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From observed parenting to parents' neuropsychology: a research project aimed at finding the best interventions to support parent-child relationships and at understanding how these interventions work

Submission date
13/05/2021

Recruitment status
No longer recruiting

Registration date
25/06/2021

Overall study status
Completed

Last Edited
03/11/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The term substance use refers to the use of drugs or alcohol, and includes substances such as cigarettes, illegal drugs, prescription drugs, inhalants and solvents. Parental substance use represents a severe risk factor for parenting and child development. Given the wide range of undesired outcomes linked to this condition, it is important to find interventions that adequately support parenting strategies and parent-child relationships in all those cases where parents struggle with substance use. Moreover, it is important to better understand how parenting interventions work, exploring which psychological factors could support/obstacle expected changes.
This study aims to investigate whether the Video-feedback Intervention to promote Positive Parenting and Sensitive Discipline (VIPP-SD) is effective at improving the quality of parenting and parent-child relationships of mothers who struggle with substance use. The intervention adopts the video-feedback technique and is aimed at improving the caregiver-child relationship and the management of daily disciplinary situations, preventing or reducing child difficult behaviors. The study also aims to better understand which psychological aspects in the parent support the intervention effect.

Who can participate?
Mothers of children aged between 14 months and 6 years old, willing to support research on parenting interventions and eager to better understand how parent-child communication works. The study is open to mothers with and without substance use problems.

What does the study involve?
All the mothers participating will be asked to fill in questionnaires about parent and child wellbeing, complete a set of computer tests, and interact with their children during structured and free-play sessions that will be video-recorded. Mothers with substance use difficulties and

their children will also participate in the VIPP-SD intervention, an evidence-based intervention aimed to support parenting strategies and parent-child relationships. The program is carried out at the family's home or at the facility where mother-child pairs live (in the case of residential treatment). The VIPP-SD consists of 7 sessions of about 2 hours each, every visit starts with a video-recording session, after which the recordings of the previous visit are viewed and discussed by the caregiver and intervener.

What are the possible benefits and risks of participating?
Benefits of taking part in the study include:
1. Improving the understanding of how parent-child communication works and how to support it
2. Improving interventions that support parents and parent-child relationships in difficult conditions
3. Spending precious time with their child during different interactive situations
4. Contributing to scientific knowledge
5. Accessing specialized treatment with no costs
No risks of participating in the study have been identified yet.

Where is the study run from?
The study is run from the University of Padua, Italy (Alessio Porreca, Pietro De Carli, Prof. Alessandra Simonelli), and supported by a network of national and international collaborations (Prof. Marinus van IJzendoorn, Prof. Marian Bakermans-Kranenburg, Prof. Lavinia Barone).

When is the study starting and how long is it expected to run for?
October 2018 to May 2025

Who is funding the study?
University of Padua (Italy) as part of Dr Alessio Porreca's doctoral program

Who is the main contact?
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Additional identifiers

Protocol serial number
UNIPD34

Study information

Scientific Title
From observed parenting to parents' neuropsychology: study on the cognitive mechanisms involved in parenting behaviors and in parenting interventions

Acronym
FOP

Study objectives

1. The researchers expect that after the administration of the video-feedback intervention to promote Positive Parenting and Sensitive Discipline (VIPP-SD), the quality of observed parenting behaviors in mothers with Substance Use Disorder (SUD) receiving treatment (SUD experimental group) increases more or decreases less than in mothers with SUD undergoing treatment as usual (SUD control group).
2. The researchers expect that (A) the administration of the VIPP-SD modifies parents' performance on a series of tasks and self-report measures aimed at investigating cognitive mechanisms in the SUD experimental group with respect to the SUD control group and that (B) these changes will be associated with improvements in the quality of observed parenting behaviors in the SUD experimental group. Moreover, the researcher expect that (C) after the administration of the VIPP-SD, perceived parenting stress in the SUD experimental group decreases compared to the SUD control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2020, Comitato Etico Della Ricerca Psicologica (Area 17) (Dipartimenti/Sezione di Psicologia, Università di Padova, Via Venezia 8, 35131, Padova, Italy; +39 (0)49 827 6600; comitato.etico.area17@unipd.it), ref: 3475

Study design
Randomized wait-list controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parenting intervention in mothers with Substance Use Disorder

Interventions
Mothers with SUD receiving the intervention (SUD experimental group) will be compared to mothers with SUD undergoing treatment as usual (SUD control group) and to low-risk mothers.

Randomization of the SUD group to the SUD experimental and SUD control group will be carried out a priori and each participant will be assigned to a predetermined condition once enrolled in the study. A blocked randomization with randomly selected block sizes, stratified with respect to the child’s gender and age will be adopted. Randomization will be carried out through computer-generated random number lists.

Mothers in the SUD group will be administered the VIPP-SD, an evidence-based intervention, aimed at improving sensitive parenting and sensitive discipline, as well as the caregiver-child relationship. The program adopts the technique of the video-feedback and consists of 7 sessions of approximately 2 hours each. Every visit starts with a recording session, after which the recordings of the previous visit are viewed and discussed by the caregiver and intervener.

At the end of the trial, mothers in the SUD control group will receive treatment as well.

Intervention Type
Behavioural

Primary outcome(s)
1. Quality of observed parenting behaviors measured using observational scales applied at videotaped mother-child interactions at pre-test, post-test, and 2 months follow-up
2. Cognitive mechanisms measured using computerized neuropsychological tasks and self-report measures at pre-test, post-test, and 2 months follow-up

Key secondary outcome(s))
Perceived parenting stress measured using self-report measures at pre-test, post-test and 2 months follow-up

Completion date
01/05/2025

Eligibility

Key inclusion criteria
SUD groups (both experimental and control):
1. History of SUD diagnosis, intended as severe substance use, abuse, or dependence according to criteria outlined by principal diagnostic manuals (Diagnostic and Statistical Manual of Mental Disorders, International Classification of Diseases). Substances of interest involve one or more of the following: alcohol; caffeine; cannabis; hallucinogens; inhalants; opioids; sedatives, hypnotics, or anxiolytics; stimulants; tobacco; and other or unknown substances.
2. Treatment in residential and outpatient facilities that treat SUD and other psychiatric disturbances
3. Mother of a child aged between 12 months and 6 years old
4. Lives with the child or in close contact with him/her (at least 4 times per week)

Low-risk group:
1. Absence of history of SUD diagnosis, intended as severe substance use, abuse, or dependence according to criteria outlined by principal diagnostic manuals (Diagnostic and Statistical Manual of Mental Disorders, International Classification of Diseases)
2. Absence of history of treatment in residential and outpatient facilities that treat SUD and other psychiatric disturbances
3. Mother of a child aged between 12 months and 6 years old
4. Lives with the child or in close contact with him/her (at least 4 times per week)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
SUD groups:
1. Presence of diagnosed psychotic disorders in an active phase
2. Presence of organic brain disorders that prevent the execution of the tasks
3. Presence of child developmental pervasive disorders

Low-risk group:
1. Presence of diagnosed psychotic disorders in an active phase,
2. Presence of organic brain disorders that prevent the execution of the tasks
3. Presence of child developmental pervasive disorders
4. History of SUD diagnosis

Date of first enrolment
15/03/2020

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
Italy

Study participating centre
Università degli Studi di Padova
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Sponsor information

Organisation
University of Padua

ROR
https://ror.org/00240q980

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Padova (as part of Dr Alessio Porreca's doctoral program)

Alternative Name(s)
University of Padova, University of Padua, UNIPD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/07/2022	25/07/2022	Yes	No