

# Breaking Free Online Health and Justice outcomes in prisons

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<b>Registration date</b> 01/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/09/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

An extensive body of evidence-based literature may be found to support psychosocial intervention approaches for drug and alcohol difficulties within criminal justice populations. However, limited research has been conducted to date regarding with the use of online interventions in this population. This study therefore aims to find out whether Breaking Free Online Health and Justice, a web-based computerised treatment programme for people with alcohol and/or drug problems, can support services users in UK prisons to stop using drugs and alcohol and make changes to their lifestyle, health and whether these changes will be maintained following completion of the treatment. The aims of the Breaking Free programme is to enable people to understand what might be driving their drugs 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.

### Who can participate?

1. Male or female participants with problem alcohol and/or drug use aged 18 to 65 years
2. Participant is willing and able to give informed consent for participation in the study
3. Is serving a prison sentence of at least 4 months
4. Problem alcohol and/or drug use present for more than 12 months
5. Participant is not following standard treatment for alcohol and/or drug misuse at the time of recruitment into the study
6. Willing to follow a treatment for problem alcohol and/or drug use for 4 weeks
7. Willing to provide outcome measures at 3- and 6-months follow-up
8. Concomitant alcohol and drug/s use permitted, as well as any prescribed medication

### What does the study involve?

This is a randomised controlled study, which means it will compare people who have used the Breaking Free programmes with people who have not used them in a randomised manner, that is, based on chance.

The participants will be randomly allocated to one of the following groups:

1. Breaking Free Online Health and Justice treatment programme assisted by a trained service worker (investigational group) plus standard treatment.

## 2. Standard treatment (control group).

This study will consist of a 4-week treatment period for problem alcohol and drug use, via the Breaking Free programme which will be provided in addition to the standard treatment provided by prison alcohol and drug misuse services. The treatment sessions will have a total duration range of 8 sessions run over a period of 4-weeks, with each session lasting 60 minutes. All participants will be asked to provide urine samples to test for drug use and also answer questions about their alcohol or drug use and how this affects their lifestyle before and after receiving treatment and later on, at 3 and 6 months. The total duration of the study is 9 months for all participants.

### What are the possible benefits and risks of participating?

Participants will receive a treatment programme which will aim to help them to understand their difficulties and to gain control by following a personalised model. However, as may happen with the standard treatment, it is possible that they may, or 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 and families and the whole of society.

There are no known risks or adverse effects expected. Any information you provide will be used only for the purposes for which it is collected, and not in any other way without your consent.

### Where is the study run from?

The study will take place in participating alcohol and drug services within UK prisons, these will be the main contact point for future participants.

### When is the study starting and how long is it expected to run for?

January 2014 to April 2022

### Who is funding the study?

Breaking Free Online Ltd (UK)

### Who is the main contact?

Dr Sarah Elison-Davies (Research Director)  
selison@breakingfreegroup.com

### Study website

<http://www.breakingfreeonline.com>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Sarah Elison-Davies

### Contact details

Breaking Free Online Limited  
Williams House  
Manchester Science Park

Lloyd Street North  
Manchester  
United Kingdom  
M14 6SE  
+44 (0)161 834 4647  
selison@breakingfreegroup.com

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

A parallel-group comparison of the 8-session Breaking Free Online Health and Justice programme delivered over 4-weeks as an adjunct to standard treatment for substance misuse, in criminal justice settings

### **Study objectives**

Current hypothesis as of 19/01/2018:

This multi-centre randomised controlled study aims to measure the changes that the Breaking Free Online Health and Justice programme, 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.

Current hypothesis as of 21/08/2014:

This multi-centre randomised controlled study aims to measure the changes that the Breaking Free Online Health and Justice, and Breaking Free Pillars of Recovery group and key working programmes, 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.

Previous hypothesis:

This multi-centre randomised controlled study aims to measure the changes that Breaking Free Online, 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 problem and whether these changes will be maintained after 12 months of completion of the treatment.

