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The Impact of a Brief Online Mindfulness Intervention to Support Erectile Dysfunction in African Caribbean Men: A Pilot Waitlist Controlled Randomised Controlled Trial and Content Analysis

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ABSTRACT

Limited clinical trials have evaluated the effectiveness of mindfulness for sexual functioning in men and the existing studies have targeted white male populations. The present study aimed to evaluate the effectiveness of a Mindfulness-Based Cognitive Intervention (MBCI) for erectile dysfunction (ED) in $n=68$ African Caribbean men aged 31–50 years old. A mixed methods approach was adopted to establish the feasibility of a brief online MBCI, using a waitlist-controlled randomised trial with an active and delayed group and a content analysis. Participants completed a series of assessments measuring ED, sexual self-efficacy, well-being, and cognitive mindfulness at weeks 0, 4, and 12 (follow-up). They also completed a series of feedback questions on their experiences of the intervention at weeks 0, 4, and 12. Higher levels of erectile functioning, cognitive mindfulness, sexual self-efficacy, and well-being were reported post-intervention and at the 12-week follow-up. A content analysis of participant feedback responses yielded favourable outcomes, with participants suggesting that they continue to engage in cognitive mindfulness exercises to support them in “having better sex”. This research is the first to look at MBCI in African-Caribbean males with ED and demonstrated the effectiveness of this online intervention; however, it warrants replication with a larger group of ethnically and culturally diverse participants with ED.

El Impacto de una Breve Intervención de Atención Plena en Línea para Apoyar la Disfunción Eréctil en Hombres Afrocaribeños: Un Ensayo Piloto Controlado, Aleatorio, Controlado en Lista de Espera y Análisis de Contenido

RESUMEN

Ensayos clínicos limitados han evaluado la eficacia de la atención plena para el funcionamiento sexual en hombres y los estudios existentes se han dirigido a poblaciones masculinas blancas. El presente estudio tuvo como objetivo evaluar la eficacia de una intervención cognitiva basada en la atención plena (MBCI) para la disfunción eréctil (DE) en $n = 68$ hombres afrocaribeños de entre 31 y 50 años. Se adoptó un enfoque de métodos mixtos para establecer la viabilidad de una MBCI breve en línea, utilizando un ensayo aleatorio controlado en lista de espera con un grupo activo y retrasado y un análisis de contenido. Los participantes completaron una serie de evaluaciones que midieron la disfunción eréctil, la autoeficacia sexual, el bienestar y la atención cognitiva en las semanas 0, 4 y 12 (seguimiento). También completaron una serie de preguntas de retroalimentación sobre sus experiencias de la intervención en las semanas 0, 4 y 12. Se informaron niveles más altos de funcionamiento eréctil, atención cognitiva, autoeficacia sexual y bienestar después de la intervención y en las 12.-seguimiento semanal. Un análisis de contenido de las respuestas de los participantes arrojó resultados favorables, y los participantes sugirieron que continuaran realizando ejercicios de atención cognitiva para ayudarlos a “tener un mejor sexo”. Esta investigación es la primera que analiza la MBCI en hombres afrocaribeños con disfunción eréctil y demuestra la eficacia de esta intervención en línea; sin embargo, justifica su replicación con un grupo más grande de participantes con disfunción eréctil étnica y culturalmente diversos.

Palabras clave:

Disfunción eréctil
Caribe africano
Atención cognitiva
autoeficacia sexual
bienestar

Erectile Dysfunction (ED) is the inability to achieve or maintain an erection in at least 75% of sexual attempts, including masturbation and sexual intercourse (American Psychiatric Association, 2013). It is estimated that up to half of men aged between 40 and 70 may experience ED in the UK (National Health Service., 2023). ED's aetiology can be organic (associated with high blood pressure, cancer, high cholesterol, and diabetes) or psychogenic, along with varied psychopathologies, including substance use, anxiety and depression (American Psychiatric Association, 2013; Del Río et al., 2015). Additional risk factors include hypogonadism, urinary tract infections (UTI), cardiovascular problems, and prescription medications (Yafi et al., 2016).

According to Laumann et al. (2007), the effect of lifestyle and health variables on ED varies for different ethnic groups. In a population study based in the United States, White men were found to be more likely to develop ED who were aged 70 years and above and diagnosed with diabetes. For African American men, ED was prevalent among those with severe UTIs and diabetes and Hispanic men aged 60 years and above with UTIs, hypertension, and psychopathologies. The risk of ED was lower for African American and Hispanic men compared to White men who exercised and were in a supportive relationship. However, research examining ED, ethnicity, risk factors, and management remains sparse.

