Cover page

Title: A preliminary RCT online Mindfulness-Based-Cognitive-Intervention (MBCI) for African Caribbean men with Erectile Dysfunction (ED)

NIH- NA not NHS

Ethically approved: 12/12/2019

Statistical analysis plan/methodology

Method

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, study 1 (the experimental group receiving MBCI) and study 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). Qualitatively participants were asked to complete 9 feedback questions based on their experiences of the MBCI. 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 will be developed where a link to the study contents will be accessible via Facebook, Linkedin, Reddit and Twitter. All participants will include 40 African Caribbean men with ED aged 18 years and above. Of the sample, 20 had been randomly allocated to the experimental group and 20 to a waitlist control group. 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.

Materials

(a) Questionnaires

Five Facet Mindfulness Questionnaire (Baer et al., 2006)

This is a 15-item questionnaire which consists of 5 response categories (1=never or rarely true through to 5= very often/always true). Cronbach's alpha ranges between 0.69-0.76. There are 7 reversed items. Subscale scoring is divided into 5 areas including observing, describing, acting with awareness, non-judging and non-reactivity. Higher scores reflect higher levels of mindfulness endorsement.

International Index of Erectile Functioning (Rosen et al., 1997)

This consists of 15 questions with 6 response categories measuring erectile functioning, satisfaction and desire for the last 4 weeks. Cronbach alpha= 0.82 to 0.93. The response categories range from 0=no sexual activity to 5=almost always/always. Subscale scoring is divided into 5 areas including sexual activity, sexual intercourse, sexual stimulation, sexual, ejaculation and orgasm. There is no reverse scoring where scores range from 0 to 75, the latter being higher levels of erectile functioning.

This study will include 2 subscales including erectile functioning and overall satisfaction for statistical analysis.

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

A positively worded 7 item questionnaire with 5 response categories looking at functioning and feeling aspects of well-being. The response categories include 1=none of the time to 5=all of the time. Cronbach alpha- 0.89-0.91. There is no reverse scoring. Scores range from 7 to 35 where the latter is the highest level of wellbeing.

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

Feedback questions as part of the follow-up in this study consisted of 9 open-ended questions related to the participants' experiences and views of the MBCI intervention.

(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). These have been used because they have been rigorously tested to evidence their effectiveness (Munir et al., 2018). The 93 behaviour change techniques are the active ingredients of behaviour change where each intervention is likely to consist of more than one BCT and serve as having more than one function (BCTTv1, Michie et al., 2013). Tables 1 and 2 include the mapping and links between these domains as the developing intervention.

A detailed description of the contents of the intervention

The principal researcher provided details of the intervention including psychoeducation about ED to the team and participants and has been included in the education sessions. Part of this programme involved research assistants who implemented the assessments and took pre and post output measurements of the intervention using wellbeing, mindfulness, ED and sexual self-efficacy assessment tools. The mindfulness box included an array of at-home exercises, educational materials, and cognitive templates on ED, mindfulness, and sexual behaviour education. The mindfulness specialist predominately delivered this intervention. The main exercises included mindfulness, breathing exercises, relaxation techniques, being mindful of the senses and the body and understanding of the self (adapted Bossio et al., 2018).. In total, 14 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 Domain	BCT	Principle Researcher	Education sessions	Research assistants	Mindfulness box	Mindfulness practitioner
1.1	goal setting (behaviour)	x	x	x	x	x
1.2	problem solving	x	x	x	x	x
1.3	goal setting (outcome)	x	x	x	x	x
1.4	action planning	x	x	x	x	x
1.7	review outcome goals	x	x	x	x	x
2.3	self-monitoring			x	x	x

3.1	social support	x		x		x
4.1	instruction on how to perform behaviour		x		x	x
4.3	re-attribution					x
6.1	demonstration of the behaviour					x
7.1	prompts/cues	x	x		x	x
8.1	behavioural practice/rehearsal					x
9.1	credible source	x	x		x	
10.4	social reward	x	x	x	x	x
11.2	reduce negative emotions					x
12.4	distraction					x
12.5	adding objects to the environment	x	x		x	x
12.6	body change					x
13.1	identification with self as role model	x	x	x	x	x
13.2	framing/reframing				x	x
13.4	valued self identity	x				x
13.5	identity associated with changed behaviour					x
15.2	mental rehearsal of successful performance					x
15.3	focus on past success					x
15.4	self-talk				x	x
16.2	imaginary reward					x

Techniques within this RCT	**Intervention target**	**BCT taxonomy**
Cognitive		
Psychoeducation 13.2,15.4	Understanding ED	1.1, 1.2, 4.1, 4.3, 7.1, 9.1, 11.2,
	Emotional, physical, behavioural and cognitive.	1.3, 1.4, 1.7
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 with sexual difficulties	4.3, 11.2, 13.2, 15.4
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 mental and emotional well-being	3.1, 10.4, 13.1, 13.4
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 environment	behaviours which promote relaxation and ambience	12.5

