Official Title: Influence of Edible Marijuana on Endurance Exercise Performance

NCT Number: NCT05192239, Unique Protocol ID: 2827

Document Date: 12/31/2022

PROTOCOLS

#2827 - Influence of edible marijuana on endurance exercise performance

Protocol Information

Submission Type	Review Type	Status	Time in Current Status
Close Request	--	**Closed**	**Since January 3 – 6 months**

Initial Approval Date	Initial Review Type
Nov 30, 2021	**Full Board**

Close Comment

Thank you for informing the IRB that the work associated with this protocol is complete. To comply with federal regulations, please be sure to securely keep all research records, including signed informed consent documents, for a period of 3 years from this date.

Let us know if you have any questions.

csu_irb@colostate.edu

Feedback

Protocol Close Request Form

Close Request

Completed Date

December 31, 1969

Summary of Findings

A manuscript was accepted for publication in the journal, Frontiers In Physiology. Here is the title and abstract: Edible marijuana and cycle ergometer exercise Purpose: There is extensive public and scientific interest in the influence of cannabis and the psychoactive cannabinoid, delta-9-tetrahydrocannabinol (THC), on exercise performance. Unfortunately, recent, up-to-date studies are lacking. The aim of the current study was to address the hypothesis that ingestion of edible marijuana, prior to exercise, would have unfavorable effects on the physiological response to exercise and on exercise performance. Methods: 17 Healthy adult male and female habitual exercisers, who were regular users of cannabis products, were screened for study participation. 10 were enrolled, and data from 9 [8 males, 1 female, aged 25±3 years, with peak oxygen uptake of 56.5±11.7 ml/kg/min (mean ± SD)] were retained. Participation included two exercise sessions, each preceded by self-administration and ingestion of either edible marijuana (containing 10 mg THC) or placebo. Cardio-respiratory responses (via indirect calorimetry) to stationary cycle ergometer exercise (8 min at 50, 100 and 150 W) were recorded before completion of a 20-min Functional Threshold Power test (FTP20) and a sprint test involving maximal effort until volitional fatigue. Results: Edible marijuana increased the concentration of circulating THC and THC metabolites, and evoked sensations of intoxication and altered psychoactive state. Cardio-respiratory responses to staged cycle ergometer exercise were normal and were unaffected by edible marijuana. Compared with placebo, edible marijuana did not influence FTP20 (Placebo 253±75 vs THC: 251±72 W (mean±SD); $p > 0.45$) or peak power output during the sprint test (Placebo: 710±201 vs. THC: 732±136 W; $p = 0.864$). Conclusion: 10 mg of THC, when ingested prior to exercise by regular exercisers and habitual users of cannabis, had little effect on the physiological response to standardized cycle ergometer exercise, and was neither ergogenic nor ergolytic. The manuscript is available here: https://pubmed.ncbi.nlm.nih.gov/36545283/

In the box below, please attach any relevant publications that resulted from the data collection for this study, and/or any other relevant documentation that should be kept with this file.

Close Request Questions

Completed As Planned?

Yes

Please state the number of participants enrolled in this study.

17

Please state the number of participants who completed this study.

10

Please state the number of participants who withdrew from this study.

7

Were there any unanticipated problems or adverse events that were *not previously* reported to the IRB?

No

General Information

Principal Investigator

Bell, Christopher

Lead Unit

Health + Exercise Science (CO-1582)

Title

Influence of edible marijuana on endurance exercise performance

People

People

Person

Bell, Christopher

Home Unit

Health + Exercise Science (CO-1582)

Email Address

christopher.bell@colostate.edu

Phone

CSU Status

Researcher Role

Principal Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Person

Ewell, Taylor Russell

Home Unit

Health + Exercise Science (CO-1582)

Email Address

taylor.ewell@colostate.edu

Phone

7197611417

CSU Status

Other

Researcher Role

Key Person

Contact Roles

Permissions

Full Access

People Attachments

Person

Abbotts, Kieran Shay Struebin

Home Unit

Health + Exercise Science (CO-1582)

Email Address

kieran.abbotts@colostate.edu

Phone

CSU Status

Other

Researcher Role

Key Person

Contact Roles

Permissions

Full Access

People Attachments

Person

Butterklee, Hannah Michelle

Home Unit

Health + Exercise Science (CO-1582)

Email Address

hannah.butterklee@rams.colostate.edu

Phone

4258989294

CSU Status

Other

Researcher Role

Key Person

Contact Roles

Permissions

Full Access

People Attachments

Person

Bomar, Matthew Charles

Home Unit

Health + Exercise Science (CO-1582)

Email Address

matt.bomar@rams.colostate.edu

Phone

6262962552

CSU Status

Other

Researcher Role

Key Person

Contact Roles

Permissions

Full Access

People Attachments

No

Legacy eProtocol ID number

If applicable, enter the ID number this study was previously assigned in eProtocol.

