

Impulsive Lifestyle Counselling (ILC)

Submission date 17/07/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/10/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/06/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Some people who abuse alcohol or other drugs also have persistent problems with impulsive behaviour, crime and aggression. This is called an antisocial personality disorder. There is currently no specialized help for people with these problems in outpatient substance abuse treatment services.

Who can participate?

Men and women, aged over 17, who have attended substance abuse treatment services in Denmark.

What does the study involve?

The study involves a brief interview and the completion of a questionnaire. After this, half the participants receive the best standard of care at their local substance abuse treatment unit. The other half receive the same care plus six sessions of counselling and information about impulsive and aggressive behaviour. The treatment to which a participant is allocated to is decided by a process called randomisation, which is like a coin toss. Three months after this, all participants are invited to an interview about their current situation and the treatment they have received.

What are the possible benefits and risks of participating?

There are no immediate benefits to participating. If the counselling program turns out to be helpful, participation may help future patients receive a better standard of care. The same standard of care applies to all patients whether or not they choose to participate, and they can withdraw from the study at any time.

Where is the study run from?

University of Aarhus (Denmark).

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

March 2012 to July 2013

Who is funding the study?

1. Reckitt Benckiser (Denmark)
2. University of Aarhus (Denmark)

Who is the main contact?
Associate Professor Morten Hesse
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
438155 ILC

Study information

Scientific Title
The efficacy of the Impulsive Lifestyle Counselling as an addition to standard substance abuse treatment

Acronym
ILC

Study objectives
The Impulsive Lifestyle Counselling will reduce aggression and drug use in outpatients with substance use disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Denmark

Study design

Multisite open randomized trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

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

Antisocial personality disorder

Interventions

Treatment as usual (TAU):

All participants in the control group receive treatment as usual, i.e. whatever treatment they would have received if the trial had not been taking place. Treatment as usual include casework, whatever counseling models each of the participating clinics provide, opioid substitution treatment, referral to psychiatric treatment as needed.

Experimental treatment:

Patients in the experimental condition receive treatment as usual, and are additionally offered a 6-session therapy based on the Lifestyle Issues program developed by Glenn D. Walters. In line with the Criminal Lifestyle Theory, the ILC program is presented as an approach to change the clients life.

All six sessions take one hour. The first 5 sessions focus on separate issues: session 1 focuses on educating the client about the treatment approach, increasing awareness of problems associated with an impulsive lifestyle, and identifying client goals. Session 2 uses a problem-solving approach to identify concrete difficult situations that the client encounters in daily life. Session 3 focuses on streetwise pride and client experiences of self-esteem based on streetwise pride. Session 4 addresses pro-social and antisocial values, session 5 focuses on social networks and their push or pull effect regarding change of lifestyle, and session 6 is a booster session which takes place 6 weeks after session 5. Here the client is invited to discuss the issues that have come up in previous sessions. All sessions are described in a detailed manual with pre-printed handouts and pre-printed homework assignments.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Aggression, measured using the Buss-Perry Aggression Questionnaire and Self-Report of Aggression and Social Behavior Measure
2. Drug use, measured using the Addiction Severity Index Composite score and Percent days abstinent

Secondary outcome measures

1. Perceived help for antisocial personality disorder
2. Readiness to change antisocial behaviour, measured using the adapted readiness ruler
3. Staff-rated improvement in in-clinic antisocial behaviour, general antisocial behaviour, and substance use

Overall study start date

01/03/2012

Completion date

01/07/2013

Eligibility**Key inclusion criteria**

1. Antisocial personality disorder according to the MINI International Neuropsychiatric Interview
2. Seeking treatment for a substance use disorder

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Psychosis
2. Not able to speak Danish
3. Will not giving consent
4. Plans to relocate
5. Serving in prison or due to go into residential rehabilitation over the next three months.

Date of first enrolment

01/03/2012

Date of final enrolment

01/07/2013

Locations

Countries of recruitment

Denmark

Study participating centre

University of Aarhus

Copenhagen

Denmark

2300

Sponsor information**Organisation**

Reckitt Benckiser Pharmaceuticals (UK)

Sponsor details

103-105 Bath Road

Slough

United Kingdom

SL1 3UH

Sponsor type

Industry

Website

<http://www.reckittbenckiser.com>

ROR

<https://ror.org/01g87hr29>

Funder(s)**Funder type**

Industry

Funder Name

Reckitt Benckiser (Denmark)

Funder Name

Aarhus Universitet

Alternative Name(s)

Aarhus University, Universitas Arhusiensis, AU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Denmark

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/11/2015		Yes	No
Other publications	post-hoc secondary analysis	09/01/2017		Yes	No
Results article		10/06/2022	13/06/2022	Yes	No