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The Addiction Recovery Clinic (ARC): personalised behavioural intervention for opioid use disorder

Submission date
13/05/2013

Recruitment status
No longer recruiting

Registration date
23/05/2013

Overall study status
Completed

Last Edited
08/04/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[ ] Statistical analysis plan

[X] Results

[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Illicit heroin (illicit drug) has a very high risk of addiction, the main symptom being compulsive drug use despite significant health and social harms. Currently, the majority of people presenting to specialist NHS community treatment clinics have established harmful illicit opioid addiction (drug addiction) but the addiction to cocaine adds considerable severity and this type of patient has a relatively poorer treatment outcome compared to primary heroin users. In the NHS, the standard treatment to heroin dependence is the prescription of a substitute (full or partial) μ-opioid agonist (a medicine) taken once daily along with general counselling support (TAU). About 60-70% retained in treatment for at least six months. However, not all patients derive a clinical benefit. Some respond initially, then resume heroin use during the treatment; a minority deteriorate progressively during the treatment. A Personalised Behavioural Intervention (PBI) has been developed which adapts and integrates techniques from evidence-based, approved psychological treatment for patients who have not responded to standard treatment. The aim is to enable these patients to refrain from heroin and cocaine use.

Who can participate?
Patients who attend Lorraine Hewitt House (LHH), an NHS treatment centre in London and who have received at least 6 weeks of treatment within the clinic service but are still using heroin or cocaine

What does the study involve?
The PBI combined with TAU is compared against TAU alone. Potential participants are selected from those who self-report of heroin use or cocaine use via an interview which is confirmed by an on-site urine test for the presence of these drugs. All participants are provided with written and verbal information about what is required during participation in the study. Those patients refusing to participate receive the standard treatment package at LHH. Participants are randomly allocated to one of two groups using an automated system. Thereafter, participants in the PBI group attend 12 weekly PBI sessions and TAU sessions (case management and general counselling) weekly or fortnightly. Participants in the TAU group only attend case management and general counselling support sessions on a weekly or fortnightly basis. All participants

continue to receive treatment as clinically indicated with supervised consumption at community pharmacies. A variety of factors are measured at baseline and at the final follow-up. Further, some of the factors are measured at three points during the 12-week treatment period. In addition, participants are also given the option of participating in two further studies:
1. To provide a DNA sample for research into genetic factor links to treatment response
2. To participate in a longer term study to find out what happens to participants in the study over the next 5 years
They are asked to allow their personal details to be flagged on three public databases: National Drug Treatment Monitoring System (NDTMS), Police National Computer (PNC), NHS Registry of Births and Deaths (NHSCR).

What are the possible benefits and risks of participating?
There are no confirmed direct benefits to participants. There are no greater risks than would occur in the standard treatment program.

Where is the study run from?
Lorraine Hewitt House (LHH), an NHS treatment centre in London, UK

When is the study starting and how long is it expected to run for?
October 2012 to April 2018

Who is funding the study?
Action on Addiction (UK)

Who is the main contact
Prof. John Marsden
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Contact information

Type(s)
Scientific

Contact name
Prof John Marsden

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ARC2_LHH_2013

Study information

Scientific Title
The Addiction Recovery Clinic (ARC): personalised behavioural intervention for opioid use disorder: a randomised controlled trial

Acronym
ARC

Study objectives
Is there any difference in the clinical and cost effectiveness of a 12-week personalised behavioural intervention (PBI) and treatment-as-usual (TAU) compared to TAU alone at achieving heroin and cocaine abstinence and improved health-related quality of life economic outcomes among patients continuing to receive specialist NHS addictions treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bromley London NRES Research Ethics Committee, 05/06/2013, ref: 13/LO/0640

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Opiate dependency

Interventions
Personalised Behavioural Intervention (PBI): The PBI will be delivered in 12 one hour sessions weekly. The PBI will be tailored to each clients needs and circumstances. The PBI psychologists on the ARC team at LHH will work with clients using techniques derived and adapted from four core therapeutic approaches below recommended by the National Institute of Clinical Excellence. A menu of additional therapeutic methods will be available for use delivered according to patient preference and clinical indication e.g. 12-step facilitation.
1. Motivational enhancement therapy
2. Cognitive behavioural coping and skills training
3. Contingency management (reinforcement therapy)
4. Community reinforcement approach (network member support for recovery)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Self-report of heroin use or cocaine use via structured clinical interview and individual diary record, confirmed by rapid-result (on-site) urine screen for morphine and cocaine metabolites. Outcome measures taken at baseline following recruitment into the study and at 14 weeks after recruitment on last day in the study

Secondary outcome measures
Current secondary outcome measures as of 02/05/2017:
Measured at baseline and at 14 weeks after recruitment on last day in the study
1. Percentage of self-reported heroin and cocaine abstinent days during 28 days prior to final follow-up interview
2.Recorded treatment retention and psychological therapy adherence rates
3. Measures of heroin and cocaine craving
4. Measures of the overall costs associated with PBI/TAU and TAU alone treatment configurations

Previous secondary outcome measures:
Measured at baseline and at 14 weeks after recruitment on last day in the study:
1. Recorded treatment retention and psychological therapy adherence rates
2. Measures of heroin and cocaine craving
3. Measures of the overall costs associated with PBI/TAU and TAU alone treatment configurations

Overall study start date
05/10/2012

Completion date
20/04/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/05/2017:
1. 18 years of age or older (no upper limit, but generally <60yrs)
2. Undergoing treatment at Lorraine Hewitt House for a minimum of 6 weeks by the date of randomisation
3. Able to comprehend English to the extent required by the study protocol
4. Demonstrates verbal understanding of the study patient information material
5. Able to provide written consent and can understand and confirm willingness to comply with the protocol
6. Current diagnosis of opioid dependence
7 .Currently prescribed methadone or buprenorphine mono or combination therapy
8. Self reported use heroin and/or cocaine use (verified by urine drug screen toxiology test)
9. Voluntarily seeking treatment and able to attend the clinic as described in the protocol
10. Lives in sufficiently stable accommodation in the community, with a personal phone
11. Can nominate at least one locator individual (e.g. a family member, friend or recovery mentor) with a verifiable address and a telephone number which we can call to assist as necessary with the arrangement of follow-up appointments

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Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
380

Key exclusion criteria
1. Clinically significant medical conditions other than addiction that may compromise subject safety or study conduct; or any abnormality which, in the investigator's judgment, is clinically significant.
2. Current criminal justice involvement with legal proceedings and in the opinion of the chief Investigator, is expected to fail to complete the study protocol due to incarceration or relocation from the centre's catchment area
3. Current (past 30 day) suicidal planning or recent (past six months) suicidal ideation or suicide attempt
4. Active, uncontrolled severe mental illness (e.g. psychosis, bipolar I disorder, schizoaffective disorder - addressed in routine admissions protocol) and/or a history or evidence of organic brain disease or dementia that would compromise the participant's ability to comply with the study protocol
5. Has been in any research study in the past 30 days or an intervention research study in the past 6 months

Date of first enrolment
05/06/2013

Date of final enrolment
21/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lorraine Hewitt House
London
United Kingdom
SW9 8DG

Sponsor information

Organisation
King's College London (UK)

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Action on Addiction

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are 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?
Protocol article	protocol	01/02/2017		Yes	No
Results article	results	01/05/2019		Yes	No
HRA research summary			28/06/2023	No	No