

Sociodemographic profile and natural history of crack use among users of different Brazilian states

Submission date 07/08/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/09/2021	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

In Brazil, crack cocaine was initially restricted to the city of Sao Paulo, later spreading to the whole country during the 90's and 2000's. During these two decades, governmental efforts were established, creating the biggest substance use disorders program in Latin America. Studies were conducted in 1996 to 1997 and 2012 to 2013 to investigate patterns of consumption, severity of dependence and cocaine-related problems among snorted and smoked cocaine users in Sao Paulo, Brazil. This study aims to compare the characteristics of crack cocaine users seeking treatment in 1996 to 1997 and 2012 to 2013.

Who can participate?

Crack cocaine users who started treatment during the period of the study in drug treatment programs in six states of Brazil and the Federal District

What does the study involve?

Participants are interviewed to examine their sociodemographic characteristics and patterns of drug use (i.e., age, gender, marital status, educational level and family composition, crack cocaine use, time since first use, frequency of crack use, company of use, job problems related to crack cocaine, arresting, treatment).

What are the possible benefits and risks of participating?

The benefits of participating include improving knowledge about crack use and providing scientific evidence to create treatment models and public policies aimed at these users. There are no risks of participating.

Where is the study run from?

Alcohol and Drugs Research Unit (Brazil)

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

January 2012 to January 2014

Who is funding the study?
National Council for Scientific and Technological Development (Cnpq)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAAE 00559212.1.0000.5505 Opinion number 434882

Study information

Scientific Title
Twenty-five years of crack cocaine use in Brazil: changes on user's profile who are seeking help
This study, involving multiple Brazilian regions, aimed to compare the profile of crack cocaine users seeking treatment sixteen years apart.

Study objectives
To compare the profile of crack cocaine users seeking treatment sixteen years apart (1996 - 2012) investigating sociodemographic characteristics and pattern of crack cocaine use.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Two cross-sectional studies conducted in 1996 to 1997 (N=133) and 2012 to 2013 (N=577) investigating characteristics of crack cocaine users

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Screening

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

Severity of dependence and cocaine-related problems

Interventions

These are two cross-sectional studies conducted in 1996 to 1997 and 2012 to 2013 to investigate patterns of consumption, severity of dependence and cocaine-related problems among snorted and smoked cocaine users in Sao Paulo, Brazil, with its results published elsewhere. The original study interviewed regular crack-cocaine users (at least twice a week for the previous three months). Subjects were recruited from public and private clinics (n=382). For comparisons with the present study, the trialists selected only those who were aged 18 and above, use to smoke cocaine as their main route of administration, were in treatment at the time of the interview and were not living on the streets (final sample=133).

Data was collected in drug treatment programs in six Brazilian States and the Federal District. 133 individuals were interviewed in 1996 and 577 in 2012. The Intake Questionnaire and the Maudsley Addiction Profile was used as a basis for the interviews to examine sociodemographic characteristics and patterns of drug use.

Intervention Type

Other

Primary outcome measure

1. Sociodemographic profile
2. Pattern of use in crack users

Measured using structured interview based on the Intake Questionnaire and the Maudsley Addiction Profile (MAP) in 1996 and 2012

Secondary outcome measures

Severity of dependence and cocaine-related problems, measured using structured interview based on the Intake Questionnaire and the Maudsley Addiction Profile (MAP) in 1996 and 2012

Overall study start date

01/01/2012

Completion date

01/01/2014

Eligibility

Key inclusion criteria

1. A sample of 20 therapeutic communities was selected in six states of Brazil and the Federal District. All of them were in accordance with the operating standards of the Brazilian Federation of Therapeutic Communities (FEBRACT) and with the health safety requirements for the operation this type of institutions, provided by the National Health Surveillance Agency (RDC Nº29/2001, ANVISA)
2. All crack cocaine users who initiated treatment between the referred period where invited to participate in the study

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

In total 719 participants were interviewed, from those 577 (80,2%) gave formal consent to participate and complete the whole interview.

Total final enrolment

577

Key exclusion criteria

Patients living on the streets were excluded from the final sample

Date of first enrolment

01/09/2012

Date of final enrolment

01/09/2013

Locations

Countries of recruitment

Brazil

Study participating centre**Alcohol and Drugs Research Unit**

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04038-000

Sponsor information

Organisation

National Council for Scientific and Technological Development (Cnpq)

Sponsor details

SHIS QI 1 Cj B - Blocks A, B, C and D - Blue Lagoon

Brasília-DF

Brazil

71605-001

Sponsor type

Research council

Website

<http://www.cnpq.br>

ROR

<https://ror.org/03swz6y49>

Funder(s)

Funder type

Research council

Funder Name

National Council for Scientific and Technological Development (CNPq)

Results and Publications

Publication and dissemination plan

The study protocol, statistical analysis plan and others will be able in Open Science Framework. Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/08/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository, Open Science Framework (<https://osf.io>). Type of data that will be shared: Sample questionnaire and database. When the data will become available: Already available. How long: Undetermined time. By what access criteria the data will be shared: Free access by weblink. With whom: for now only with researchers involved in the study.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Comparison of 1997 and 2013 users	01/12/2019	08/09/2021	Yes	No
Results article	Factors association with early initiation of crack use	23/04/2021	08/09/2021	Yes	No