General Questionnaire

Application Type

Full Board

Does this study include use of existing data or biospecimens?

No

Does this study include use of student educational records and data?

No

Does this study include the use of human blood, cells, tissues or body fluids?
Yes

Does this study include evaluation of medical equipment or devices?
No

Does this study include evaluation of drugs, biologics, reagents or chemicals?
No

Is this study a clinical trial?
Yes

Does this study include the use of Protected Health Information (PHI)?
No

Is this study a Graduate Level Thesis or Dissertation Project?
No

Is this study another type of class project?
No

Is the project funded?
No

Study Participants

Subjects Checklist (Select All that Apply)
Adults
University students

Collaborators

Will Colorado State serve as the Single IRB for other collaborating institutions on this study?
Yes, Colorado State University is the Single IRB for this study.

Summary and Purpose

Proposed Start Date

December 1, 2021

Proposed End Date

November 30, 2022

Provide a brief summary or abstract of the project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.
Lots of people, including athletes and people who like to exercise regularly, enjoy marijuana. Some people believe marijuana might improve their ability to exercise. There are no recent, up-to-date scientific studies to suggest that this belief is right or wrong. The goal of this study is to determine the influence of marijuana on exercise performance.

Describe the purpose for the proposed project.
The purpose of the proposed project is to provide athletes and the scientific community with data pertaining to the acute influence of edible marijuana on exercise performance, and the physiological responses to standardized exercise. Specifically, we wish to determine: 1. The influence of edible marijuana on cardio-respiratory and metabolic responses to standardized cycle ergometer exercise. 2. The influence of edible marijuana on endurance exercise (time-trial) performance.

What do the investigators hope to learn from the project?
We wish to determine if edible marijuana, ingested prior to exercise, is ergogenic (improves performance) or ergolytic (decreases performance). We hypothesize that edible marijuana will be ergolytic.

Describe how sharing results of this study could influence behavior, practice, theory, future research designs. Specifically, how will study results apply to a larger population than the studied participants?

The use of cannabis derived products, including marijuana, is highly prevalent among athletes. This use appears to be partially motivated by the belief that marijuana may improve exercise performance. There are no convincing scientific data to support this belief. Our study will provide athletes with information that will allow them to make an informed decision pertaining to the potential futility of using marijuana to improve exercise performance. Further, use of marijuana is currently banned by the Word Anti-Doping Agency (WADA) and there have been several high profile incidents of elite athletes misusing marijuana and receiving potentially career-ending punishments (e.g. US sprinter Sha'Carri Richardson). Should our hypothesis be correct, our study may help to persuade athletes from engaging in prohibited behavior. In addition to athletes, there is considerable scientific interest in marijuana. For example, at the time of preparing this submission (Oct 5) our recent study in which we described the pharmacokinetics of edible marijuana has been accessed/reviewed over 1,300 times since publication on August 20. In addition, the potential influence of cannabis derived products on exercise has been a key invited topic at several recent international scientific meetings, including the European Congress of Sports Science. In summary, we anticipate that our study has the potential to influence decisions pertaining to the use of marijuana made by athletes and habitual exercisers worldwide. Further, we believe that the study will result in a publication that will be welcomed by the scientific community and in part help address the current paucity of up-to-date physiological information addressing a very relevant topic.

Background

Provide a brief overview of the relevant background. Discuss the present knowledge, appropriate literature and rationale for conducting the research.

We have attached several scientific review papers addressing the subject of the potential influence of marijuana on exercise performance. The main take home messages are: - the use of marijuana by athletes of varying ages and abilities is highly prevalent - many athletes appear to believe consuming marijuana prior to exercise will improve exercise performance - there is very little in the way of scientific evidence describing the influence of marijuana on exercise performance - the most relevant studies on this topic were completed 35-45 years ago and do not reflect modern marijuana behaviors (e.g. smoking vs. edible marijuana, and potency/dose of marijuana) nor do they utilize modern, sensitive physiological instruments - recent scientific reviews conclude with pleas for up-to-date research, and acknowledgement of the logistical difficulties of cannabis research - using our established naturalistic (self administration) experimental model, CSU is perfectly positioned to address the questions raised in the scientific reviews while remaining compliant with state law and institutional rules.

Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training).

The Principal Investigator has been studying human physiology, including exercise physiology, since 1988. All members of the research team contributed to the experimental procedures and data collection in our recently published field-based study, Pharmacokinetic Investigation of Commercially Available Edible Marijuana Products in Humans: Potential Influence of Body Composition and Influence on Glucose Control (Pharmaceuticals (Basel). 2021 Aug 20;14(8):817). Collectively, the research team has extensive experience with all of the described procedures, and each of the individual procedures have been previously approved by the CSU-IRB.

Explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research.

All members of the research team are residents of Colorado, are athletic (or at least are habitual exercisers), and all have previous experience conducting human physiology field-based research pertaining to marijuana consumption.

Procedures

List all research activity procedures in which a participant will be involved, including follow-up procedures. Please provide details.

Procedure Description

Establishing Relevant Physiological Characteristics of Study Participants and Habituation to Exercise Protocols. Session 1 - Overview Participants will answer questions pertaining to health, medical history and habitual use of marijuana. They will be assessed for body composition, maximal oxygen uptake and electrocardiographic responses to exercise. Session 2 - Overview The purpose of this session is to habituate the participants to the exercise testing protocol. Habituation/familiarization with protocols decreases within participant variability. Participants will perform standardized stationary cycle ergometer exercise, and then complete a performance test (time-trial). Session 3 - Overview This session will be identical to session 2. Session 1 - Detailed description. This visit is a one time visit with duration of ~ 90 minutes. During this visit participants will complete the Informed Consent, provide a brief medical history, answer questions pertaining to habitual use of marijuana, and will undergo basic measures of body composition (height, weight, and waist and hip circumference, and DEXA), and maximal oxygen uptake (VO2max). An exercise stress test, with 12-lead ECG and blood pressure measurement will also be completed. The medical history questionnaire will help identify contra-indications to study participation. Questions pertaining to habitual marijuana use will confirm that participants meet the inclusion criteria and may also serve as a co-variable: it is possible that the interaction between marijuana and exercise performance may be influenced by degree of habitual consumption. Previously we have demonstrated that body composition is a known physiological determinant of the resultant circulating concentrations of cannabis-derived products following ingestion. While not a primary outcome, DEXA data will be used as an important statistical co-variable in our final analysis. The graded exercise stress test with 12-lead ECG and blood pressure measurement will be used to identify potential contraindications to study participation. The guidelines provided by the American College of Sports Medicine pertaining to physician supervision will be followed. During the graded exercise test, exhaled gases will be collected in order to calculate maximal oxygen uptake (VO2max). The VO2max measurement will characterize the endurance capacity of the participants; this is a standard and indeed expected measurement for all human studies of endurance exercise physiology. Session 2 - Detailed description The purpose of this session is to habituate the participants to

the exercise testing protocol. Habituation/familiarization with protocols decreases within-participant variability (i.e. the day-to-day differences between test results). Participants will perform standardized stationary cycle ergometer exercise, and then complete a performance test (time-trial). Standardized stationary cycle ergometer exercise will comprise 24-minutes of cycling: 8 minutes at 50 Watts, 8 minutes at 100 Watts, and 8 minutes at 150 Watts. During this cycling heart rate and blood pressure will be measured and recorded. Exhaled gases will be collected in order to calculate oxygen uptake (VO2), carbon dioxide production (VCO2) and ventilation (VE). The rationale for the chosen work rates is they represent low-to-moderate intensity exercise, and they will provide three observations that will be used to determine the relationship between work rate and cardio/respiratory/metabolic responses to standardized exercise. This information will provide insight as to the physiological responses to controlled exercise and may explain and differences we may detect in un-controlled, exertion driven exercise (i.e. the time-trial). The rationale for the duration of each stage (8 minutes) is this duration is adequate for the participants to attain steady-state physiology. Participants will then be asked to cycle a distance equivalent to 10-km (~6 miles) as quickly as possible, on the stationary ergometer (i.e. a laboratory based time-trial). Previous studies have demonstrated that practice visits helps to improve time-trial performance in subsequent tests. This type of exercise test is a standard protocol in our lab (See Protocols 09-1363H, 10-2065H, 15-5979H, 11-2626H, 11-3032H, 13-4366H, 16-6570H, 17-7252H, etc.). Following completion of the time-trial, participants will complete one 30-second bout of high intensity cycle ergometer exercise (also known as a Wingate Test) during which we will measure peak power output. This type of exercise is a standard procedure in our lab (See Protocols 09-1124H, 09-1363H, 10-2065H, and 15-5979H) and has been safely performed in young and older, previously sedentary and endurance trained adults. Session 3 - This session will be identical to session 2.

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Standard of Care or Established Practice

Where and when will this procedure take place?

These procedures will be completed during the first three study visits. These procedures will take place in the Human Performance Clinical Research Lab, in the Department of Health and Exercise Science, on the main CSU Campus.

Who will conduct this procedure?

Personnel
Bell, Christopher

Personnel
Ewell, Taylor Russell

Personnel
Abbotts, Kieran Shay Struebin

Personnel
Butterklee, Hannah Michelle

Personnel
Bomar, Matthew Charles

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

3 Sessions: Session 1 ~ 90 minutes. Session 2 ~ 60 minutes. Session 3 ~ 60 minutes Total time commitment for the first 3 sessions = 90+60+60 = 210 minutes (3 hours 30 minutes)

Describe how the data will be collected (i.e. in person or online).

