Plan Overview

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Title: Registered report for an online intervention study testing the Monitor and Acceptance Theory of the therapeutic mechanisms of mindfulness for chronic stress reduction

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Project abstract:

Mindfulness-based psychological interventions (MBIs) are effective in reducing chronic stress, yet little is known about their therapeutic mechanisms. One possibility is that MBIs act by training attention monitoring and acceptance skills and that the interaction between these enhanced skills would drive chronic stress reduction. However, only preliminary evidence supports this model. This theory-driven online intervention study will test the hypothesis that MBIs can enhance psychological monitoring and acceptance skills in chronically stressed individuals. Moreover, the study will test whether pre-post intervention reductions in self-reported chronic stress are moderated by changes in monitoring and acceptance measures. Chronically stressed adults will participate in two online experimental sampling sessions during which they will complete self-reported measures and a behavioural task. In between the two experimental sessions, half of the volunteers (i.e., the MBI group) will participate in a validated evidence-based online MBI. The rest of the volunteers will join a waitlist-control group. We will then investigate changes in monitoring and acceptance skills and if changes in monitoring and acceptance moderate chronic stress reduction. [A summary of the results and conclusions will be added a Stage 2.]

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Registered report for an online intervention study testing the Monitor and Acceptance Theory of the therapeutic mechanisms of mindfulness for chronic stress reduction

Data Collection

What data will you collect or create?

Data will be collected in two general phases. These are the Screening and Experimental phases.

The screening phase will be the first part of the study. During this phase, we will collect consent forms from people who will consent to participate in the experiment and screening data that we will use to screen participants for eligibility. Data from participants that are ineligible for the study, will be deleted immediately, while data from eligible participants will be kept. This is the data that we will collect during the screening phase:

A. With the consent form, we will obtain the following data: name, surname, and email address. This will be used only to keep in contact with the participant for the reminder of the study. Also, we will obtain consent.

B. With the screening questionnaire, we will obtain the following information (note: answers are Yes or No).

1. Are you between 18 and 65 years of age?

Please Select... Yes No

1. Do you speak English fluently (e.g., did you understand the participant information sheet and consent form without any issues and can follow a conversation in English)?

Please Select... Yes No

1. Do you have normal or corrected to normal vision (i.e., can you see your screen with or without glasses or contacts)?

Please Select... Yes No

1. Are you willing and able (to the best of your knowledge) to join an online mindfulness programme (pre-recorded) and practice mindfulness for (minimum) two hours per week for the duration of the course (minimum 4 to maximum 12 weeks depending on the frequency of your practice)?

Please Select... Yes No

1. Are you willing and able (to the best of your knowledge) to practice the homework mindfulness exercises proposed in the course for minimum 2h per week?

Please Select... Yes No

1. Can you confirm that you are not currently receiving any form of psychotherapy and have no plans to start a psychotherapeutic programme during the study?

Please Select... Yes No

1. If you are currently taking any form of psychiatric medication, are you willing to maintain the existing dosage or notify the experimenter if you change dosage during the study?

Please Select... Yes No

1. Can you confirm that you do not have a personal or family history of psychotic illnesses (e.g., bipolar disorder or schizophrenia) or personality disorders (e.g., narcissistic personality disorder)?

Please Select... Yes No

1. Can you confirm that you do not have a personal history of neurological illnesses (e.g., brain stroke)?

Please Select... Yes No

1. Do you have regular access to the internet via a computer desktop or laptop?

Please Select... Yes No

1. Do you have regular access to one of the following web browsers: Chrome, Firefox, Safari, or Microsoft Edge?

Please Select... Yes No

1. Can you confirm that you do not have previous meditation experience (i.e., you sometimes meditate; being a yoga, tai chi, or chi/qi gong practitioner does not count for the purposes of this study)?

Please Select... Yes No

In addition to the above, we will obtain scores in the Perceived Stress Scale (PSS). We collect PSS score now because we will include only participants that score 29 or above in the scale. Also, these scores constitute the baseline PSS scores in our study.

The experimental phase will follow the screening phase. During this phase we will sample the following data (see below) at pre-intervention and post-intervention in the MBI group. Moreover, we will sample the following data (see below) at baseline, pre-intervention, and post intervention for the waitlist control group.