Varied biopsychosocial interventions are available to support ED, including pharmaceuticals, psychoeducation, Cognitive Behavioural Therapy (CBT) and psychodynamic therapies (Frühaufer et al., 2013). CBT targets body image, spectating and sexual performance anxiety (Stephenson & Kirth, 2017). An emerging intervention for sexual well-being is mindfulness, which focuses on the present moment and brings negative thoughts during sex to one's awareness with acceptance (Bossio et al., 2018). A meta-analysis on the effects of Mindfulness-Based Interventions (MBI) on sexual dysfunction yielded a low-to-moderate effect size of $d = 0.55$ in favour of MBI for sexual well-being (Banbury et al., 2021). Of seven related studies, only one study with ten White men has been conducted, and no study has included people from ethnic minority backgrounds. Bossio et al. (2018) used a mixed design to raise awareness about the representativeness of gender and counselling in healthcare and clinical trials. Outcomes identified men's willingness to access and engage in therapeutic-based interventions. In the UK, men's comparative reluctance, when measured against women's, to access psychological therapies has been demonstrated (e.g., for anxiety and depression) (Seidler et al., 2016). This may be due to perceived facets of masculinity being reinforced by gendered societal roles (Seidler et al., 2016). Concerning Black, ethnic and minority groups, there are further cultural and ethnic intersections in health disparities affecting access to healthcare (e.g., Meyer & Zane., 2013).

Based on this review of the available literature, the present study aimed to evaluate the effectiveness of a Mindfulness-Based Cognitive Intervention (MBCI) for ED in African Caribbean men. The intervention embraces recent changes in the UK National Health Service (NHS), focusing on online healthcare (e.g., Van Lankveld, 2016) and mental health among Black and minority communities. No clinical studies have yet been conducted with African Caribbean men using mindfulness for ED. This research wanted to endorse equity in clinical trials conducted among diverse groups.

For some men, talking about sex can be embarrassing and one way to mitigate this is by using digital health that makes healthcare more accessible and effective (Jedamzik, 2019). Therefore, it was decided to develop an online MBCI. Furthermore, the development of this MBCI has been guided by the "Behaviour Change Techniques Taxonomy" (BCTTv1, Michie et al., 2013) to ensure reliability in its application. Briefly, behaviour plays a crucial role in health and well-being, and health-related behaviours could impact the risk of ED. The BCTTv1 comprises 93 "Behaviour Change Techniques" (BCT) organised into 16 groups (including goals and planning, feedback, and monitoring). BCTs selected via a triangulation process maximised the development and delivery of this intervention.

It was hypothesised in the present study that the active and delayed groups would report higher levels of erectile functioning, mindfulness, sexual self-efficacy, and well-being post-intervention and at follow-up. Further, it was predicted that a significant difference would exist between acquired and lifelong ED with substance use, exercise, and prescription medication use.