Questionnaires may be completed in advance of Session 1 online (via email) or in-person. All other activities will be completed in person.

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Procedure Description

Physiological Responses to Standardized Exercise and Time-Trial Performance - placebo vs. edible marijuana. Sessions 4 and 5 will comprise two almost identical sessions that will be very similar to Sessions 2 and 3. Primary differences will be: (1) the venue for the sessions: these will be field-based locations. Based on our previous protocol (Protocol # 1909) these locations will typically be residential locations chosen by the research participants. (2) these visits will involve ingestion of either a placebo (something that has no physiological effect) or edible marijuana. (3) Additional procedures will include blood collection (detailed below), and pre-session preparation (marijuana abstention, etc. - detailed below). The need for a field-based, off-campus location is dictated by CSU rules banning the possession of marijuana on campus. Consistent with our previously approved protocol, the venue will be chosen by the participant (e.g. a residential location occupied by the participant and/or friends/relatives of the participant). To remain in compliance with state law and CSU rules, we will follow the same procedures described in our previous protocol. Participants will purchase their own edible marijuana from a licensed distributor. Participants will be instructed to purchase Ripple Blood Orange Gummies (Stillwater Brands, Commerce City, CO). Our rationale for this product is based on our established scientific experience: from our previous protocol (published manuscript attached) we obtained detailed pharmacokinetic information on the rates of absorption and elimination of this product. The dose of edible marijuana will be 10 mg of delta-9-tetrahydrocannabinol (THC). This is considered an industry standard dose, and was the dose studied in our previous protocol. We will purchase the placebo. This will be a THC-free candy (Welch's Fruit Snacks (Park Ridge, NJ). This is the placebo we used in our previous protocol. Consistent with good science, our intention is to use a randomized, double-blind, placebo-controlled, cross-over study design. Participants will place 2 marijuana gummies (i.e. the equivalent of 10 mg THC) into an envelope provided by the research team. The research team will place 2 THC-free placebo gummies into an identical envelope. The envelopes will be sealed. The participant will be provided with two sticky labels, one labeled “A” and the other “B”. While blindfolded, the participant will be asked to secure the labels to the envelopes. A member of the research team will keep a record of the key (i.e. which letters correspond to marijuana and placebo). At no

time will a member of the research team handle the marijuana or the envelope containing the marijuana. A coin toss will determine which envelope will be opened and the contents consumed. The participant will be responsible for keeping the remaining envelope for the final session (Session 5). Prior to Sessions 4 and 5 participants will be instructed to abstain from use of all products derived from cannabis for 96 hours, from alcohol and caffeine for 24 hours, and vigorous exercise for 18 hours. To standardize pre-session nutrition, 1 hour prior to session initiation each participant will be instructed to ingest 1x350 mL bottle of a liquid meal (Ensure) and 1 x sports bar. These will be provided by the research team. An intravenous catheter will be placed in a dorsal hand vein, and the hand, wrist and forearm will be wrapped in a heated blanket. The participants will also be instrumented for measurement of heart rate and blood pressure. Approximately 8 mL of blood will be sampled. This will be analyzed for THC and THC metabolites and will be used to confirm cannabis abstention. Participants will open the randomly assigned envelope and self administer the contents. 10 minutes later the participants will begin the standardized stationary cycle ergometer exercise described in Session 2 and 3. The only additional measurement will be blood lactate concentration at the end of each 8-minute stage (requiring ~2 mL of blood per sample). After a brief (5 minutes) opportunity to stretch, drink water, etc., participants will complete the time-trial described in Session 2 and 3. The only additional measurement will be blood lactate concentration at the end of the trial (requiring ~2 mL of blood) and additional blood samples taken (~8 mL) immediately prior to and following the time trial to be analyzed for THC and THC metabolites. This will allow us to estimate the THC exposure during the exercise time trial. Finally, after a brief (5 minutes) opportunity to stretch, drink water, etc., participants will complete the 30-second cycle ergometer sprint described in Session 2 and 3. Blood lactate will be determined 5-minutes following the completion of the sprint. Session 5 will be identical to Session 4. These sessions will be separated by a minimum of 5-days. To minimize the influence of circadian variation, Session 5 will be completed at approximately the same time of day as Session 4. Total blood collection for Session 4 will be 34 mL. Total blood collection for Session 5 will be 34 mL.

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Standard of Care or Established Practice

Where and when will this procedure take place?
Two almost identical sessions (Sessions 4 and 5). These will be field-based locations. Based on our previous protocol (Protocol # 1909) these locations will typically be residential locations chosen by the research participants.