Demographics (only sampled at pre-intervention or waitlist control baseline):

Age (years), sex assigned at birth (male vs. female), education (years), and ethnicity (White, Black, Asian, or Other (please specify)). The demographics questionnaire takes approximately two minutes to complete.

Attention Monitoring:

We will obtain performance scores (reaction times) in the orienting and target detection subscales of the Attentional Networks Test (ANT; Fan et al., 2002). According to Lindsay & Creswell (2017), monitoring relies on target detection and orienting, two key attentional subsystems (Petersen & Posner, 2012). The ANT was specifically designed to measure performance in these attentional subsystems. Moreover, the ANT is used in the few existing studies of the association between monitoring and chronic stress. The duration of the ANT task is approximately 25 minutes.

Acceptance:

We will obtain scores in the acceptance subscales of the Five Facets of Mindfulness Questionnaire (FFMQ – nonreactivity and nonjudgement subscales; Baer et al., 2006; Lindsay and Creswell, 2017). The two subscales will be combined to obtain a single measure of acceptance. We decided to create a composite score of the two subscales because both correspond with the concept of acceptance (Lindsay and Creswell, 2017). Moreover, preliminary results from ongoing research conducted in our laboratory shows that the FFMQ composite acceptance score is strongly and significantly associated with the PSS ($p < 0.001$*; r = - 0.62; r2 =* 0.39). The FFMQ consists of a total of 39 questions on a frequency scale from 1 to 5, where 1 = never or very rarely true and 5 = very often or always true.

The nonjudgement subscale consists of eight questions and the nonreactivity subscale consists of seven questions. The subscales of the FFMQ have good construct validity and reliability. Administering this scale takes approximately five minutes.

Chronic stress:

We will obtain scores in the Perceived Stress Scale (PPS; Cohen et al., 1983). Participants will answer 14 questions on a frequency scale from 0 to 4, where 0 = never and 4 = very often. The PSS was designed to measure stress in the general population along the dimensions of unpredictability, uncontrollability, and overload that relate to the risk for developing adverse health outcomes. It has strong construct validity and reliability across gender, socioeconomic status, age groups, ethnicity, and other demographic characteristics (Cohen et al., 1983). The PSS is widely used in studies investigating chronic stress and is employed in one of the few existing studies of the association between monitoring and chronic stress. This questionnaire takes approximately two minutes to complete.

Intolerance of Uncertainty Scale-12:

We will obtain scores in the Intolerance of Uncertainty Scale, 12 item version (IUS; Carleton et al., 2007). Participants will answer 12 questions on a scale from 1 to 5, where 1 = not at all characteristic of me and 5 = Entirely characteristic of me. This scale was designed to measure how much people find uncertainty aversive. It has been theorized that IU might be a transdiagnostic phenomenon across several affective disorders. This questionnaire takes approximately 2 minutes to complete.

Anxiety Sensitivity Index:

We will obtain scores in the Anxiety Sensitivity Index (ASI; Peterson and Reiss, 1992). Participants will answer 16 questions on a scale from 1 to 5, where 1 = very little, 2 = little, 3 = some, 4 = much, 5 = very much. This scale was designed to measure fear of anxiety and it has been theorized that AS might be a transdiagnostic phenomenon across several affective disorders. This questionnaire takes approximately 5 minutes to complete.

Repetitive Thinking Questionnaire-10:

We will obtain scores in the Repetitive Thinking Questionnaire (RTQ; McEvoy et al., 2014). Participants will answer 10 questions on a scale from 1 to 5, where 1 = not true at all, 3 = somewhat true, and 5 = very true. This scale was designed to measure the tendency to engage in repetitive thinking. It has been theorized that RT might be a transdiagnostic phenomenon across several affective disorders. This questionnaire takes approximately 2 minutes to complete.

In addition to the above, we will collect the following data (see below) at the beginning and at the end of the intervention for the MBI group; and at the beginning and at the end of the intervention, and the waitlist phase in the waitlist control group.

GAD-7:

We will obtain scores in the Generalised Anxiety Disorder questionnaire (GAD; Spitzer et al., 2006). Participants will answer 7 questions on a scale from 1 to 4, where 1 = not at all sure, 2 = several days, 3 = over half of the days, and 4 = nearly every day. This scale was designed to screen for GAD. The GAD is automatically administered by the MBI provider. This questionnaire takes approximately 2 minutes to complete.

