KEY INFORMATION FOR:
"The Effects of Cannabidiol (CBD) Cream on DOMS and Performance After Exercise"

We are asking you to choose whether or not to volunteer for a research study about cannabidiol (CBD) cream use after a lower body resistance exercise. We are asking you because you are physically healthy and can be available for 5 sessions over the span of 2 weeks. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to determine CBD cream's effects on muscle soreness and lower body performance following resistance training.

By doing this study, we hope to learn whether or not CBD cream is effective in reducing muscle soreness. The use of CBD cream in this study is exempt from any federal regulations because the product contains less than 0.3% dry weight THC and its contents have been tested by a laboratory certified by Colorado's Department of Public Health and Environment. Your participation in this research will last about 4-5 hours spread across 5 different sessions over the span of 2 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may choose to volunteer for this study if you are interested in exercise science research methods, resistance training, optimizing performance, recovery methods for decreasing soreness, and CBD. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose to not volunteer for this study if you wish to continue your normal exercise training or use other recovery methods during the duration of the study. These activities are prohibited during the 2-week period you are participating in the study. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Stuart Best, PhD of the University of Kentucky, Department of Kinesiology and Health Promotion at stuart.best@uky.edu or (859) 257-9852.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

The following list consists of the exclusion criteria that will disallow participation in the study: 1) if you currently have a lower body injury, or have been injured in the previous 3 months; 2) if you are outside of the desired age range of 18-45; 3) if you cannot be available for 5 sessions over the span of 2 weeks; 4) if you are allergic to any of the ingredients contained within the CBD or placebo generic moisturizer creams (a full list is displayed in the Appendix); 5) if you are pregnant.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the University of Kentucky. Testing will occur in the Seaton Center Building, Multi-Disciplinary Science Building, and the Funkhouser building where the research equipment necessary for data collection is located. Your participation in this research will last about 4-5 hours spread across 5 different sessions over the span of 2 weeks. Each session's specific duration will vary, but no session will last longer than 90-minutes.

WHAT WILL YOU BE ASKED TO DO?

The study will involve five visits (including this one). The description below details exactly what you will be doing for every visit. You will be randomly placed in one of three groups (CBD, Placebo, or Control). For the specific description of each protocol; see 'PROTOCOL DESCRIPTIONS'.

<table>
<tr><th>Groups 1 and 2 (CBD and Placebo)</th><th>Group 3 (Control)</th></tr>
<tr><td colspan="2">Session 1 – Intro Session (Same for All Groups)
Informed Consent
Pre-Study Q&A
Bod Pod
Pressure-Pain Threshold Test
Vertical Jump Test
Peak Isokinetic Torque Test</td></tr>
<tr><td>Session 2 – Fatigue Protocol
Pre-Session Q&A
Pressure-Pain Threshold Test (Pre-Fatigue/Cream)
Fatigue Protocol
Post-Fatigue Q&A
Cream Application
Post-Cream Q&A
Pressure-Pain Threshold Test (Post-Fatigue/Cream)
Vertical Jump Test</td><td>Session 2 – Fatigue Protocol
Pre-Session Q&A
Pressure-Pain Threshold Test (Pre-Fatigue)
Fatigue Protocol
Post-Fatigue Q&A
Sitting Rest
Post-Rest Q&A
Pressure-Pain Threshold Test (Post-Fatigue)
Vertical Jump Test</td></tr>
<tr><td>Session 3 – 24-Hours Post
Pre-Session Q&A
Pressure-Pain Threshold Test (Pre-Cream)
Vertical Jump Test (Pre-Cream)
Cream Application
Post-Cream Q&A
Pressure-Pain Threshold Test (Post-Cream)
Vertical Jump Test (Post-Cream)</td><td>Session 3 – 24-Hours Post
Pre-Session Q&A
Pressure-Pain Threshold Test (Pre-Rest)
Vertical Jump Test (Pre-Rest)
Sitting Rest
Post-Rest Q&A
Pressure-Pain Threshold (Post-Rest)
Vertical Jump Test (Post-Rest)</td></tr>
<tr><td>Session 4 – 48-Hours Post
Pre-Session Q&A
Pressure-Pain Threshold Test (Pre-Cream)
Vertical Jump Test (Pre-Cream)
Cream Application
Post-Cream Q&A
Pressure-Pain Threshold Test (Post-Cream)
Vertical Jump Test (Post-Cream)</td><td>Session 4 – 48-Hours Post
Pre-Session Q&A
Pressure-Pain Threshold Test (Pre-Rest)
Vertical Jump Test (Pre-Rest)
Sitting Rest
Post-Rest Q&A
Pressure-Pain Threshold (Post-Rest)
Vertical Jump Test (Post-Rest)</td></tr>
<tr><td colspan="2">Session 5 – 72-Hours Post (Same for All Groups)
Pre-Session Q&A
Pressure-Pain Threshold Test
Vertical Jump Test
Peak Isokinetic Torque Test
Post-Study Q&A*
Variations between Cream and Control groups
*Cream and Control versions differ</td></tr>
</table>

