

Study Protocol:

A semi-structured interview study of gender-specific lived experiences of people engaging with digital cognitive behavioural therapy ('Breaking Free Online') for substance use disorder

Short Protocol Title: Qualitative study – people engaging with digital substance
Substance Use Disorder treatment

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Study Synopsis

Study Title	A semi-structured interview study of gender-specific lived experiences of people engaging with digital cognitive behavioural therapy ('Breaking Free Online') for substance use disorder
Internal ref. no. / short title	Qualitative study - people engaging with digital substance use disorder treatment
Study Design	Semi-structured qualitative interview study
Study Participants	Adults receiving treatment for substance use disorders
Planned Sample Size	60
Planned Study Period	18-months (including data analyses and preparation for publication)

Abbreviations

BBV	Blood Borne Viruses
BCT	Behavioural Change Technique
BFO	Breaking Free Online
CAT	Computer Assisted Therapy
CBT	Cognitive Behavioural Therapy
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GMMH	Greater Manchester Mental Health Trust
HMP	Her Majesty's Prison
HRA	Health Research Authority
ICF	Informed Consent Form
LBM	Lifestyle Balance Model
NHS	National Health Service
PHQ-4	Patient Health Questionnaire-4
PI	Principal Investigator
REC	Research Ethics Committee
RPM	Recovery Progression Measure
SDS	Severity of Dependence Scale
SUD	Substance Use Disorders
WHOQoL-BREF	World Health Organization Questionnaire Quality of Life Scale

1. Introduction

The nature and severity of substance use disorders (SUD) can vary from individual to individual, with multiple factors being associated with the initiation of substance use, progression to SUD, clinical complexity, and response to treatment. Gender in particular has been found to be a differentiating factor – specifically, published comparative research has demonstrated significant differences between men and women in terms of their routes into SUD, the kinds of substances used, and comorbid conditions (Becker et al., 2017; Zakiniaiez & Potenza, 2018). There is also now a growing evidence-base demonstrating how specific gender-related issues may be associated with substance use (Ka Hon Chu & Kazatchkine, 2020; Lyons et al., 2015). Treatment services are often also perceived as being ‘male-centric’, with men making up a larger proportion of the treatment population compared to other gender identity groups (Public Health England, 2018). This would indicate that the treatment system would benefit from engaging under-represented gender groups through the introduction of novel interventions that can overcome many of the barriers they might face that can prevent them from presenting to services.

This qualitative interview study will therefore explore gender-specific lived experiences of people who have engaged with either community or prison SUD treatment services. Specifically, this study will include participants who have engaged with a novel digital cognitive behavioural therapy (CBT) programme for SUD, ‘Breaking Free Online’ (BFO). Because of its confidential nature, this novel intervention has the potential to help people with SUD who may otherwise be under-represented in SUD service to access evidence-based treatment where previously that may have felt unable to access such support. Additionally, through better understanding the unique ways in which gender may be associated with different lived experiences of SUD and treatment, adaptations can be made to how BFO is delivered with different gender groups to most effectively meet their needs. This study will include both cisgender and transgender women and men.

1.1. Gender differences in substance use, clinical complexity, engagement with services and treatment outcomes

Before providing a discussion of gender-related difference in SUD, it is important to define what is meant by ‘gender’ and distinguish this concept from that of ‘sex’. ‘Sex’ is biologically driven, and despite common assumptions that people are either born ‘female’ or ‘male’, biological sex is not binary. Although a full discussion of the complexities of biological sex is outside the scope of this protocol, it is worth noting that sex is a complex construct determined by chromosomes, hormones and internal and external genital morphology (Karkazis, 2019) and does not always cause a person to be completely ‘female’ or completely ‘male’. Conversely, ‘gender’ is socially constructed, and reflects an individual’s personal sense of their gender, whether that be a woman, man, neither or both. The literature reports a number of important gender-related differences in not only pathways into substance use and SUD, but also the profiles of clinical complexity associated with SUD, likelihood of engaging with services and treatment outcomes. However, much of this literature has focussed on cisgender women and men, rather than other gender groups such as transgender and non-binary people.

