Study Protocol

1. Title

The role of natural environments in the effectiveness of brief Mindfulness-based stress reduction (MBSR): a randomized controlled trial

2. Protocol contributors

Eun Yeong Choe, Department of Landscape Architecture, University of Sheffield, UK

Anna Jorgensen, Department of Landscape Architecture, University of Sheffield, UK

David Sheffield, School of Psychology, College of Health, University of Derby, UK

3. Study period

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4. Introduction

With the prescription of antidepressants at record levels, and a huge demand for psychological therapies, health and social care providers are interested in cost-effective interventions to improve wellbeing and to prevent mental health problems. At the same time, there is a renewed interest in complementary and alternative therapies, such as yoga, meditation practices, and aromatherapy to support psychological resilience and prevent mental illness.

Mindfulness practice has grown quickly as one such complementary and alternative approach to coping with certain forms of mental illness and symptoms of poor mental and physical health. Mindfulness-Based Stress Reduction (MBSR) (1) offers an intensive 8-week programme (as well as shorter 4-6-week versions) involving a range of formal sitting and walking meditation, body scanning, mindful movement and informal mindfulness practices. Reviews of the effects and clinical effectiveness of MBSR indicate positive results in terms of the treatment of a range of different physiological and psychosocial conditions, including stress reduction and relief from emotional distress, depression and anxiety. Whilst this evidence demonstrates the significant mental health and wellbeing benefits of mindfulness-based interventions, there has been little research into combining mindfulness with restorative experiences, such as exposure to nature.

This research aims to investigate whether the effectiveness of MBSR is enhanced when combined with the benefits of being exposed to natural environments. The study incorporates the restorative effect of nature into MBSR and assesses the effectiveness of the combined intervention in different settings.

5. Trial design

Randomized controlled trial

In order to compare the effectiveness of MBSR in different settings, participants were randomly assigned to 6-week MBSR in one of three different environments (i.e. natural outdoor, built outdoor and indoor). Participants' health and wellbeing outcomes were measured at four times during the research period: at baseline, after the third MBSR session, the completion of the six-week MBSR and one month after completion of the six-week MBSR.

6. Methods

6.1 Eligibility criteria

Participants were recruited from adults aged 18 and over who are staff or students in the University. This research excluded vulnerable participants, such as people with severe and enduring mental health conditions (i.e. currently receiving treatment for such conditions). Participation in the study is entirely voluntary. In the recruitment email, the details of the study were fully explained and the information sheet and consent form were attached. Participants who want to take part were invited to complete and return the consent form accessed via a link in the recruitment email. The participants were also required to complete a screening questionnaire to register their interest in the project.

In terms of collecting hair cortisol, participants were eligible to participate if they attended at least five of the six MBSR sessions. On the basis of guidelines from prior studies (2), samples were excluded if participants reported using dye or bleach on their hair in the past year or were currently using pharmaceutical glucocorticoids.

6.2 Interventions

- **Mindfulness-Based Stress Reduction (MBSR)**

The participants were asked to attend a brief version of the MBSR programme lasting six weeks. The brief MBSR (3,4) included mindfulness meditation/exercises and group discussion led by a qualified mindfulness instructor (see Table 1).

Table 1 Brief mindfulness-based stress reduction (MBSR) programme

6-week MBSR Programme

WEEK 1	'Stepping out of Automatic Pilot' *'What is Mindfulness?' Introduction. How can it benefit us?* *Raisin Practice* *Breath and sounds meditation*
WEEK 2	'Living in our Heads' *Body Scan – Using our Body to regain freedom from being caught up in our habitual thought patterns*
WEEK 3	'The Stress Reaction Cycle' *Looking at our habitual responses. Discussing the ABC model of behaviour* *Exploring our individual stress reactivity.' The Sea of Stress Reactions'*
WEEK 4	'Recognising Aversion' *Looking at our tendency to judge situations against how we want them to be rather than how they are* *Practicing allowing feelings/thoughts/sensations to be there* *'Exploring the Difficult Meditation'*
WEEK 5	'Lifestyle choices' *How can I best look after myself?* *Listing daily activities and asking yourself whether they are nourishing or depleting* *The Breathing Space Meditation as an Action Step* *Mindful Movement-gentle movements to enhance relaxation and awareness*
WEEK 6	'Keeping your Mindfulness Alive' *Daily Mindfulness* *The Befriending Meditation*

