

Mindfulness, wellbeing, and engagement

Submission date 16/06/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/08/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/07/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This research aims to broaden the scientific understanding of how and why people engage with different kinds of mindfulness, in order to gain a better understanding of how mindfulness interventions could be developed to increase participation and engagement, one of the key barriers to implementation. If this research pinpoints areas for development, it would have real-life impacts on implementing interventions and increasing mental wellbeing. As this research focuses on online interventions, understanding the specific factors that impact engagement, could lead to the delivery of more engaging online psychological interventions, increasing accessibility to mental wellbeing interventions.

Who can participate?

Healthy adults who are not experiencing any severe mental health issues.

What does the study involve?

This study seeks to explore the impacts of pre-exposure to both seated and movement-based mindfulness on participant engagement with an 8-week mindfulness programme. The study will be separated into two parts.

Part A: Engagement with mindful movement and seated mindfulness in a 4-week long programme of 10 minutes a day.

Participants will engage with a 10-minute-long online mindfulness practice daily, that is either mindfulness movement or seated mindfulness over a 4-week long period. The mindfulness audio will be from the Oxford Mindfulness Centre's Mindfulness-Based Cognitive Therapy (MBCT) programme. Permissions to use these have been granted. Baseline measures will be taken at the beginning of the four weeks, and the mindfulness, wellbeing and rumination scales will be taken again at the end of Part A. Additionally data on the engagement of participants with the practices will be collected from Moodle. Further, participants will be asked how much they practised at the end of the study. Participants will then be invited to Part B of the study, to measure the uptake pre-exposure to mindfulness has on the uptake of an 8-week long programme.

Part B Engagement with an online 8-week long mindfulness programme.

Participants will engage with audio practices from the Palouse online Mindfulness-Based Stress

Reduction (MBSR) programme, which consists of 30-minute-long mindfulness exercises daily for an 8-week period. Participants who did not complete Part A, will have baseline measures taken at the beginning, and all participants will complete the measures again at the end of the 8 weeks. Data between the three groups will be compared (previous exposure to mindful movement, previous exposure to seated mindfulness, and no pre-exposure to mindfulness). Engagement with the practices will be recorded via Moodle. At the end of the study, participants will be asked questions to identify barriers to engagement and whether they experienced any adverse effects. They will also be asked if they felt that Part A had an impact on how they experienced Part B.

What are the possible benefits and risks of participating?

As mindfulness can increase psychological distress due to its focus on present moment awareness, participants are given this information in the information sheet. Participants are further given advice on mental health organisations and the NHS and encouraged to contact them if they experience any adverse effects at both the beginning and end of both parts of the study. Further, participants are reminded throughout the study that they can drop out or omit any questions in the questionnaires if they would prefer. Contact details of both the researcher and researcher supervisor are given to participants for a point of contact in case any queries or concerns arise. Another concern is that some of the practices include mindfulness movement. Although these are simple stretches, participants are forewarned in the project advert and the information sheet that if they have any concerns that they should consult their GP. As this study is looking at mindfulness in the general population, participants will be asked if they are experiencing any severe mental health issues currently, and if they answer yes will be directed to a page saying that they do not meet the criteria to take part in the study. On this page, participants will be given advice on support organisations again.

Where is the study run from?

University of St Andrews (United Kingdom)

When is the study starting and how long is it expected to run for?

January 2022 to June 2023

Who is funding the study?

University of St Andrews (United Kingdom)

Who is the main contact?

Miss Rachel Gibson
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Contact information

Type(s)

Principal Investigator

Contact name

Miss Rachel Gibson

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Bridging the gap between mindfulness and wellbeing: The role of engagement (MWE)

Study objectives

This research will investigate which individual difference factors impact engagement with an online mindfulness intervention. It will further explore whether the type of mindfulness experience impacts engagement with further mindfulness, and how this relates to wellbeing. As this is exploratory research, no hypotheses have been made. The following questions will be addressed:

1. Part A

1.1. Engagement and wellbeing: Does the type of mindfulness practice impact participant engagement and mental well-being outcomes?

1.2. Engagement and wellbeing: Do individual difference factors, including demographics, previous experience of mindfulness, and rumination interact with the type of mindfulness practice to impact engagement and wellbeing?

2. Part B

2.1. Uptake: Is the uptake of an 8-week long mindfulness course impacted by pre-exposure to mindfulness practice, and if so does it differ depending on the type of mindfulness practice experienced? Further, is there an interaction between individual difference factors and the type of mindfulness practice on the uptake of an 8-week long mindfulness course?

