**Participant Information Sheet/Consent Form**

Health/Social Science Research

***Adult providing own consent***

Orygen

|  |  |
| --- | --- |
| **Title** | *A Feasibility Study Exploring the Benefits of Sudarshan Kriya Yoga in Young People with Symptoms of Anxiety or Depression* |
| **Short Title** | *BREATHE*  |
| **Protocol Number** |  |
| **Project Sponsor** | *Orygen* |
| **Coordinating Principal Investigator** | *Dr Aswin Ratheesh* |
| **Location**  | *Orygen, Parkville Clinic* |

**Part 1 What does my participation involve?**

1. Introduction

You are invited to take part in the research project called *A Feasibility Study Exploring the Benefits of Sudarshan Kriya Yoga in Young People with Symptoms of Anxiety or Depression (BREATHE)* because you have been experiencing symptoms of anxiety and/or depression and you are seeking help to manage these symptoms. This research project is investigating a distinct style of yogic breathing that has been practiced throughout the world as a treatment for various disorders.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part in the study. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or health worker.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the use of your personal and health information as described below.

You will be given a copy of this Participant Information and Consent Form to keep.

1. What is the purpose of this research?

Anxiety and depression are common mental health issues reported by young people. For many young people, currently available treatment options are not sufficient to help with their difficulties. Therefore, the research team are interested in evaluating alternative approaches to helping young people with depression and anxiety symptoms.

Yoga, meditation, and mindfulness approaches have been associated with improved mental health outcomes in research involving adults with depression or anxiety. A particular type of yoga, termed *Sudarshan Kriya Yoga* (SKY) has been beneficial for these people in research studies. An adapted version of this yoga has been developed for youth in university settings called The Sudarshan Kriya Yoga Campus Happiness Program (SKY-CHP). The Sudarshan Kriya Yoga Campus Happiness Program includes interactive group processes, experiential learning, breathing techniques, yoga, and meditation. It also involves a focus on teaching stress-management, coping strategies, and social connectedness. The Sudarshan Kriya Yoga Campus Happiness Program takes place over a period of 3 days, after which, all participants practice Sudarshan Kriya Yoga daily at home. The researchers involved in this project have adapted the Sudarshan Kriya Yoga Campus Happiness Program, in collaboration with young people and clinicians to make it appropriate for young people with depression or anxiety related difficulties. In this project, we are hoping to understand how feasible and acceptable this modified intervention is among young people with such difficulties (BREATHE project).

We are inviting young people aged 18-25 seeking treatment for anxiety and/or depressive symptoms to take part in this study. The *BREATHE* project is designed to determine if the adapted Sudarshan Kriya Yoga Campus Happiness Program would be acceptable for young people seeking help for anxiety and/or depression symptoms. All participants will practice an adapted form of Sudarshan Kriya Yoga Campus Happiness Program, adjusted specifically for this research project. There is no control or placebo group for this study. The reason for this is that we want to know if a treatment option such as Sudarshan Kriya Yoga Campus Happiness Program is something young people seeking help would want to partake in.

This research has been initiated by the Coordinating Investigator, Dr Aswin Ratheesh who is a psychiatrist at Orygen and a researcher at the University of Melbourne.

The funding for the trial has been provided through the Hearts and Minds Foundation. The Sudarshan Kriya Yoga Campus Happiness Program comes from the non-profit organization called the Art Of Living (AOL) Foundation. The instructor for the BREATHE study will be a graduate of the AOL teacher training program. The instructor and an Orygen clinician will lead each of the SKY-CHP lessons.

* 1. *What is Sudarshan Kriya Yoga (SKY)?*

Sudarshan Kriya Yoga (SKY) is a breathing-based meditation technique that encompasses positional and breathing-based steps. The program includes a short stretching sequence followed by 3-rounds of 4-specific breath control techniques (pranayama), while in a seated/kneeling position with eyes-closed. Stage 1 is Ujjayi breath and involves slowly breathing in and upon breathing out, you pretend as if you are trying to fog up a window (with your mouth closed). During Ujjayi, you also hold your hands in 3 different positions as you progress through. Stage 2 is Bhastrika and involves breathing in while raising your arms above the head while inhaling and bringing them down again and breathing out sharply. Stage 3 involves a slow breath in, followed by a slow breath out while chanting Om. Stage 4 is SKY breathing, which involves long breaths, followed by short breaths and fast-paced breaths. The final component is 10 minutes of silent lying down meditation.

