**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 from October 4th.**
4. **Agree to watch an orientation video before the start of the study.**
5. **Agree to complete online surveys before the start of the study, during the study, and after the study.**
6. **Acknowledge that you will pay subsidized admission (£138) to attend one ‘Taking it Further’ course.**
7. **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 October 4th 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* (February 1st 2022; Tuesdays, 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 this alternative date/time does not work, please email Shannon at [shannon.maloney@psych.ox.ac.uk](mailto:shannon.maloney@psych.ox.ac.uk) in the first instance. In summary, the treatment and control group will both be invited to complete online research surveys from October 4th, but the treatment group will be offered the Taking it Further course right away whereas the control group will be offered the course at a later time.
8. ***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](mailto: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=1184>

The registration form will assess your eligibility for the study. **You will need to register by September 15th, 2021 (12:00 midnight, UK Time).**

**The registration form will also include the first survey link, which you will also need to complete by September 15th, 2021 (12:00 midnight, UK Time)**. If you have not already completed this survey, please follow this link to do so: <https://psychiatryoxford.qualtrics.com/jfe/form/SV_01lPrBQn9JjffsW>

Once you have registered and have completed the first survey, you should receive an email from me (Shannon Maloney, [shannon.maloney@psych.ox.ac.uk](mailto:shannon.maloney@psych.ox.ac.uk)) to inform you of your eligibility status. A trained mindfulness teacher may also reach out to ask some questions and to ensure that it is the right time for you to take part in the mindfulness course.

1. **ORIENTATION SESSION**

One week after completing the first survey, you will be emailed the second survey which will include an **orientation video**. This orientation video will give you more information about the ‘Taking it Further’ programme and this research study. Please complete this survey and watch orientation video by **September 22nd, midnight, UK Time**.

Participants that have completed the orientation video will then be randomized into one of two groups (‘Treatment’ or ‘Control’). You will be notified of your allocation over email and given a **Participant ID**, **Unique Code 1,** and **Group Number.** You will need to keep track of these codes and enter them into the surveys when prompted.

If you are allocated to Treatment, then you will take part in a twelve-week TiF course that will begin on October 4th 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 (February 1st; 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](mailto: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.

Session 1: October 4th, 10 am-12:15 pm, UK Time

Session 2: October 11th, 10 am-12:15 pm, UK Time

Session 3: October 18th, 10 am-12:15 pm, UK Time

Session 4: October 25th, 10 am-12:15 pm, UK Time

Session 5: November 1st, 10 am-12:15 pm, UK Time

Session 6: November 8th, 10 am-12:15 pm, UK Time

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

Session 8: November 22nd, 10 am-12:15 pm, UK Time

Session 9: November 29th, 10 am-12:15 pm, UK Time

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

Session 11: December 13th, 10 am-12:15 pm, UK Time

Session 12: December 20th, 10 am-12:15 pm, UK Time

1. **SURVEYS**

**Once you have been allocated to your groups, you will receive the next survey link, to be completed**

**by midnight, London Time, October 3rd.** This survey will be completed right before the October 4th start date.

From there, both groups will be invited to complete surveys the day after week 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, Unique Code 1** and **Group Number** to complete all surveys.

**Step-by-step Summary:**

1. You will need to first register online using this link <https://registrations.oxfordmindfulness.org/?cid=1184> and complete the first survey <https://psychiatryoxford.qualtrics.com/jfe/form/SV_01lPrBQn9JjffsW> by September 15th at midnight, UK Time.
2. You will then receive the next survey one week later which will include watching an orientation video, which you must complete by September 22nd, midnight, UK Time.
3. The next survey will be administered a few days before the start date and you will allocated to the treatment or control group. You will also be given your **Participant ID**, **Unique Code 1** and **Group Number.** Please complete the survey by October 3rd, midnight, UK Time.
4. 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**, **Unique Code 1**, and **Group Number** for these surveys.
5. **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 a few days before the start date. If you have any questions or cannot find the calendar, please email Shannon. You should also receive reminders on specific deadlines by email as well.

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. Please read this document to help determine if it is the right time for you to take part: <https://www.oxfordmindfulness.org/course-suitability/>

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 read our policies of reimbursement: <https://www.oxfordmindfulness.org/about-us/courses/terms-and-conditions/>

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](mailto:shannon.maloney@psych.ox.ac.uk) or Willem at [willem.kuyken@psych.ox.ac.uk](mailto: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](mailto: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](mailto:shannon.maloney@psych.ox.ac.uk)