Protocol

**Title:** Managing Patient Comfort During Dermatologic Procedures: A Randomized Controlled Trial

**Protocol Number:** MA 041916

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Table of Contents

STUDY TITLE

1. STUDY OBJECTIVES
2. STUDY DESIGN
3. BACKGROUND AND RATIONALE
4. STUDY POPULATION
   4.1 Inclusion criteria
   4.2 Exclusion criteria
5. STUDY PROCEDURES:
   5.1 Consent
   5.2 Intervention
6. DATA COLLECTION AND REPORTING:
   6.1 Primary Outcome Measures
   6.2 Secondary Outcome Measures
7. DATA DISCLOSURE AND SUBJECT CONFIDENTIALITY
8. EFFICACY ASSESSMENT
9. SAFETY ASSESSMENT
10. STATISTICAL CONSIDERATIONS
11. STUDY SITE
12. ETHICAL CONSIDERATIONS
   12.1 Human Subjects Protection
   12.2 Consent Form
   12.3 Protocol Amendments
   12.4 Retention of Records
   12.5 Use of Information and Publication
13. References

APPENDIX I: The 6-item State-Trait Anxiety Inventory
APPENDIX II: Postoperative Survey
STUDY TITLE: Managing Patient Comfort During Dermatologic Procedures: A Randomized Controlled Trial

1. STUDY OBJECTIVES:

The goal of this study is to deduce the effect of holding a patient’s hand on anxiety and pain during dermatologic procedures.

2. STUDY DESIGN:

This study is a pilot cross-sectional study of 135 subjects, aged 18 and above from the Northwestern dermatology clinic, undergoing dermatologic procedures. There will be 45 subjects in each study arm.

The first arm will consist of subjects who will have a researcher hold one hand. The second arm will be given a stress ball to hold. The third arm will be the control arm with no handholding or stress ball (treatment as usual).

Subjects will be randomized to be in the handholding, stress ball, or control study arms. The randomization will be 1:1:1. All procedures will be performed by one surgeon in the Department of Dermatology who will be not be blinded to which subjects are receiving the intervention.

We will evaluate if the handholding or stress balls used in this study are of utility to decrease patient anxiety and pain.

3. BACKGROUND AND RATIONALE:

Dermatologic surgery is unique in that many procedures are performed with the patient under local anesthesia. Being awake during the procedure can contribute to increased levels of anxiety. During surgery, patients may find it difficult to speak and to see the surgeon around. If local anesthetic is administered facially, anticipation of the prick of a needle can bring even more unease.

Touch is one of the five senses that can play a valuable role in the provision of health care. Touch can create a warmth and closeness that helps patients tolerate discomfort and decreases anxiety (1). Additionally, physical touch is seen as conveying respect by the caregiver, and creating a feeling of comfort (2). For patients in a long-term care facility, touch has been shown to elicit a positive response (3). In another study, elderly residents also felt more affection and immediacy when subjected to a nurse’s touch (4). Touching can also give patients confidence in the quality of care provided (5).

Hand-holding is a cost-free, safe intervention with potential to improve the patient and caregiver experience (6). Hand-holding has been utilized to relieve anxiety in a variety of procedures with local anesthesia, including cataract surgery and percutaneous vertebroplasty (7, 8). Because of the unique characteristics of dermatologic surgery, interventions to relieve anxiety are valuable and could improve patient satisfaction and experience. Multiple relaxation strategies have been
employed in dermatologic surgery, but hand-holding has yet to be explored (9). One study investigating anxiety during a dermatologic procedure assessed if playing self-selected music during the procedure would decrease patient anxiety levels (10). Subjects in the music group showed significantly lower anxiety scores, demonstrating the potential for interventions in dermatology to make a meaningful difference for patients.

Stress balls are another potential source of distraction and anxiety relief during local anesthetic procedures. A study of minimally invasive venous surgery investigated the affect of holding stress balls on patient anxiety, finding that intraoperative anxiety ratings were lower in the patients that were given stress balls (11). This finding may be applicable to dermatologic procedures.