1. What does participation in this research involve?

In the BREATHE study, everyone will receive the adapted Sudarshan Kriya Yoga Campus Happiness Program. If you agree to participate, you will be allocated to the next available spot within a group. Each group will consist of 5 to 10 young people who will engage with the adapted Sudarshan Kriya Yoga Campus Happiness Program together over a period of 3 days. After this, everyone from the group will be encouraged to practice adapted Sudarshan Kriya Yoga breathing intervention in their own time, at least until the end of the month. You will also meet with a researcher four times over the course of the month (see the timeline below). At each of these meetings, there is an interview with a researcher and some questionnaires for you to fill out, which is detailed is this section. If you agree to participate in this study, we will first ask you some questions to make sure that you are eligible. If you are not eligible to participate or if you choose not to participate, the researcher will discuss other options with you.

* 1. BREATHE Study Timeline

****

* 1. Screening & Consent

Before you begin in the study, a member of the research team will go through the screening and consent process, which will involve asking some brief questions to make sure that you are eligible to take part. Eligibility for the BREATHE study means that you are experiencing symptoms of anxiety and/or depression, are between the ages of 18 and 25, and can provide details for an emergency contact person and a clinician (e.g., your local doctor). If you are eligible and interested, a member of the research team will go through the consent process with you. This involves reading and talking about all the information included in this document to make sure that you understand what is involved in taking part in this study. Once this has been completed, the research team member will organise a time that suits you, to complete your first assessment (known as *baseline*) prior to the first day of the adapted Sudarshan Kriya Yoga Campus Happiness Program.

1. Study Visits

As you can see above on the timeline, there will be questionnaires to complete at the screening visit to ensure you are right for the study. You will then complete questionnaires at baseline, 15-days, and 30-days. These questionnaires take about 30-60 minutes to complete. At each time point (see above assessment timeline) you will receive an email or text message with a link that will take you to the self-report questionnaires. You call fill in these questionnaires in your own time, and the research assistant will send you a reminder if you have forgotten to open the link or if you haven’t finished all the questionnaires. The last element of the study is to gather electrophysiological data. This includes a non-invasive EEG imaging session at baseline and day-30 of the study. The total time for the baseline and final visit (Day-30) will be about 2 to 3 hours. The total time for Day-15 will be about 1 to 2 hours. This equates to around 8 hours of participation time over 1-month.

* 1. Reimbursement

There are no additional costs associated with participating in this research project. You will receive $30 an hour (min $30) for each assessment visit. Given the estimated hours required for each of the study visits, we expect the reimbursement amounts to be $60 (maximum $90) for baseline and Day-30 visits, and $30 (maximum $60) for the screening and Day-15 visits. This includes costs for travel, parking, meals, and other expenses associated with the research project visit. You will be paid by electronic funds transfer directly into a nominated bank account.

* 1. Interviews

At each study assessment you will be asked to take part in an interview. The interviews will be conducted by a member of the research team who will ask you a number of questions regarding your symptoms, mood, and how things have been for you lately. These may occur in person, over the telephone, or via Telehealth.

* 1. Self-report questionnaires

We will give you a series of questionnaires about your mental state. The research team will generate a link unique to you and send it to you via email.

* 1. Qualitative Interview

At the conclusion of the study, you will be asked to take part in a qualitative interview with a study team clinician. You will be asked open-ended questions regarding the BREATHE study, that will provide us with information on your experience of the adapted Sudarshan Kriya Yoga Campus Happiness Program and the trial itself. For these interviews, we will audio-record the interviews to ensure the information we ask of you is accurate.

* 1. Electrophysiological Markers (optional)

At two study visits, you will be asked to take part in electroencephalogram (EEG), which is a non-invasive and painless procedure that measures your brains electrical activity. During this time, we will also ask you to perform two tasks that measure how your brain responds to sights and sounds. To do all of this, a cap containing several electrodes will be placed on your head, and an odourless hypoallergenic gel will be applied to ensure that the activity of your brain is recordable by the electrodes. You will need to wash your hair either just before you come in for the EEG session, or the night before your EEG session. It is important that you don’t use any type of hair product (for example, hair conditioner, gel, spray, cream, foam, or mousse) before the session as these substances can make EEG recordings difficult. Four additional electrodes will be attached to the face using adhesive tape. The skin under the electrodes will be cleaned with an alcohol wipe. It is also important that you do not consume any caffeine, alcohol, or recreational drugs from the time you wake up until the time of the recording. Afterwards, you will be given the option to have a shower or wash your hair.

