

PARTICIPANT INFORMATION SHEET

Version 1.1, 24/04/17

Title of Project: *Mindfulness Online STress intervention for family carers of children and adults with Intellectual Disability (MOST-ID): A feasibility study of Be Mindful*

Name of researcher(s): *Samantha Flynn, Professor Richard Hastings, Christine Koulla Burke, Simon Howes, Professor Yona Lunsky and Associate Professor Jonathan Weiss*

Introduction

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. You can talk to others about the study before you decide whether to take part.

(Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about how we will carry out the study)

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part.

PART 1

What is the study about?

The Mental Health Foundation have developed an online mindfulness-based training programme called *Be Mindful*. *Be Mindful* has 10 easy-to-follow online sessions, featuring videos and interactive exercises, are presented by qualified mindfulness trainers, and the course can be completed in as little as 4 weeks (although most people take longer). *Be Mindful* helps people to look after their own emotional well-being.

We want to find out if *Be Mindful* helps family carers of children with learning disabilities (sometimes called intellectual or developmental disabilities) to look after their emotional well-being. To do this, we would need to run a big study and ask a lot of family carers to be involved. However, before we can do this, we need to run this smaller study, which is called a feasibility study. We will check out if the research works well so that a much bigger study can be planned in future. We are inviting you to take part in the feasibility study.

In this study, all family carers will take part in *Be Mindful* and some family carers will be randomly selected to also receive additional telephone support from parents who have been trained to deliver telephone coaching for *Be Mindful*. All family carers will be asked to complete questionnaires on three different occasions.

Why have I been approached?

You have been invited to take part in this study as you are a family carer of a child or adult with learning disability.

Do I have to take part?

No. It is entirely up to you to decide.

You have already been given brief information about the study, and you indicated that you would like to have more information. Please read through this information sheet which describes the study in more detail. You can ask any questions you have by contacting the researcher named at the end of this information sheet. When you have read the information sheet, and if you are happy to take part in the study, we will ask you to sign a consent form to confirm that you have agreed to take part. You will be free to withdraw at any time, without giving a reason and this will not affect you or your circumstances in any way.

What will happen to me if I take part?

A researcher will first call you to check that you are eligible to take part in the study. You will be asked to answer some questions about your child with learning disability to check this. The answers to these questions will be looked at by members of the research team to check that you are eligible to take part in the study. You will have the opportunity to ask the researcher questions about the study during this telephone call. During this telephone call, the researcher will also ask you whether you consent to take part in the study, and if you do, they will ask you some questions about your child from an assessment called the Vineland Adaptive Behaviour Scales (VABS).

If you are eligible to take part in the study, and still wish to take part, a researcher will arrange to collect some information from you using various questionnaires. You will have the choice to complete these questionnaires by post, telephone, or online.

The questionnaires may take up to about 40 minutes to complete. The questionnaires ask about your well-being, positive perceptions, relationship with your partner (if relevant), perceptions about family life and parenting, and relationship with your child. If you do not want to answer individual questions, then you can leave them blank.

Whether you will receive *Be Mindful* on its own, or with the additional telephone support will be decided at random (like tossing a coin). Half of the family carers will receive *Be Mindful* on its own, and the other half will also receive additional telephone support. This is so that we can compare the questionnaire answers of family carers who received *Be Mindful* on its own, and those who also received telephone support. It is the best way to show whether there are any differences between the two groups.

Everyone taking part will be contacted by the researchers again after approximately 3 months and 6 months to complete the same questionnaires. Each time, it will be up to you to decide whether you would to complete questionnaires online, over the telephone, or have questionnaires posted to you.

We will also ask some family carers to have an interview with a researcher to tell us more about your experience of taking part in the research, and your experience of *Be Mindful*. It will be your choice whether or not to take part in an interview if invited and further information will be provided to you to help make this decision at the time. At this stage, we only need to know if it is OK for us to contact you later to invite you to take part in an interview.

We will also ask for one of your *Be Mindful* telephone support sessions to be audio-recorded. Only the study team will hear these recordings to check on how the telephone support session was delivered. You will have the opportunity to opt out of this at the time.