PHQ-9:

We will obtain scores in the Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001). Participants will answer 9 questions on a scale from 1 to 4, where 1 = not at all, 2 = several days, 3 = more than half days, and 4 = nearly every day. This scale was designed to evaluate depression severity. The

PHQ-9 is automatically administered by the MBI provider. This questionnaire takes approximately 2 minutes to complete.

Perceived stress Scale-10:

The perceived stress scale 10 item version (PSS-10) is similar to the PSS-14 items version, mentioned above. The PSS-10 is automatically administered by the MBI provider. We chose to administer the PSS-14 in addition to the PSS-10 for several logistical reasons. For example, as the PSS-10 is automatically administered by the MBI provider to our participants at the beginning of the MBI course, this questionnaire would be administered to participants *after* the beginning of the study. This would mean that we would not be able to screen our participants on the basis of scoring more than 29 on the PSS-14 *before* the study begins.

Finally, we will ask all participants to keep a diary to record the time they spent practicing homework mindfulness exercises during the MBI programme.

How will the data be collected or created?

Data will be collected via questionnaires and tasks shared online via Gorilla Experiment Builder. During data collection, data will be stored on Gorilla Experiment Builder. The format of this data is the one used on this platform. Once collected data will be merged in one single dataset listing all the variables collected using the measures mentioned above, plus time and group. This dataset will not contain any information that could potentially be used to identify our participants. This dataset will then be used for our planned data analyses. Once the analyses are concluded, we will try to publish on Open Science journals and, if required, we will shared out anonymised dataset. We will name and organise our dataset depending on the target journal's guidelines on data sharing and community standards.

Documentation and Metadata

What documentation and metadata will accompany the data?

A "read me" file with the explanation of all variables in the dataset will be provided.

Ethics and Legal Compliance

How will you manage any ethical issues?

Ethical issues will be handled as specified on the documents submitted for ethical approve to the University of Surrey Ethics Committee and Research Integrity and Governance Office. Moreover, all data generated in this study will be handled in accordance with the current Data Protection Legislation. Identifiable data will be accessible by Francesco Saldarini and Professor Mark Cropley only until the end of data collection. At the end of data collection, all data will be collated in a single anonymised dataset. This dataset will be saved stored electronically on University of Surrey secure

services (i.e., University One Drive). If necessary, data will be shared with the supervisory team via University One Drive. This version of the dataset might be shared with other researchers and/or on official data sharing platforms. According to University Policy, all project data will be held for a minimum of six years and all research data for a minimum of 10 years.

During data collection data will be saved on Gorilla Experiment builder which will also be used for data collection. One all data is collected, it will be collated in a single anonymised dataset, stored on University of Surrey secure services, and deleted from Gorilla.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The only copyright issues we can foresee regard the licence we will give to our data and that may result from this study and code used to analyse it. It would be our preference to share our data CC BY-SA 4.0 creative commons license (https://creativecommons.org/licenses/by-sa/4.0/), and code will be shared under a Mozilla Public Licence (https://choosealicense.com/licenses/mpl-2.0/). The shared data and code will be accompanied by the relevant meta-data, that will also report the licences for both. However, we will consider less restrictive licenses, if this will be required by a journal or data sharing repository in the spirit of Open Science.

Storage and Backup

How will the data be stored and backed up during the research?

During data collection data will be saved on Gorilla Experiment builder which will also be used for data collection. Once all data is collected, it will be collated in a single anonymised dataset, stored on University of Surrey secure services, and deleted from Gorilla.

How will you manage access and security?

During data collection, access will be granted only to Francesco Saldarini and Professor Mark Cropley.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data mentioned in the data collection paragraph minus any identifiable information.

What is the long-term preservation plan for the dataset?

The anonymised dataset will be preserved according to the University of Surrey policy. Once shared

on an official repository, the dataset may be maintained indefinitely.

Data Sharing

How will you share the data?

Data will be shared on official research depositories or with other researchers for collaborative secondary data analyses, as needed. We will share data through secure means (e.g., encrypted university emails).

Are any restrictions on data sharing required?

The shared data will be anonymous.

Responsibilities and Resources

Who will be responsible for data management?

Mr Francesco Saldarini under the supervision of Professor Mark Cropley.

What resources will you require to deliver your plan?

N/A.