1. What do I have to do?

Your participation in the study will involve setting aside some time for on the occasions described above to complete the research assessments as well as taking part in the adapted Sudarshan Kriya Yoga Campus Happiness Program. The initial research assessments and baseline electrophysiological data will take place at a convenient time for you. The study team will ask you about your medical history, and about any current medications you are taking. There are no significant lifestyle restrictions you need to follow whilst taking part in the study, however, we ask that you do not enter into any other research projects over the course of the study without discussing it with a member of the research team.

We would also like to collect the contact details of a person you nominate (e.g., family member, close friend) to help us ensure that we can keep in contact with you throughout the study (in case your details change), or following the study, should we wish to have further contact with you. We would also like to collect details of your clinician (e.g., your local doctor) to ensure the study will not interfere with any of your current medical needs. No information provided to us during the course of your involvement will be shared with them, except for letting them know that you have been involved in a study with us, and that you provided their details to assist us in contacting you. If you wish to make any changes to an existing treatment plan during your participation in this study, please consult with your medical team for the best advice.

1. Other relevant information about the research project

We are aiming to recruit a total of 30 young people to take part in this research project. All participants will be recruited from Orygen, Parkville, Orygen-associated headspace clinics, and the community. Recruitment will be continuous throughout the study, so if you miss the start of one group, you can join the next available group. Each group will begin the intervention when sufficient participant numbers become available.

1. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with Orygen, or the University of Melbourne. If you chose not to take part, you can still receive care from your GP, the Parkville Clinic, your preferred headspace centre, and any other supports that may come with these services.

1. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, the findings of this study may help us to provide a new avenue of treatment for young people experiencing anxiety and/or depressive symptoms.

1. What are the possible risks and disadvantages of taking part?

*Psychological Distress*

For some people, being interviewed about their condition or answering questionnaires may cause distress. If you become upset or distressed as a result of your participation in the research, you should let someone from the research team know immediately. If you are distressed, a trained and qualified clinician will be able to support young people with managing their distress. You can also seek support from your treating team. In addition, you may prefer to suspend or end your participation in the research if distress occurs.

*Group Participation*

The 3-day adapted Sudarshan Kriya Yoga Campus Happiness Program will be conducted in groups of 5 to 10 young people. In the current climate, these groups will take place online via Zoom or other communication network. Some people may find social situations like this challenging and experience distress regarding their participation. If this occurs, you may choose to take a break from the session you are in or withdraw from the research project if you find it too uncomfortable. During each Sudarshan Kriya Yoga Campus Happiness Program session, a clinical member of the BREATHE research team will be present to support all participants.

*Risks related to EEG*

While EEG is a non-invasive procedure, there may be mild risks associated with it. The EEG procedure requires cleaning areas on the skin with an alcohol wipe in preparation of electrode placement, this may cause some redness or irritation to the skin. In addition, during EEG preparation, gel is placed in the hair, which can be easily washed off after the EEG test. These procedures might be slightly uncomfortable but are not painful and do not cause any physical damage to the skin. Throughout the EEG, you will be able to tell the researcher about any discomfort or distress and will be asked about this.

1. What if new information arises during this research project?

Sometimes, during a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor or researchers will tell you about it and discuss with you whether you want to continue in the research project. If you decide to continue in the research project you will be asked to sign an updated consent form.

1. What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

1. Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include decisions made by the investigators or local regulatory/health authorities.

1. What happens when the research project ends?

We expect that the research project will be completed in late 2022. If you wish to receive information about the results of the project, please let the research team know and a summary of the study results will be sent to you at the end of the project.

# **Part 2 How is the research project being conducted?**

1. What will happen to information about me?

By signing the consent form, you consent to relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and will be securely stored. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law, or if you consent to its use in future research.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Orygen, the institution relevant to this Participant Information Sheet, the University of Melbourne Ethics Committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. Researchers will store all the information collected via assessments, strictly confidential. This includes electronic or digital information kept on storage media or recording equipment, such as interview audiotapes.

