Title: Mindfulness-Based-Cognitive-Intervention for African Caribbean Men with Erectile Dysfunction

Study Protocol: ethically approved 20/01/2021

Study commencement: 01/10/2022

Study completion: 01/03/2023

Study protocol including statistical analysis plan

Methods

Design

A mixed study approach was used including a randomised controlled study with an experimental and waitlist control group. Further, a summative content analysis was conducted based on participant feedback responses. Participants were randomly allocated to one of two groups, group 1 (the experimental group receiving MBCI) and group 2 (the control waitlist group). The two groups were compared for differences in MBCI effectiveness in relation to sexual functioning, mindfulness, well-being and sexual self- efficacy (Kendall., 2013). A snowballing sampling method using social media including for example WhatsApp, TikTok, Linkedin, Facebook was used to research sensitive issues among populations that might be difficult to reach (Browne, 2005). Participants A google form was developed where a link to the study contents was made accessible via Facebook, Linkedin, Reddit and Twitter. All participants included 68 African Caribbean men with ED aged 18 years and above. Of the sample, 34 had been randomly allocated to group 1 and 34 to group 2. Participants had access to a password-protected laptop/computer and understand English at a suitable level. Further, participants were registered with a GP service (GP will be informed as this is an intervention). Sexuality and the individuals partnered status did not form part of the exclusion criteria. Those without ED, taking prescription medication including Viagra and were not registered with a GP were excluded from this study.

Assessment tools

Demographic Information Demographic information included ethnicity, partnered status, sexuality, age, employment status, children, cancer type, cancer treatment used, other health concerns, sexual difficulties, prescription medications and substance use including alcohol consumption and smoking, and levels of exercise.

The International Index of Erectile Function (IIEF-5) Questionnaire (Rhoden et al., 2002)

Consists of five questions with five response categories measuring erectile functioning. For the purpose of this study, erectile functioning and satisfaction were measured. Response categories

ranged from 0=no sexual activity to 5=almost always/always. Though response categories for each question varied including 0= very low to 5 very high. Scores 5-7 are suggestive of severe erectile dysfunction; and between 22-25 no erectile dysfunction.

The Sexual Self-Efficacy Erectile tool (SSES-E; Libman et al.,1985)

This is a 25-item questionnaire which focuses on sexual confidence and behaviour change associated with therapy. Participants' responses are measured via a 10-item scale ranging from 10 to 100. Here, 10 is the lowest level of self-efficacy and 100 is the highest. There are no reverse questions. The Cronbach's alpha for men with erectile difficulties is α =0.88 (high) and for men without erectile difficulties, α =0.62 (low to moderate). There is no other sexual self-efficacy questionnaire which has been developed for men. Adjustments to this questionnaire had been made in which less than 5% of the original questionnaire remained.

The Short Warwick–Edinburgh Mental Wellbeing Scale (SWEMWBS) (Tennant et al., 2007)

A positively worded seven item questionnaires with five response categories measuring functioning and feeling aspects of wellbeing. The response categories are 1=none of the time to 5=all of the time. Cronbach alpha 0.89-0.91. Scores range from 7 to 35 where the latter is the highest level of wellbeing.

The Cognitive and Affective Mindfulness Scale-Revised (CAMS-R; Feldman et al., 2007)

This is a 10-item measure with four response categories 1= rarely/not at all to 4 = almost always, with higher scores indicating higher levels of mindfulness (range 4-40). An example question is: "I can accept things I cannot change". Cronbach's alphas ranged between 0.82 and 0.84. Questions used in the content analysis A series of questions were asked throughout the duration of the MBCI. Participants were encouraged to leave one feedback per question to ensure that the team got a sense of the group's thoughts and feelings about the intervention collectively, rather than a disproportionate number of respondents.

The feedback outcome was obtained using Mentimeter, then coded and inputted into SPSS.

- Week 0: Question 1: What are your thoughts about receiving this MBCI?

Question 2: If you had a choice of practitioner who was going to deliver this intervention, what would your preferences be?

Question 3: What are your thoughts about your current erectile functioning?

