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Pilot Feasibility Study of Cognitive Control in Cocaine Dependence

Submission date
25/08/2015

Recruitment status
No longer recruiting

Registration date
28/08/2015

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Heroin and crack cocaine are amongst the most addictive drugs on the market, and are two of the most commonly treated drug problems by the NHS in England. In many cases however, treatment is do not work, as the drug is being taken by the user at the same time as they are being treated. There are currently no NICE-approved medications for people who are dependent on cocaine available, and the existing talking therapies that are provided have not been found to be particularly effective for routine users. National outcome monitoring data for England shows that 60% of heroin users and 70% of cocaine users continue to use these drugs after 6 months of treatment, and so better treatments are urgently required. 'Craving' is considered to be one of the most important parts of addiction, and the main reason for continued use and relapse. Similarities have been found between these the behaviour accompanying these cravings and to the behaviour of people suffering from post-traumatic stress disorder (PTSD). It may therefore be possible to adapt memory consolidation techniques (a process of changing memories stored in the long-term memory) used in cognitive behavioural therapy for people with PTSD, to target cravings. This study aims to find out whether these techniques could be used to reduce the intensity of cravings in cocaine dependant individuals.

Who can participate?
Adults with a current diagnosis of cocaine dependence who want to reduce or quit taking cocaine.

What does the study involve?
At the start of the study, all participants take a questionnaire in order to find out how intense their craving is. Participants are then randomly divided into two groups. The first group (experimental group) takes part in a five day memory reconsolidation (to modify the "positive" memories of the effects of the drug) and cognitive restructuring (learning to identify and resist irrational thoughts) protocol. The second group (control group) receives no intervention. The questionnaire about their craving intensity is then repeated after one week, four and twelve weeks..

What are the possible benefits and risks of participating?
A potential benefit is that the participants in the experimental group will be taking part in a new

protocol that is designed to make them more aware of the things that trigger their drug use and may be able to have greater control over their cravings. There are risks to participants because the study is intended to induce urges to use cocaine and in order to investigate assess craving reduction over the course of the study. There are measures in place to help the participants however, such as receiving a 'talk down' session so that they will not leave until the cravings have subsided, as well as being offered transport home.

Where is the study run from?
1. Beresford Project, South London and Maudsley NHS Foundation Trust (UK)
2. Lorraine Hewitt House, South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2016 to February 2018

Who is funding the study?
Kings College London, Biomedical Research Centre (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1.0

Study information

Scientific Title
Pilot Feasibility Study of Cognitive control in cocaine dependence: A multi-centre randomized controlled trial to pilot targeting craving for cocaine using memory reconsolidation techniques

Study objectives
This pilot study has two aims:
1. To evaluate the feasibility of our research data collection, craving cue-reactivity and cognitive restructuring methods
2. To ascertain the clinically meaningful effect on craving intensity arising from our addiction cognitive control intervention to inform a formal randomized controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee, Fulham (London), 12/05/2015, ref: 15/LO/0656

Study design
Multi-centre randomized controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cocaine dependence

Interventions
Informed, consenting adult participants will be randomised remotely by the Clinical Trials Unit Kings College, London to one of two conditions:

Experimental Group: Experiment: Baseline cocaine craving provocation and assessment: research follow-ups at 1 and 4 weeks. After baseline assessment experimental participants will be encouraged to 'relive' craving and cocaine use memories followed in week 1 by a 5-day memory reconsolidation and cognitive restructuring protocol targeting repeated cocaine craving. Research follow-ups at 1 and 4 weeks, and at 12 weeks.

Control Group: Baseline and repeated cocaine craving provocation, assessment and research follow-ups at 1 and 4 weeks, and at 12 weeks

A 'talk down' procedure will be undertaken at the end of each session to ensure a participant does not leave a research session until any cravings induced are negated.

Intervention Type
Behavioural

Primary outcome measure
Change in craving intensity. Measured using the craving experience questionnaire (CEQ-11), adapted for cocaine for this study, at weeks 1 and 4 post randomization.

Secondary outcome measures
1. Physiological parameters during the craving provocation and memory reconsolidation and cognitive restructuring sessions: pulse rate, heart rate variability, electrodermal activity and skin conductance response. Mean and peak values will be computed: Days 1 to 5 of the intervention period
2. Self-report of cocaine useis assessed using a modified time-line follow-back (calendar prompt) interview to record instances of cocaine use during the study at weeks 1, 4 and 12 post randomization
3. Urine toxicology screening (UDS). By instant result immunoassay device for cocaine metabolite (benzolyecgonine) and morphine (morphine 2000 assay) at weeks 1, 4 and 12 post randomization and days 1 to 5 of the intervention
4. Audio-visual recordings: On a voluntary basis, each CRF session will be audio and video recorded via CCTV at the CRF
5. Treatment retention is assessed by recording the number of experimental participants who complete the 5-day CRF programme

Overall study start date

01/06/2015

Completion date
02/02/2018

Eligibility

Key inclusion criteria
1. Adult (between 18 and 50 years old)
2. English speaking
3. Current diagnosis for cocaine dependence (ICD-10)
4. Self-reported regular cocaine use (weekly) and cocaine-positive UDS during screening
5. Motivation to reduce or quit cocaine use

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Current diagnosis of post-traumatic stress disorder (DSM-5)
2. Current non-medical benzodiazepine or harmful alcohol use (>50 units per week men; >35 units women)
3. Use of heroin or cocaine in the 24 hours before first CRF session
4. Clinically significant on-going medical problems that might make participation unsafe
5. Acute housing instability
6. Uncontrolled serious psychiatric illness
7. Significant neuro-cognitive functioning (<18, Montreal Cognitive Assessment)
8. Pregnant or breast feeding
9. Current enrollment in an addiction treatment related clinical research study

Date of first enrolment
01/06/2015

Date of final enrolment
30/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Beresford Project
South London and Maudsley NHS Foundation Trust
36-42 Hare Street
Woolwich
London
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SE18 6LZ

Study participating centre
Lorraine Hewitt House
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Sponsor information

Organisation
Kings College London

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
Kings College London (Biomedical Research Centre)

Results and Publications

Publication and dissemination plan
Two papers will be published in a peer review journal (to be determined).

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
Participation level data it is not expected to be made available due to conditions of research ethical approvals secured for the study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018		Yes	No
HRA research summary			20/09/2023	No	No