More men use illicit substances of most kinds than women (European Monitoring Centre for Drugs and Drug Addiction, 2005) and there may also be some differences between women and men in age of onset of the use of some substances (Lewis et al., 2014). Though women may often initiate

substance use at a later age than men, the progression of women to SUD may be more rapid (Lewis et al., 2014) – this process, termed ‘telescoping’ (Piazza et al., 1989), has been found to be a robust effect (Zakariaeiz & Potenza, 2018). Once progressed to SUD, women may also demonstrate greater clinical complexity, with higher prevalence and severity of comorbid mental health difficulties and greater psychosocial impairment than men (Polak et al., 2015). Women are also more likely than men to be victims of violence and abuse, particularly intimate partner violence, which can complicate treatment and outcomes (Keyser-Marcus et al., 2015). Though both women and men with SUD may engage in illegal activities to fund their substance use, men may be more likely to engage in theft/robbery or illicit drug dealing, whereas women may be more likely to engage in sex work (Grella, 2003).

There are also gender-related differences in terms of treatment seeking, which along with the differences in profiles of clinical complexity, may account for the different treatment outcomes seen amongst women and men. Historically, the treatment population has been comprised of significantly more men than women (European Monitoring Centre for Drugs and Drug Addiction, 2005) – there may be multiple reasons why fewer women present to services compared to men. One important barrier for women may be stigma, and the ways in which substance-using women may be perceived by society (van Olphen et al., 2009), especially as women are more likely to be principal caregivers to children (Radcliffe, 2011) and other family members (Sharma et al., 2016). Many women who are also mothers may be concerned about the involvement of child protection services if they present to SUD treatment services (Lussier et al., 2010). Additionally, many services may be unable to provide gender-responsive interventions, which can be particularly important for those women who have been traumatised by intimate partner and sexual violence, and other forms of abuse (Saxena et al., 2014).

Findings around gender-related differences in treatment outcomes are mixed, with some studies demonstrating that men may fare less well than women (Green, 2006) and others demonstrating that outcomes for men and women are comparable (Hser et al., 2003). However, what is apparent is the importance of tailoring treatment to the specific needs of individuals, evidenced by the fact that women experience better outcomes when they are able to access gender-responsive services that address the specific difficulties they may be facing (Saxena et al., 2014).

Transgender people may be at higher risk for alcohol use disorders and negative alcohol-related consequences, such as engaging in physical altercations and experiencing sexual assault (Ruppert et al., 2021). This review also found that studies demonstrated higher rates of injection drug use, crack cocaine and methamphetamine use in transgender women in comparison to other gender identity groups. Reasons for these higher rates of substance use in transgender women have been explored in the literature, with a recent review suggesting that transgender women may be more likely to experience marginalisation, transphobic discrimination, sex work and mental health issues such as trauma and depression, in comparison to other gender identity groups (Cotaina et al., 2022).

Transgender people may demonstrate higher rates of SUD compared to the general population (Cotaina et al., 2022; Kidd et al., 2023) – transgender individuals who use substances may also be more likely to experience severe mental health issues (Kidd et al., 2023). Additionally, substance use can be associated with risky sexual behaviours, potentially increasing the risk of HIV and other STIs for transgender people (Cotaina et al., 2022). Transgender individuals also experience a range of social issues, including discrimination and lack of acceptance, which can lead to social isolation, and the use of substance use as a coping mechanism (Wolfe et al., 2021). This stigma and discrimination can create obstacles to seeking and accessing substance use treatment, as can lack of

knowledge and negative attitudes among healthcare providers about trans-specific experiences and needs (Glynn & van den Berg, 2017), and inadequate provision of trans-inclusive substance misuse services (Connolly & Gilchrist, 2020).

1.2. Gender-related health issues for men and women residing in prisons

One group of substance-involved people who have specific healthcare needs are people in prison. Healthcare within the prison estate for England and Wales faces continued pressures due to austerity measures and reductions in budgets, whilst the prison population continues to grow (Ismail, 2019). Health inequalities experienced by the prison population due to a number of social determinants, are reflected in higher levels of mental and physical health difficulties than are seen in the general population (Baybutt et al., 2018).