Method

Design

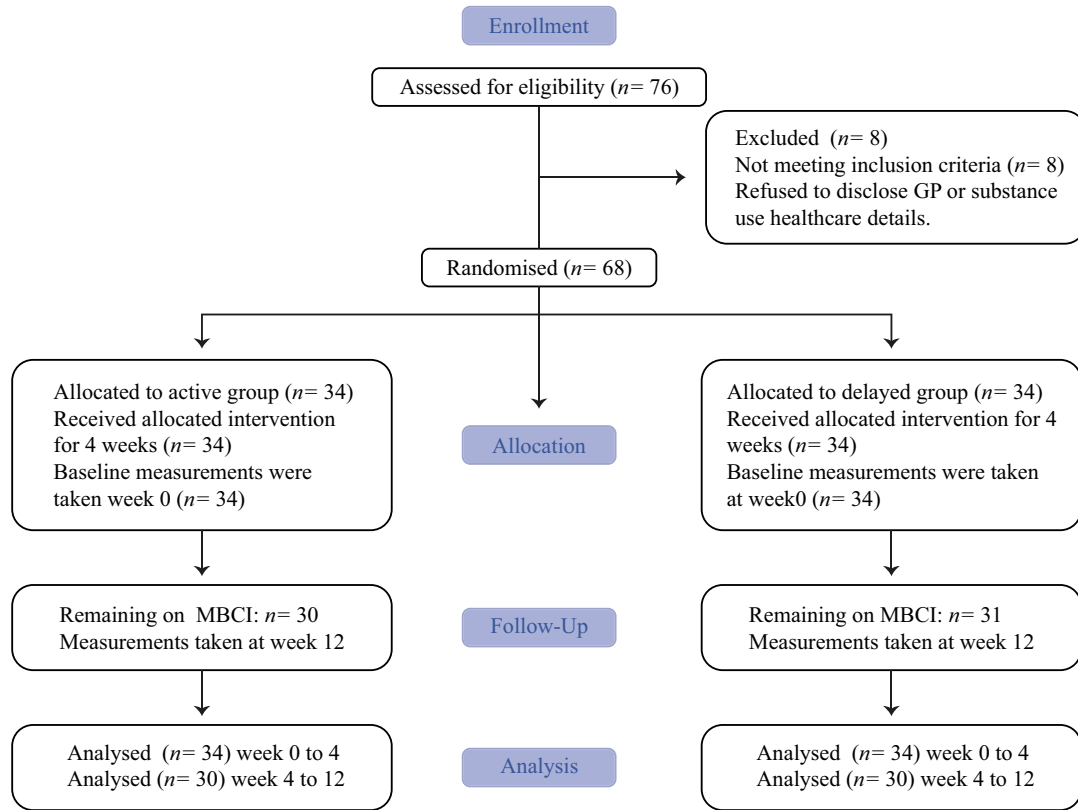
A mixed methods approach was adopted, including a waitlist control RCT and a participant-based summative content data analysis. Individuals were randomly allocated to group 1 or group 2. Group 1 is the active group receiving MBCI and group 2 is the delayed group. Group 2 received the MBCI in week 4 when Group 1's MBCI was finished. The two groups were compared for differences in erectile functioning, well-being, mindfulness, and sexual self-efficacy at 0, 4 and 12 weeks. A snowballing sampling method was used to promote the study via LinkedIn, Reddit, Facebook, and Twitter.

Further, the study was presented in "The Black, African, Asian Therapy Network" (BAATN) newsletter and promoted via The Dominican Emz radio show. A content analysis using Mentimeter was conducted on participants' feedback on the MBCI intervention. Mentimeter is a software app used to create anonymous presentations with real-time feedback. This encouraged participants to voice their views throughout receiving this intervention.

Participants

A Google form was developed, and a link to the study contents was made accessible via Facebook, Reddit, LinkedIn, and Twitter. Interested parties contacted the principal researcher. Participants were 68 African Caribbean men with ED aged 28 to 50+ years old. Half of the sample was randomly allocated to either group one or two. Those without ED, who were not registered with a doctor, who had compromised capacity (Mental Capacity Act., 2005) or who took Viagra/Sildenafil were excluded from this study. Concerning the participant CONSORT diagram shown in Figure 1, of 76 participants assessed for eligibility in this study, eight were excluded by the inclusion/exclusion criteria. Attrition rates were low, with seven participants from the active and delayed groups lost at follow-up or discontinued during the intervention.

Figure 1
CONSORT 2010 Flow Diagram for ED and MBCI



Materials and Guiding Framework for MBCI and ED

The development of the MBCI was based on capability, opportunity, and motivation to perform a behaviour (COM-B) and the behavioural taxonomy BCTTv1 (Michie, 2014; Michie et al., 2013). These frameworks were used because they have been rigorously assessed to evidence intervention effectiveness. The behaviour change wheel consists of three layers, including capability (physical and psychological), opportunity (physical and social) and motivation (reflective and automatic). The COM-B model is supported by the “Theoretical Domains Framework” (TDF), which consists of 12 domains, including knowledge, skills, social/professional role and identity, beliefs about capabilities, beliefs about consequences, motivation and goals, memory, attention and decision processes, environmental context and resources, social influences, emotion regulation, behavioural regulation, and nature of the behaviour. We proposed 10 of these domains, which had been mapped to BCTs. The 93 BCTs are the active ingredients of behaviour change whereby each intervention is likely to consist of more than one BCT and serve more than one function. The COM-B model can be linked to psychological theories such as social cognitive theories and sexual self-efficacy (Bandura, 1997). Team triangulation ensured consistency in the optimal use of the BCTs in mapping them to the TDFs. This guided the development and delivery of the MBCI.

