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Interview study of the experiences of people engaging with the 'Breaking Free Online' digital therapy program for substance use

Submission date
20/06/2024

Recruitment status
Recruiting

Registration date
17/07/2024

Overall study status
Ongoing

Last Edited
18/08/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The nature of substance use difficulties can vary from person to person. For example, research has shown that a person's gender can be related to when they might first start using substances, what kinds of substances they use, and what mental health and other conditions they might experience alongside their substance use. Treatment services have often also traditionally been quite 'male-centric', with more men accessing treatment for substance use difficulties than women. Therefore, services might benefit from understanding how they might better bring women into treatment and meet their needs. This qualitative interview study will therefore explore the lived experiences of women who have received treatment for their substance use – specifically, women who have engaged with a digital treatment and recovery program for substance use difficulties, 'Breaking Free Online' (BFO). Because of its confidential nature, this novel intervention has the potential to help women with substance use challenges to access treatment where previously they may have felt unable to access such support.

Who can participate?
Cisgender or transgender women currently receiving treatment for their substance use who are over the age of 18 years, who are receiving either community-based treatment at Greater Manchester Mental Health (GMMH) Foundation Trust, or prison-based treatment provided by Spectrum Community Health CIC.

What does the study involve?
Interested parties can ask a member of the recovery staff to contact the Breaking Free research team on their behalf. Individuals receiving support for substance use in the community will be contacted directly by a member of the Breaking Free team, who will explain more about the research and, if they wish to participate, arrange a date and time for the interview. In the community, interviews can be conducted face-to-face at the service where treatment was received or via the internet using Microsoft Teams. A member of the Breaking Free research team will send an invite and link to the meeting via email and can also assist with using Teams if

necessary. For those receiving support for substance use difficulties in prison, a member of staff can contact the Breaking Free research team to arrange a date and time for a visit to explain the research and conduct the interview if the individual agrees to participate.

All participants will sign a consent form before their interview, which will take between 45 to 60 minutes and will be digitally recorded. The recording will be transcribed into a typed version, after which the digital recording will be deleted. The typed version of the interview will be anonymized, ensuring that any names or information that could be linked to a specific person are removed.

What are the possible benefits and risks of participating?
There may be some possible benefits to participating in the study. For example, speaking to a trained researcher about experiences related to substance use, life events that might be connected to substance use, and experiences of treatment and recovery might be helpful. Additionally, by sharing their experiences, participants will help ensure that the Breaking Free programme is delivered in a way that is sensitive to women's experiences and needs. It is unlikely that any harm will come to participants as a result of taking part in the study. However, because the main focus of this study will be on personal experiences, some of which might be difficult to think and talk about, participants' well-being will be a major priority during their participation. Participants do not have to discuss any topics or life experiences that might cause them to feel upset or distressed. If any upsetting emotions are experienced during the study, participants are encouraged to let the team know, and support will be provided in collaboration with their recovery team.

Where is the study run from?
TELUS Health Limited

When is the study starting and how long is it expected to run for?
September 2022 to August 2027

Who is funding the study?
TELUS Health Limited

Who is the main contact?
Dr Sarah Elison-Davies (Chief Investigator), sarah.elisondavies@telushealth.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
320529

Central Portfolio Management System (CPMS)
61692

Study information

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

Study objectives
The aims of this study are as follows:
1. Interview women in treatment for substance use disorder (SUD) about their paths to substance use, their lived experiences when living with SUD, and their experiences of treatment.
2. Specifically, interview women in SUD treatment who are engaging with the Breaking Free Online (BFO) program – interviews will also include questions on their views of BFO in terms of its user interface user journey, and clinical content.
3. Use qualitative data collected from interviews to develop materials to support the delivery of BFO with women – these materials will be in the form of a manual which can be used by practitioners supporting women 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/04/2023, Wales Research Ethics Committee 4 - Wrexham (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road, Wrexham, CF11 9AB, United Kingdom; +44 (0)2922 941119; Wales.REC4@wales.nhs.uk), ref: 23/WA/0051

