**The ‘Taking it Further’ Programme**

**PARTICIPANT INFORMATION SHEET**

Central University Research Ethics Committee (CUREC) Approval Reference: R75514/RE001

1. ***Why is this research being conducted?***

To investigate the effects of a tailored mindfulness programme, called [**‘Taking it further’**](https://www.oxfordmindfulness.org/learn-mindfulness/course-types/mindfulness-taking-it-further/), on well-being and mental health over time.

1. ***Why have I been invited to take part?***

You have been invited because you:

1. **Are 18 years old or over.**
2. **Completed either a Mindfulness-Based Cognitive Therapy (MBCT) or Mindfulness-Based Stress Reduction (MBSR) course at some point in the past.** Any MBCT course within the ‘family of MBCT’ (e.g. MBCT for Life [MBCT-L], MBCT-Finding Peace in a Frantic World [MBCT-FP], MBCT for Depression [MBCT-D]) are acceptable. Introductory or taster sessions are not applicable. Trained mindfulness teachers are not eligible to take part.
3. **Expressed an interest in taking part in a 12-week research study through the Oxford Mindfulness Centre.**
4. **Agree to be available to begin the 12-week study on June 28th (Mondays Weekly, 10-12:15pm, UK Time).**
5. **Agree to complete an orientation session before the start the study.**
6. **Agree to complete online surveys before the start of the study, during the study, and after the study.**
7. **Acknowledge that you will receive subsidized admission (£138) to attend one ‘Taking it Further’ course.**
8. **Acknowledge that you will be randomized into one of two groups.** This means that you may be offered the ‘Taking it Further’ mindfulness course starting June 28th or at a later date. For those that will receive the ‘Taking it Further’ course at a later date, you will be offered a course *within 4 months* (October 4th 2021; Monday, 10:00-12:15 UK Time). You will be encouraged to attend this scheduled course since this is when we know our teachers will be available. However, in the case that the dates do not work, you will be offered a voucher to attend a course at a different time (contingent on teacher availability) within 1-year of your preferred start date. If you believe that you will not be able to attend the arranged course in October, please email Shannon at shannon.maloney@psych.ox.ac.uk.
9. ***Do I have to take part?***

No. You can ask questions about the research before deciding whether or not to take part. If you do agree to take part, you may withdraw yourself from the study, without giving a reason, by advising the research team of this decision. If you do decide to withdraw your data, you will need to email Shannon at shannon.maloney@psych.ox.ac.uk by **January 1st 2022**. After this date, the data will be anonymised and impossible to link back to individual participants. Therefore, after this date we will be unable to remove the data.

1. ***What will happen to me if I take part in the research?***

If you take part in this research, you will be invited to go through the following stages:

1. **REGISTRATION**

Our study advertisements should provide a **registration link** that will allow you to register online with the Oxford Mindfulness Centre (OMC) and express an interest in this research study. If you have not registered already, please follow this link to do so: <https://registrations.oxfordmindfulness.org/?cid=1117>

The registration form will assess your eligibility for the study. **You will need to register by June 14th 2021 (12:00 midday, UK Time).**

Once you have registered, you should receive an email from the research team (Shannon Maloney, shannon.maloney@psych.ox.ac.uk) to inform you of your eligibility status. You may be asked some questions to clarify your registration form and you will be asked to review the document you are reading through now (participant information sheet) along with the consent form, which will provide more information about the study. You will be prompted to complete the informed consent form online when you receive your first survey, so you don’t have to fill out this form at this stage.

If you would like to take part in the study after reviewing these documents, please inform the research team by emailing Shannon at shannon.maloney@psych.ox.ac.uk. If you do not do this, then you will not receive information on the next steps, so please remember to do this.

You will then receive an email outlining your **Participant ID** and **other unique codes** that you will need to keep track of for the full duration of the study. You will also receive a **link to the first survey** that will prompt you to input these codes. Please keep track of these codes and do not share them with anyone. If you have lost your code, please email Shannon in the first instance. The survey will include an electronic informed consent form and some questions regarding your well-being and mindfulness practice.