Assessment Tools

Preliminary Screening Tool PHQ-9 for Inclusion/Exclusion Criteria

The Patient Health Questionnaire (PHQ-9) was used to measure levels of depression, with internal reliability within the range of 0.86–0.89 (Kroenke et al., 2001). This 9-item measure requires that participants rate the regularity of present difficulties during the past 2 weeks (e.g., trouble falling, staying asleep, or sleeping too much). Scores indicate the presence and severity of the depression, with a maximum score of 27 and a minimum score of zero. Scores of 0, 5, 10, 15, and 20 indicate minimal, mild, moderate, moderately severe, and severe depression, respectively.

Demographic Information

Demographic information included ethnicity, partnered status, sexuality, age, employment status, children, other health concerns, sexual difficulties, prescription medications and substance use, including alcohol consumption and smoking, and levels of exercise. Of the sample, 11.8% (n = 8) were aged between 18-30 years, 55.9% (n = 38) 31-50 years, 32.4% (n = 22) were aged 50 years and above. The sample consisted of 70.6% (n = 48) African and 29.4% (n = 20) Caribbean, who were predominately partnered

82.4% ($n = 56$), identified as heterosexual 91.2% ($n = 62$) and were either prescribed heart medication 32.4% ($n = 22$) or insulin for diabetes 14.7% ($n = 10$). Alcohol use predominated with levels of 14 and above units of alcohol weekly. Substance use consisted of cocaine, 17.6% ($n = 12$), amphetamine/speed, 29.4% ($n = 20$) and no substance use, 52.9% ($n = 36$). Of the sample, 82.4% ($n = 56$) had lifelong, and 17.6% ($n = 12$) had situational ED.

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 this study, erectile functioning and satisfaction were measured. Response categories ranged from 0=to 5and each question varied including 0 = *very low* to 5 = *very high*. Scores of 5-7 suggest 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 $\alpha = 0.88$ (high) and for men without erectile difficulties, $\alpha = 0.62$ (low to moderate). There is no other sexual self-efficacy questionnaire which has been developed for men. This questionnaire had been adjusted and less than 5% of the original questionnaire remained.

The Short Warwick-Edinburgh Mental Well-being Scale SWEMWBS (Tennant et al., 2007)

A positively worded seven-item questionnaire with five response categories measuring functioning and feeling aspects of well-being. 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, with the latter having the highest level of well-being.

The Cognitive and Affective Mindfulness Scale-Revised CAMS-R (Feldman et al., 2006)

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 MBCI (please see Table 3). Participants were encouraged to leave one feedback per question to ensure that the team got a collective sense of the group's thoughts and feelings about the intervention rather than a disproportionate number of respondents. The feedback outcome was obtained using Mentimeter, then coded and inputted into SPSS.

Procedure

Following ethical approval by the University research ethics review panel, this clinical trial was registered with clinicaltrials.gov (NCT05167955). Details of the study were made available online via social media sites LinkedIn, Reddit, Twitter and Facebook. The BAATN published details of the study in their Newsletter dated 13/12/2021, and a radio discussion about this research was aired on a live Radio UK show - The Dominican, on 09/04/2022. Those interested in participating 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 4 and 12. Participants were randomised into the active or delayed group in which the delayed group received the intervention at week 4. The main exercises included mindfulness, breathing, relaxation techniques, being mindful of the senses and the body and understanding enjoyable sex (Bossio et al., 2018). Four one-to-two-hour online weekly group sessions took place for one month. Feedback on the intervention was sought throughout the intervention using Mentimeter, by which a content analysis of participants' responses regarding their experience was conducted at each point.

Participants were ensured confidentiality and anonymity concerning their engagement in the programme. They were also reminded that they could withdraw from the study without repercussions and did not have to answer all the assessment questions. Researchers in the team had experience working in healthcare with vulnerable and diverse groups. They had been versed in the distress protocol before the research 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 under the General Data Protection Regulation/Data Protection (2018).

Statistical Analyses

A within-subjects ANOVA was used to compare means of study variables measured across weeks 0, 4, and 12 weeks for both groups (active and delayed groups). 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 in weeks 0, 4, and 12 of the MBCI intervention, and a summative content analysis was used to analyse secondary data outcomes.

Results

Cronbach α for the questionnaires used in this study was moderate to high, ranging between .848 and .952 (see Table 1). All adapted questionnaires had sound psychometric properties and were considered reasonable for the current study.

Table 2 shows that the overall means and standard deviations were recorded for groups 1 and 2 (within the study design) for erectile functioning, mindfulness and cognition, well-being, and sexual self-efficacy across weeks 0, 4, and 12.

