FORMED CONSENT FORM FOR ADULT PATIENTS

Study Project Title: The Effect of Cold Spray and Stress Ball Methods on Pain During Intramuscular Injection: A Randomized Controlled Study

Study Official**:** Handan Aydın Kahraman

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NCT Number: [To be assigned upon registration]

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You are invited to participate in a research study titled "The Effect of Cold Spray and Stress Ball Methods on Pain During Intramuscular Injection: A Randomized Controlled Study." You are invited to participate in this study because your medical condition meets the study criteria. This study is being conducted for research purposes, and participation is completely voluntary. Before you decide whether or not to participate, we want to inform you about the study. After you have fully understood the information about the study and your questions have been answered, you will be asked to sign this form if you wish to participate. This research is conducted under the responsibility of Assistant. Prof. Dr. Handan AYDIN KAHRAMAN,Esra Aydın and İbrahim NAS Department of Nursing Fundamentals.

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1. What is the purpose of this study; how many other people will participate in this study besides me?

- The purpose of this study is to comparatively evaluate the effects of cold spray and stress ball squeezing methods on pain during intramuscular (IM) injection, and to examine their effectiveness in reducing pain compared to standard practice.
- A total of 66 patients will participate in this study, including yourself.

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2. Should I participate in this study?

Your decision to participate in this study is entirely voluntary. Even if you sign this form now, you are free to withdraw from the study at any time without giving any reason. If you choose not to participate or decide to withdraw from the study, the researcher (nurse) will apply the most appropriate treatment plan for you. Similarly, the nurse (researcher) conducting the study may decide that it would not be beneficial for you to continue in the study and may remove you from the study; in this case, the most appropriate treatment will be chosen for you.

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3. What can I expect if I participate in this study?

You are required to receive an Intramuscular (IM) injection as part of your prescribed diagnostic and treatment procedures. IM injection can cause pain and discomfort, but it is possible to

reduce the pain experienced using certain methods and techniques. Cold spray and stress ball squeezing are methods that may reduce pain during IM injection. When you receive your IM injection for treatment, the effect of these methods on the pain you experience will be evaluated and compared to standard practice. The order of the method applied will be determined by a random draw.

- **Cold Spray Method:** Before the IM injection, cold spray will be applied for 5 seconds from a distance of 15 cm to an approximately 10cm2 area at the planned injection site. The IM injection will then be performed within 15 seconds, following the standard protocol. After the procedure is completed, your pain level will be assessed.
- **Stress Ball Method:** You will be instructed on how to use the stress ball. After the injection site (ventrogluteal region) is randomly determined, a medium-firm stress ball will be given to your non-injection hand, and you will be asked to rhythmically squeeze and release it throughout the procedure. The IM injection will be performed according to the standard protocol. After the procedure is completed, your pain level will be assessed.
- **Standard Method (Control Group):** You will receive only the standard IM injection procedure without any additional interventions. After the procedure is completed, your pain level will be assessed.

The study is expected to last approximately 5 minute. Pain will be assessed using the Visual Analog Scale (VAS) within the first minute after the injection.

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4. Are there any risks or discomforts to participating in this study?

IM injections inherently involve a degree of pain and discomfort. While this study aims to reduce this pain, some level of discomfort will still be experienced during the injection process.

- **Potential Side Effects of Cold Spray:** Cold sprays are generally safe; however, very rarely, skin irritation or temporary discomfort may occur. The spray is applied from a distance to minimize these risks.
- **Potential Discomfort from Stress Ball:** Using a stress ball is generally safe and does not have significant side effects. Some minor hand fatigue might occur if squeezed very vigorously.
- **General Injection Risks:** As with any injection, there is a very small risk of bruising, bleeding, or infection at the injection site. All injections will be performed by a qualified researcher following sterile and standard procedures to minimize these risks.
- **Privacy and Confidentiality:** Your personal information will be kept confidential, but as with any research, there is a minimal risk of a breach of confidentiality. Strict measures will be taken to protect your data.

If any harm or discomfort occurs as a result of your participation in this research, all necessary medical interventions will be provided by us, and all expenses related to this will be covered by us.

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5. What are the benefits of participating in this study?

IM injection is a distressing procedure that causes pain and anxiety for patients. There is a need for evidence on the effectiveness of different methods to reduce pain and anxiety in patients undergoing this procedure. We want to benefit from your experiences to determine the effect of cold spray and stress ball application on IM injection-related pain. The findings of this research may also form a basis for future research on the subject. Your participation will contribute to scientific knowledge, potentially improving patient care for future individuals undergoing IM injections.

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6. What is the cost of my participation in this study?

You will not incur any financial burden by participating in this study, nor will you receive any payment.

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7. How will my personal information be used?

Your personal information will be used in the research to conduct the study and statistical analyses, but your identity will be kept confidential. Only when necessary, ethics committees or official authorities may review information related to you. At the end of the research, you have the right to request information regarding your own results. The study results may be published in medical literature at the end of the study, but your identity will not be disclosed.

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8. Whom can I contact for more information?

If you require additional information about the study, please contact the following person:

Name: Esra Aydın **Title:** [e.g., Researcher / Nurse] **Phone:** (0….) [Gümüşhane University School of Health Services Vocational College]

PARTICIPANT'S DECLARATION

I have not encountered any coercive behavior regarding my participation in this research. I also know that if I refuse to participate, this will not harm my medical care or my relationship with my physician in any way. I can withdraw from the research at any time during the project without giving any reason (however, I am aware that it would be appropriate for me to notify the researchers in advance of my withdrawal to avoid causing them difficulty). Furthermore, I may be excluded from the research by the researcher provided that my medical condition is not harmed in any way. I am not incurring any financial responsibility for the expenses to be incurred for the research. I will also not be paid. I know that the confidentiality of my personal information obtained from the research will be protected. I have been given the necessary assurance that in the event of any health problem arising from the research application, all necessary medical interventions will be provided (and I will not incur any financial burden

related to these medical interventions). I know that if I encounter a health problem during the research, I can call Esra Aydın at (0…….. Gümüşhane University SHMYO) at any time.

I have understood all the explanations given to me in detail. Under these conditions, I voluntarily agree to participate in the said clinical research, without any pressure or coercion. A copy of this signed form will be given to me.

Participant's Name, Surname: Address: Phone: Signature: Date:

Researcher's Name, Surname, Title: Address: Phone: Signature: Date: