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### **Original Article**

## Risperidone as a treatment for childhood habitual behavior

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#### **ABSTRACT**

**Objective:** The aim of this study was to investigate the effect of adding risperidone to the general behavioral treatment of masturbation in children 3-7 years old.

**Methods:** A 4 week randomized clinical controlled trial was designed in year 2009. Samples have been chosen from children who have been referred to the Child and Adolescence Psychiatric Clinic of Isfahan University of Medical Sciences. Ninety children were recruited at the study and randomly allocated into the risperidone and control groups (44 and 46 respectively). The risperidone group was medicated simultaneously by behavioral treatments and 0.25-I mg of risperidone daily while the controls only received the behavioral treatments.

**Findings:** The mean  $\pm$  SD age of the risperidone and control groups was 5.3  $\pm$  1.1 and 4.9  $\pm$  1.1 years, respectively. The mean  $\pm$  SD of the period of suffering from masturbation was 3.4  $\pm$  1.2 and 3.8  $\pm$  1.7 months in the risperidone and the control groups, respectively. At the beginning of the study, the mean frequency of masturbation in control and the risperidone groups was 2.6  $\pm$  0.9 and 2.7  $\pm$  0.9 times/day, whereas after the 4<sup>th</sup> week, it decreased to 1.4  $\pm$  0.6 and 1.1  $\pm$  0.5 times/day, respectively. The results showed a more reduction in the mean frequency of masturbation in the risperidone group significantly.

**Conclusion:** In comparison to the general behavioral treatment, risperidone in addition to the behavioral treatment will probably reduce the frequency of masturbation in children more effectively.

**Keywords:** Behavioral problems; behavioral treatment; children habitual behavior; children masturbation; risperidone

#### INTRODUCTION

Childhood masturbation means self-stimulation of sex organs, which is carried out by an immature child. Although, the sexual organs are usually discovered by the child in the second half of the 1st year of his/her life, masturbation that is to say the rhythmical touching of the sexual organ, is usually not seen in children before 2.5 years old. In addition, similar acts to masturbation like vibrating are seen in younger ages in some children. The most incidence of masturbation is seen in the 4th year of life and

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then reaches its peak in the years of puberty. About 90-94% of males and 50-60% of females experience masturbation at some part of their development.<sup>[6,7]</sup>

There are different opinions about the normality or abnormality of masturbation. However, it is necessary to define natural sexual behavior according to the society, religion, culture, and family backgrounds. Otherwise, normal sexual behavior cannot be distinguished. [8-10]

Attitudes towards the pathology of masturbation in children are contradictory, but findings such as the continuation of masturbation in some children,<sup>[11-13]</sup> the higher prevalence of sleep disorder in children with the masturbation,<sup>[11]</sup> the relationship between masturbation and other behavioral and emotional problems,<sup>[13-17]</sup> and the co-morbidity of disorders such as encopresis, enuresis, pica, conduct disorder, and Attention deficit-hyperactivity disorder (ADHD) with masturbation,<sup>[13]</sup> highly indicate that masturbation should be considered as a pathologic behavior.

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According to the Islamic culture, masturbation is known to be a moral wrongdoing and this behavior is considered as a problem in the Moslems society.

Because of the contradictory viewpoints about the normality or abnormality of this behavior, few studies have been conducted regarding the pharmaceutical methods in treating masturbation of children. In one study on children suffering from Autism, which simultaneously where experiencing masturbation, the efficacy of the Mirtazapine on decreasing this behavior was investigated and the results revealed that this drug effectively reduced the frequency of masturbation. [18]

In other habitual behaviors, such as nail biting and head banging, the treatment consists of behavioral treatment and/or drug therapy.<sup>[19]</sup> The drug therapy itself is made up of atypical antipsychotic drugs, which the uses are increasing because of their low drug interactions and side-effects.<sup>[19]</sup>

Based on the clinical experience of researchers in treating children suffering from ADHD and masturbation with risperidone and integrating experiences for medicating children with masturbation who were referred to the psychiatric clinic of children, the hypothesis of risperidone as a possible effective drug in reducing of masturbation had built up.