- Week 4: Question 4: How is your erectile functioning now at the end of this MBCI?

Question 5: What are your experiences of receiving this intervention?

- Week 8: How is your ED at follow-up?
- Question 7: Any thoughts about whether you will continue to practise mindfulness to help your ED?
- Question 8: If you had an opportunity to receive this intervention again, would you prefer it delivered online or in person?
- Question 9: Would you have preferred this intervention to be delivered over a longer duration?
- Question 10: Is there anything else you would like to add about your experiences of this MBCI?

(b) Intervention developed for this study

The development of the MBCI has been based on a behavioural taxonomy using the BCTTv1 (Michie et al., 2016). Tables 1 and 2 include the mapping and links between these domains as the developing intervention.. In total, 16 domains have been included in the development of this intervention. Of these, 26 out of the 93 BCTs listed in the BCTv1 taxonomy were identified. Table 1: Behaviour Change Techniques in Each Component of the online MBI BCT BCT Principle Researcher Education Research Mindfulness Mindfulness Domain sessions assistants box practitioner Techniques within this Intervention target BCT taxonomy RCT Cognitive Psychoeducation Understanding ED 1.1, 1.2, 4.1, 4.3, 7.1, 9.1, 11.2, 13.2,15.4 Emotional, physical, behavioural 1.3, 1.4, 1.7 and cognitive. Sexual self-efficacy Being sexually confident 1.2,1.4, 1.9, 2.3, 11.2, 15.3 16.2 Cognitive reframe/self talk Challenging thoughts associated 4.3, 11.2, 13.2, 15.4 with sexual difficulties Behavioural Reward and reinforcement Encourage new behaviour coupled 1.2, 1.4, 4.1, 8.1, 8.2 with positive feedback 10.7, 10.10, 11.2, 14.4, 15.2 Self-care Behaviours which promote physical 3.1, 10.4, 13.1, 13.4 mental and emotional well-being Self-monitoring Monitor behaviour towards goals 1.1, 1.2, 1.3, 1.4, 1.9, 2.2, 2.3, 2.7 Creating a suitable behaviours which promote 12.5 environment relaxation and ambience MBCT Providing group support Creating a supportive environment 3.1, 10.4, 13.1, 13.4 and altruism encouragement and positive reinforcement Understanding emotions Recognising and developing emotions 1.2, 3.1, 5.6, 8.1, 11.2 and coping strategies 12.4 Goal setting/smart goals SMART goals for ED 1.1, 1.2, 1.3, 1.4, 1.9, 2.2 2.3, 2,7 Self-directed meditation Creating better awareness of 1.9, 4.1, 6.1,8.1, 11.2,15.2 body, mind and breathing Body scan Bringing attention and awareness 4.1, 6.1, 8.1, 11.2, 15.2 to different areas of the body. Top to toe. Mindfulness practices Being aware of the present moment 4.1, 6.1,8.1, 11.2, 12.6 12.4, 15.2, 16.2 Mindfulness stretching Mind and body connection 4.1, 6.1, 8.1, 11.2, 12.6, 15.2, 16.2 Self-compassion Encouraging a positive self-identity 11.2, 13.1, 13.2, 13.4, 13.5

Procedure

In accordance with the BPS code of ethics and conduct (internet mediated, 2017) and following ethical approval from LMU ethics review panel, this clinical trial was registered with www.clinical.gov. Those interested in taking part signed a consent form which authorised the principal researcher to contact their General Practitioner (GP). Those accepted onto the programme provided written consent. Baseline questionnaire measures were taken at week 0 and repeated at weeks four and eight. The main exercises included mindfulness, breathing exercises, relaxation techniques, being mindful of the senses and the body and understanding enjoyable sex (adapted Bossio et al., 2018). Four one-to-two-hour online weekly group sessions took place over the duration of one month. Feedback on the intervention was sought throughout the intervention using Mentimeter, by which a content analysis of participants' experiences was conducted at each point. Participants were ensured confidentiality with respect to their engagement in the programme and anonymity. They were also reminded that they could withdraw from the study at any point and with no repercussions and did not have to answer all the assessment questions. Researchers in the team had experience of working in healthcare with vulnerable and diverse groups. They had been versed with the distress protocol prior to the research being started to support the recognition of distress among the participants. All responses generated from participants in this study were stored on a password protected

computer in accordance with the General Data Protection Regulation (2018); Data Protection Act (2018).