STUDY RESTRICTIONS

The following list are all of the restrictions during the study; if you violate any of these restrictions, your participation in the study may be terminated: 1) physical activity outside of the study; 2) any external recovery methods (i.e., stretching, compression garments, massage, foam rolling, ice, water therapy, soothing/recovery creams, heat pads, etc.); 3) any pain-relieving medication (i.e., Acetaminophen, Advil, Ibuprofen, etc.).

PROTOCOL DESCRIPTIONS

Print-Out Questionnaires

- Pre-Study Q&A (Print-Out Medical and Exercise Questionnaire) – This questionnaire serves as a medical and exercise history questionnaire. Fields will revolve around demographic information, medical history, training history, and current physical status (particularly pertaining to soreness). These measures will be used to: 1) ensure you are safe to begin exercise, and 2) establish baseline data for recurring fields in REDCap questionnaires.

REDCap Questionnaires

- Pre-Session Q&A – This questionnaire is completed at the beginning of Sessions 2-5. Its purpose is to check-up on your soreness levels and make sure you are obeying the study restrictions.

- Post-Fatigue Q&A – This questionnaire is completed immediately following the Fatigue Protocol. Its purpose is to monitor any physical or psychological changes after the exercise protocol.

- Post-Cream Q&A – This questionnaire is completed immediately following cream application for Groups 1 and 2 (cream groups). Its questions are very similar to the Post-Fatigue Q&A, but it includes extra questions regarding the cream.

- Post-Rest Q&A – This questionnaire is completed immediately following sitting rest for Group 3 (control group). Its questions are very similar to the Post-Fatigue Q&A, but it includes extra questions regarding the rest period.

- Post-Study Q&A (Cream) – This questionnaire is completed at the conclusion of the study for Groups 1 and 2. It resembles the Pre-Session Q&A, but it also includes extra questions about your experience with the cream.

- Post-Study Q&A (Control) – This questionnaire is completed at the conclusion of the study for Group 3. It is identical to the 'cream' version, but it omits all questions and fields regarding the cream.

Bod Pod

The Bod Pod Gold Standard Body Composition Tracking System is a tool used to determine body composition. Body composition measurements will be assessed including fat-free mass (FFM; kg), fat mass (kg), and percent fat (%Fat).

Pressure-Pain Threshold Test (PPT)

The pressure-pain threshold test (PPT) is designed to provide measure of muscular soreness. The test involves the researcher applying pressure with an instrument on four points on your lower body (one on each quadriceps and one on each hamstrings). You will tell the researcher when you start to feel discomfort or pain rather than general pressure. The purpose of the PPT is to keep a constant log of soreness within your quadriceps and hamstrings and measure and compare how these numbers change over the course of the study.

Vertical Jump Test

The vertical jump test was chosen as the study's primary performance measure because it is a common metric to assess lower body performance and fatigue in athletes. Furthermore, it targets the same muscle groups involved in the exercise protocol. During this test, you will jump up as high as you can three times. The best of three trials will be recorded.

Cream Application

If you are in the CBD or Placebo groups, either CBD cream (CBD group) or moisturizing cream (Placebo group) will be applied in according to the manufacturer's recommendations. You will apply the cream to a standardized cadence on your quadriceps throughout the duration of the study.