### **Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Current ethics approval as of 18/09/2020:

Approved 30/08/2017, NHS North West Greater Manchester West REC (Health Research Authority, Third Floor, Barlow House, Minshull Street, M1 3DZ); ref 17/NW/0422

Previous ethics approval:

Research Ethics Committee (UK) and R&D Offices (UK)

## **Study design**

Multi-centre randomised controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other

## **Study type(s)**

Treatment

## **Participant information sheet**

<http://mesarch.coventry.ac.uk/wp-content/uploads/2019/10/Cohort-study-PIS-ONLINE.pdf>

## **Health condition(s) or problem(s) studied**

Alcohol and/or drug misuse/dependence in prisoners

## **Interventions**

Current interventions as of 19/01/2018:

1. Standard treatment - prior to performing the standard treatment, assessments /questionnaires are carried out as routine by the key workers in the alcohol and drug misuse services. The most used of these assessments is the Treatment Outcome Profile (TOP). The main components of the standard low-intensity interventions, defined as motivational and treatment engagement tools to reduce substance misuse, are delivered by the key workers in the alcohol and drug misuse services and include techniques such as Motivational Interviewing and Contingency Management. Some participants will be required to follow high-intensity interventions for drug-specific and/or common mental health problems, delivered by a specialist psychological therapist through CBT-based interventions. The treatment may also require delivering Detoxification and prescriptive basic ITEP (International Treatment Effectiveness Programme)

2. Intervention group: the Breaking Free Online Health and Justice (online programme) is administered

This treatment programme aims to help people to understand the difficulties driving their drug and alcohol use and to gain control by following a personalised Lifestyle Balance Model that helps them prioritise the areas on which they need to focus to resolve their difficulties. Psychometric assessments will be performed which comprise standardised validated questionnaires.

Previous interventions as of 21/08/2014:

1. Standard treatment - prior to performing the standard treatment, assessments/questionnaires are carried out as routine by the key workers in the alcohol and drug misuse services. The most used of these assessments is the Treatment Outcome Profile (TOP). The main components of the standard low-intensity interventions, defined as motivational and treatment engagement tools to reduce substance misuse, are delivered by the key workers in the alcohol and drug misuse services and include techniques such as Motivational Interviewing and Contingency Management. Some participants will be required to follow high-intensity interventions for drug-specific and/or common mental health problems, delivered by a specialist psychological therapist through CBT-based interventions. The treatment may also require delivering Detoxification and prescriptive basic ITEP (International Treatment Effectiveness Programme)

2. Intervention group: the Breaking Free treatment programmes will be administered:

2.1. Breaking Free Online Health and Justice (online programme)

2.2. Breaking Free Pillars of Recovery (group and key working programme)

This treatment programme aims to help people to understand the difficulties driving their drug and alcohol use and to gain control by following a personalised Lifestyle Balance Model that helps them prioritise the areas on which they need to focus to resolve their difficulties. Urinalysis and psychometric assessments will be performed which comprise standardised validated questionnaires.

Previous interventions:

1. Standard treatment - prior to performing the standard treatment, assessments/questionnaires are carried out as routine by the key workers in the alcohol and drug misuse services. The most used of these assessments is the Treatment Outcome Profile (TOP). The main components of the standard low-intensity interventions, defined as motivational and treatment engagement tools to reduce substance misuse, are delivered by the key workers in the alcohol and drug misuse services and include techniques such as Motivational Interviewing and Contingency Management. Some participants will be required to follow high-intensity interventions for drug-specific and/or common mental health problems, delivered by a specialist psychological therapist through CBT-based interventions. The treatment may also require delivering Detoxification and prescriptive basic ITEP (International Treatment Effectiveness Programme)

2. Intervention group: the Breaking Free Online treatment programme will be administered. This web-based computerised treatment programme aims to help people to understand their difficulties and to restore 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 the cause of and maintain alcohol or drug dependence. A psycho-social assessment will be performed which comprises standardised validated questionnaires. The programme includes features like the personal progress check during the treatment and a personal toolbox of resources that can be downloadable (print, email or MP3 audio).