Magnifying the health burden is the pervasiveness of SUD in prisons, and increased incidences of drug poisoning, and non-fatal and fatal overdoses (Duke et al., 2024). SUD affects prisoner physical health in myriad ways, including via respiratory illnesses from inhalation of substances (Rayner & Prigmore, 2008), poor dietary choices, (Sandwell & Wheatley, 2009), poor dental hygiene resulting from substance use (Walsh et al., 2008) and a lack of self-care (Heidari et al., 2014). This population also presents a significant risk of overdose when re-entering society following release, due to a decreased tolerance to substances compared to their levels of consumption when entering prison (Larsen et al., 2022).

There are some important gender-specific health issues prison residents experience.

- Women prison residents have high levels of mental health needs including major depressive disorder, bipolar disorder, schizophrenia spectrum disorder, and schizoaffective disorder (Steadman et al., 2009). Self-harm and attempted suicide are also higher amongst the female prison population compared to the male population (Liebling & Maruna, 2013). Substance-involved women in prison are also at greater risk of associated harms from substance use – for example, this population has a greater incidence of blood borne viruses (BBV) including HIV and Hepatitis C than men who are imprisoned and the general population (Anders et al., 2017). In addition, a review conducted to inform the development of health care services for women's prisons identified trauma exposure as being instrumental in many women's pathways to crime, with incarcerated women often been victims of much more serious offences such as rape and grievous bodily harm, than those for which they are convicted, including non-violent drugs and property offences (Jewkes et al., 2019). A systematic review of studies conducted across 10 countries also demonstrated higher prevalence of SUDs in women in prison compared to men (Fazel et al., 2017).

In the general population men account for 80% of all suicides, with this being magnified in prisons, where the rate ranges between three and eight times higher making it the number one cause of death (Zhong et al., 2021). For the male prison population there are other distinct health concerns that are disproportionate, such as the growth in performance and image enhancing drugs (PIED: Barkham, 2022) with many resulting in reduced appetite, aggression, and unhealthy injecting practices due to the lack of access to needle and syringe exchange programmes (NEX). There is also increased risk of sexually transmitted infections (STI) for men in prison population due to the lack of access to barrier

forms of contraception (i.e. condoms) and BBV transmission stemming from unprotected sex (Scott et al., 2015).

1.3. Using digital technologies to overcome barriers to SUD treatment: Breaking Free Online

Digital interventions can increase access to evidence-based treatment for historically underrepresented service user groups who often are not able to access treatment services due to multiple systemic barriers (Tofighi et al., 2018). For example, digital interventions for SUD can overcome treatment access barriers including rurality and proximity to services and can also allow access to treatment in a confidential manner to overcome stigma (Carroll & Rounsaville, 2010).

One such digital intervention is ‘Breaking Free Online’ (BFO: e.g. Elison-Davies et al., 2021; Elison, Jones, et al., 2017; Elison, Ward, et al., 2017), a tailorable digital CBT programme designed to support recovery from SUD and concurrent mental health issues. BFO is appropriate for addressing a wide number of substances as it has been designed to target the biopsychosocial and lifestyle factors that underlie SUDs more generally. The programme has been delivered via UK-based treatment services for the past 10-years, has a growing evidence-base, and since 2019 has been delivered as standard treatment in both Canadian community and US correctional treatment settings.

BFO can be delivered as a self-directed ‘self-help’ programme, or as a structured one-to-one or groupwork ‘computer assisted therapy’ (CAT) programme where sessions are facilitated by a practitioner. In order to support practitioners who are delivering the programme as CAT, manuals have been developed that provide them with guidance around delivering the programme content in both one-to-one and group settings. This includes guidance on supporting service users to reflect on their own experiences, discuss content of individual strategies of the programme, and find ways to practice the skills they are learning from the programme outside of the BFO sessions.

When an individual first uses BFO, they complete an assessment of their substance use, mental health and wider biopsychosocial functioning. Included in this assessment is the ‘Recovery Progression Measure’ (RPM: Elison et al., 2016; Elison, Dugdale, et al., 2017), which measures baseline levels of functioning across six biopsychosocial domains. BFO then uses data gathered from the completion of the RPM to populate a six-domain model (see Figure 1), the ‘Lifestyle Balance Model’ (LBM: Davies et al., 2015). The LBM acts as a clinical formulation to help the user understand the specific issues and domains of functioning that may be implicated in their substance use and provides access to the clinical content of the programme.