Who will conduct this procedure?

Personnel
Bell, Christopher

Personnel
Ewell, Taylor Russell

Personnel
Abbotts, Kieran Shay Struebin

Personnel
Butterklee, Hannah Michelle

Personnel
Bomar, Matthew Charles

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

Both sessions will last approximately 90 minutes.

Describe how the data will be collected (i.e. in person or online).

In person.

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Privacy and Confidentiality

Explain how the established data management plan along with consent processes and other elements of the research design address the following.

Privacy is considered from the perspective of the participant and is a right to be protected. Privacy refers to an individual's interest in controlling others' access to themselves. Based on their privacy interests, participants may want to control:

- **The time and place where they give information**
- **The nature of the information they give**
- **Who receives and can use the information**

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center identified as such by signs on the front of the building.

Describe how you will protect subject's privacy.

Participants will be given the opportunity to respond to the screening questionnaire via email, from a location of their choosing, or in person, in a private interview room in the Human Performance Clinical Research Lab. The information provided by the participants will include pertinent medical history. We believe the risk/benefit of providing this information is appropriate in order to identify potential contra-indications for study participation (see exclusion criteria) and minimize the risk of an adverse event. The first three study visits will take place in a private/secure research space within the Human Performance Clinical Research Lab; only members of the research team will have access to this space during the subjects' visits.

Confidentiality is about data. Confidentiality pertains to protecting information from disclosure based on an agreement between the participant and the researcher. When an individual shares information in a relationship of trust and expects it to be kept private or will be disclosed only with specific permissions, researchers must uphold this agreement and maintain data appropriately.

Describe how you will maintain the confidentiality of subjects' information.

Participants will be identified only on a signed consent form and initial screening form that will be kept locked and separate from other research data. Each subject will be assigned a randomly generated 8-locked and separate from other research data. Each subject will be assigned a randomly generated 8-character code (e.g. 12698afd) that will be used to identify them in association with all other research data and blood or tissue samples. Records identifying individuals will be kept in Dr. Bell’s office/laboratory in a locked cabinet and will be destroyed (shredded) following completion/publication of the project.

Biospecimens

Identify which type(s) of biospecimens will be used as part of this research project:

Blood

Are the specimens known to be diseased or dangerous

No

Will tissues be stored for future research projects?

No

Will tissues or associated data be sent out of this institution as part of a research agreement under a Data Use Agreement or Material Transfer Agreement?

No

Do you require approval through the Institutional Biosafety Committee (IBC)?

Yes

IBC Project Approval Request Form (PARF)# or pending

Pending

IBC Agent Approval Request Form (AARF)# or pending

N/A

For more information or support, contact the CSU IBC at: RICRO_IBC@colostate.edu

Clinical Trial

Will participants will be prospectively assigned to one or more interventions (including placebo or other control)?

Yes

Will the study evaluate the effects of the intervention on health-related outcomes (biomedical or behavioral)?

Yes

Does this study involve an FDA-regulated drug or device?

No

Will the study be conducted as a

Single-Site Clinical Trial

Will this study be posted on ClinicalTrials.gov?

Yes

ClinicalTrials.gov Registration# (or pending)

Pending

Additional information and support available through CSU Quality Assurance: RICRO_QA@colostate.edu

Participant Population

Are you interacting or intervening with participants?
Yes

Provide an estimate of the anticipated participant total.
30

Are you analyzing existing data records or biospecimens?
No

Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.) This should match your screening, consent, and recruitment materials.

Please list all inclusion criteria
Age 21-40 years, inclusive Body mass greater than 110 lbs (50 kg) Habitual user of cannabis; average use cannabis is minimum of once per month during the previous year Prior use of cannabis product containing at least 10 mg of THC with no adverse reaction Habitual exerciser: exercised a minimum of 5 days per week, for a minimum of 30-minutes/session, during the previous year.

Please list all exclusion criteria
Identification of a contra-indication to exercise during a 12-lead exercise stress test. Pregnant or trying to become pregnant. Breastfeeding. Recipient of treatment for psychotic or bipolar disorder during the previous 2 years Recipient of treatment for Schizophrenia during the previous 2 years Planned surgery scheduled within 2-weeks of study participation

What is the rationale for studying the requested group(s) of participants?
Rationale for the inclusion criteria: Legal age limit for cannabis use in Colorado is 21 years. Body mass greater than 50 kg to remain compliant with IRB for repeated blood sampling. Habitual use of cannabis and prior use of cannabis containing 10 mg of THC: we wish to avoid potential side-effects and unpredictable reactions associated with first-time cannabis use. Habitual exerciser: this study will be most relevant to athletes and people regularly engage in exercise, thus we will recruit people who best fit this description.