* 1. Data Storage

During this study, all your records will be kept strictly confidential. Any paper records will be kept in a locked office at Orygen. Electronic copies of confidential information will be password protected and accessed only by researchers involved in this project. Your data will have a unique code, which may be documented in your research and/or health records. This code is used to de-identify your information for publication or sharing purposes. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. Your code number will be linked to your personal details, which are kept in a separate password-protected file, for the purpose of contacting you for further information, follow-up appointments, or contacting you for future research projects. Only study team members will have access to the link between the unique code and your personal details.

* + 1. Cloud Storage

Your study data may be stored in the Cloud. “In the Cloud” refers to servers in a data centre that are managed by a third party and accessible through the Internet. Your de-identified data will be encrypted and stored on a secure Cloud server to prevent improper access. These data will be a part of a broader Orygen database.

1. Future Unspecified Research

All data collected from you will be retained for a minimum of 15 years and may be retained indefinitely. With your consent, your data may also be used by Orygen for future research to answer research questions, which have not yet been identified yet, and which may or may not be related to this current research. Your de-identified data may also be shared with open-source journals. Any future research projects which seek to use your data must have been reviewed by a Human Research Ethics Committee and given their approval.

By consenting to your data being used for future research, you consent to the possible transfer of your data to domestic and international collaborators both within and outside of Australia.

* 1. Publication

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

1. Freedom of Information

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

1. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of loss or injury, the parties involved in this research project have agreed to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participating in a Clinical Trial. A copy of these guidelines is available from the study staff or can be accessed online at the Medicines Australia website.

1. Who is organising and funding the research?

This research has been initiated by the Coordinating Investigator, Dr Aswin Ratheesh, Orygen and Centre for Youth Mental Health, University of Melbourne. The project is sponsored by Orygen and funding for the trial has been provided through the Hearts and Minds Foundation.

1. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the University of Melbourne.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007; updated 2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

1. Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, please contact:

Research contact person

|  |  |
| --- | --- |
| Name | Dr James Kean |
| Position | Project Manager |
| Telephone | 0425 735 847 |
| Email | James.kean@orygen.org.au |

Clinical contact person

|  |  |
| --- | --- |
| Name | Dr Jesse Gates |
| Position | Senior Psychologist, Orygen  |
| Telephone |  |
| Email | Jesse.gates@orygen.org.au |

Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne (Project ID: 21316). If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact:

Complaints contact person

|  |  |
| --- | --- |
| Name | Research Integrity Administrator |
| Position | Office of Research Ethics and Integrity, University of Melbourne, VIC 3010 |
| Telephone | +61 8344 1376 |
| Email | research-integrity@unimelb.edu.au |

All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.

Emergency contacts

If you require emergency assistance, please contact one of the following services

(available 24/7):

• Lifeline on 13 11 14

• Suicide line on 1300 651 251

• The Youth Access Team on 1800 888 32

**Consent Form -** *Participant*

|  |  |
| --- | --- |
| **Title** | *A Feasibility Study Exploring the Benefits of Sudarshan Kriya Yoga in Young People with Symptoms of Anxiety or Depression* |
| **Short Title** | *BREATHE* |
| **Protocol Number** |  |
| **Project Sponsor** | *Orygen* |
| **Principal Investigator** | *Dr Aswin Ratheesh* |
| **Location**  | *Orygen, Parkville Clinic* |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand that my participation in this project is for research purposes only.

I give permission for my doctor(s) and the research team at Orygen to communicate regarding my health and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as and understand that I am free to withdraw at any time during the study without explanation or prejudice or affecting my future health care.

I understand that the data from this research may be stored indefinitely.

I understand that I will be emailed a signed copy of this document to keep.

**I consent to the collection, storage, and use of my de-identified data for:**

|  |  |  |
| --- | --- | --- |
| This research project | Yes  ☐ | No  ☐ |
| Any current or future research projects, including storage of my data in the Orygen Registry | Yes  ☐ | No  ☐ |

**Contact for future research:**

|  |  |  |
| --- | --- | --- |
| I consent to being contacted again in the future to participate in a different Orygen research project | Yes  ☐ | No  ☐ |
| I consent to being contacted again in the future regarding any opportunities to provide a young person’s perspective about this study or research more generally | Yes  ☐ | No  ☐ |
| I would like to obtain an email copy of the results.  | Yes  ☐ | No  ☐ |

Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Declaration by Participant

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |
|  |

|  |
| --- |
| Witness to the informed consent process (optional)Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\* Witness is not to the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Researcher†**

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.