The *Be Mindful* programme

The *Be Mindful* programme is an online mindfulness training programme. The programme guides participants through all the elements of Mindfulness-Based Cognitive Therapy to support your emotional and well-being needs. Ten easy-to-follow online sessions, featuring videos and interactive exercises, are presented by qualified mindfulness trainers, and it can be completed in as little as 4 weeks (although most people take a bit longer).

The programme can be followed from any device with a web browser and internet connection, such as mobile phones and tablets, including being saved as a web-app on the devices homepage. You will be asked to practice some things in your daily life, and full information about what to do and how to do it are provided within the programme. You will be able to download course materials and tools to help you to track your progress as you complete the programme. You will also receive some emails to support you throughout the programme.

Some family carers will also receive three 30 minute telephone support sessions from a trained parent mentor who also has a child with learning disability. These telephone support sessions will support family carers alongside their completion of the *Be Mindful* programme. At the end of the study, we will be asking parent mentors about their experiences of delivering the telephone support sessions, but they will not divulge personal information about the family carers they supported.

What are the possible disadvantages of taking part in this study?

The questionnaires, *Be Mindful* programme, and additional telephone support sessions include positive things, but will also ask you to reflect on challenges you may face with your child. However, we do not think that taking part in the study will pose any risk to family carers or their children. Should you have any concerns, please contact the research team using the contact information at the end of this information sheet.

What are the possible benefits of taking part in this study?

The *Be Mindful* programme has been successful in improving the well-being of participants who are not family carers of a child with learning disability. Because *Be Mindful* has not yet been tested with family carers who have a child with learning disability, we do not know yet if it will benefit you. By taking part in this study you will be helping the researchers to answer whether the *Be Mindful* programme can be delivered to family carers who have a child with learning disability, and whether the research works well so that a much bigger study can be planned in future. The results of this study may benefit family carers of children with learning disability in the future.

Expenses and payments

We cannot pay you to take part in this study. However, we will provide you with a £10 high street voucher each time you complete the package of questionnaires as a thank you.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the Study Manager or Chief Investigator who will do their best to answer your questions (contact details on the

last page). If you remain unhappy and wish to complain formally, please contact the University of Warwick (contact details can be found on the last page). If you remain unhappy and wish to complain formally, please contact the University of Warwick (contact details can be found on the last page).

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

Who is organising and funding the study?

The study is being led by researchers at the University of Warwick and is being conducted with other team members at the Mental Health Foundation, University of Toronto, and York University, Canada. The study is being funded by the Baily Thomas Charitable Fund.

What will happen if I don't want to carry on being part of the study?

You can withdraw from the study at any time, without giving a reason, and without affecting you in any way. If you do decide to withdraw from the study, you will be able to elect to have your data removed as well. If the study is stopped for any other reason, we will inform you.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services

University House

University of Warwick

Coventry

CV4 8UW

Email: researchgovernance@warwick.ac.uk

Tel: 024 76 522746

Will my taking part be kept confidential?

Yes, all information about you will be handled in confidence and will only be seen by the research team. Study data stored at the University of Warwick will be kept separate from personal information (names and addresses). Only members of the research team will have access to view identifiable data. However, in some instances, officials from regulatory authorities may need to access data for checking the quality of the research. All members of the research team and regulatory bodies are trained in data protection issues and are bound by data protection law. Study data will be kept securely for 10 years in line with the University of Warwick's policies.

What will happen to the results of the study?

A report of the research results will be completed and sent to Baily Thomas Charitable Fund who are paying for the study. Results will be published in scientific journals and presented at scientific meetings. You will not be identified in any report, publication or presentation. Once the research study is complete, we will send you information about the results of the research.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Humanities and Social Science Research Ethics Committee (HSSREC): **58/17-18**

What if I want more information about the study?

If you have any questions about any aspect of the study, or your participation in it, not answered by this participant information sheet, please contact:

Samantha Flynn (Study Manager) Tel: 07823 362152
Richard Hastings (Chief Investigator) Tel: 02476 552197

Thank you for taking the time to read this Participant Information Sheet.