Is parent-child interaction therapy effective on aggression and biological indices in pre-school children with parents who use high-potency cannabis? A double-blind randomized controlled trial study in an Iranian sample

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Abstract
BACKGROUND: Improving interpersonal interactions between parents and the child can indirectly reduce the extrapolation behavioral problems, including aggression in children.

METHODS: Among parents who used high-potency cannabis (marijuana or ‘gol’ as it is called in Iran) and lived in Tehran, Iran, sixty four caregivers and an Iranian child were selected through respondent-driven sampling and studied in the form of a double-blind randomized controlled trial (RCT) (TCTR20180804001) with repeated measurements method and a 6-month follow-up. The changes in the aggression and cortisol levels were repeatedly evaluated during 12 weeks of interactive treatment and analyzed by Monte Carlo test, repeated measures correlation (rmcorr), and generalized estimating equation (GEE) via SPSS software. Statistical significance was accepted on the level of P < 0.01.

RESULTS: 12 weeks of Parent-Child Interaction Therapy (PCIT) had a significant effect on the reduction of aggression and the salivary cortisol level in children (P < 0.01). However, the results did not remain stable till the 6-month follow-up stage (P = 0.067). Also, results revealed a significant relationship between aggression index and the level of cortisol (P < 0.01).

CONCLUSION: Since the core of the damage resulted from illicit drug abuse is reflected in interactive activities, improving social interactions can be considered as the key to the treatment of addiction.

KEYWORDS: Aggression; Tetrahydrocannabinol; Addiction; Problem Behavior; Child; Preschool

Introduction
The appearance of anxiety and depression syndrome in children may have extraversion problems for the children, such as family functioning disruption, school absenteeism, difficulty in academic performance, aggression, and social interaction deficit in youth period.1

High-potency cannabis (marijuana or ‘gol’ as it is called in Iran) is a type of tetrahydrocannabinol (THC), and using ‘gol’ has significantly been increased in Iran during
the past few years. The use of cannabis (acute and chronic use) is associated with adverse damages for psychological health.²

On the other hand, the cortisol secretion is increased due to stressors stimuli. Some research has shown that a significant correlation exists between the cortisol level and mood and behavioral indices, and cortisol could be used as a biomarker in evaluating psychological indices.³

Parent-Child Interaction Therapy (PCIT) is an evidence-based and short-term therapy which is based on interest and social learning theory; this theory is used in children with age of 2 to 8 years who have a history of disruptive behavior disorders. This treatment could be effective in developing relationships between the child and parents through active listening, empathy, eye contact, refinement, and summarizing instead of criticism.⁴ Several studies have shown that PCIT is effective in reducing the extraversion problems.⁵⁻⁷

Many studies have been carried out on the use of PCIT in children's extraversion problems, but there are a few studies in the sample of THC users. Therefore, in this study, we intend to explore the effectiveness of PCIT in reducing aggression and the cortisol level in pre-school children with parents who use high-potency cannabis.

**Materials and Methods**

The current study was a double-blind randomized controlled trial (RCT) with repeated measures and a 6-month follow-up that was done during March 2015 to October 2016. The participants were 64 Iranian caregivers who were selected through respondent-driven sampling method and by Office software, they were assigned to treatment group (n = 33) of parent-child interaction (main protocol) or placebo group (n = 31) (Figure 1).

The criteria for entry into the study were: 1) children with age of 5 to 7 years, 2) the recognition of dependence to ‘gol’ with a specific dose for at least one of the parents, 3) the diagnosis of aggression and behavior disorder in both clinical domains and evaluation of questionnaires, 4) age range of 20-45 years for parents, and 5) the ability to read and write.

The exclusion criteria for the mother and the child were as follows: 1) having natural intelligence less than 70 and 2) use of psychiatric medications more than three months due to the likely effects on psychological syndrome.

![Figure 1. Flow diagram of the progress through the phases of a parallel randomized trial of two groups](image-url)
The PCIT was conducted in two phases of child-directed interaction (to develop communication) and parent-directed interaction (to improve interactive discipline) in 12 sessions.