Peak Isokinetic Torque Test

The Peak Isokinetic Torque Test will use the Biodex, an isokinetic dynamometer. We will use this device to determine peak isokinetic torque, which is the maximum force produced at a constant speed. You will perform a maximal-effort leg extension and leg curl on this device. The exact protocol is listed below:

Movement	Contraction	Leg	Sets and Reps	Speed	Rest
Knee Extension	Concentric	Dominant	1 set 5 reps	60º / s	2 min before next movement
Knee Flexion	Concentric	Dominant	1 set 5 reps	60º / s	2 min before next movement
Knee Flexion	Eccentric	Dominant	1 set 5 reps	60º / s	2 min before next movement
Knee Extension	Eccentric	Dominant	1 set 5 reps	60º / s	2 min before next movement
Knee Extension	Concentric	Non-dominant	1 set 5 reps	60º / s	2 min before next movement
Knee Flexion	Concentric	Non-dominant	1 set 5 reps	60º / s	2 min before next movement
Knee Flexion	Eccentric	Non-dominant	1 set 5 reps	60º / s	2 min before next movement
Knee Extension	Eccentric	Non-dominant	1 set 5 reps	60º / s	End of protocol

Fatigue Protocol

The Fatigue Protocol, or the exercise protocol, will use the Biodex, similar to the Peak Isokinetic Torque Test. The purpose of delivering this protocol is to establish fatigue in the lower body muscles (quadriceps and hamstrings). You will perform a maximal-effort leg extension and leg curl on this device. The exact protocol is listed below:

Movement	Contraction	Leg	Sets and Reps	Speed	Rest
Knee Extension	Concentric and Eccentric	Dominant	5 sets 10 reps	60º / s	30 sec between sets --- 2-min before next movement
Knee Flexion	Concentric and Eccentric	Dominant	5 sets 10 reps	60º / s	30 sec between sets --- 2 min before next movement
Knee Extension	Concentric and Eccentric	Non-dominant	5 sets 10 reps	60º / s	30 sec between sets --- 2 min before next movement
Knee Flexion	Concentric and Eccentric	Non-dominant	5 sets 10 reps	60º / s	30 sec between sets --- End of protocol

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risks associated with participation in this research study are risks which accompany involvement in exercise. Some of these risks and discomforts may include: muscle soreness, stiffness and/or tightness, temporary “tingly” or numb sensation due to cream application, minor discomfort due to the PPT test, irritated skin due to cream application, an abnormal response in blood pressure, fainting, a breach of confidentiality, a positive drug test for up to two weeks after the completion of the study, previously unknown risks or side effects involving the equipment and products used in the study and, in extremely rare instances, heart attack, stroke, or death. If you have any questions or concerns regarding risks or discomforts, please let the researcher know immediately.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, some people have experienced positive physical adaptations due to the weight training protocol such as lower body hypertrophy or increased lower body strength. Furthermore, by participating in this study, you will be helping to create the foundational work for future cannabidiol and recovery research. Not only will you learn more about weight training, but we hope you will also learn more about CBD and a proper research environment.

IF YOU DON’T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs to participate in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. When your information is referred to, it will always be using your unique subject ID, which will never be revealed to be connected to your name. The confidentiality of your data will be a priority over the duration of the study and beyond the conclusion of the study, as the IDs and the decoding of these IDs will be stored within a password-protected personal computer. All data that is collected via a printed-out document will be stored and protected safely in a locked filing cabinet. All data that is collected electronically will be stored and protected safely in a password-protected personal computer. This electronic data will be collected via REDCap using your unique subject ID. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet. All efforts will be taken to ensure the records that could identify you are kept private. All materials and data collected during the duration of the study will be used strictly for research purposes; they may be used for written interpretation after the conclusion of the study, but your identity will never be revealed. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All paper data records and computer records will be kept for 8 years following the completion of the study and then destroyed, via shredding for paper documents and scrubbed from the computer for electronic documents.

You should know that in some cases we may have to show your information to other people. For example, to ensure the study is conducted properly, officials of the University of Kentucky may look at or copy pertinent portions of records that identify you. Furthermore, the law may require or permit us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study if you are still meeting the restrictions criteria (listed under ‘STUDY RESTRICTIONS’). It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should you should contact the University Health Service (859-323-2778) if you are a student, or your primary care physician or dial 911 in an emergency. A medical professional will determine what type of treatment, if any, that is best for you at that time. Please inform Srikanth Nithyanandam, MD at sri.nisi89@uky.edu after medical treatment has occurred.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility or may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances);

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

If requested, the investigators can discuss your test results with you.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 2 times per year.