Primary study design
Observational

Study design
Semi-structured qualitative interview study

Study type(s)
Other

Health condition(s) or problem(s) studied
Substance use disorders (SUD)

Interventions
From enrolment, participants will complete an informed consent procedure with a member of the Breaking Free research team. Participants will also be interviewed either in-person or via Microsoft Teams for those accessing treatment in the community – those accessing treatment in prison will be interviewed in person. Each interview will be digitally recorded, either using a digital Dictaphone for in-person interviews or, through using the 'record' function in Microsoft Teams. Digital recordings of in-person interviews will be sent to a professional transcription service to be transcribed verbatim – audio recordings of interviews will be deleted immediately following transcription. Transcriptions of Microsoft Teams interviews will be automatically generated using this functionality in the Teams application – audio recordings of interviews conducted via Teams will also be deleted immediately following transcription. All interview transcripts will be stored digitally on a secure cloud-based storage platform – all transcripts will be fully anonymised with any participant identifiable information deleted from the transcript.

Interview transcripts will be analysed using thematic analysis. Themes that will be explored in this study include, but are not limited to, the following:

What are the aetiological factors that can lead women to develop a SUD?
What kinds of consequences do women with SUD face as a result of their substance use?
What are women's experiences of seeking and accessing treatment and support for their SUD?
What are women's experiences of engaging with BFO when they are working on their recovery from SUD?
How do women feel about their future when they are working on their recovery from SUD (and rehabilitation from offending)?
Themes will be identified, and data conceptualised, through a number of theoretical lenses:

Feminist theory – there are several models of feminist theory, though the commonality among all of them is the attention towards power imbalances, oppression, and social justice. Feminist theory has been used in previous qualitative research involving women with SUD, including substance-involved mothers serving prison sentences.
Transgender theory – 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 – this theory provides a qualitative analytic framework to allow conceptualisation of how systems of power affect those who are most marginalised 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).

Intervention Type
Behavioural

Primary outcome(s)
Themes identified using feminist, transgender and intersectionality theories will be measured in interview transcripts using thematic analysis including, but not limited to, the following:
What are the aetiological factors that can lead women to develop a SUD?
What kinds of consequences do women with SUD face as a result of their substance use?
What are women's experiences of seeking and accessing treatment and support for their SUD?

What are women’s experiences of engaging with BFO when they are working on their recovery from SUD?
How do women feel about their future when they are working on their recovery from SUD (and rehabilitation from offending)?

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/08/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 18/08/2026:

1. Cisgender or transgender man or woman 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 the time of consent, as determined by Investigator
5. Problem alcohol or drug use present for ≥12 months at the 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

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Previous key inclusion criteria:

1. Cisgender or transgender woman 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 the time of consent, as determined by Investigator
5. Problem alcohol or drug use present for ≥12 months at the 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

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 18/08/2026:

1. Not receiving treatment for SUD
2. Has not engaged with BFO
3. Under 18 years old on the day of consent
4. Detention under the Mental Health Act at the time of consent
5. Untreated or unmanaged mental health difficulties that might impair the ability to participate in the interview
6. Clinically significant intellectual or developmental disability which may impair the ability to provide consent and participate in the interview

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Previous key exclusion criteria:

1. Gender identity that is not cisgender or transgender woman
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 the ability to participate in the interview
7. Clinically significant intellectual or developmental disability which may impair the ability to provide consent and participate in the interview

Date of first enrolment
01/09/2024

Date of final enrolment
01/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Trust Headquarters
Bury New Road
Prestwich
Greater Manchester
England
M25 3BL

Sponsor information

Organisation
Telus (Canada)

ROR
https://ror.org/040vbkv27

Funder(s)

Funder type
Industry

Funder Name
TELUS Health Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0	19/05/2025	07/11/2025	No	No