- **Environmental settings**

Figure 1 shows the schematic overview of the experimental set-up. Participants were exposed to one of the three different environments located in Sheffield, UK. These three environmental settings were chosen for this study within a radius of 200m of the main campus: a) a park, representing a natural outdoor setting, b) a shelter, representing a built outdoor setting, and c) a seminar room in the basement, representing an indoor setting. A park setting is a public park with an area of over 5 hectares near the university. The park is a well-managed green area with trees, shrubs, flower beds, lawns and a lake including facilities such as benches, wooden bridges, bandstands and monuments. The experiment was carried out in a location defined by planted areas containing shrubs and small trees, with some distant views. There was background noise during the experiment, such as people talking and laughing in the distance, and birds singing. A shelter was chosen as a built outdoor setting. The shelter is surrounded by concrete and brick-built walls and buildings, with no visible vegetation. There was background noise, such as passing cars and the sound of traffic lights. The indoor setting was a seminar room. This room was a white-painted room without windows in the basement of a university building.
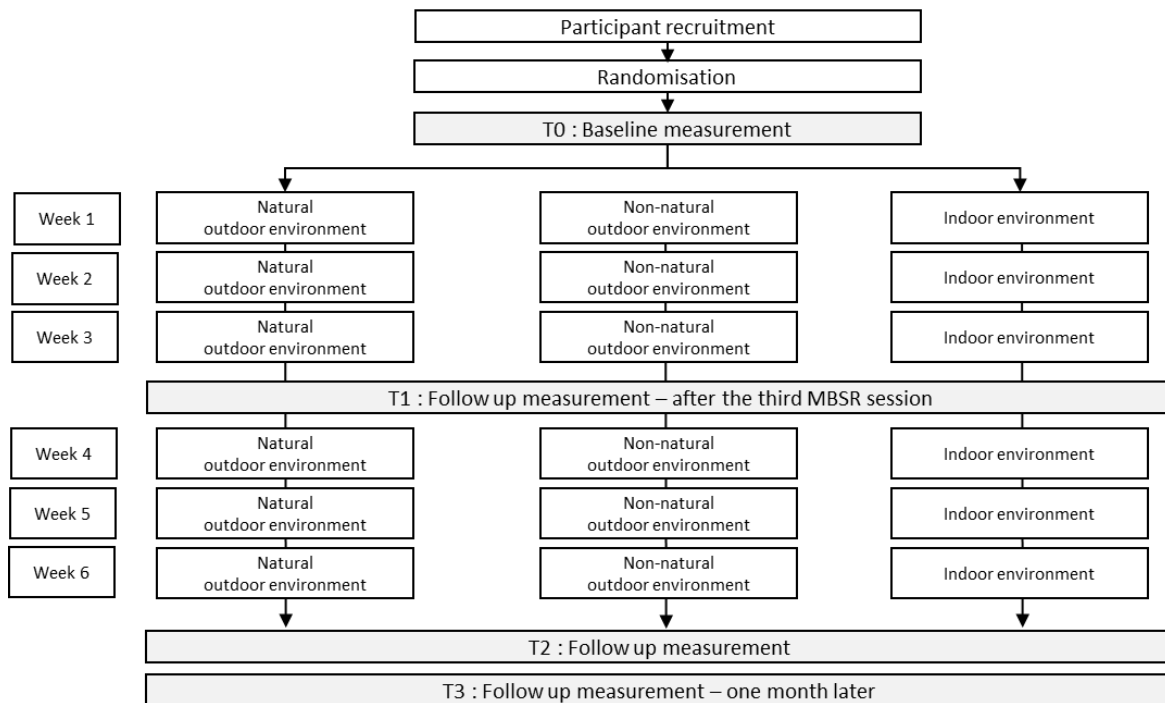
Figure 1 Study design

7. Outcomes

Psychometrically validated questionnaires were selected to measure participants' changes in relation to their levels of mindfulness and their mental health and wellbeing outcomes during the period of research. We asked participants to complete a questionnaire four times during the research period at before MBSR (T0), during MBSR (T1), after MBSR (T2) and one-month follow-up (T3).