Table 1
The Cronbach's Alpha for the Included Questionnaires

Questionnaire	Cronbach Alpha α
The International Index of Erectile Function (IIEF-5) Questionnaire (Rhoden et al., 2002)	.848
The Sexual Self-Efficacy Erectile tool (SSES-E; Libman et al., 1985)	.896
The Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) (Tennant et al., 2007)	.952
The Cognitive and Affective Mindfulness Scale-Revised (CAMS-R; Feldman et al., 2006)	.939

Table 2
Erectile Functioning (IIEF-5), Mindfulness and Cognition (CAMS-R), Well-Being (SWEM WBS), and Sexual Self-Efficacy (SSES-E) in Men Assigned to Group 1 or Group 2 at Weeks 0, 4, and 12

Measure	Active group		Delayed group	
	Mean	SD	Mean	SD
IIEF-5				
Week 0	6.67	1.03	6.74	1.05
Week 4	12.43	1.41	12.44	1.50
Week 12	13.78**	1.48	13.45**	1.57
CAMS-R				
Week 0	18.67	4.90	18.26	4.41
Week 4	34.07	3.47	33.59	3.16
Week 12	34.40**	3.14	33.94**	3.33
SWEM WBS				
Week 0	10.17	2.35	10.56	2.23
Week 4	28.50	2.26	27.79	2.37
Week 12	28.37**	2.04	27.55**	2.51
SSES-E				
Week 0	22.53	3.78	16.09	2.66
Week 4	41.67	7.59	41.38	7.09
Week 12	62.43**	10.03	61.70**	7.14

Note. ** Significant $p < .001$ (within subjects)

A repeated measures ANOVA was conducted to analyse the interaction effects of ED with mindfulness, sexual self-efficacy, and well-being. The statistical significance viewpoint using partial eta-squared (η_p^2) as an effect size was further illustrated using confidence intervals (e.g., Lakens, 2013). For group 1, Mauchly's Test of Sphericity for ED suggested that the assumption had been violated, $\chi^2(2) = 14.892$, $p < .001$. Therefore, a Greenhouse-Geisser correction was used. Time significantly affected ED over weeks 0, 4 and 12, $F(2,28) = 4035.914$, $p < .001$, $\eta_p^2 = .997$. The fixed effect was strong, with narrow confidence intervals (CI 95%) between 13.179 and 14.287. There was also a significant effect of time on mindfulness, $F(2,28) = 1230.707$, $p < .001$, $\eta_p^2 = .989$. The fixed effect was strong, with narrow confidence intervals (CI 95%) between 16.674 and 19.973. For sexual self-efficacy, $F(2,28) = 17.205$, $p < .001$, $\eta_p^2 = .551$ with narrow confidence intervals (CI 95%) between 11.342 to 13.952 and well-being, $F(2,28) = 927.410$, $p < .001$, $\eta_p^2 = .985$ with narrow confidence intervals (CI 95%) between 27.288 to 29.007. There was a significant interaction effect between ED, mindfulness, sexual self-efficacy, and well-being, $F(14, 16) = 94.733$, $p < .001$, $\eta_p^2 = .991$.

For group 2, Mauchly's Test of Sphericity for ED suggested that the assumption had been violated, $\chi^2(2) = 33.634$, $p > .001$. Therefore, a Greenhouse-Geisser correction was used. Time significantly affected ED over weeks 0, 4 and 12, $F(2,29) = 3269.321$, $p < .001$, $\eta_p^2 = .996$. The fixed effect was strong with narrow confidence intervals (CI 95%) ranging between 11.917 to 12.965. There was also a significant effect of time on mindfulness, $F(2,29) = 42.704$, $p < .001$, $\eta_p^2 = .747$. The fixed effect was strong with narrow confidence intervals (CI 95%) between 16.725 and 19.804. For sexual self-efficacy, $F(2,29) = 4359.298$, $p < .001$, $\eta_p^2 = .997$ with narrow confidence intervals (CI 95%) between and well-being, $F(2,29) = 602.767$, $p < .001$, $\eta_p^2 = .977$ with narrow confidence intervals (CI 95%) between 15.162 to 17.015 and 9.748 to 11370, respectively. An overall interaction effect between ED, mindfulness, sexual self-efficacy, and well-being was also significant, $F(14, 16) = 59.658$, $p < .001$, $\eta_p^2 = .985$.

