Participant Information Leaflet
PORTLAOISE PROGRAMMES

Study title: A Randomised Control Trial of an adapted Mindfulness Based Stress Reduction programme for parents and caregivers of children with ADHD

You are being invited to take part in a research study to be carried out in HSE Laois/Offaly by a research team affiliated with University College Dublin.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

This study is being done to evaluate an 8-week Mindfulness-Based Stress Reduction programme which has been adapted for parents/caregivers of children with ADHD. Mindfulness-Based Stress Reduction is a programme which teaches people various skills to pay attention to the present moment, on purpose, non-judgementally. Mindfulness-based stress reduction programmes have been found to reduce stress and increase wellbeing in various populations.

We would like to evaluate if the programme is effective in increasing mindfulness in parenting, increasing parental wellbeing, and reducing parental stress. We also hope to evaluate if the programme has any impact on reducing inattention, impulsivity and hyperactivity in parents and in children and in increasing parents' and children's ability to manage their emotions. We would also like to see if the programme is effective in increasing heart rate variability, which is the variation in time between heartbeats. We are also interested in parents'/caregivers' overall views and experience of the programme.

This information will help us to understand if this is a useful programme for parents/caregivers of children with ADHD and will help us to create a manual for future programmes. We are interested in evaluating a programme which is not already routinely provided by HSE Laois/Offaly. Therefore, individuals must volunteer to participate in the study in order to participate in the programme.

Who is organising and funding this study?

This study is being conducted by the following research team: Anna Berry, Trainee Clinical Psychologist, UCD School of Psychology; Professor Alan Carr, Head of UCD School of Psychology; Professor Fiona McNicholas, Consultant Child and Adolescent Psychiatrist, Lucena Clinic; Cormac Lynch, Accredited Mindfulness Teacher, Accredited Mindfulness Teacher, MSc in Mindfulness-Based Approaches; Dominic Cogan, Accredited Mindfulness Teacher, and Ken Kilbride, CEO ADHD Ireland. Anna Berry is completing a doctorate in clinical psychology at UCD and this study will be part of her thesis. The Accredited Mindfulness Practitioners will be paid for facilitating the Mindfulness courses by UCD academic child psychiatry funds acquired by Professor Fiona McNicholas. No other researchers in the study are being paid to either conduct or to recruit participants to the study. Several grants for the study have been applied for, however the outcome of these applications has not yet been decided on. Should the study receive additonal funding, participants will be made aware of this.

Why am I being asked to take part?

You have been asked to take part as you are a parent/caregiver of a child (4-18 years old) with a diagnosis of ADHD.

How will the study be carried out?

The Mindfulness programme will begin approximately in either March 2020 or April 2020 for 8 weeks. Participants will be asked to complete questionnaires after we first recruit you to the study, approximately January 2020, and possibly 3 months after completing the programme. This data will be analysed in approximately August 2020, once it has all been collected. Some participants will be invited, at random, to participate in a focus group to discuss their experience of the programme. The focus group conversation will be recorded and this data will be analysed in approximately August 2020, once the focus groups have been conducted. We hope that 100 people in total will take part the study, with approximately 25 people in each mindfulness group. Of these 100 people, we hope to recruit 35 people from Laois/Offaly, 35 people from Lucena, and 30 people via ADHD Ireland, a charity for individuals affected by ADHD.

What will happen to me if I agree to take part?

If you decide to take part in the research:

If you decide to take part, you must complete the attached consent form and either leave this in the attached sealed envelope with the administrator of the service your child attends, or

return this directly to Anna Berry, by email or registered post, on the contact details provided below. You will then be contacted by Anna Berry on the details you provide on the consent form, who will invite you to attend a pre-course meeting, in which more detailed information about the course will be provided, which you may attend if you wish. You will be sent an 'assessment letter' and the questionnaires. The questionnaires will take approximately 30-45 minutes to complete. You will then be offered a place by the research team, at random, on one of these programmes, with a start date in March 2020 or in April 2020. You must be a participant in this research study in order to receive this mindfulness intervention.

The programme will involve attending one 2-hour session a week for 8 weeks (evening time) and one retreat day between week 7-8 (Saturday). This will involve you travelling to Treo Nua, Family Resource Centre, Portlaoise, to attend. The programme also involves daily mindfulness practice for 6 days of the week throughout the programme (approximately 45minutes - 1 hour per day). You will be asked to complete a 'Mindfulness Practice Recording Form' each week to document your home practice. You will also be invited to provide weekly heart rate variability measurements. This will require downloading Welltory, a free app, to a smartphone and using this app to take a weekly measurement, for 9 weeks. This measurement is taken by holding your index finger to the camera and flash for approximately 100 seconds. This is not mandatory and participants can participate in this study without downloading this app and providing these measurements.