Will you use a screening procedure, instruments, tools, questionnaires etc.?
Yes

Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire), if applicable at then end of the form.
See Attached Questionnaire. Potential participants will be screened prior to consent and enrollment. We will ask a series of questions in a phone or in-person interview at the discretion of the participant. All willing individuals that meet the enrollment criteria will be eligible to participate.

Recruitment Process

Describe the procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

Participant Group Descriptor

Adult males and females who are habitual exercisers and habitual users of cannabis.

Please describe the recruitment process:
Direct advertising Referrals Organization mailing lists

Planned Subject Identification Methods
Direct advertising
Referrals
Organization mailing lists

Will a specific agency or institution provide access to prospective subjects?
No

Please select the recruitment personnel

Bell, Christopher

Ewell, Taylor Russell

Abbotts, Kieran Shay Struebin

Butterklee, Hannah Michelle

Bomar, Matthew Charles

No

Planned Recruitment Materials/Methods
***(All advertising must be submitted for review in its final printed/recorded form)**
Note: Attach copies of ALL recruitment materials in the attachment Section
Flyers/posters
Email

Is there any possibility that potential participants may feel coerced to participate?
No

Is there any possibility that potential participants may feel undue influence to participate?
No

Participant Compensation/Costs

Will participants be compensated?
Yes

Form of Compensation

Cash or Check

What is the approximate monetary value?
$100

Describe the remuneration plan.

Participants will not receive remuneration for Sessions 1-3. Participants will be paid $40 on completion of Session 4, and $60 on completion of Session 5. Typically, the information provided from Session 1 is a motivational factor for participants who are habitual exercisers. An equivalent "fitness assessment" might cost $200-300, or more. Sessions 2 and 3 are essentially supervised workouts.

Will a 1099 be issued?

No

Will participants incur any costs to participate in this research?

Yes

Explain. This should be clearly outlined in the consent form.

To remain compliant with state law and university regulations, study participants must purchase their own marijuana. The typical price for Ripple Blood Orange Gummies is $18-20 for 20 gummies. The product is sold in units of multiple servings. This is clearly outlined in the consent form.

Risks and Benefits

Minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [Department of Health and Human Services 45 CFR 46.102(j)]

Please indicate the researchers' evaluation of the overall risk level, and describe all known risks or discomforts associated with the study procedures, as prompted below. Note that any risks identified here should be consistent with risks you will disclose to participants in the consent process.

Greater than Minimal Risk

Are there risks associated with physical well-being?

Yes

Please describe.

Venous Blood Sampling Minor discomfort of having the needle inserted and taped to an hand/wrist. In about 1 in 10 cases, a small amount of bleeding will occur under the skin that will cause a bruise. The risk of forming a blood clot in the vein is about 1 in 100, and the risk of significant blood loss is 1 in 1,000. Body Composition The risks associated with the DEXA are very low. The maximum radiation dose subjects will receive in this study is less than 1/3000th of the federal and state occupational whole body dose limit allowed to radiation workers. Put another way, subjects will receive less than 1.3 mrem from this scan and they already receive approximately 450 mrem /year from normal background radiation dose in Colorado. The more radiation one receive over the course of one's life, the more the risk increases of developing a fatal cancer or inducing changes in genes. The radiation dose subjects receive from this scan is not expected to significantly increase these risks, but the exact increase in such risks is not known. There are no discomforts associated with this procedure. Women who are or could be pregnant should receive no unnecessary radiation and should not participate in this study. Exercise Stress Test, Time-Trial and Wingate Test There is a very small chance of an irregular heartbeat during exercise (< 1% of all subjects). Other rare risks of a stress test are heart attack (< 5 in 10,000) and death (<2 in 10,000). Wearing a mouthpiece and nose-clip can sometimes cause dryness in the mouth and mild discomfort. Exercise can make people feel very tired. Very difficult exercise might make people feel dizzy or queasy; people may faint or vomit. Further, very difficult exercise performed by people who don't usually exercise is likely to induce considerable muscle soreness and increase the risk of minor musculoskeletal injuries (sprains and strains). Ingestion of Edible Cannabis (From WebMD and Drugs.com) (also see "Psychological Well-Being) Cannabis might cause fast heartbeat and high blood pressure. It might also increase the risk of a having heart attack. Certain chemicals in cannabis can weaken the immune system. This might make it more difficult for the body to fight infections. Cannabis might increase the risk of an allergic reaction in people with allergies to foods like tomatoes, bananas, and citrus fruit. It is unclear if cannabis worsens chronic liver disease. While some weak evidence suggests that there might be a link, other evidence has not found a link. Using cannabis after having a stroke might increase the risk of having a second stroke. Cannabis affects the central nervous system or the brain and nerves. It might slow the central

nervous system too much when combined with anesthesia and other medications during and after surgery.

