesia
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Sponsor / Institution	National Taiwan University Hospital, Hsin-Chu Branch, Taiwan
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Principal Investigator	Hsueh-Ling Chang, RN
Study Contact	Principal Investigator or authorized study personnel, Department of Nursing, National Taiwan University Hospital, Hsin-Chu Branch. Institutional telephone: 03-5326151 ext. 522181.

Public Posting Note: This blank/redacted version omits participant-specific identifiers, signature blocks, mailing-address fields, national ID fields, medical record fields, and direct personal mobile numbers, in compliance with 42 CFR 11.48(a)(5).

Key Information

- Why is this study being conducted? This study is being conducted to evaluate whether using a stress ball during outpatient hand surgery under local anesthesia can improve heart rate variability and reduce postoperative anxiety and pain.
- Expected duration of participation and procedures to be followed: The study begins when you agree to participate, sign the original approved consent form, and complete the preoperative assessments. It ends after you complete the immediate postoperative assessments.
- During surgery, a portable electrocardiograph recorder will be used to measure heart rate variability continuously.
- You will be randomly assigned to either the stress ball group or the control group. You and the study physician cannot choose the group.

Study Introduction

You are being invited to participate in this clinical trial/research study. This form provides information about the study. The principal investigator or authorized study personnel will explain the study to you and answer any questions you may have. Please do not sign the original approved study consent form until all of your questions have been answered to your satisfaction.

You do not need to decide immediately whether to participate. Please consider your decision carefully before signing. You may participate in this study only after signing the original approved consent form. Even after you agree, you may withdraw from the study at any time without giving any reason.

Study Summary

Outpatient hand surgery under local anesthesia is commonly performed while patients remain conscious. Remaining awake during the procedure may cause anxiety or fear. Heart rate variability is an objective measure derived from electrocardiography and reflects autonomic nervous system regulation during the procedure.

This study is a single-center, two-arm, parallel-group randomized controlled trial. Participants will be randomly assigned in a 1:1 ratio to a stress ball group or a control group using a computer-generated randomization sequence. Participant blinding is not feasible because participants will know whether they are using a stress ball. Statistical analyses will be performed by an independent statistician blinded to group allocation.

The purpose of this study is to evaluate whether intraoperative stress ball use enhances intraoperative heart rate variability and reduces postoperative anxiety and pain in patients undergoing outpatient hand surgery under local anesthesia without sedation.

1. Purpose of the Study

(1) To evaluate the effect of intraoperative stress ball use on intraoperative heart rate variability in

patients undergoing outpatient hand surgery under local anesthesia without sedation.

(2) To evaluate the effect of intraoperative stress ball use on postoperative state anxiety.

(3) To evaluate the effect of intraoperative stress ball use on postoperative pain intensity.

2. Background of the Study

Most outpatient procedures are performed under local anesthesia. During the procedure, patients remain conscious, which may cause anxiety and fear. Anxiety is an emotional state involving fear, uneasiness, or concern about uncertainty. Preoperative anxiety may be associated with physiological and psychological responses and may negatively influence postoperative recovery.

Stress ball use is a simple, low-cost, non-pharmacological strategy. It may reduce procedure-related stress through distraction, active hand movement, and tactile input. This study evaluates whether use of a stress ball during surgery can improve objective physiological indicators and patient-reported postoperative outcomes.

3. Inclusion and Exclusion Criteria

The physician or relevant research staff conducting this study will discuss the eligibility requirements with you. You are asked to truthfully disclose your past health conditions and recent medication use. If you do not meet the eligibility criteria, you will not be able to participate in this study.

Inclusion Criteria

- Adults aged 18 years or older who are able to communicate in Mandarin or Taiwanese Hokkien.
- Patients scheduled to undergo outpatient hand surgery under local anesthesia.

Exclusion Criteria

- Use of anxiolytics or sedatives within one week prior to surgery.
- Concurrent bilateral hand surgery during the same operative session.
- Known cardiac arrhythmia or use of a cardiac pacemaker, because ectopic beats and paced rhythms may invalidate heart rate variability analysis based on RMSSD.