Do you give your permission to be contacted in the future by Joseph Pastina or Stuart Best, PhD regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about thirty people to do so.

Joseph Pastina is a graduate student pursuing his Master of Science degree in Exercise Physiology at the University of Kentucky. He is being guided in this research by Stuart Best, PhD. There may be other people on the research team assisting at different times during the study.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

Appendix: Risks

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Delayed-onset muscle soreness	It commonly occurs	It will not impact your overall health; you will feel muscle aches for 24-72 hours after exercise	It will go away in 24-72 hours
Stiffness and/or tightness	It commonly occurs	It will not impact your overall health; you will feel muscle tightness for 24-72 hours after exercise	It will go away in 24-72 hours
Temporary "tingly" or numb sensation due to cream application	It sometimes occurs	It will not impact your overall health; you will feel a sensation that will alleviate muscle soreness temporarily	It will go away after a short amount of time
Minor discomfort due to the PPT test	It sometimes occurs	It will not impact your overall health; you will feel pressure and a short interval of discomfort	It will go away almost immediately
Irritated skin due to cream application	It is uncommon	It will not impact your overall health; those with a known or unknown allergy to any of the creams' ingredients may experience a temporary rash (see ingredients on next page)	It will go away after a short amount of time
Abnormal response in blood pressure	It is uncommon	Serious	Yes, it will stabilize with the cessation of physical activity
Fainting	It is uncommon	Serious	No, but it can be prevented by using proper breathing techniques and ensuring stable blood sugar
Breach of confidentiality	It is very uncommon	Serious	No, but it can be prevented through the study's implemented precautions to ensure subject confidentiality
Positive drug test for up to two weeks after the completion of the study	It is very uncommon	Serious	No, but because the CBD product has been batch tested by a certified laboratory to contain no THC, it is extremely unlikely
Heart attack	It is extremely uncommon	Extremely serious	No
Stroke	It is extremely uncommon	Extremely serious	No
Death	It is extremely uncommon	Extremely serious	No

Appendix: CBD Cream Information

Product: Myaderm Advanced RX Fast Acting Relief Cream (Myaderm, Englewood, Colorado USA)

Ingredients: Water, Cannabidiol (CBD), Isopropyl Palmitate, Propylene Glycol, Caprylic/Capric Triglyceride, Dimethicone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Octyldodecanol, Lecithin, Phenoxyethanol, Ethylhexylglycerin, Trolamine, Squalane, Polysorbate 60

Appendix: Placebo Cream Information

Product: Gold Bond Diabetics' Dry Skin Relief Lotion (Gold Bond Diabetics' Dry Skin Relief Lotion, Chattanooga, Tennessee USA)

Ingredients: water, glycerin, hydroxyethyl urea, dimethicone, jojoba esters, petrolatum, cetyl alcohol, distearyldimonium chloride, aloe barbadensis leaf juice, stearyl alcohol, cyclopentasiloxane, cetearyl alcohol, behentrimonium methosulfate, glyceryl stearate, methyl gluceth-20, avena sativa (oat) kernel extract, chamomilla recutita (matricaria) flower extract, bisabolol, zingiber officinale (ginger) root extract, tocopheryl acetate, dimethicone/vinyl dimethicone crosspolymer, magnesium ascorbyl phosphate, polysorbate 60, retinyl palmitate, stearamidopropyl PG-dimonium chloride phosphate, butyrospermum parkii (shea) butter extract, propylene glycol, steareth-21, hydrolyzed jojoba esters, diazolidinyl urea, panthenol, butylene glycol, methylparaben, EDTA, propylparaben, boswellia serrata gum, dipropylene glycol, potassium hydroxide

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- ***If Appendices are used, list here***

You will receive a copy of this consent form after it has been signed.

_____	_____
Signature of research subject	**Date**
_____	
Printed name of research subject	
_____	_____
Printed name of [authorized] person obtaining informed consent	**Date**
_____	
Signature of Principal Investigator or Sub/Co-Investigator	