Are there risks associated with psychological well-being?
Yes

Please describe.
Ingestion of Edible Cannabis (From WebMD and Drugs.com) (also see "Physical Well-Being) Use of cannabis is likely to lead to an altered state of consciousness. The user may feel "high", very happy, euphoric, relaxed, sociable and uninhibited. The user may experience distorted perceptions of time and space. The user may feel more sensitive to things around them, and may also experience a more vivid sense of taste, sight, smell and hearing. Using cannabis might make manic symptoms worse in people with bipolar disorder. Cannabis use, especially frequent use, might increase the chance of getting depression. It can also worsen symptoms of depression and increase thoughts about suicide in those that already have depression. Using cannabis might make symptoms of schizophrenia worse.

Are there risks associated with economic well-being, including employability?
Yes

Please describe.
Participants wishing to seek/maintain employment with institutes that frequently perform drug testing should not participate. Given that the participants will all be habitual users of cannabis, this risk is low and the situation unlikely.

Are there risks associated with social well-being, including reputational risks?
No

Describe how the benefits of the research justify the likely risks to participants.

The use of cannabis by athletes is widespread. Many athletes believe cannabis may improve their performance during training and competition. There are no up-to-date data to support these beliefs. Our study will inform athletes and others considering cannabis use in conjunction with exercise of the actual effects and determine whether cannabis/marijuana is ergogenic (less likely) or ergolytic (more likely).

Describe direct research benefits to the participants, if any.

If the participants fall into the category of athletes/exercisers who use cannabis prior to and/or during exercise, they will learn if/how if affects their performance and their physiological response to exercise.

Describe the indirect research benefits to society.

Our study will address a knowledge gap identified by several independent scientific groups; thus the proposed project is a response to recommendations for future research. The general public may benefit from the ability to make informed decisions as to the interaction between exercise and cannabis.

Data Management

Data management plans, including plans for data sharing, are integral to project development. How you decide to collect, store, share and/or destroy data impacts your consent process, research procedures, data analysis, and publication.

Responses in this section constitute your plan. For guidance on how to answer these questions and plan for the data lifecycle, reference the resources and tools listed here.

Data Management Services at CSU Libraries
General guidance and unfunded projects (DMPTool)
Funder-specific guidance and templates (DMPTool)

If you choose to create a standalone data management plan (DMP) for your own purposes or at the direction of a funding agency, please attach that document to your protocol, also.
A DMP fillable template is available from CSU Libraries.

How will the data be stored and backed up during the research?

As per advice provided by the IRB during previous protocol reviews, we will employ the 3-2-1 approach to data management. Specifically, our data are stored on a password protected PC within the lab, on a secure on-campus server maintained (and backed up) by our college, and on a secure external (off-campus) server (OneDrive). The data are typically stored as an Excel file, but also as a csv file (i.e. in a format not dependent on the availability of a specific platform (OS) or software edition.

Who will be responsible for data and access management, and security?

Data Access Responsibility

Bell, Christopher

Data Access Responsibility

Ewell, Taylor Russell

Data Access Responsibility

Abbotts, Kieran Shay Struebin

Data Access Responsibility

Butterklee, Hannah Michelle

Data Access Responsibility

Bomar, Matthew Charles

Who will have access to study records or specimens?

Personnel

Bell, Christopher

Personnel

Ewell, Taylor Russell

Personnel

Abbotts, Kieran Shay Struebin

Personnel

Butterklee, Hannah Michelle

Personnel

Bomar, Matthew Charles

Will any external personnel have access to study records or specimens?

No

How will you share the data?

There are no plans/needs to share data at this time.

Will identifiable data collected as part of the research be released in identifiable form? (e.g., pictures, recordings, responses to research questions, quotes)

No

Will the identifying information be destroyed at a specific date? For guidance, please reference any associated contract or grant (if applicable) and/or the CSU Research Data Policy.

Yes

Destruction Date

December 31, 2026

What is the long-term preservation plan for the dataset?

Study data and consent documents will be kept for a minimum of three (3) years after the completion of the study by the PI. Following which hard (paper) copies will be shredded, and electronic records containing identifying information deleted. Study data and consent documents will be kept for a minimum of three (3) years after the completion of the study by the PI. Data records will be kept in Dr. Bell's oece/laboratory in a locked cabinet. Only the research team will have direct access to the data. If required, data maybe released to governmental entities authorized to inspect research records. Specimens will be kept in a secure space within the Human Performance Clinical Research Lab; only members of the HPCRL will have access to this space.

Do you intend to deposit your research data/specimens into a repository for future use?

No

Consent/Assent

Consent

The informed consent process involves presenting potential research participants with the key elements of a research study and what their participation will involve before they decide whether to participate. Please visit the IRB website for templates and guidelines on what information to include.