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Current primary outcome measure as of 18/09/2020:

Substance consumption assessed by online self-administered psychosocial assessments at baseline, 4 weeks, 3 months and 6 months post-treatment

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Previous primary outcome measure as of 30/08/2019:

Proportion of participants who have achieved a reduction from baseline in substance use consumption assessed by online self-administered psychosocial assessments

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Previous primary outcome measure from 21/08/2014 to 30/08/2019:

Proportion of participants who have achieved a reduction from baseline in substance use consumption assessed by urinalysis

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Original primary outcome measure:

Proportion of participants who have achieved a reduction from baseline in substance use consumption assessed by online self-administered psychosocial assessments

## **Secondary outcome measures**

Current secondary outcome measures as of 18/09/2020:

All measures assessed at baseline, 4 weeks, 3 months and 6 months post-treatment

1. Mental health sequelae assessed using the Patient Health Questionnaire (PHQ-4), which has been built into the 'progress check' function of the Breaking Free Online digital platform, which is completed by participants assigned to the Breaking Free treatment arm at 4-weeks post treatment-engagement, and into paper questionnaires for all other participants and timepoints
  2. Re-offending. Participants are asked at each follow-up whether they have exhibited any behaviour that has seen them get 'in trouble' with the authorities.
  3. Treatment engagement and treatment completion rates assessed using the Breaking Free digital platform
  4. Perceived ability to reduce or abstain from using alcohol or drugs assessed using the Severity of Dependence Scale (SDS), which has been built into the 'progress check' function of the Breaking Free Online digital platform and is completed by participants assigned to the Breaking Free treatment arm at 4-weeks post treatment-engagement, and into paper questionnaires for all other participants and timepoints
  5. Total amount of time spent engaged with each of the three treatments assessed using the Breaking Free digital platform
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Previous secondary outcome measures as of 19/01/2018:

1. Self-reported substance dependence
  2. Mental health sequelae
  3. Re-offending
  4. Treatment engagement and treatment completion rates
  5. Perceived ability to reduce or abstain from using alcohol or drugs
- Total amount of time spent engaged with each of the three treatments
-

Previous secondary outcome measures as of 21/08/2014:

1. Self-reported substance use
  2. Mental health sequelae
  3. Re-offending
  4. Treatment engagement and treatment completion rates
  5. Perceived ability to reduce or abstain from using alcohol or drugs
- Total amount of time spent engaged with each of the three treatments
- 

Previous secondary outcome measures:

1. Change of health outcomes from baseline compared to standard treatment assessed by online self-administered psychosocial assessments:
  - 1.1. Treatment engaging and treatment completion rates
  - 1.2. Perceived ability to manage risk in using alcohol or drugs (including injecting risk behaviour)
  - 1.3. Perceived emotional well-being
  - 1.4. Perceived physical health, mental health and lifestyle
2. Change of social function outcomes from baseline compared to standard treatment assessed by online self-administered psychosocial assessments (only applicable to the relevant investigational populations):
  - 2.1. Reoffending
  - 2.2. Perceived ability to engage with education/employment

**Overall study start date**

01/01/2014

**Completion date**

22/04/2022

## Eligibility

### Key inclusion criteria

Current inclusion criteria as of 30/08/2019:

1. Male or female participants with problem alcohol and/or drug use aged 18 to 65 years
2. Participant is willing and able to give informed consent for participation in the study
3. Is serving a prison sentence of at least 4 months
4. Problem alcohol and/or drug use present for more than 12 months
5. Participant is not following standard treatment for alcohol and/or drug misuse at the time of recruitment into the study
6. Willing to follow a treatment for problem alcohol and/or drug use for 4 weeks
7. Willing to provide outcome measures at 3- and 6-months follow-up
8. Concomitant alcohol and drug/s use permitted, as well as any prescribed medication

Previous inclusion criteria from 19/01/2018 to 30/08/2019:

1. Male or female participants with problem alcohol and/or drug use aged 18 to 65 years
2. Participant is willing and able to give informed consent for participation in the study
3. Is serving a prison sentence of at least 4 months
4. Problem alcohol and/or drug use present for more than 12 months
5. Participant is not following standard treatment for alcohol and/or drug misuse at the time of recruitment into the study