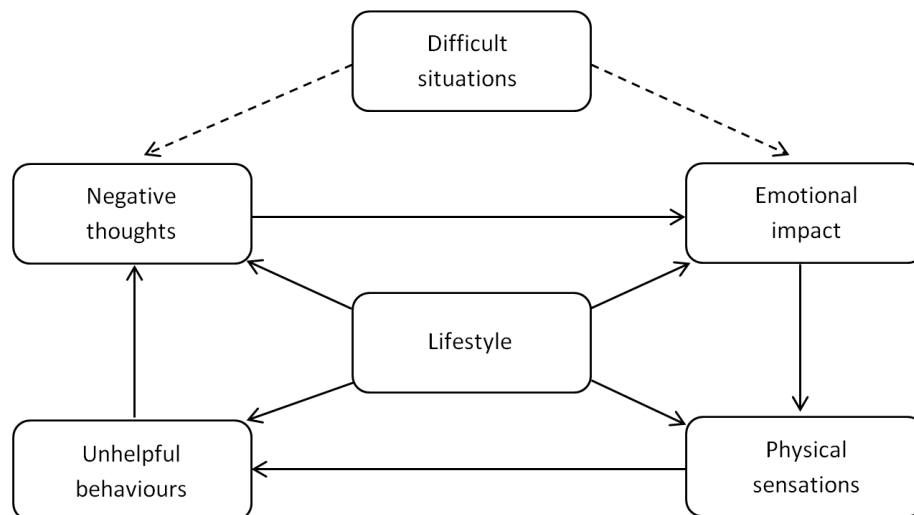


Figure 1: The Lifestyle Balance Model

Based on RPM scores, each of the domains of the LBM are coloured either green, amber, or red, indicating respectively, ‘little’, ‘moderate’ or ‘significant’ impairment. Tailoring advice then guides the user to concentrate on completing clinical content of the programme that is able to address the domains of their functioning in the LBM where they may be experiencing the greatest levels of impairment (amber and red domains of the LBM). Individuals are able to address these domains of functioning by completing 12 core evidence-based clinical intervention strategies, or ‘behavioural change techniques’, (BCTs: Michie et al., 2013) that are included in BFO that have been demonstrated to be effective in reducing substance use and improving mental health and broader biopsychosocial functioning. These BCTs are informed by therapeutic approaches such as CBT (Beck et al., 2011), relapse prevention (Marlatt & Donovan, 2005), mindfulness (Marlatt et al., 2010), and motivational enhancement (Miller & Rose, 2015), amongst others. Table 1 provides a full description of the individual BCTs in BFO, the purpose of each of these BCTs, and the therapeutic approaches informing these BCTs.

Table 1. The ‘behavioral change techniques’ (BCTs) contained within Breaking Free Online

Content in Breaking Free Online	Description of strategy	Therapeutic approaches underpinning strategies	BCT taxonomy (V1) techniques (number in taxonomy)
Baseline and progress check assessments	Monitor behaviour to provide feedback about progress towards goals; Encourage new behaviours via positive feedback	Goal setting; self-monitoring	Self-monitoring of behaviour (2.3); Feedback on outcome(s) of behaviour (2.7)
Lifestyle Balance Model	Generic formulation; Idiosyncratic formulation; Personalized feedback; Case formulation – understand the links between situations, thoughts, emotions, behaviours, physical sensations, and lifestyle	Node-link mapping (International Treatment Effectiveness Project (ITEP); Cognitive-behavioural therapy (CBT)	Information about antecedents (4.2); Information about health consequences (5.1); Salience of consequences (5.2); Information about social and environmental consequences (5.3); Information about emotional consequences (5.6)
Difficult situations domain of LBM	Assessment; Self-monitoring; Standardized measures; Psycho-education on impact of problematic situations; Intervention to help people in distress access support; Recognize–avoid–cope; Relapse prevention for coping with environmental/situational/emotional triggers; Creating action plans on how to avoid or cope in high risk situations	All structured therapeutic approaches; Psychoeducation; Guided self-help; Relapse prevention; Refusal skills	Social support (unspecified) (3.1); Reduce negative emotions (11.2); Problem solving (1.2); Action planning (1.4); Instruction on how to perform the behaviour (4.1); Behavioural practice/rehearsal (8.1); Behaviour substitution (8.2); Avoidance/reducing exposure to cues for the behaviour (12.3); Goal setting (behaviour) (1.1)
Negative thoughts domain of LBM	Psychoeducation on impact on negative thoughts; Mind traps; Cognitive restructuring; Challenge thoughts that may be unhelpful	Psychoeducation; Guided self-help; International Treatment Effectiveness Project (ITEP); Cognitive-behavioural therapy (CBT)	Information about antecedents (4.2); Information about health consequences (5.1); Salience of consequences (5.2); Information about social and environmental consequences (5.3); Information about emotional consequences (5.6); Re-attribution (4.3); Framing-reframing (13.2)