MBCT

Providing group support and altruism	Creating a supportive environment encouragement and positive reinforcement	3.1, 10.4, 13.1, 13.4
Understanding emotions	Recognising and developing emotions and coping strategies	1.2, 3.1, 5.6, 8.1, 11.2 12.4
Goal setting/smart goals	SMART goals for chemsex	1.1, 1.2, 1.3, 1.4, 1.9, 2.2 2.3, 2,7
Self-directed meditation	Creating better awareness of body, mind and breathing	1.9, 4.1, 6.1,8.1, 11.2,15.2
Body scan	Bringing attention and awareness to different areas of the body. Top to toe.	4.1, 6.1, 8.1, 11.2, 15.2
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. Details of the study became available online via social media sites Linkedin, Reddit, Twitter, Facebook and TikTok. The information sheet contained details of the study 4 example questions which will be asked as part of the assessment. It was hoped that it had provided interested parties a better understanding of the nature of the study and whether they would be comfortable answering personal and sexually-delicate questions. Those interested in participating signed a consent form via google and a password protected email which authorises the principal researcher to contact their GP and healthcare/wellbeing centre they were affiliated with. The study aimed to recruit 40 African Caribbean men aged 18 years and above. Once this has been received participants will have access to all the materials in BOX. An individual BOX folder will be set up per participant to be anonymous to other group members. The team will have access to identities so that we can monitor that the intervention is being delivered according to protocol. Participants demographic information will be stored in BOX in accordance with the Data Protection Act (2018). Study group 1 will complete a series of self-report questionnaires throughout the programme at wk 0 (baseline), 4,

8 and 12. All materials and assessments will be in English. Group 2 will not have access to the materials until wk 4 where they commence the programme.

Each of the modules were set up in an online folder on BOX and divided into education, training, modelling, and enablement (Cane, O'Conner & Michie., 2012). Education would include all the information on ED, sexual wellbeing, and mindfulness along with additional resources. Training provides the instructions on how to go about engaging in these online activities (adapted Hucker & McMabe., 2015). Modelling provides examples in action such as men discussing their experiences of ED including verbal persuasion and challenging negative self-talk, and how to go about doing the exercises, and enablement is aimed at increasing their capability of engaging in these activities towards wellbeing (Bandura., 1997). This would be further supported by charts, self-monitors, diaries and YouTube links. At-home activities including prompts, action plans, and cues will be supportive intervention components (Cadogan et al., 2015). We also wanted to work through realistic changes in participants' environments to support mindfulness ambience and sexual arousal.

Face-to-face MBCI meetings will take place via zoom and will last approximately 2 hours per each week for 4 weeks. Follow up monitoring will also be encouraged at wk 12. Levels of ED, sexual self-efficacy and wellbeing will be taken at baseline 0 weeks and assessments should take no longer than 15 minutes to complete. This will be repeated at weeks 4, 8 and 12. Outcomes will be compared with baseline measurements (Hucker & McCabe., 2015; Bossio et al., 2018). A further brief feedback form will be sent to these men at wk 8 as its important to establish their overall views, expectations and experiences of the programme and their suggestions for improving it (Ekman et al., 2011). Throughout the duration of the study, participants will be ensured confidentiality with respect to their engagement in the programme. They will also be reminded that they can withdraw from the study at any point and with no repercussions and that they do not have to answer all the assessment questions if they so wish. If there are any concerns that the participant was experiencing distress because of the study, a suitable referral would be made if needed. This was also mirrored in the debrief form which listed support counselling services. The majority of the researchers in the team have experience of working in healthcare with vulnerable groups and among diverse client groups. The team was versed with the distress protocol prior to the research being initiated to support the team, recognise distress among the participants and act quickly and accordingly. The team member experienced in mindfulness was a registered counsellor. The practitioners in the team were governed by an accrediting body.

All responses generated from the participants in this study were stored in a password protected computer and stored in accordance with the General Data Protection Regulation (2018); Data Protection Act (2018). For participants who did not wish their responses to be included in the study, were afforded an opportunity to have their responses removed up until the initial data analysis at week 4. All information will be stored for 5 years prior to being terminated. Participant responses will be stored in BOX.

Statistical analysis

A Cronbach alpha was conducted on ALL assessments used in this study. ED, well-being and sexual efficacy (DV) were dependent on the MBCI (IV). A two-way repeated-measures MANCOVA (control for baseline measurements) compared the means of these variables taken at 0, 4, 8, and 12 wks for groups 1 and 2. This estimated any significant differences with the outcomes of these variables for groups 1 and 2 and between them taken at each time interval. Covariate baseline measurement had been adjusted to establish whether the MBCI estimate was biased. A series of paired sample t-tests compared the dependent variables pre and post-tests and follow-up outcomes.

Feedback was taken from participants at 8 wks when the MBCI terminates. A summative content analysis using non-parametric tests will statistically analyse secondary data outcomes. These will include Chi-Square, Mann Whitney U and Kruskal Wallis tests.

R software will be used to carry out the main statistical analysis and SPSS 26 for the content analysis.

Information Sheet/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. Once this has been received you will be will be issued with an anonymized Box account to access the materials. Consent may be done electronically or if you do not have an electronic signature you can print out sign and send whether via email or post. Please let us know if you cannot sign electronically.

The team 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 4, 8 and 12 weeks. Outcomes will be compared with baseline measurements. We also want to make sure that the effects of MBI last. 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 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. A further brief feedback form (9 questions only) will be sent on completion of this study. Its important to establish their overall views, expectations and experiences of the programme and their suggestions for improving it.

It is also preferable that you are not taking Viagra for ED as we want to make sure its the mindfulness intervention which is having a positive impact on sexual well being.

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 sign it - and scan it to s.banbury1@londonmet.ac.uk. A password encrypted email will be provided.