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Cannabidiol as an Adjunct for the Treatment of Anorexia Nervosa (CAFTAN): An Open Label Pilot Trial with Extension in Young People

Participant Information Sheet
Young Persons aged 15-18

(1) Introduction

You are invited to participate in a research study, Cannabidiol (CBD) for the Treatment for Anorexia Nervosa (CAFTAN). This information sheet tells you about the study. It will help you choose if you want to participate in the study or not. You can ask your parents, carer, friend or doctor if you need. You do not have to join this study if you do not want to.

Before you think of joining this study, you should know why and how the research is being done. Please read this information sheet carefully.

(2) What is the purpose of this study?

The purpose of this research study is to see if cannabidiol (CBD), a chemical obtained from the cannabis plant, can help with your eating disorder symptoms. We believe CBD will help to reduce your anxiety around food and weight gain and improve your relationship with food and body image.

You will be given CBD every day in addition to the first 3 months of Maudsley Family-Based Treatment (MFBT) (10 sessions), where your parents and family will help you to rebuild a healthy relationship with eating and food. Previous research studies have shown that CBD reduces anxiety in teenagers. If CBD is helping you, you will have an option to continue taking CBD for another 3 months until the end of MFBT (Overall 20 sessions).

(3) Why have I been invited to this study?

You are invited to take part in this study because you have anorexia nervosa, are aged 12-18, are about to commence MFBT and are in the care of a doctor.

(4) Do I have to be in this study?

You do not have to participate in this study if you don't want to. The doctors and therapists will take the best care of you as they have in the past, regardless of whether you are in the study or not.

If you choose to participate, you can leave the study at any time. All you need to do is tell one of the researchers or your parents/carers that you don't want to take part anymore.

(5) What will happen to me in this study?

Previous research studies have shown that CBD reduces anxiety in teenagers. You will be given CBD every day for 3 months during the first 3 months of Maudsley Family-Based Treatment (MFBT) (10 sessions) where your parents and family will help you to rebuild a healthy relationship with eating and food. These pills will be given to you by your parent/guardian.

You will start taking 1 CBD pill a day during the first week, and by week 4 – week 12 you will be taking 4 CBD pills a day, 2 in the morning and 2 at night.

If CBD is helping you, you will have an option to continue taking CBD for another 3 months until the end of MFBT (Overall 20 sessions over 24 weeks). You will continue taking 4 pills a day and completing monthly questionnaires. You, your parents, your doctor and research team will have to agree to this. You will also have to continue seeing your therapist and doctor during this time.

During treatment you will be asked to complete some questionnaires about how you are feeling. There will be five questionnaires that will ask you about your mood, your thoughts about food and your body image. Each questionnaire will take between 5-25 minutes to complete. You will be asked to complete these questionnaires at week 1, monthly for 12 weeks, week 24 and 3-months post study.

You will have to meet with your doctor regularly so that they can check that you are healthy enough to continue being in the study. You will have to provide small amounts of urine once a month to make sure you are well and healthy and to check that CBD is being absorbed.

At the end of the study and at 3-months post, you will be asked to complete some more questionnaires and have your weight recorded.

(6) Can anything bad happen, is CBD safe?

The risk of anything bad happening is extremely low. There can be a few side effects with CBD. It is possible you might experience some sleepiness, headaches, abdominal (tummy) discomfort during treatment. You may also experience nothing at all.

If you feel sick or if you notice any strange or bad feelings during the study, example throwing up, very painful stomach aches or chest pains, especially if they are unexpected or severe, you should let your parents or doctors know right away.

You can contact the therapist who is treating, your GP, trial doctor [E: karen.spielman@sydney.edu.au] or the study coordinator, [Sarah-Catherine Rodan **T: +61 4 03224986**].

(6.1) For GIRLS: Are there risks if you get pregnant?

We do not know the effects of CBD on the unborn child. You cannot be in the study if you are pregnant. If you are sexually active and have started menstruating, even if you have lost your period, you will be asked to use a study-approved birth control method and agree to try not to get pregnant during the study. You can discuss study-approved birth control methods with your doctor. If you have lost your menstrual periods you can still get pregnant. It is important that you contact your doctor right away if you think you may be pregnant, if you have missed a period or it is late, or you have a change in your usual menstrual cycle (for example, heavier or lighter bleeding than usual, or bleeding between periods). If you do become pregnant during the study, you will no longer be given CBD, MFBT will continue as usual and you will be referred to appropriate services as determined by your therapist and doctor.

(6.2) For BOYS: Are there risks if I get someone pregnant?

If you are currently sexually active, you will need to use a study-approved birth control method, and/or agree to not try to get someone else pregnant. You should contact the treating team, with the partner's consent and make sure that the partner knows that you are taking CBD.

(7) Will there be any benefits for me in this study?

We cannot promise that you will receive any benefits from this research study; however, possible benefits may include feeling less anxiety and fear towards eating and weight gain at mealtime. You may feel happier overall and obsess less about food and weight.

(8) How will my privacy be protected?

Your privacy will be protected at all times in this study. Unless you allow us, we will not tell anybody else you are or have been a part of this study. We will not release any information to anybody else that could be used to identify you, unless we are required to do so by law. For example, researchers are required to report if a participant is believed to be at risk of harm.

In order to protect your privacy, the study team will remove any information that may be used to identify you from any study documents, and instead of your name appearing on them, you will be identified by a study code number that applies only to you. Only this code number will be used on any research-related information collected about you for this study, so that your identity as part of the study will be kept completely private. Only the study team will have the ability to link this code number with your personal information, and the linking information will be kept in a secure and protected server.

Your data will be stored for a minimum of 15 years after the study finishes or until the youngest participant turns 25.

If you decide to leave the study, we will not collect any more information about you. We would like to keep the information we have already collected about you to help us ensure that the results of the research project can be measured properly. Please let us know if you do not want us to do this.

(9) What will happen to the study results?

We would like to share the study results by publishing them in journal articles and / or presenting them at conferences. We will make sure that information is published /presented in such a way that you are not identifiable, unless you have given us permission to do so.

You can also tell us on the consent form if you want to receive a simple summary of the study findings for information.

(10) Who should I contact if I have any questions?

If you have any questions or want more information about this study before or during participation, you can talk to the trial coordinator, Sarah-Catherine Rodan on **+ 61 403 224 986**, or the doctor from our research team [E: drkarenspielman@gmail.com].

You can also ask your parents/carers to talk to us.

(11) Who do I contact if I have concerns about the study?

This study has been approved by the Sydney Local Health District (RPAH Zone) HREC (protocol number X21-0440). Please talk to your parents/carers if you are worried about being in this study, or you have a complaint. They can talk to Sarah-Catherine Rodan on **0403 224 986**. or they can contact the Human Research Ethics Committee on (02) 9515 6766 or SLHD-RPAEthics@health.nsw.gov.au".

You can also call the Kids Helpline (telephone number: 1800 551 800) or Lifeline (telephone number: 13 11 14) at any time.

Appendix A
List of Investigators

Principal Investigator (Trial Oversight)

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Principal Clinical Investigator (Medical/Supervision of Trial doctor)

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Co-investigator (Trial doctor/GP specialist)

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Co-investigator (Trial Oversight)

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Co-investigator (Clinical trial coordinator/PhD Student)

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