Saliva samples (2 milliliters) were collected in three intervals by a synthetic cotton swab. The synthetic cotton swab was placed in the baby's mouth for a time of sixty seconds; the samples were centrifuged at room temperature at a rate of 3000 rpm for 15 minutes and tested with a highly-sensitive enzyme-linked immunosorbent assay (ELISA). This assay uses a solid-phase enzyme immunoassay (EIA) to detect the existence of a ligand (usually a protein) in a liquid sample using antibodies directed against the protein to be measured. In the present study, a structured clinical interview, a demographic questionnaire that was made by the researcher, Aggression Questionnaire, and an immunoassay method were used. ELISA has been used as a diagnostic tool in medicine, plant pathology, and biotechnology, as well as a quality control check in various industries.

The present study was part of a research project approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran (TCTR20180804001). The stages of the study were carried out after obtaining informed written consent from the parents (and the verbal consent of the child) and according to the latest version of Declaration of Helsinki.

Results

The coded disorders in children were as follows: separation anxiety (27%), generalized anxiety disorder (GAD) (24%), specific phobia (16%), social phobia/agoraphobia (13%), injury phobia (11%), and obsessive-compulsive disorder (OCD) (9%). The caregiver's relationship with the child was as parent caregivers (81%), foster mother (8%), grandparents and grandmothers (5%), aunt (4%), and kinship careers (2%).

In order to evaluate the changes in the anxiety and levels of salivary cortisol in children, generalized estimating equation (GEE) was used via SPSS software (version 20, IBM Corporation, Armonk, NY, USA). Statistical significance was accepted on the level of $P < 0.010$. GEE is an approach to fit a marginal model for longitudinal/clustered data analysis, and it has been increasingly used in clinical trials and biomedical studies.

The changes of the two indices were significant. To determine the relationship between anxiety and level of cortisol, repeated measures correlation (rmcorr) was used. The results revealed that a significant relationship existed between anxiety index and cortisol level ($P < 0.010$).

Discussion

The findings of the study showed that PCIT reduced both anxiety and cortisol indices. However, the changes were not constant till the follow-up stage. In line with the results of this study, the results of a study by Pirnia et al. that investigated the effectiveness of PCIT on the anxiety index of pre-school children showed that this therapy was effective in reducing the anxiety index. The results of another study carried out by Thomas et al. also showed that PCIT significantly reduced the children's externalizing behaviors. In addition, the results of Herschell et al. and Pirnia et al. studies showed that PCIT was effective in reducing child maladaptive behaviors, parenting style, and psychological syndrome.

However, the results of this study revealed that the effectiveness of this therapy on anxiety and cortisol level indices was not stable till 6-month follow-up stage. In contrast with our results, the study of Graziano et al. showed that the effectiveness of PCIT was maintained in 6-9-month follow-up.

The findings of this study also showed that a
direct relationship existed between the level of cortisol and aggression. These results, in line with the findings of Pirnia et al.,\textsuperscript{3} showed that a significant relationship existed between the cortisol level and mood index. In contrast with the results of this study, Pirnia et al.\textsuperscript{10} showed that there was no significant relationship between the cortisol level and psychological indices.

This study had some limitations. The most important limitation was that evaluating the dose and concentration of the consumed THC was not possible. It is suggested that the relationship between the concentration of cannabis and the cortisol level be investigated in future studies. Also, evaluating the mediating role of mother's cortisol in the relationship between the psychological problems of mothers and children can be a suitable route for future studies.

\textbf{Conclusion}

This study was conducted to examine the effectiveness of PCIT on aggression and the cortisol level in pre-school children with parents who use THC. The findings showed that twelve weeks of PCIT significantly reduced children's aggression and salivary cortisol level. Also results revealed that there was a significant relationship between aggression index and cortisol level. These results showed that improving social interactions could be considered as the key to the treatment of addiction.

\textbf{Conflict of Interests}

Authors have no conflict of interests.

\textbf{Acknowledgments}

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\textbf{References}