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Emotions domain of LBM	Psychoeducation on impact on emotions; Attention narrowing; Attention switching; Emotional regulation; Recognize/understand/normalize emotions; Developing more appropriate coping strategies	Psychoeducation; Guided self-help; Coping strategy enhancement (CSE); Mindfulness-based cognitive therapy	Information about antecedents (4.2); Information about health consequences (5.1); Salience of consequences (5.2); Information about social and environmental consequences (5.3); Information about emotional consequences (5.6); Behavioural practice/rehearsal (8.1); Reduce negative emotions (11.2); Problem solving (1.2); Social support (unspecified) (3.1); Behavioural practice/rehearsal (8.1); Distraction (12.4)
Physical sensations domain of LBM	Psychoeducation on impact of physical sensations; Urge surfing; Body scanning; Relapse prevention-based techniques	Psychoeducation; Guided self-help; Mindfulness-based cognitive therapy	Information about antecedents (4.2); Information about health consequences (5.1); Salience of consequences (5.2); Information about social and environmental consequences (5.3); Information about emotional consequences (5.6); Instruction on how to perform a behaviour (4.1); Behavioural practice/rehearsal (8.1); Reduce negative emotions (11.2)
Unhelpful behaviours domain of LBM	Psychoeducation on impact of destructive behaviours; Activity scheduling; Behavioural activation; Encourage new behaviours via positive feedback; Increase activity to increase energy levels and relieve boredom	Psychoeducation; Guided self-help; Cognitive-behavioural therapy (CBT)	Information about antecedents (4.2); Information about health consequences (5.1); Salience of consequences (5.2); Information about social and environmental consequences (5.3); Information about emotional consequences (5.6); Non-specific reward (10.3); Non-specific incentive (10.6); Reward approximation (14.4); Rewarding completion (14.5); Goal setting (behaviour) (1.1); Action planning (1.4)
Lifestyle domain of LBM	Psychoeducation on impact of lifestyle; Creating SMART goals for recovery; Goalsetting Increase treatment engagement and retention. Increase readiness to change behaviour	Psychoeducation; Guided self-help; Motivational enhancement therapy (MET); Implementation intentions	Goal setting (behaviour) (1.1); Problem solving (1.2); Goal setting (outcome) (1.3); Action planning (1.4); Non-specific reward (10.3); Focus on past success (15.3)

1.4. Digital and health literacy within the substance-involved population

When exploring the appropriateness of a digital treatment program such as Breaking Free for people with SUD, ascertaining the impact of ‘digital literacy’ and ‘health literacy’ on the ability of such individuals to engage with this modality of treatment should be prioritised. The United Nations Educational, Scientific and Cultural Organization (UNESCO) defines digital literacy as *“the confident and critical use of a full range of digital technologies for information, communication and basic problem-solving in all aspects of life”* (UNESCO, 2025). The World Health Organization (WHO) defines health literacy as *“being able to access, understand, appraise and use information and services in ways that promote and maintain good health and well-being”* (WHO, 2024).