6. Willing to follow a treatment for problem alcohol and/or drug use for 8 weeks
7. Willing to provide outcome measures at 6-months follow-up
8. Concomitant alcohol and drug/s use permitted, as well as any prescribed medication

Previous inclusion criteria from 21/08/2014 to 19/01/2018:

1. Male or female participants with problem alcohol and/or drug use aged 18 to 65 years
2. Participant is willing and able to give informed consent for participation in the study
3. Is serving a prison sentence of at least 4 months
4. Problem alcohol and/or drug use present for more than 12 months
5. Participant is not following standard treatment for alcohol and/or drug misuse at the time of recruitment into the study
6. Willing to follow a treatment for problem alcohol and/or drug use for 12 weeks
7. Willing to provide outcome measures at 6-months follow-up
8. Concomitant alcohol and drug/s use permitted, as well as any prescribed medication

Previous inclusion criteria:

1. Male or female participants with problem alcohol and drug use aged 18 to 65 years
2. Participant is willing and able to give informed consent for participation in the study
3. E-mail account user for the length of the study
4. Problem alcohol and drug use present for more than 6 months
5. Admitted at point of referral via standard services
6. Not following standard treatment for alcohol and drug misuse at the moment of study recruitment
7. Willing to follow a treatment for problem alcohol and drug use for 12 weeks
8. Willing to provide outcome measures at follow-up time points (3, 6 and 12 months after treatment)
9. Concomitant alcohol and drug/s use permitted, as well as any prescribed medication

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

128

### **Key exclusion criteria**

Current exclusion criteria as of 19/01/2018:

1. Male or female participants with problem alcohol and/or drug use aged under 18 or over 65 years
2. Participation in any other alcohol and/or drug-related clinical studies\*
3. Is serving a prison sentence of less than 4 months
4. Participants detained under the Mental Health Act
5. Participants with a known and diagnosed intellectual or developmental disability which may

impair their ability to engage with the Breaking Free Online Health and Justice treatment programme and complete the necessary assessment measures included in the methodology

6. Participants who report they are pregnant
7. Non-English-speaking participants (study information material and programme only produced in English)

Previous exclusion criteria as of 21/08/2014:

1. Male or female participants with problem alcohol and/or drug use aged under 18 or over 65 years
2. Participation in any other alcohol and/or drug-related clinical studies\*
3. Is serving a prison sentence of less than 4 months
4. Participants detained under the Mental Health Act
5. Participants with a known and diagnosed intellectual or developmental disability which may impair their ability to engage with the Breaking Free Online Health and Justice and Breaking Free Pillars of Recovery treatment programmes and complete the necessary assessment measures included in the methodology
6. Participants who report they are pregnant
7. Non-English-speaking participants (study information material and programme only produced in English)

Previous exclusion criteria:

1. Participants with problem alcohol and drug use aged under 18 or over 65 years
2. Participation in any other alcohol and drug related clinical studies\*
3. Detained under the Mental Health Act
4. Presence of permanent cognitive impairment or psychotic symptoms
5. Participants who are known to be pregnant
6. Non-English speaking participants (as study information material and programme only produced in English)

\* = With the exception of the Integrated Drug Treatment System (IDTS) Evaluation

**Date of first enrolment**

14/02/2019

**Date of final enrolment**

08/09/2021

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Breaking Free Online Limited**

Williams House

Manchester Science Park

Lloyd Street North

Manchester

United Kingdom  
M14 6SE

**Study participating centre**

**HMP Kirkham**  
Freckleton Road  
Preston  
United Kingdom  
PR4 2RN

**Study participating centre**

**HMP Preston**  
2 Ribblesdale Lane  
Preston  
United Kingdom  
PR1 5AB

## **Sponsor information**

**Organisation**

Breaking Free Online (UK)

**Sponsor details**

Williams House  
Manchester Science Park  
Lloyd Street North  
Manchester  
England  
United Kingdom  
M14 6SE

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.breakingfreeonline.com>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Breaking Free Online Ltd (UK)

## Results and Publications

**Publication and dissemination plan**

Results from data analyses will be published in high-impact peer reviewed journals when all data have been collected and analysed.

**Intention to publish date**

01/10/2022

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	03/11/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No