A series of T-tests compared groups 1 and 2 means at weeks 0, 4 and 12. There were no significant differences at week 0 for ED, mindfulness, or well-being $p \geq .05$. There was a significant difference with sexual self-efficacy, $t(33) = 10.335$, $p < .001$. At week 4, there were no significant differences between groups 1 and 2 self-reported ED, $p \geq .05$. There were significant differences with sexual self-efficacy, $t(33) = 2.931$, $p = .006$, cognitive mindfulness, $t(33) = 2.925$, $p = .006$ and well-being, $t(33) = 2.435$, $p = .021$. There were no significant differences at week 12 follow-up between groups 1 and 2 in ED, $p > .05$. There were significant differences with sexual self-efficacy, $t(29) = 2.186$, $p = .037$, cognitive mindfulness, $t(29) = 2.954$, $p = .017$ and well-being, $t(29) = 3.002$, $p = .005$. ED for group 1 at week 4 compared to group 2 at week 0 was significantly different, $t(33) = 5.853$, $p < .001$.

Finally, a Mann-Whitney U test was conducted to identify significant differences between acquired and lifelong ED across demographic variables. Results indicated that those with acquired ED had higher levels of prescription medication use, $Z = [-2.780]$, $P = [<.005]$ and engaged in higher levels of exercise than those with lifelong ED, $Z = [-3.329]$, $p = [<.001]$. Further, those with lifelong ED engaged in higher levels of substance use (e.g., cocaine/cannabis), $Z = [-3.409]$, $p = [<.001]$ including smoking than those with acquired ED, $Z = [-2.409]$, $p = [<.001]$.

Content Analysis

Mentimeter outcomes for all participants were taken at weeks 0, 4 and 12 (Table 3).

Discussion

This preliminary study aimed to identify whether a brief online MBCI can successfully improve erectile functioning in African Caribbean men with erectile dysfunction. The intervention mapped the domains of the theoretical domains framework to the behaviour change techniques, in which selected BCTs had been operationalised to maximise the development and delivery of this intervention. Levels of self-reported erectile functioning, mindfulness, sexual self-efficacy, and well-being had improved for both groups during and post MBCI at follow-up. The outcomes of this study went beyond erectile functioning in which an interaction effect was statistically significant between erectile functioning, well-being, sexual self-efficacy and mindfulness.

Table 3
A Content Analysis Based on Participant Feedback

Week 0	
Question 1:	What are your thoughts about receiving this MBCI?
Number of Responses:	43
32.6% (n=14) were uncertain about what to expect, 25.6% (n=11) stated White privilege, 20.9% (n=9) fear of failure, 16.3% (n=7) not sure, 4.7% (n=2) hopeful.	
Question 2:	What would your preferences be if you had a choice of practitioner who would deliver this intervention?
Number of Responses:	50
64% (n=32) requested a male Black practitioner 16% (n=8) a female Black practitioner 20% (n=10) stating not bothered	
Question 3:	What are your thoughts about your current erectile functioning?
Number of Responses:	59
33.9% (n=20) reported shame, 30.5% (n=18) embarrassment, 18.6% (n=11) bad, 13.6% (n=8), not a man, 3.4% (n=2) terrible.	
Week 4	
Question 4:	How is your erectile functioning now at the end of this MBCI?
Number of Responses:	57
41.1% (n=28) reported better, 15.8% (n=9) better sex, 14% (n=8) inclusive, 12.3% (n=7) more awareness of the sexual moment 7.4% (n=5) masculine.	
Question 5:	What are your thoughts on receiving this intervention?
Number of Responses:	59
39% (n=23) stated good, 27.1% (n=16) felt better, 13.6% (n=8) straightforward, 10.2% (n=6) inclusion, 10.2% (n=6) enjoyed it.	
Week 12	
Question 6:	How is your ED at follow-up?
Number of Responses:	53
32% (n=17) stated sex is better, 28.3% (n=15) still good, 20.8% (n=11) works, 13.2% (n=7) not perfect but ok, 5.7% (n=3) still trying.	
Question 7:	Any thoughts about whether you will continue to practise mindfulness to help your ED?
Number of Responses:	46
34.8% (n=16) reported yes, 23.9% (n=11) definitely, 17.4% (n=8) don't know, 15.2% (n=7) when needed, 8.7% (n=4) sometimes.	
Question 8:	If you could receive this intervention again, would you prefer it delivered online or in person?
Number of Responses:	45
80% (n=36) stated online, 13.3% (n=6) either 6.7% (n=3) in person	
Question 9:	Would you have preferred this intervention being delivered over a longer duration?
Number of Responses:	47
80.9% (n=38) stated no, 10.6% (n=5) yes, 8.5% (n=4) do not know.	
Question 10:	Is there anything else you want to add about your experiences of this MBCI?
Number of Responses:	34
41.2% (n=14) stated thank you, 29.4% (n=10) keep going 29.4% (n=10) no.	