The literature suggests that some individuals with SUD may have low levels of digital literacy, often due to having poor access to digital resources, including digital devices and data (Hampton et al., 2024). Levels of health literacy amongst this population can also be low in comparison to the general population (Degan et al., 2021), with this having a potentially detrimental effect on health service utilisation. In particular, the substance-involved prison population may have some of the lowest levels of digital and health literacy, given generally poor access to digital technologies in many prison settings (Knight et al., 2024) and the prevalence of poor general literacy and dyslexia amongst this population (Alexander-Passe, 2025; Morken et al., 2021).

Such inequalities in digital and health literacy may exacerbate health inequalities experienced by substance-involved people. Given healthcare services have increasingly moved to the online space in the past decade or so (Allcock et al., 2024), digital skills, and access to digital technology, are vital for being able to make healthcare appointments, communicate with healthcare professionals and order medications (Heponiemi et al., 2022). Developing ‘digital health literacy’ skills is also becoming increasingly important in being able to access health advice and information, which tends to be available predominantly online (van Kessel et al., 2022). Therefore, obtaining the views of substance-involved people on the impact of digital health literacy skills on ability to access digital health interventions like Breaking Free, may allow barriers and facilitators to be better understood.

1.5. Aims and rationale

The literature reports a number of gender-specific differences in terms of the psychosocial difficulties that might lead different gender groups to start using substances, the clinical complexities they experience when they have a SUD, and the relative availability of gender-responsive treatments. Data collected from individuals who have engaged with BFO via UK treatment settings demonstrate that approximately 45% of these individuals identify as being women. This is in contrast to the most recent data available from the UK National Drug Treatment Monitoring System (NDTMS) (Public Health England, 2019) which indicates that between 2018 – 2019, only 31% of the treatment population were women, in comparison to 69% being men. A recent study also found that women seeking treatment in the UK were more likely to report specific needs in relation to mental health and relationships with children or partners whilst men were more likely to reports needs in relation to physical health (Andersson et al., 2021). This would indicate that, in the UK at least, there is a need for gender responsive SUD interventions that are able to address the specific needs of certain groups, especially women.

This qualitative study will therefore explore, via a mixture of semi-structured one-to-one qualitative interviews and focus groups (depending on the practicality of utilising these two data

collection methods in the real-world treatment settings in which data will be collected), gender-specific issues faced by cis and transgender women, and cis and transgender men, who have engaged with the BFO program to address their SUD. We acknowledge that it is likely that more cisgender women and men will participate given that transgender women and men may not be very well represented in treatment services. However, even if only a small number of transgender women and men take part in the study, we feel it is important they are able to voice their experiences – this could form the foundation of a future, more focussed study exploring the lived experiences of specifically transgender women and men. Additionally, given the mental health and BBV burden of women and men who are imprisoned, we include this group in the study also. The aims of this study are therefore as follows:

- i) Interview women and men in treatment for SUD about their paths to substance use, their lived experiences when living with SUD, and their experiences of treatment.
- ii) Specifically, interview women and men in SUD treatment that are engaging with the BFO program – interviews will also include questions on their views of BFO in terms of its user interface user journey, and clinical content.
- iii) Use qualitative data collected from interviews to develop gender-responsive materials to support the delivery of BFO with women and men – these materials will be in the form of a manual which can be used by practitioners supporting women and men to work through the program. Content will provide guidance on managing gender and trauma-related issues, and how to help women to experience optimal benefits from the clinical content in BFO.

1.6. Research questions

There are a number of specific research questions in this study – these questions are broad in nature and require in-depth information to be gathered in order to answer them. Therefore, the chosen methodology of in-depth, semi-structured interviews was deemed to be more appropriate than alternatives, e.g. structured questions.

- i. What are the aetiological factors that can lead women and men to develop a SUD – are there any gender-related differences in these aetiological factors?
- ii. What kinds of consequences do women and men with SUD face as a result of their substance use – are there any gender-related differences in these consequences?
- iii. What are women's and men's experiences of seeking and accessing treatment and support for their SUD – are there any gender-related differences in treatment seeking and access?
- iv. What are women's and men's experiences of engaging with BFO when they are working on their recovery from SUD – are there any gender-related differences in these experiences of engaging with BFO?
- v. How do women and men feel about their future when they are working on their recovery from SUD (and rehabilitation from offending) – are there any gender-related differences in how women and men feel about their ongoing recovery (and rehabilitation)?

