ISRCTN13694016 https://doi.org/10.1186/ISRCTN13694016

Breaking Free Online computer-assisted-therapy plus standard treatment versus standard treatment alone in participants with substance use disorders

Submission date
07/04/2021

Recruitment status
Recruiting

Registration date
25/05/2021

Overall study status
Ongoing

Last Edited
19/12/2024

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:
There is a growing evidence base to support the clinical effectiveness of computer-assisted therapies (CAT), designed to provide access to evidence-based therapeutic interventions such as cognitive-behavioural therapy (CBT) via the internet. Online interventions have not only been indicated to be effective at reducing levels of anxiety and depression when compared to standard treatment, but have also become increasingly popular in the treatment of substance use disorders (SUD). In substance-using populations, accessing interventions online may help to overcome barriers such as stigma and confidentiality concerns, and may also allow those who would otherwise be unable to access traditional services, for example, due to childcare/work responsibilities, rurality, or limited mobility, to access treatment.

In addition to these pre-existing barriers, 2020 saw severe disruption to in-person mental health and addiction services due to the coronavirus (COVID-19) pandemic. Effective, evidence-based support that can be delivered remotely is therefore likely to become increasingly important as healthcare services adapt to a new normal.

The Breaking Free Online (BFO) programme is a CAT intervention designed to help people understand what might be driving their drug and alcohol use, and provide them with skills and resources to help them gain control by following a personalised Lifestyle Balance Model that helps them prioritise the areas on which they need to focus to resolve the issues that are causing their difficulties. Typically delivered as either a one-to-one/group-working face-to-face intervention or self-directed programme within services, this study aims to evaluate the effectiveness of BFO when delivered via a 'telehealth' model. It is hoped that this study will allow services to determine the best way to deliver BFO as CAT in a post-COVID-19 environment.

Who can participate?
Adults experiencing problem alcohol and/or drug use for ≥12 months before entering the study. Participants must be able to read, write and communicate in the English language and be able to

access an internet-enabled device for the duration of the study. Participants will be excluded if they are pregnant, have participated in any other alcohol and/or drug-related clinical studies within the previous year, have used the Breaking Free Online programme within the last 12 months, or are detained under the Mental Health Act at the time of entering the study.

What does the study involve?
After being provided with information regarding the study and having the opportunity to ask questions, all individuals interested in participating will be asked to sign an Informed Consent Form. After informed consent is obtained, participants will enter a screening period, during which their eligibility for inclusion will be determined. Once determined to be eligible, participants will be randomised (randomly allocated) to either the Control group or Interventional group, with an equal chance of being in either group and shall be asked to complete an online baseline questionnaire. This questionnaire contains questions relating to the participant's substance use and frequency, quality of life, and mental health status, and takes around 10 minutes to complete.

After the baseline questionnaire is complete, participants will enter an 8-week treatment period. During this treatment period, participants in the Control group will receive standard treatment. Standard treatment may differ depending on the individual participant, and shall be decided by the participant's drug/alcohol service. It is expected that standard treatment will be delivered as a once-weekly session, lasting approximately 1 hour. Participants in the Intervention group will also receive standard treatment as above, and will also receive access to Breaking Free Online Limited. Intervention arm participants shall be encouraged to use the Breaking Free Online programme once weekly outside of their standard treatment. These participants shall also receive bi-weekly 'Recovery Check-In' phone calls, where they will have the opportunity to talk through their use of the programme with a recovery practitioner.

At the end of the treatment period, all participants will be asked to complete an end-of treatment online questionnaire. They will also be asked to complete an online questionnaire 3-months and 6-months after the end of the treatment period. These questionnaires shall be nearly identical to the baseline questionnaire completed before treatment started, and shall take approximately 10 minutes to complete. After the 6-month follow-up questionnaire has been completed, the participant's involvement in the study is over. Participants may, if they wish to, also take part in a post-trial qualitative interview where they will be asked questions about their use of the Breaking Free Programme. This post-study interview is completely optional.

What are the possible benefits and risks of participating?
Participants will receive a treatment programme that aims to help them to understand their difficulties with drugs and alcohol, and encourages them to gain control of these difficulties. However, as may happen with the standard treatment, it is possible that they may not, see any changes in their drug or alcohol use, lifestyle, or health due to taking part in this study. The information from this study will be used to further understand and make recommendations that may help the alcohol and drug services improve the treatment they provide for people with alcohol and drug problems, which will in return have potential benefits for the participants, families, and the whole of society.

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust (UK). Due to COVID-19 restrictions, it is possible that much of the study will be conducted remotely.

When is the study starting and how long is it expected to run for?
November 2020 to November 2025

Who is funding the study?
The Breaking Free Group (a wholly owned subsidiary of TELUS Health (UK) Ltd)

Who is the main contact?
1. Dr Sarah Elison-Davies, arah.elisondavies@telushealth.com (Research Director)
2. Lauren Pittard, lauren.pittard@telushealth.com (Clinical Research Manager)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
291734

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 291734

Study information

Scientific Title
A randomised, open-label, parallel-group study examining outcomes of Breaking Free Online computer-assisted-therapy plus standard treatment versus standard treatment alone in participants with substance use disorders: a telehealth approach

Study objectives
To measure the changes that the Breaking Free Online programme (delivered as a telehealth intervention) together with the standard treatment for alcohol or drugs, may be able to make on the lifestyle, health, and social function of people with alcohol or drug problems and whether these changes will be maintained after 6 months of completion of the treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/08/2021, Greater Manchester West REC (Meeting held by video-conference via Zoom, Manchester, -, United Kingdom; +44 (0)2071048379; gmwest.rec@hra.nhs.uk), ref: 21/NW/0191

Study design
Open-label parallel-group longitudinal randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact us to request a participant information sheet.