You must complete this survey by **12:00 midnight, June 14th, UK Time**.

1. **ORIENTATION SESSION**

Before the start of the study, you must watch an orientation video. This orientation video will give you more information about the ‘Taking it Further’ programme and this research study. You must watch the orientation video by **June 21st, midnight, UK Time**. Once you have completed your orientation, you will be invited to complete another online survey which will ask some questions about your well-being and mindfulness practice For this survey, please remember to have your **Participant ID** and **other unique codes** on hand.

You must complete this stage by **midnight June 21st, 2021**.

Participants that have completed the orientation session, will then be randomized into one of two groups (‘Treatment’ or ‘Control’). You will be notified of your allocation over email and given a **Course ID.**

If you are allocated to Treatment, then you will take part in a twelve-week TiF course that will begin on June 28th and you will be asked to complete some surveys over the course of the twelve weeks which will track changes in your well-being and mindfulness skills.

 If you are allocated to Control, then you will be invited to complete some surveys over the course of twelve weeks, to track changes in your well-being and mindfulness skills, and you will be offered a TiF course at a later date (October 4th; 10:00-12:15 London Time). If this re-arranged time does not work for you, please email Shannon at shannon.maloney@psych.ox.ac.uk.

**If you have been allocated to Treatment,** please ensure that you can make the dates and times for all twelve sessions for your preferred start date.

**June 28th:**

Session 1: June 28th, 10 am-12:15 pm, UK Time

Session 2: July 5th, 10 am-12:15 pm, UK Time

Session 3: July 12th, 10 am-12:15 pm, UK Time

Session 4: July 19th, 10 am-12:15 pm, UK Time

Session 5: July 26th, 10 am-12:15 pm, UK Time

Session 6: August 2nd 10 am-12:15 pm, UK Time

Session 7: August 9th, 10 am-12:15 pm, UK Time

Session 8: August 16th, 10 am-12:15 pm, UK Time

Session 9: August 23rd, 10 am-12:15 pm, UK Time

Session 10: August 30th,10 am-12:15 pm, UK Time

Session 11: September 6th, 10 am-12:15 pm, UK Time

Session 12: September 13th, 10 am-12:15 pm, UK Time

1. **SURVEYS**

**Both Treatment and Control** will receive an online survey link to complete the day before the start date (June 27th). **Please complete this survey by midnight, London Time, June 27th.**

Both Treatment and Control will then be invited to complete a survey the day after session 4, 8, and 12. You will be given a calendar to help keep track of these dates and you will also be reminded by email. Generally, for the surveys, you will be asked to complete them by midnight on the day that they are administered, so please check your emails regularly and if you haven’t received one, please check your ‘spam’ and/or ‘deleted’ folders and email Shannon if you are having trouble finding the email. You will be reminded throughout the study, but if you have any questions or concerns please email Shannon in the first instance.

These surveys will ask about your well-being, mental health, quality of life, and about particular mindfulness skills. Please complete these surveys honestly and if you have any questions please email Shannon before you submit the survey.

Please remember that you will need your **Participant ID, Course ID** and **other unique codes** to complete all surveys.

**Step-by-step Summary:**

* You will need to first register online using this link (<https://registrations.oxfordmindfulness.org/?cid=1117>))and review this information sheet and consent form
* If you have consented to take part you need to complete the first survey and remember to input your **Participant ID** and **other unique codes**.
* You will then need to watch an orientation video before the start of your course. At the end of the orientation video, you will be asked to complete another survey. Be sure to again remember your **Participant ID**, and **other unique codes**.
* The day before your preferred start date, you will be emailed another survey link to complete. You must complete this survey before the start date. Please remember your **Participant ID**, **Course ID**, and **other unique codes.**
* Over the course of twelve weeks, you will be asked to complete online surveys the day after week 4, 8, and 12. The survey completed the day after week 12 marks the end of the research study. Please again remember your **Participant ID**, **Course ID**, and **other unique codes** for all surveys.
1. **MINDFULNESS COURSE**

For the ‘Taking it Further’ programme, you will be invited to attend twelve weekly group-sessions online which will be led by a trained mindfulness teacher. The groups will be kept small to optimize your learning experience. Each weekly session will involve mindfulness practices and reflection and you will be invited to practice in your own time every day for 30-45 minutes outside of the weekly group sessions over the course of the programme.