To our knowledge, no study has been conducted to compare human touch through handholding to stress balls. Our study will contribute to the existing body of research by investigating if human connection through handholding can confer any additional benefit over the contact with a stress ball.

Handholding and stress balls are nontoxic, free interventions with low risk and a potential benefit. Studies assessing the effect of handholding or stress balls on anxiety and pain in the outpatient setting are limited, and are absent with regard to dermatological surgeries. If a simple, standardized technique of handholding or stress ball provision proves to be successful in reducing anxiety or pain, it would be of considerable clinical utility in dermatologic procedures.

4. STUDY POPULATION:

4.1 Inclusion Criteria:

- Age 18 and older
- Undergoing a dermatologic procedure
- Willing and able to understand and provide informed consent and communicate with the investigator

4.2 Exclusion Criteria:

- Subjects who have wound healing problems
- Subjects who are unable to understand the protocol or to give informed consent
- Subjects with self-reported mental illness or other psychological conditions, such as psychotic disorders, mood disorders, anxiety disorders, cognitive disorders, depression with psychotic features, dissociative disorders

5. STUDY PROCEDURES:

5.1 Consent:

Prior to their initial encounter with the operating physician, potential subjects will be screened with the inclusion criteria and, if they qualify, will be approached by the researcher. Subjects will
be given the opportunity to participate and sign the Informed Consent form. Additionally, the subjects will be informed that they can opt out of the study at any point and will be given the opportunity to ask any questions before the start of the procedure. Subsequently, subjects will be randomized to one of three test groups (handholding, stress ball, control).

5.2 Intervention:

Because of the visible nature of the interventions, neither patients nor surgeons will be blinded to the group assignments.

**Hand-Holding Arm (Group A)**
On the day of surgery, subjects in the hand-holding arm will have one hand clasped by a researcher during the entirety of the procedure. The researcher’s fingers will be closed (not interlocked) and the hand will be placed on top of the patient’s hand. The researcher will keep the hand still and will not tap or rub the patient’s hand.

**Stress Ball Arm (Group B)**
On the day of surgery, subjects in the stress ball arm will have a stress ball to hold in one hand during the entirety of procedure. The stress ball will be a plain white sphere around the size of a palm.

**Control Arm (Group C)**
On the day of surgery, subjects in the control arm will receive the standard of care for dermatologic procedures and will not be touched aside from the necessary touch to perform the procedure.

**All Subjects**
For all subjects in the three different study arms, the primary outcomes will be measured immediately after the procedure. Measures will not be taken before the procedure to avoid bias in the non-blinded subjects. Subjects will complete the 6-item State-Trait Anxiety Inventory (STAI), a visual analog scale for anxiety ranging from “no anxiety at all” to “extremely anxious”, and a visual analog scale for pain ranging from “no pain at all” to “worst possible pain.” Additionally, patients will answer three questions about satisfaction and time spent researching the procedure. Heart rate and blood pressure will be measured before and after the procedure.

6. DATA COLLECTION AND REPORTING:

6.1 Primary Outcome Measures

Primary outcome measures of anxiety include scores on the STAI (Appendix I), visual analog scale (Appendix II), and physiologic measures (blood pressure, heart rate). These measures will be compared among the three groups.

6.2 Secondary Outcome Measures
The secondary outcome of patient satisfaction will be measured with a 5-point scale. Another secondary outcome of pain will be assessed with a visual analog scale. A free response question about time spent researching the subject will be used to assess correlations with anxiety. These measures will be compared among the three groups.

7. DATA DISCLOSURE AND SUBJECT CONFIDENTIALITY:

Subject medical information obtained as a result of this study is considered confidential and disclosure to third parties other than the principal investigator and the co-investigators is prohibited. Patient data will be kept confidential; all data will be kept in a locked cabinet accessible only by PI and study staff.