Health condition(s) or problem(s) studied
Substance Use Disorders

Interventions
Participants shall be randomised in a 1:1 manner to either receive Breaking Free Online plus concurrent Standard Treatment, or Standard Treatment alone. Interventions shall be delivered over an 8-week period, with participants in the intervention arm being encouraged to access the programme once weekly for approximately one hour per session. Standard Treatment shall also be delivered over 8 weeks, with the frequency of sessions being determined by the study site's standard procedures.

Standard Treatment:
Due to the heterogeneity of substance use disorders, standard treatment shall differ for each participant enrolled in the trial. Standard treatment shall be decided by the healthcare professional involved in the participant's care, and shall be documented within the case report form.

Breaking Free Online:
'Breaking Free Online' (BFO) is a tailorable Computer Assisted Therapy (CAT) 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 a target the biopsychosocial and lifestyle factors that underlie SUDs more generally. BFO has traditionally been delivered as a self-directed 'self-help' programme or as a structured one-to-one or groupwork programme where sessions are facilitated by a practitioner. For the purposes of this study, BFO shall be delivered via a 'telehealth' model, in which self-directed use of the programme is supported by 'recovery check-in' phone calls on a bi-weekly basis for an 8 week period.

Where possible, engagement shall also be assessed via qualitative data, collected via semi-structured interviews with both participants and practitioners at the end of the study. These interviews will explore a number of topics, including participants' experiences of substance misuse and previous treatment they might have received. Participants will also be interviewed about their views of the BFO program, how they think it might be improved and any barriers or facilitators of implementation of the programme via a telehealth model. These interviews will be conducted within using videoconference software (e.g. GoToMeeting, Zoom, Microsoft Teams etc.) and will last approximately 30-45 min.

Intervention Type
Behavioural

Primary outcome measure
Efficacy of Breaking Free Online measured using self-reported substance use using questions about weekly primary substance use ('How many days in the past week did you use [primary substance]?', and 'How much [primary substance] did you use each day?') and use and frequency of use of secondary substances ('Do you use any other substances in addition to [primary substance]?', 'How many days in the past week did you use [secondary substance]?', and 'How much [secondary substance] did you use each day?') at baseline, 8 weeks, 3, and 6 months

Secondary outcome measures
1. Efficacy of Breaking Free Online measured using the following at baseline, 8 weeks, 3, and 6 months:

1.1. Severity of substance dependence measured using the alcohol and drug-specific versions of the Severity of Dependence Scale (SDS)
1.2. Prevalence and severity of concurrent depression and anxiety measured using the Patient Health Questionnaire (PHQ-4)
1.3. Quality of life measured using the World Health Organization Quality of Life measure (WHOQoL-BREF)
1.4. Biopsychosocial functioning measured using Recovery Progression Measure (RPM)
2. Participant engagement with BFO measured using the following
2.1. The number of hours participant spends on BFO, the number of BCTs completed within BFO (how many of the 12 BCTs in the program were completed), and the total number of times each BCT was completed, captured by the backend BFO database during the 8 week treatment period
2.2. Qualitative data collected via semi-structured interviews with both participants and practitioners at 8 weeks

Overall study start date
10/11/2020

Completion date
01/11/2025

Eligibility

Key inclusion criteria
1. Aged ≥18 years or above on the day of consent
2. Experiencing problem alcohol and/or drug use at the time of consent, as determined by Investigator
3. Problem alcohol or drug use present for ≥12 months at the time of consent, as self-reported
4. Willing to comply with an 8-week treatment programme for problem alcohol and/or drug use
5. Willing to provide outcome measures post-treatment, and at 3- and 6-months follow-up
6. Able to read, write and communicate in the English language
7. Able to access an internet enabled device for the duration of the study
8. Able to access a telephone or video-communication enabled device for the duration of the 8-week treatment period
9. Willing and able to give informed consent for participation in the study, and capable of understanding and complying with protocol requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
183

Key exclusion criteria
Current participant exclusion criteria as of 05/07/2023:
1. Participation in any other alcohol and/or drug-related clinical studies within 12 months prior to the date of consent
2. Detention under the Mental Health Act at the time of consent
3. Clinically significant intellectual or developmental disability which may impair the ability to engage with the Breaking Free Online treatment programme and/or complete the necessary assessment measures included in the methodology, as determined by the Investigator
4. Pregnancy (as self-reported) at the time of consent
5. Use of the Breaking Free Online programme for the purposes of alcohol or drug use intervention within 12 months prior to study enrolment

Previous participant exclusion criteria:
1. Participation in any other alcohol and/or drug-related clinical studies within 12 months prior to the date of consent
2. Detention under the Mental Health Act at the time of consent
3. Clinically significant intellectual or developmental disability which may impair the ability to engage with the Breaking Free Online treatment programme and/or complete the necessary assessment measures included in the methodology, as determined by the Investigator
4. Pregnancy (as self-reported) at the time of consent
5. Previous use of the Breaking Free Online programme for the purposes of alcohol or drug use intervention

Date of first enrolment
03/07/2023

Date of final enrolment
01/11/2025

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
The Breaking Free Group (a wholly owned subsidiary of TELUS Health (UK) Ltd)

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Sponsor type
Industry

Website
https://www.breakingfreegroup.com

Funder(s)

Funder type
Industry

Funder Name
The Breaking Free Group (a wholly owned subsidiary of TELUS Health (UK) Ltd)

Results and Publications

Publication and dissemination plan
Results from data analyses shall be published in high-impact peer reviewed journals once all data have been collected and analysed.

Intention to publish date
10/10/2026

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	01/04/2021	04/11/2021	No	No
Protocol article		02/06/2023	05/06/2023	Yes	No
HRA research summary			28/06/2023	No	No