The default process for gaining consent is to use a signed form. Knowing that this does not always make sense, the IRB can approve alterations to what information is included, waive the requirement to get a signature or waive the requirement to obtain consent altogether when the request meets specific criteria.

Follow the prompts below to describe all consent processes and provide justification for any requested alterations or waivers.

Will informed consent be obtained from all research subjects (and/or their parents or legally authorized representatives)?

Yes

CSU Consent Personnel

Bell, Christopher

Ewell, Taylor Russell

Abbotts, Kieran Shay Struebin

Butterklee, Hannah Michelle

Bomar, Matthew Charles

No

Are you requesting a waiver of documentation of consent?

No

Consent

You do not have any procedures that include deception. If you are going to deceive or incompletely inform any subjects about any aspect of this study describe in the procedures section.

List each consent process

Who will obtain subjects consent?

Personnel

Bell, Christopher

Personnel

Ewell, Taylor Russell

Personnel

Abbotts, Kieran Shay Struebin

Personnel

Butterklee, Hannah Michelle

Personnel

Bomar, Matthew Charles

Which participant group is this consent process for?

All participants.

How is consent being obtained?

Whenever possible, participants are provided with a copy of the informed consent in advance (usually via email) for review at their convenience. During the actual in-person consent process, research team members review the form line-by-line, ask the participant questions ascertain correct comprehension, answer questions posed by the participant, and obtain written signatures.

Will non-English speaking participants be enrolled?

No

Non-English speaking participants will be unable to provide informed consent.

Are any subjects unable to legally provide consent?

No

Conflict of Interests

For guidance on how to answer these questions and information please visit the CSU Conflict of Interest page.

Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

No

Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

No

Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

No

Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

No

Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

No

Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

No

Significant Financial Interest: Please check Yes or No for each item below.

Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

No

Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

No

Minimizing Risks and Disclosure to Subjects

Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

No

By submitting this form, you are attesting that you have read Colorado State University's policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Attachments

Attach all relevant documentation to your research in this section. Please label each item appropriately, so your IRB reviewers understand the purpose and population each document aims to address. Please delete the existing attachment and upload the Tracked Changes version and Clean revised document for review to update or revise any existing attachments.

Any documentation that a participant will see must be reviewed and approved by the IRB, including consent, recruitment, communications, tools, instruments, etc. Additional documents required for review include funding proposals, contracts, letters of agreement, methodology, related approvals, etc. For more information and guidance on what documentation to attach, please visit the IRB website.

Answers within your application indicate that the following documentation is required:

Attachment Type

Other

Attachment

CANNABIS ATHLETIC PERFORMANCE.PDF

Name

Cannabis and Athletic Performance

Attachment Type

Other

Attachment

CANNABIS EXERCISE PERFORMANCE GATORADE.PDF

Name

Cannabis and Exercise Performance

Attachment Type

Other

Attachment

ACUTE EFFECTS OF MARIHUANA SMOKING ON MAXIMAL EXERCISE PERFORMANCE.PDF

Name

Marijuana and Maximal Exercise

Attachment Type

Other

Attachment

PHARMACOKINETIC INVESTIGATION OF COMMERCIALLY AVAILABLE EDIBLE MARIJUANA.PDF

Name

PK Edible Marijuana - CSU Study

Attachment Type

Recruitment Materials

Attachment

2827 RECRUITMENT FLYER.DOCX

Name

Recruitment Flyer

Attachment Type

Recruitment Materials

Attachment

2827 RECRUITMENT EMAIL.DOCX

Name

Recruitment email

Attachment Type

Screening Tool or Procedure

Attachment

2827 SCREENING FORM 10072021.DOCX

Name

2827 Screening Form

Attachment Type

Other

Attachment

CANNABIS USE AND SPORT.PDF

Name

Cannabis Use and Sport

Attachment Type

Consent

Attachment

2827 CONSENT 102721.DOCX

Name

Consent - Revised and Updated Oct 27

Obligations

The Principal Investigator is ultimately responsible for the conduct of this project. Obligations of the Principal Investigator include the following:

- **Receive IRB approval or determination prior to enrolling any subjects or collecting any data intended for research use.**
- **Manage and maintain all research records, including consent retention, for at least three (3) years after the close of the study, or longer per sponsor requirement.**
- **Ensure that personnel training status remains current.**
- **Provide all subjects a copy of the signed consent form, when applicable.**
- **Keep protocol up to date by submitting amendments for review and approval before instituting changes in any aspect of the study.**
- **Maintain current protocol approval by submitting renewals, as required.**
- **Promptly report any violations, deviations, unanticipated problems or adverse events to the IRB.**
- **Notify the IRB when the study is complete and take steps to close the protocol.**

I understand that as the Principal Investigator I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all applicable policies and regulations. I understand and agree to the obligations listed above.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge.

Administrative Details Form

Determinations

Review Type

Study Status