2. Method

2.1. Design

This study will be a semi-structured qualitative interview study exploring gender-specific lived experiences of people in SUD treatment, with qualitative data being used to develop resources to help practitioners supporting women and men with SUD to engage with a digital CBT treatment program, 'Breaking Free Online (BFO)'.

2.2. Participants

Participants will be 30 cisgender or transgender women, and 30 cisgender or transgender men, currently receiving treatment for SUD who are over the age of 18 years. Participants will be receiving either community-based treatment or prison-based treatment (the 'host institutions'). Inclusion and exclusion criteria are as follows:

- Inclusion criteria:
 1. Cisgender or transgender woman or man receiving treatment for SUD.
 2. Has engaged with BFO as part of their SUD treatment.
 3. Aged 18 years or above on the day of consent.
 4. Experiencing problem alcohol and/or drug use at time of consent, as determined by Investigator.
 5. Problem alcohol or drug use present for ≥ 12 months at time of consent, as self-reported.
 6. Willing to participate in a semi-structured qualitative interview.
 7. Able to read, write and communicate in the English language.
 8. Willing and able to give informed consent for participation in the study.
- Exclusion criteria:
 1. Gender identity that is not cisgender or transgender woman or man.
 2. Not receiving treatment for SUD.
 3. Has not engaged with BFO.
 4. Under 18 years old on the day of consent.
 5. Detention under the Mental Health Act at the time of consent.
 6. Untreated or unmanaged mental health difficulties that might impair ability to participate in the interview.
 7. Clinically significant intellectual or developmental disability which may impair ability to provide consent and participate in the interview.

2.3. Recruitment

Participants will be recruited from the host institutions – promotional materials such as posters and leaflets will be distributed across all treatment sites within the host institutions. Additionally, in-person and virtual meetings will be held with staff working at the host institutions to inform them of the study, its aims, and the inclusion and exclusion criteria. Information about the study will also be emailed by the host institutions to their staff teams. Additionally, permission will be sought from the host institutions for members of the research team to attend, where appropriate, service user meetings and events where information about the study can be disseminated. For women receiving treatment in community settings, social media channels will also be used, where links to study information and contact details for the research team will be provided.

2.4. Informed consent

Participants must personally sign and date the latest approved version of the Informed Consent form before any study activities are undertaken. Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing the following: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part. It will also be clearly stated that the participant is free to withdraw from the study at any time without providing a reason, and without this affecting their future care.

The participant will be allowed as much time as they need to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained via a participant dated signature and dated signature of the Investigator. A copy of the signed Informed Consent will be given to the participant and a copy will be retained at the study site.

2.5. Study Visits

Interviews will be conducted either virtually via videoconferencing software (MS Teams, Zoom etc) where possible, or a member of the research team will visit participants to conduct in-person interviews. These interviews will be conducted at the treatment service (community or prison). For participants receiving treatment in the community, where possible interviews will be arranged to coincide with a day when the participant is visiting the service to receive treatment so as to reduce burden. However, where this is not possible, participants will be reimbursed their travel expenses. For those participants receiving treatment in the community who may have difficulties that might prevent them from attending the service in person (e.g. due to mobility, mental health, financial, childcare issues etc), a member of the research team will visit the participant in their home to conduct the interview.

2.6. Discontinuation/withdrawal of participants from the study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with study requirements
- Withdrawal of Consent
- Loss to follow up.

Withdrawal from the study will result in exclusion of the data for the participant from analysis, including all demographics data provided, and audio and text-based transcriptions of interviews. Any participants who withdraw before the end of the study (please see definition below) will be replaced through recruitment of a new participant. The reason for withdrawal by the researcher (and by participant, if this information is volunteered) will be recorded in a study file.

2.7. Definition of end of study

The end of the study is defined as when the sixtieth participant has been interviewed, all data have been transcribed and analysed, and the findings of the study have been written up in the form of a manuscript for submission to a journal for publication.