Once you have completed the programme, you will be invited to complete the questionnaires again to help us to determine if the programme has been effective for you. Some participants will also be asked to fill in these questionnaires 3 months following the programme.

Following the programme, some participants will be selected at random and invited to participate in a focus group, which will last approximately 1.5 hours, to provide us with information about their experience of the programme. You do not have to participate in the focus group if you do not want to.

We will analyse all the data gathered which will tell us if the programme has been effective and useful. We will not require any additional medical information from you and we will not look at your medical records. There will ne no blood samples or physical data taken.

If you decide not to take part in the research:

This is a research study evaluating an intervention, which is not already routinely provided by HSE Laois/Offaly. Therefore, individuals must volunteer to participate in the study to receive the intervention. It is completely voluntary and your choice if you would like to participate. It will not affect access of you or your child to services if you decide not to take part.

If you decide to withdraw from the study:

Participants will be able to withdraw their questionnaire data from the study at any point up *until August 2020*, as this is the point when the data will be analysed. To do this, participants will contact Anna Berry and provide their unique data identification number. Their questionnaires will then be removed from the study and confidentially destroyed. Withdrawal

from the study will not affect access of you or your child to services. If you choose to participate in a focus group, it will not be possible to withdraw your data from the focus group data as this will be the mixed data of a group of participants. It will therefore be impossible to identify and distinguish your data from that of the other participants.

Video/and or Audio recordings?

The focus groups will be digitally audio-recorded. Anna Berry and her supervisor, Professor Alan Carr, will have access to these recordings. To ensure anonymity, when audio-recording are being typed up, no names or identifiable information will be included in the transcription. The recordings will be permanently deleted once verified and Anna Berry will then consult with personnel from UCD School of Psychology Information and communications technology department, to verify that any recordings have been completely deleted from the digital recording device.

What are the benefits?

Participants will have the opportunity to take part in a Mindfulness-Based Stress Reduction programme free of cost, which has been specifically adapted for parents/caregivers of children with ADHD. The benefits of mindfulness programmes have been widely evidenced in research and it is hoped that parents will benefit personally from participation. Taking part in this research will help us improve the services and supports we offer parents of children with ADHD, as it will provide us with information about whether parents find this programme useful and beneficial.

What are the risks?

Risks of participating are that difficult or upsetting feelings or thoughts may arise for some people during mindfulness practice. Participants will be encouraged to discuss with the facilitators should this occur and to make the facilitators aware, prior to beginning the course, if they are currently managing or have previously any difficult issues which they feel may arise for them during mindfulness practice. There is also a risk that participants may push themselves too far physically during mindful movements. Participants will be encouraged either not to engage in or alter any movements which they feel are too strenuous for their body.

The study requires that you travel to Treo Nua, Family Resource Centre, Portlaoise, to participate in the programme and that you spend approximately 30 minutes completing the questionnaires at 2 or 3 different time points. To protect participants' personal data provided on the consent forms, consent forms will initially be stored in paper format in a locked filing cabinet at Anna Berry's HSE working base. All data will then be scanned onto an encrypted USB stick and all paper documents will be confidentially shredded. Data will be kept on this USB stick for 10 years, then destroyed by Anna Berry.

Will it cost me anything to take part?

There are no costs to taking part in the programme itself. You however may have travel expenses to and from the programme itself (e.g. bus or fuel costs).

Is the study confidential?

Yes. All your information provided to the research team will not be shared with anyone outside of the research team. The only limit to this confidentiality is if you provide information which suggests that a child is at risk of being harmed, or has previously been harmed, then the research team have a duty of care to report this information to Tusla, which is the Child and Family Agency.

The questionnaires and forms you complete will be pseudo-anonymised, whereby you will create a unique identification code and mark this on each form, which only you will be aware of. The only data which will not be pseudo-anonymised in this way is the consent form, which will contain your name, address or email, and your phone number. This is so that we can use your information to contact you during the study. The consent forms and the questionnaires will be securely stored in a locked filing system at a HSE site, then transferred on to an encrypted USB stick. The questionnaire data will then be analysed on a password protected laptop. The focus groups will be recorded and the audio-recorder will be stored in a secure filing system. These recordings will then be typed up on a password protected laptop. Recordings will be deleted once verified. These transcripts will then be analysed for common themes in what people have said. No names or identifiable information will be included in the typed discussion which takes place during the focus groups. Anna Berry will securely destroy all data after 10 years.