- **Level of mindfulness**

The Five Facet Mindfulness Questionnaire (FFMQ-SF) (5) was used to indicate the level of mindfulness and other related variables, such as psychological symptoms and wellbeing (6). The five facets consisted of five subscales: non-judging, non-reactivity, acting with awareness, describing and observing.

- **Mental health and wellbeing outcomes**

In this study, wellbeing measures are classified to represent hedonic or eudaimonic aspects of wellbeing. Hedonic wellbeing focused on measuring the frequency and intensity of pleasant and unpleasant emotions using Positive and Negative Affect Schedule (PANAS) (7). PANAS comprises two 10-item subscales designed to measure positive and negative feelings. In addition, eudaimonic wellbeing outcomes are assessed using the Rumination-Reflection Questionnaire (RRQ) (8) which includes the 12 items rumination

subscale that measures a tendency to retrace one's past actions and the 12 items reflection subscale which measures genuine curiosity about the self. This study also examined psychological health related to the negative emotional states associated with depression, anxiety and stress using the Depression Anxiety Stress Scales (DASS-21) (9,10).

- **Hair cortisol concentration (HCC)**

Hair cortisol concentration (HCC) is used as a marker of chronic stress. Cortisol is commonly known as the stress hormone because it is released via the hypothalamic-pituitary-adrenal (HPA) in higher doses under stressful conditions (11). The extraction of cortisol from hair has been developed as a new method to measure cortisol exposure in humans. Assuming hair grows approximately 1 cm per month, hair analysis provides the possibility to show the average long-term activity of cortisol exposure, and to compare several hair segments/months with each other, including segments before the presence of a stressful event. For example, HCC from a 3 cm of hair sample can reflect the past 3 months of cortisol secretion (12).

8. Assignment of interventions: allocation, blinding

The sample size was determined a priori based on a power analysis. For power = 0.8, and an effect size of f(v) = 0.25, this study needed 99 participants. A sample of 99 participants was randomly selected by stratified random sampling to ensure a representative number of male (37 male, 37%) and female (62 female, 63%) university students and staff.

Using a random number generator, we assigned the participants into three MBSR groups (natural outdoor vs. built outdoor vs. indoor group). All participants are prevented from knowing certain information that may somehow influence them i.e. the participants were blinded in the sense that they did not know whether they or others attend MBSR in different settings.

9. Statistical methods

Mindfulness, mental health and wellbeing outcomes

An intention-to-treat (ITT) analysis was used for DASS-21 outcomes in which all participants were included (n=99) in the statistical analysis and analysed according to the group they were originally assigned. ITT analysis is widely used to avoid over-optimistic results of the effectiveness of an intervention resulting from the removal of non-compliers by including protocol deviations and withdrawal, all of which are likely to occur in actual clinical practice (13). Firstly, Chi-squared and ANOVA were used to examine differences at baseline. Next, MANOVA was used to examine interaction effects using three environments (natural outdoor, built outdoor and indoor settings) x four times (before MBSR (T0), during MBSR (T1), after

MBSR (T2) and one-month follow-up (T3). If there was a significant environment by time interaction, follow-up analysis was performed using t-tests. All analysis was carried out using SPSS 24.0 using an alpha of .05. We also report effect size, indicating small (η^2= .01), medium (η^2= .06), and large (η^2= .14) effects (44).

Hair cortisol concentration (HCC)

Hair samples were analysed by following standard procedure at the biomarker analysis laboratory at Anglia Ruskin University, UK. The cortisol result was adjusted for the individual hair weight of the sample and the result of HCC was reported in pg/mg. HCC from a 4 cm hair sample reflects the past 4 months of cortisol secretion; The 1cm segment most proximal to the scalp was assayed to indicate the one-month follow-up cortisol output. The second most proximal 1cm segment represented the month after the experiment. The third most proximal 1cm segment was assayed to indicate cortisol output for the month during the intervention, and the fourth most proximal 1cm segment was assayed to indicate cortisol output for the month before the intervention. Statistical analysis of HCC was carried out using SPSS 24.0 using an alpha of .05. MANOVA was used to determine whether there is a significant environmental effect on changes in HCC.

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