The benefits of this intervention for ED corroborate with earlier research (Bossio et al., 2018; Van Diest et al., 2007). Similarly, there was a moderate improvement in erectile functioning post-intervention. Indeed, levels of self-reported ED went from severe to moderate levels. This study compared lifelong ED with those with acquired ED. Reported outcomes for substance use were higher in lifelong than acquired ED. Those with acquired ED were more likely to be on prescription medication and exercise than those with lifelong ED. Minimal research has compared acquired versus lifelong ED; however, research looking at acquired PE (premature ejaculation) has shown increased comorbidity with ED than lifelong PE (e.g., Hartmann et al., 2005; Peugh et al., 2001). Multiple studies have observed that ED and PE are often comorbid in up to 50% of cases (e.g. Laumann et al., 2007; Porst et al., 2007). Similarly to the outcomes in this study, substance use has also been reported in those with lifelong PE (Hartmann et al., 2005; Peugh et al., 2001). Indeed, in a sample of $n = 925$ men with a history of substance use and $n = 82$ men without a history of substance use, among those with a history of substance use, higher levels of lifelong ED, trait and state anxiety and lower levels of sexual intimacy were reported (Del Rio et al., 2015). The current study did not include co-occurring sexual dysfunctions with ED which is a consideration for future research (e.g., Şerefoğlu et al., 2014). Of interest, the current study consisted of several stimulant users. Whilst research suggests that stimulants can aggravate symptoms of ED (Del Rio et al., 2015; Chou et al., 2015), understanding the psychological implications of self-medicating ED with stimulants would be of interest. To expand, research establishing whether there is a perceived expectation that stimulants support sexual functioning among those with ED would be of interest. Finally, a better comprehension of the needs of those with acquired versus lifelong ED is needed.

All participants' mindfulness levels increased during the current MBCI and continued at follow-up. Mindful exercises centred on a compassionate, non-judgmental approach to encourage participants to be less self-judgemental during the sexual act. Part of this includes being immersed in the sexual moment which can help minimise spectating during sexual intimacy (Dunkley et al., 2015). Spectatoring has been shown to impact sexual functioning, including the ability to achieve or maintain an erection (Carvalho, & Nobre., 2010, 2011). Additional intervention components included psychosexual education, graded sexual skills response and cognitive restructuring/reframing. The cognitive reframe reassigned meaning to the sexual act, thus aimed at modifying a negative self-evaluation during the sexual act (Van Lankveld., 2016). The intention is to replace negative automatic thoughts and experiences with less critical cognition during sexual intimacy. According to Zlomuzica et al. (2015), self-efficacy is an important part of cognitive reframing. Positive changes have been associated with improved behavioural and emotional responses to perceived anxiety-provoking situations. This increases the extinction of an unwanted behavioural response to a stimulus, including during the sexual act.

Furthermore, levels of reported Sexual Self Efficacy (SSE) increased throughout the delivery of this intervention which continued at follow-up. Steinke et al. (2008) state that SSE is critical to successful sexual function. Their study of 59 men with heart failure and compromised sexual functioning found that higher levels of sexual functioning were associated with higher levels of SSE. A further study constructed an SSE measure to distinguish between

men with or without erectile problems based on responses from 60 men (Steinke et al., 2008). These authors found SSE to predict sexual functioning and suggested that SSE is vital in assessing sexual difficulties. Whilst sexual confidence and SSE are two separate constructs, they nonetheless overlap. In Van Diest et al., (2007) study, a gradual increase in SSE and improvement in sexual functioning in men with ED was found.

Moreover, the qualitative component of the research of Bossio et al. (2018) yielded a central theme of self-efficacy. In Bossio et al. (2018) study, participants reported that learning the practical tools associated with mindfulness and psychoeducation had supported the development of self-awareness and self-acceptance. Associated with sexual self-efficacy is well-being and increased well-being supports sexual personal and interpersonal well-being (Dewitte et al., 2021).