3. Data Analysis and Management

3.1. Data Analysis

Before each interview is conducted, a demographic details questionnaire will be completed with each participant. Demographic data collected using these questionnaires include:

- Date of birth
- Age
- Gender identity
- Sexual orientation
- Marital status
- Number of children/dependents
- Educational status
- Occupational status
- Ethnicity

When each interview is conducted it will be audio recorded and then fully transcribed – text transcriptions will be analysed using thematic analysis (Braun & Clarke, 2006). Themes will be identified, and data conceptualised, through a number of theoretical lenses:

- Feminist theory – there are several models of feminist theory (Nes & Iadicola, 1989), though the commonality among all of them is the attention towards power imbalances, oppression and social justice (Beckman, 2014; Clemans, 2005). Feminist theory has been used in previous qualitative research involving women with SUD including substance-involved mothers serving prison sentences (Allen et al., 2010).
- Masculinity theory – a number of masculinity theories will be used to conceptualise findings, including those examining hegemonic masculinities that assert men's dominance and perpetuate gender inequalities (Connell & Messerschmidt, 2005), social construction theories of gender (Addis et al., 2016). Other theories of masculinity have previously been used in studies with men who use substances (Lainas & Kouimtsidis, 2022) and men who are involved in criminal justice services (Morse & Wright, 2022).
- Transgender theory (Nagoshi & Brzuzy, 2010) – this theory considers the nature of gender and gender identity in understanding the lived experiences of transgender and transsexual individuals, and emphasises the importance of physical embodiment in gender and sexual identity.
- Intersectionality theory (Crenshaw, 2017) – this theory provides a qualitative analytic framework to allow conceptualization of how systems of power affect those who are most marginalized in society. Intersectionality theory acknowledges that people can be discriminated against and marginalised because of multiple different aspects of their identity

that ‘intersect’ and interact with one another (e.g. gender identity, ethnicity, socio-economic status, health status etc).

3.2. Data Management

Responsibility for study coordination and data management will be with the Chief Investigator, and responsibility for data analysis will be with the Chief Investigator and co-investigators. All qualitative interview data will be recorded onto an encrypted digital Dictaphone, with all data then being securely transported to the Sponsor’s offices where the interview data will be transferred to a secure cloud-based storage platform. Digital audio recordings of interviews will be sent to a professional transcription service to be transcribed verbatim – audio recordings of interviews will be deleted immediately following transcription. All interview transcripts will be stored digitally to a secure cloud-based storage platform – all transcripts will be fully anonymised with any participant identifiable information deleted from the transcript. No participant identifiable information will be included in any study findings dissemination materials. Hard copy demographic information will be stored in a secure locked filing cabinet and the Sponsor’s offices. All data will be stored for a period of 10-years in order to allow time for secondary analyses – data will be stored in such a way that is compliant with the UK General Data Protection Regulations (GDPR).

3.3. Access to Data

Direct access to data will be granted only to the Chief Investigator and co-investigators. However, data will also be made available to regulatory authorities upon request.

4. Ethical and Regulatory Approvals

This protocol, Informed Consent documentation, demographic details questionnaire, interview schedules, and any proposed advertising materials will be submitted to an appropriate Research Ethics Committee (REC), HRA, and host institutions for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

4.1. Reporting

The Chief Investigator shall submit once a year throughout the study, or on request, an Annual Progress report to the REC, HRA and host organization. In addition, an End of Study notification and final report will be submitted to the same parties.

4.2. Participant Confidentiality

Study staff will ensure that the participants’ anonymity is maintained – participants will be identified only by a participant ID number on all documents and any electronically stored data. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the UK General Data Protection Regulations (GDPR).

5. Finance and Insurance

Participants will be reimbursed for travel expenses when they are required to travel to a study visit that does not coincide with a day and time when they would be attending their treatment service for treatment. The Sponsor maintains Public Liability and Professional Liability insurance.

6. Publication Policy

The Chief Investigator (SED) will lead on analysing data and preparing manuscripts for publication and dissemination – they will also act as corresponding author and all co-investigators will act as co-authors. Participants will be asked at the point of consent if they wish to be informed of the findings of the study – for those that would like to be informed, contact details for where study findings can be posted will be taken by the researcher. Findings will be disseminated via publication in peer-reviewed journals and presentation at relevant conferences. Findings will also be disseminated to participating services and also to the general public via plain language summaries which will be provided by multiple channels including social media, and public engagement events such as webinars and in-person meetings.

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