4. Study Methods and Related Procedures

If you meet the inclusion criteria and agree to participate, you will be assigned to a study group by randomization. This means you will be assigned by chance, similar to flipping a coin. Neither you nor your study physician can choose the group to which you will be assigned. You have an equal, one-half chance of being assigned to either group.

Regardless of the group to which you are assigned, you will receive standard perioperative nursing care before, during, and after surgery under local anesthesia without sedation. This care will be provided by operating room nurses and may include postoperative education, wound care, instructions for oral

medications after surgery, and follow-up appointment scheduling.

Before surgery, baseline assessments will be performed on the day of surgery. These include a 5-minute resting heart rate variability recording while seated, a state anxiety questionnaire, and a pain assessment.

During surgery, heart rate variability will be recorded continuously by a portable electrocardiograph recorder while you are in the supine position. The recording will begin when you are positioned for surgery and continue until the end of surgery.

If you are randomly assigned to the stress ball group, the research staff will provide a commercially available soft foam stress ball, approximately 6 cm in diameter and of moderate resistance, for use in your non-operative hand. You will be asked to squeeze the ball rhythmically at a rate of approximately once every three seconds while focusing attention on the ball. You will have an opportunity to practice before entering the operating room. The intervention will begin at the initiation of surgery and continue until completion of the procedure.

If you are randomly assigned to the control group, you will receive routine operating room care. Your non-operative hand will rest naturally on the arm board without any object during surgery.

Immediately after surgery, you will complete the postoperative state anxiety questionnaire and the postoperative pain assessment.

Regardless of group assignment, your cooperation is essential in completing the questionnaires and undergoing electrocardiographic measurement during participation in this study. Each questionnaire will take approximately 5 to 10 minutes to complete. On the day of surgery, participation may require an additional approximately 20 to 30 minutes of your time.

The study assessments include:

- Basic demographic and clinical information, such as age, sex, body mass index, education level, marital status, type of surgical procedure, and relevant medical history.
- Heart rate variability measurement using a portable electrocardiograph recorder.
- State Anxiety Inventory, used to assess anxiety in a specific situation.
- Visual Analog Scale for pain, used to assess pain intensity.

5. Possible Risks, Their Frequency, and Management

This study evaluates a low-risk, non-pharmacological intervention. Possible discomforts include inconvenience or fatigue from completing questionnaires, mild physical or emotional discomfort during questions about anxiety or pain, mild skin discomfort from electrocardiograph electrodes, or hand fatigue from squeezing the stress ball.

If the interview, questionnaire, electrocardiographic measurement, or stress ball use causes physical or emotional discomfort, please contact the principal investigator or other research staff at any time for explanation or assistance. You may stop participating in study procedures at any time.

6. Alternative Treatments and Explanation

Participation in this study is entirely voluntary. If you choose not to participate, you will still receive routine treatment and routine perioperative care.

7. Expected Benefits of the Study

You may or may not receive direct benefit from participating in this study. The results of this study may provide clinical practitioners with evidence regarding whether stress ball use can help reduce anxiety and pain in patients undergoing outpatient surgery under local anesthesia, thereby supporting postoperative recovery and improving quality of care.

8. Prohibitions, Restrictions, and Participant Responsibilities During the Study

You are asked to follow the instructions of the study personnel during study assessments and, if assigned to the stress ball group, to use the stress ball as instructed during surgery. There are no additional restrictions beyond the study procedures described in this form.

9. Confidentiality of Personal Information

National Taiwan University Hospital will treat any records that could identify you and your personal privacy information as confidential in accordance with the law and will not disclose them publicly. The research staff will use a study code to represent your identity. This code will not include your name, national identification number, address, or other identifying information. If the study results are published, your identity will remain confidential.

By signing the original approved consent form, you agree that your original medical records may be directly reviewed by monitors, auditors, the Research Ethics Committee, and competent regulatory authorities in order to ensure that the clinical trial/research process and data comply with applicable laws and regulations. These personnel undertake not to violate the confidentiality of your identity. Except for institutions legally authorized to review such records, we will carefully protect your privacy.