All reports and communications relating to subjects in this study will identify each subject only by their initials and study identification number. Medical information resulting from a subject’s participation in this study may be given to the subject’s personal physician or to the appropriate medical personnel responsible for the subject’s welfare if deemed to be necessary by the principal investigator. Data generated as a result of this study are to be available for inspection on request by Food and Drug Administration or other government regulatory agency auditors, and the Northwestern University Institutional Review Board (IRB).

8. EFFICACY ASSESSMENT

Efficacy assessment will be done based on the primary outcome measures mentioned above.

9. SAFETY ASSESSMENT

We do not anticipate any adverse events associated with hand-holding.

10. STATISTICAL CONSIDERATIONS

The main primary outcome measure is patient anxiety, which will be measured by the STAI. Using one-way ANOVA to assess the differences, a standard deviation of 10 and a sample size of 41 participants per group for a total of 123 has 81% power to detect a 4 unit mean difference in scale scores across the three groups. A sample size of 45 participants per group for a total of 135 has 85% power to detect a 4 unit mean difference in scale scores. A two-sided test and type I error rate of 5% were assumed. There were no interim analyses or stopping rules.

11. STUDY SITE:

Northwestern Dermatology Clinic:
676 N. St. Clair Street, Suite 1600
Northwestern University Feinberg School of Medicine, Chicago, Illinois 60611.

12. ETHICAL CONSIDERATIONS
12.1 Human Subjects Protection

A periodic review must be submitted to the IRB at least once per year. The IRB must be notified of completion of the study. After study completion or termination, a final report must be provided to the IRB to close the study. The investigator must maintain an accurate and complete record of all submissions made to the IRB, including a list of all reports and documents submitted. Adverse events that are reported to the FDA as IND Safety Reports must be submitted promptly to the IRB per IRB guidelines. At least once per year, the IRB must review and give written approval in order to continue the study. This trial will be conducted in accordance with Good Clinical Practices and the Declaration of Helsinki.

12.2 Consent Form

Prior to study entry, written consent must be obtained from the subject. A checklist of the consenting procedures, signed by the personnel obtaining consent, must be retained in the study file.

12.3 Protocol Amendments

All changes must be submitted to the IRB. Protocol modifications that impact subject safety or the validity of the study must be approved by the IRB and submitted to the FDA before initiation.

12.4 Retention of Records

Food and Drug Administration and Good Clinical Practice guidelines require that an Investigator retain subject identification codes, subject files, and source data for the maximum period of time permitted by the hospital, institution, or private practice, but not less than 15 years after the completion or discontinuation of the trial.

12.5 Use of Information and Publication

The Principal Investigator, sub-investigators may publish the results of this study in conjunction with appropriate scientific and medical personnel.
References:
APPENDIX I:
The 6-item State-Trait Anxiety Inventory (STAI)

Subject ID: ___________________________________

Date: _________________________________________

Procedure: _______________________________________

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I feel calm</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2.</td>
<td>I am tense</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3.</td>
<td>I feel upset</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4.</td>
<td>I am relaxed</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5.</td>
<td>I feel content</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6.</td>
<td>I am worried</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Researcher Name (print): ______________________________        Date: ________________

Researcher Name (sign): ______________________________         Date: ________________
APPENDIX II:
Postoperative Survey

Subject ID: _______________

Date: _______________

Procedure: ______________________________________

0                      10
No anxiety at all      Extremely anxious

0                      10
No pain                Worst possible pain

How satisfied are you with the care you received today?

<table>
<thead>
<tr>
<th>Very dissatisfied</th>
<th>Somewhat dissatisfied</th>
<th>Neutral</th>
<th>Somewhat Satisfied</th>
<th>Very Satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

How many hours did you spend researching the procedure you underwent today?_______

Researcher Name (print): ______________________________        Date: ________________

Researcher Name (sign): ______________________________         Date: ________________