

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
07/08/2017	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
22/07/2019	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
08/09/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

In Brazil, crack cocaine was initially restricted to the city of São 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 São 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

Protocol serial number

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)

Ethics Committee of the Federal University of São Paulo, 05/04/2013, ref: Version 4 CAAE 00559212.1.0000.5505 Opinion number 434882

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

Study type(s)

Screening

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 São 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(s)

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

Key secondary outcome(s)

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

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 N°29/2001, ANVISA)
2. All crack cocaine users who initiated treatment between the referred period where invited to participate in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Street Borges da Lagoa, 570, Floor 8o, CJ 82 - Vila Clementino

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Sponsor information

Organisation

National Council for Scientific and Technological Development (Cnpq)

ROR

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

Funder(s)

Funder type

Research council

Funder Name

National Council for Scientific and Technological Development (CNPq)

Results and Publications

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?
<u>Results article</u>	Comparison of 1997 and 2013 users	01/12/2019	08/09/2021	Yes	No
<u>Results article</u>	Factors association with early initiation of crack use	23/04/2021	08/09/2021	Yes	No
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No	Yes