Statistical analyses

A mixed ANOVA was used to compare means of study variables measured across weeks 0, 4, and 8 weeks for both groups (experimental and control). A series of paired samples t-tests compared dependent variables pre- and post- tests and follow-up outcomes. Nonparametric Mann-Whitney was used to compare acquired and lifelong ED with substance use, medication use, alcohol consumption, exercise, and smoking. Feedback was taken from participants at weeks 0, 4 and 8 of the MBCI intervention and a summative content analysis using non parametric data analysis was used to analyse secondary data outcomes.

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Brief and consent form

Description of procedure: Interested parties will contact the principal researcher Sam. You will have to be registered with a GP and be part of healthcare service to be part of this research. Those of you interested in participating will have access to the consent form to complete. Consent may be done electronically or if you do not have an electronic signature you can print out a signed copy and send via email or post. Please let us know if you cannot sign electronically. The team (and GP) will have access to your identity ONLY so that we can monitor that the intervention is being delivered according to protocol. Participants will be allocated to the experimental group (Mindfulness) or control waitlist group (4 wk wait before mindfulness). Each week you will be attending an online mindfulness session for approximately 1-2 hours. The target is to aim towards improved well being and erectile functioning. The main exercises include mindfulness, breathing exercises, relaxation techniques, being mindful of the senses and the body and understanding enjoyable sex. Levels of erectile functioning, sexual self-efficacy and wellbeing will be taken at baseline 0 weeks and assessments should take no longer than 15-20 minutes to complete. This will be repeated at weeks 0, 4 and 8 weeks. We will also ask a few questions about how you are experiencing the intervention.

The questions will be delicate and of a sexual nature. Example questions are as follows. This will give you a sense of whether you will be comfortable answering these questions and being part of this study.

"When you had erections with sexual stimulation, how often were your erections hard enough for penetration?"

"When you attempted sexual intercourse, how often was it satisfactory for you?"

"Do you engage in masturbation for as long as desired?"

"Are you confident with your sexual performance?"

Additionally, diaries, self-monitoring logs and feedback will be provided throughout. It is also preferable that you are not taking Viagra for ED as we want to make sure it's the mindfulness intervention which is having a positive impact on your sexual functioning.

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Consent form (this will be set up in google form with yes no options)

(1) I am 18 years old or older

(2) I identify myself as an African Caribbean male with erectile dysfunction ED

(3) I understand that I should refrain from using Viagra or Cialis for my ED throughout the duration of this study

(4) I understand that I can withdraw from the study at any time without repercussions

(5) I have read example questions included in the information sheet and understand that similar questions of a sensitive, personal and sexual nature will be asked

(6) I understand that the study will take place over 3 months

(7) I understand that the information collected throughout the study will be confidential

(8) I understand that my name will remain anonymous throughout the study (nickname will be used during session)

(9) I understand that the study may bring up feelings of distress and make me feel upset. I will be given the opportunity and support to address any such feelings/issues with the researcher, and team during the study.

(10) I understand any data generated in the study will be destroyed 5 years (for publication purposes) after the study is assessed. However, I have the right to request the data to be destroyed once the study has been assessed.

(11) I understand information will be given to me if I need further support (health care and charity agencies).

(12) I understand I can request information about the outcome/results of the study and details of this will be in the debrief form.

(13) I am registered with a GP (general practitioner) and understand that a member of this study team will contact my GP informing him/her that I am participating in this study.

(14) Please provide the name and address of your GP surgery

(15) Please print your name and provide an electronic signature.

Please also date this. If you cannot do that please print this document out and sign it - and scan it to s.banbury1@londonmet.ac.uk. A password encrypted email will be provided.