Talking about ED can be embarrassing for men, and an online anonymous intervention can help mitigate this (Jedamzik, 2019). Digital health care allows more innovative interventions to reach broader and more diverse populations whilst minimising costs. The decision to develop a brief intervention was guided by research suggesting that mindfulness delivered over four weeks appears as effective as those delivered for up to 12 weeks (e.g. Banbury et al., 2023). Further, the decision to create an online intervention was guided by Hucker and McCabe's (2014) waitlist control study on MBCI for mixed female sexual problems. Outcomes for sexual arousal, desire, and orgasm (not pain) improved post-intervention and at follow-up (12 weeks). A subsequent review examining internet-based psychological interventions for mindfulness and sexual dysfunction suggested outcome improvements in most domains of sexual functioning, including sexual arousal, sexual desire, and sexual pleasure. Participants voiced a preference for the MBCI to be brief and online; however, this might not reflect a broader view of receiving MBCI by those who may prefer in-person delivery.

Mentimeter, in the present study, allowed participants to express their thoughts, feelings, and feedback anonymously. The outcomes of the content analysis revealed that participants had initially reported a lack of confidence, uncertainty, shame, doubt, and White privilege in their responses (taken week 0). The participants in this study had reported the term White privilege and the request for a Black male practitioner. This raises the issue of equity in healthcare. According to The British Association for Counsellors and Psychotherapists (BACP, 2018), race and ethnic distinctions must be put on the agenda if we have any relevance in the outside world when claiming that therapy changes lives. There is a need for more Black, ethnic, and minority counsellors/practitioners in healthcare and for improving information about services and access pathways for Black, minority, and ethnic clients/patients. Healthcare providers would benefit from further training in developing interventions and providing effective communication strategies to deliver culturally attuned healthcare (Meyer & Zane., 2013). A bottom-up approach to developing healthcare support might facilitate a better understanding of sexual difficulties and improve access to care, including psychosexual services.

This study has limitations. The research was deliberately narrow in focus on erectile functioning, whereas future research might target relationships and sexual satisfaction. Also, this is a preliminary study with a small sample in which outcomes should be interpreted cautiously. It is difficult to establish why attrition rates were low in

this study. Whilst speculative, the convenience of being online, the anonymity of using Mentimeter, the intervention being brief, and the use of brief questionnaires contributed to participants' engagement. However, the sustainability of the outcomes is difficult to ascertain since outcomes for well-being at week twelve in the experimental group and well-being and sexual self-efficacy in the delayed group had slightly reduced. There were significant differences in well-being, sexual self-efficacy and cognitive mindfulness at weeks 4 and 12 between groups 1 and 2. This might be due to an anticipatory effect commonly seen in waitlist-controlled groups (Knutson & Greer, 2008). The small sample might have increased type 2 errors despite the reasonable effect sizes. Future research might like to re-trial this intervention with a larger sample to establish the effectiveness of MBCI on this cohort. Rather than a waitlist control RCT, using a non-treatment control group might have provided a better understanding of the effectiveness of mindfulness in ED. Future research might also look at how a mindfulness and Sildenafil adjunct compares with either variable individually or with a no treatment control group between acquired and lifelong ED.

In conclusion, this is one of the first MBCIs for African Caribbean men with ED. Limited clinical trials have targeted African Caribbean groups in healthcare practice. This lack of representativeness in clinical trials does not support culturally attuned healthcare practice. This research wanted to contribute to developing evidence-based practice implementation towards healthcare excellence. Indeed, results look promising, where ED functioning increased along with SSE, mindfulness, and well-being for all participants, which continued through to follow-up. The intervention mapped the domains of the TDFs to the BCTs in which selected BCTs had been operationalised to maximise the development and delivery of this intervention. It is proposed that a larger-scale trial with an ethnically and culturally diverse group of male participants is carried out.

Author Contributions

Conceptualisation, Samantha Banbury (SB); Methodology, SB and Dellián Jean-Marie (DJM); Software, (DJM); Formal Analysis, SB.; Investigation, SB, DJM; Data Curation, SB.; Writing – Original Draft Preparation, SB.; Writing – Review & Editing, SB, Chris Chandler (CC), Joanne Lusher (JL), John Turner (JT); Tables and presentation (CC and JL); References – SB, DJM, CC, JL, JT; Manuscript preparation for submission- SB, CC, JL, JT.

Institutional Review Board Statement

The research complied with the British Psychological Society Code of Ethics (BPS., 2017), the GDPR and the Data Protection Act (2018). The study was ethically approved via the London Metropolitan Ethics Review Panel on 20/11/2021.

Informed Consent Statement

The research complied with the British Psychological Society Code of Ethics (BPS., 2017), the GDPR and the Data Protection Act (2018). All participants consented to participate in this study.

Data Availability Statement: Raw anonymised data sets are saved in SPSS on a password-protected computer following the Data Protection Act/GDPR (2018).

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Conflicts of Interest

The authors have no conflict of interest.

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