1. **STUDY CALENDAR**

To help keep track of when you should complete each stage, a calendar has been created and has been further divided by groups (Treatment and Control). The calendars will be sent to you as a separate attachment. If you have any questions or cannot find the calendar, please email Shannon. You should receive reminders on specific deadlines by email as well but please use these calendars to help stay on top of deadline.

1. ***Are there any potential risks in taking part?***

During the ‘Taking it Further’ programme, you will be invited to engage with some different mindfulness meditation practices. In the process of cultivating a ‘mindful state,’ participants may become aware of unpleasant thoughts and emotions. Since this awareness may cause some distress, it is strongly advised that individuals that suffer from PTSD, psychosis, trauma, bereavement, and/or any substance or drug addiction to not take part in this study at this time.

1. ***Are there any benefits in taking part?***

Mindfulness has been found to be beneficial for many people. For instance, it has been demonstrated to reduce stress and to improve mood. However, we cannot promise that you will experience these personal benefits. Our intention is to use the data collected from this study to help us understand if and how this programme works.

1. ***Expenses and payments***

You will receive admission to the Taking it Further programme at a subsidized rate of £138. Please note that if you withdraw from the study less than 24 hours before the start of the study, we will be unable to reimburse you. If you have any questions or concerns about this, please email Shannon in the first instance.

1. ***What happens to the data provided?***

The information you provide during the study is the **research data**. Any research data from which you can be identified (e.g. age, gender) is known as **personal data**.

This includes more sensitive categories of personal data such as your mental health and wellbeing.

**Personal / sensitive data** will be stored on a separate encrypted file on a secure Oxford server for the duration of the study. At the end of the study, your data will be de-identified meaning that this data could not be linked back to you. Your personal / sensitive data will only be retained for as long as it is needed.

**Other research data** (including consent forms) will be stored for at least 3 years after publication or public release of the work of the research.

 The research team will have access to the research data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research.

We would like your permission to use direct quotes anonymously in any research outputs.

We would like your permission to use de-identified data in future studies, and to share data with other researchers (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

1. ***Will the research be published?***

The research may be published in academic publications, open-access journals, or websites.

The University of Oxford is committed to the dissemination of its research for the benefit of society and the economy and, in support of this commitment, has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact and use of that research.

The research will be written up as a student’s thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives to facilitate its use in future research. If so, the thesis will be openly accessible.

1. ***Who is funding the research?***

Mind and Life Europe, an international organization that supports mindfulness research, is funding this project with the Mind and Life Europe Francisco J. Varela Research Award.

**Grant # 2020EVA-Maloney, Shannon**

1. ***Who has reviewed this study?***

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (Reference number: R75514/RE001).

1. ***Who do I contact if I have a concern about the study or I wish to complain?***

If you have a concern about any aspect of this study, please contact Shannon at shannon.maloney@psych.ox.ac.uk or Willem at willem.kuyken@psych.ox.ac.uk in the first instance and they will do their best to answer your query. The research team will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Chair, **Medical Sciences Inter-Divisional Research Ethics Committee**; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

1. ***Data Protection***

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study.

The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest.

Further information about your rights with respect to your personal data is available from <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>.

1. ***Further Information and Contact Details***

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Shannon Maloney

Department of Psychiatry

University of Oxford, Warneford Hospital, Warneford Ln, Oxford, OX37JX

University email: shannon.maloney@psych.ox.ac.uk