10. Withdrawal and Termination of the Study

You are free to decide whether or not to participate in this study. During the study, you may withdraw or discontinue your consent at any time, for any reason, without any unpleasant consequences or any effect on your future medical care.

If important new information becomes available during the conduct of the study, meaning information related to your rights or that may affect your willingness to continue participating, you will be informed and given further explanation. You may then reconsider whether to continue participating. Your decision will be entirely voluntary and will not result in any unpleasant consequences or affect your future medical care. The principal investigator may also terminate the entire study if necessary.

If you withdraw from this study, or if the investigator determines that you are not suitable to continue participating, data already obtained before your withdrawal will be retained and will not be removed. After withdrawal, you may choose how previously provided data will be handled and decide whether the principal investigator may continue to collect your data after withdrawal, for example by obtaining information on subsequent medical care from your medical records. During any continued data collection, your privacy and the confidentiality of your personal information will continue to be protected.

Options in the original approved form:

- I agree to continued collection.
- I do not agree to the continued collection or review of my data in this trial/research study, except for records that may be obtained through public databases.

11. Compensation for Injury and Insurance

All trials/research studies involve some risk. To ensure that you understand the protections available should you suffer harm due to adverse reactions resulting from participation in this study, please read the following carefully:

(1) If harm is caused by an adverse reaction in accordance with this study protocol, National Taiwan University Hospital Hsin-Chu Branch shall be responsible for compensation. However, foreseeable adverse reactions stated in the consent form will not be compensated.

(2) If an adverse reaction or injury occurs in accordance with this study protocol, the hospital is willing to provide professional medical care and consultation. You will not need to bear the necessary medical expenses required to treat such adverse reaction or injury.

(3) Other than the compensation and medical care described above, this study does not provide any other form of compensation. If you are unwilling to accept this risk, please do not participate in the study.

(4) By signing the consent form, you do not waive any of your legal rights.

(5) This study is not covered by human subject research liability insurance.

If you do suffer injury due to an adverse reaction resulting from participation in this study, the above compensation includes reasonable medical expenses, provided that the injury was not intentionally caused by you and that you complied with the medical advice of the study physician.

12. Storage, Use, and Reuse of Participant Data

During the study, depending on the type of study and the scope of your authorization, we will collect medical record data, scales, questionnaires, heart rate variability recordings, and other information related to you. A code number will be used in place of your name and related personal information.

If such information is in paper form, it will be stored separately from the signed consent form in a locked cabinet at the study institution. If it is stored electronically or entered into a database for statistical

analysis, it will be kept on a dedicated computer protected by passwords and appropriate antivirus software. These study data and information will be retained for 2 years.

If the above data and information are transmitted abroad for analysis and statistical processing, you will still receive protections consistent with domestic laws and regulations, and the principal investigator and research team will make every effort to ensure that your personal information is properly protected.

After the study is completed, the study data may be used for academic publication. No biological specimens will be collected in this study.

13. Participant Rights

If you have questions during the study about the nature of the research, have concerns regarding your rights as a patient, or suspect that you have been harmed as a result of participation in the study, you may contact the Research Ethics Committee for consultation at (02) 2312-3456 ext. 263155.

During the study, any significant new findings related to your health or disease status that may affect your willingness to continue participating will be provided to you promptly. If you decide to withdraw, your physician will arrange for you to continue receiving medical care. If you decide to continue participating, you may be asked to sign an updated consent form.

If you have any questions or conditions now or during the study, please feel free to contact Nurse Hsueh-Ling Chang of the Department of Nursing, Hsin-Chu Branch of National Taiwan University Hospital (institutional contact number: 03-5326151 ext. 522181).

The original approved consent form is provided in duplicate. One signed copy is given to the participant after the study has been fully explained.

Participant reimbursement: This study will provide NT$200 for transportation.

If, within 2 years after the study ends, an unexpected issue is identified that directly affects your safety, you will also be notified.

14. Anticipated Commercial Interests and Related Agreements Arising from This Study

No patent rights or other commercial interests are expected to arise from this study.

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