If you choose to provide heart-rate variability measures by using the Welltory app, as it is outlined on the 'sign-up' page, if you choose to 'sign up' to the Welltory app, you are agreeing to the app's privacy policy. This app captures biometric data and requests your name, email, gender, date of birth, height and weight. The app also collects data including, but not limited to: usage data; email address; universally unique identifier (UUID); device information; in-app purchases; camera permission; precise location permission (continuous); sensors permission; Bluetooth sharing permission; general activity data; body measurements & indexes; movement activity; payment data; company name; data communicated while using the service; last name; password; picture. Personal Data may be collected automatically when using Welltory. Welltory may collect, use, and share User location Data in order to provide location-based services. This type of service allows User Data to be utilized for advertising communication purposes displayed in the form of banners and other advertisements on Welltory, possibly based on User interests. The User's Personal Data may be used for legal purposes by Welltory in court or in the stages leading to possible legal action arising from improper use of Welltory or the related Services, and also may be required to reveal personal data upon request of public authorities. Welltory does not support "Do Not Track" requests. Welltory highlight that they upload all data provided to the app to their cloud. Welltory privacy policy is accessible at https://welltory.com/privacy/.

Pseudo-information (false information) may be provided to the app. It is your own choice to sign-up to this app and provide this information to Welltory and we recommend that you review the privacy policy in detail before making an informed choice about whether to sign up or not. The research team for this study are not affiliated or responsible for any breaches of Welltory's privacy policy, should a breach occur.

The results of the study will be submitted as part of Anna Berry's thesis, for publication in academic journals, and presented at future conferences, however the outcomes will appear as a group result and there will be no identifying information of any individual's involved. If you would like a summary of the results, make the facilitators aware of this and we will email you a copy of the final report.

Data Protection

Under data protection laws you have rights. The study must provide research participants with the following information. It is a legal requirement under data protection law. You have the right:

1. To know the purpose or reason for processing your personal data: Your data will be used to evaluate an adapted Mindfulness Based Stress Reduction programme for parents and caregivers of children with ADHD and make amendments for future programmes.

2. To know the legal basis under which we are processing their data: Your data is being processed under Article 6.1 (f) 'legitimate interests' and under Article 9.2 (j) 'scientific research purposes' General Data Protection Regulation 2016.

3. To know who the recipients of the data are: Your data will be accessible to the research team.

4. To know how long will the data be stored for: Your questionnaire data will be stored for 10 years after the completion of data collection in August 2020 and the focus group data will be stored for 10 years after the completion of data collection in August 2020 (Recital 39 GDPR Guidelines).

5. You have the right to withdraw your consent.

6. You have a right to lodge a complaint with the Data Protection Commissioner: The Data Protection Commissioner, Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, D02 RD28. Phone: +353 (0)761 104 800,+353 (0)57 868 4800 , 09:15 - 17:30 hrs (17:15 Friday). Website https://forms.dataprotection.ie/contact.

7. You have a right to request access to your personal data and a copy of it, until your personal data is destroyed 10 years following study completion. It will not be possible to access a copy of the focus group data as this will be the mixed data of a group of participants and it

will be impossible for the data controller to identify and distinguish your data from that of the other participants.

8. You have a right to restrict or object to processing, until the point of analysis of the questionnaire data in August 2020, by which point it will not be possible for the data controller to identify and distinguish your anonymised data from that of other participants. It will not be possible to restrict or object to processing of the focus group data as this will be the mixed data of a group of participants and it will be impossible for the data controller to identify and distinguish your data from that of the other participants.

9. You have a right to have any inaccurate information about you corrected or deleted, until the point of analysis of the questionnaire data in August 2020, by which point it will not be possible for the data controller to identify and distinguish your anonymised data from that of other participants. It will not be possible to have any inaccurate information about you corrected or deleted within the focus group data as this will be the mixed data of a group of participants and it will be impossible for the data controller to identify and distinguish your data from that of the other participants.

10. You have a right to have personal data deleted, until the point of analysis of the questionnaire data in August 2020, by which point it will not be possible for the data controller to identify and distinguish your anonymised data from that of other participants. It will not be possible to have any personal data deleted from the focus group data as this will be the mixed data of a group of participants and it will be impossible for the data controller to identify and distinguish your data from that of the other participants.

11. You have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format.

12. Your data will not be used for automated decision making, including profiling.

13. You have a right to object to automated processing, including profiling, however no automated decision making, including profiling, will occur in this study.

14. There will be no further processing of your personal data outside of the specified research study without your explicit consent.

15. Your data will not be transferred to a country outside of the EU or an international organisation.

To ensure safeguarding of your data, all data collected will be stored in a secure filing system. All questionnaires and forms will be coded with a Unique Identity Code, which only you will

know. The only exception to this is your consent form, which will contain your name, address or email, and phone number so that we can contact you during the study. No identifiable information will be within the transcription of the focus groups conversation.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

Principal Investigator: Anna Berry, Trainee Clinical Psychologist
Address: UCD School of Psychology, Newman Building, Belfield, Dublin 4
Email: anna.ni-bheara@ucdconnect.ie