2.2. Engagement: Does the type of mindfulness exposure (seated, movement, none), influence participant engagement with an 8-week long mindfulness intervention, and/or wellbeing measures? Is this impacted by individual factors, including demographics, previous experience of mindfulness, and rumination?

2.3. Barriers to engagement: What are the barriers to engagement with the 8-week-long program?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/04/2022, The School of Psychology & Neuroscience Ethics Committee, University of St Andrews (St Mary's Quad, South Street, St Andrews, Fife, KY16 9JP, United Kingdom; +44 (0)1334 462071; psyethics@st-andres.ac.uk), ref: PS16108.

Study design

Multicenter interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Engagement and wellbeing outcomes of different types of mindfulness interventions

Interventions

Study Design and Intervention

Part A of the study will randomly allocate participants to either a movement-based mindfulness group, a seated mindfulness group, or a control group, using Qualtrics, and ask them to practice daily for 4 weeks. These practices will be from the Oxford Mindfulness Centres Mindfulness-Based Cognitive Therapy (MBCT) programme and are between 8-10 minutes in length. At the end of the study, participants will be asked if they would like to continue to a second study. Participants will complete questionnaires on mindfulness, wellbeing, rumination, previous experience of mindfulness, and participant demographics. Data on the engagement with the practice will be collected from the online system Panopto to see how often the practice was played. Participants will then be asked whether they wish to continue to a second 8-week long mindfulness study.

Part B explores engagement with mindfulness and influencing factors including demographics and wellbeing. The study will investigate whether pre-exposure to a short mindfulness programme of either seated or movement-based mindfulness influences their engagement with a longer practice. The longer practice will entail the audio meditations from The Palouse Mindfulness-based Stress Reduction (MBSR) 8-week course (Kabat-Zinn, 1990). The Palouse online MBSR programme consists of 30-minute-long mindfulness exercises daily for an 8-week period. Data between the three groups will be compared (previous exposure to mindful movement, previous exposure to seated mindfulness, and no pre-exposure to mindfulness). Participants will complete the same questionnaires on mindfulness and wellbeing at the beginning of the study, at the end of Part A, and at the end of Part B. Engagement with the practices will be recorded via the online software Panopto. At the end of the 8 weeks, in addition to the previous measures, participants will be asked questions relating to how they

found the two parts of the study. Participants will be asked how much they practiced and asked to identify barriers towards partaking in the mindfulness audios. These questions will be looked at in a qualitative manner, to help guide possible areas for future research.

Intervention Type

Behavioural

Primary outcome measure

Engagement with the mindfulness interventions will be measured to determine if participants accessed the audio recordings using:

1. Panopto software through Moodle will be collected continuously throughout the 12 weeks of the study at daily timepoints to
2. Self-report questionnaires will be collected at baseline and week 4 of Part A, and baseline and week 8 of Part B
3. Participant uptake of the second part of the study will be collected at baseline of Part B of the study

Secondary outcome measures

Wellbeing measured using the Depression Anxiety Stress Scale (DASS), the Ruminative Response Scale (RRS), and the Mindful Attention Awareness Scale (MAAS), at baseline, 4 weeks, 12 weeks

Overall study start date

01/01/2022

Completion date

01/06/2023

Eligibility

Key inclusion criteria

1. Students from the University of St Andrews
2. Aged 18 years old or over
3. Not experiencing any severe mental health issues (self-reported)

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50 in each arm (3), total 150

Key exclusion criteria

1. Experiencing severe mental health issues (self-reported)

Date of first enrolment

01/08/2022

Date of final enrolment

01/03/2023

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

University of St Andrews

College Gate

North Street

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KY16 9AJ

Sponsor information

Organisation

University of St Andrews

Sponsor details

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Sponsor type

University/education

Website

<http://www.st-andrews.ac.uk/>

ROR

<https://ror.org/02wn5qz54>

Funder(s)

Funder type

University/education

Funder Name

University of St Andrews

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/04/2024

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date. Data will be fully anonymised after the end of the study and retained indefinitely on a secure university system. Participants who only take part in Part A of the study will have their data fully anonymised at the end of Part A, and participants who take part in part B will have their data fully anonymised after data collection for part B is complete. All data will be shared in an anonymised format for retention, publication, and PhD thesis, with no way to identify participants.

IPD sharing plan summary

Data sharing statement to be made available at a later date