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A Study of Cannabidiol for Anorexia Nervosa

Participant Information Sheet

Children aged 12-14 years

1. Introduction

You and your parents (or the person looking after you) are invited to participate in a study of a new medicine called cannabidiol (CBD), to see if this will help your *Anorexia Nervosa*. This information sheet tells you about the study. It will help you choose if you want to be 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.

2. What is the study about?

Previous research studies have shown that CBD reduces anxiety in teenagers. You will be given CBD every day 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 and get better from anorexia nervosa. 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, your parents, your doctor and research team will have to agree to this.

If you agree to be in the study, you will have to see your therapist, regularly see your doctor and speak with a doctor from our team. You will also have to give some pee once a month. You will start taking 1 CBD pill a day and by the fourth week you will have to take 4 pills a day. You will also be asked some questions about your anorexia nervosa, your mood and any feelings you might have. If you continue taking CBD after the first 3 months, you will continue taking 4 pills a day.

3. Is CBD safe?

The risk of anything bad happening is low. If you are not happy with the new pills, you can pull out of the study any time. You might get an upset tummy, sore head and be sleepy. You may also not experience any of those things.

If you feel sick or if you notice any strange or bad feelings during the study, for example throwing up, very sore tummy or chest, you should let your parents, therapist or doctor know right away.

4. What if I have questions?

If you have any questions about the study, your Mum or Dad or the person looking after you will have the information about who to ask. Don't be afraid to ask as many questions as you like.

If you have any questions or want more information about this study 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.

5. Do I have to say yes?

You don't have to say yes but have a talk about it with your Mum and Dad or the person looking after you and see what you think. The new pills might help you or they might not, but you might be able to help other children with anorexia nervosa in the future by being part of the study.

Thanks for thinking about being in the study and let us know your decision.

Appendix A

List of Investigators

Principal Investigator (Trial Oversight)

Name: Professor Iain McGregor
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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 (Clinical trial coordinator/PhD Student)

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Co-investigator (Trial management)

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