The aim of this study was to investigate the effect of adding risperidone to the general behavioral treatment of masturbation in children 3-7 years old.

#### **METHODS**

The sample was chosen from children who have been referred to the Child and Adolescence Psychiatric Clinic of Isfahan University of Medical Sciences. All subjects met the following inclusion criteria: (1) informed acceptance of parents to comply with the study; (2) boys and girls 3-7 years old; (3) diagnosed with masturbation problem by a psychiatrist; and (4) doing masturbation as a daily habit. Subjects also met none of the following exclusion criteria: (1) any serious medical condition that would interfere with the safe study participation; (2) any current neurological or axis I psychiatric disorders (e.g., anxiety disorders, autism and etc.) that need chronic drug treatment; (3) children who have had been treated for masturbation in the last month; and (4) infection of genitalia.

The study used a randomized, controlled clinical trial design with an active medication condition and a matching behavioral treatment. It was carried out on year 2009 and registered on Iranian Registry of Clinical Trials (www.irct.ir) with identifier Number of IRCT201110187841N1.

The study followed the Declaration of Helsinki on Biomedical Research Involving Human Subjects and was approved by the Ethics Committee of the Isfahan University of Medical Sciences. All parents of participants provided written informed consent. At the screening visit, after providing demographic data, eligible subjects were randomly assigned to risperidone and control groups. The children who were assigned to the risperidone group were treated simultaneously by behavioral treatment and risperidone while the controls only received the behavioral treatment for 4 weeks.

Behavioral treatment was carried out by parents who had been educated individually by the child and adolescence psychiatrist in the screening visit. The behavioral treatment contained: (1) to spend more time with the children at home to give them more emotional support, and (2) to distract them indirectly from masturbating when it was done by the child. Risperidone was started with 0.25-1 mg daily, according to the child's body weight and continued to the end of week four. A form was given to the parents to fill out the frequency of masturbation daily by observation at home, during the 4 week period of the study. The children were visited once a week for drug side effects.

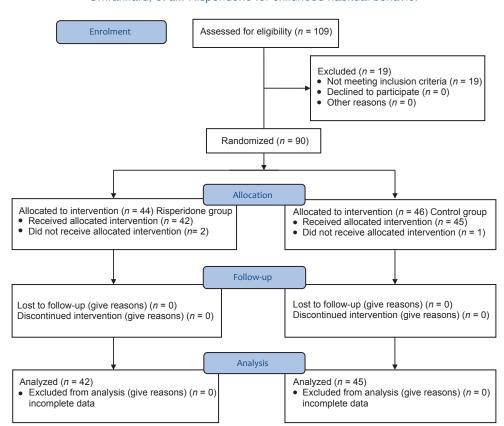
The data were analyzed to calculate the effectiveness of risperidone by fitting Repeated Measure of ANCOVA model using SPSS version 18 (SPSS, Chicago, IL). P < 0.05 showed significance.

#### **RESULTS**

A total of 109 individuals screened and 90 met all inclusion and no exclusion criteria which randomized into the study groups. Forty four participants assigned to the risperidone and 46 participants to the control groups. Two patients were eliminated from risperidone and one patient was eliminated from the control group [Figure 1]. The demographic and clinical features of the sample are reported in Table 1. There were no statistically significant imbalances on demographics or duration of the problem between two groups at baseline.

Based on the repeated measure of ANCOVA model, the frequency of masturbation decreased in both of control and the risperidone group (P=0.001), so that after 4 weeks, it declined to  $1.4\pm0.6$  and  $1.1\pm0.5$  times/day, respectively [Table 2]. However in the control group, masturbation only decreased significantly in younger children whereas in the risperidone group masturbation decreased significantly in all ages.

The results showed a significant difference in response to the treatment in control and risperidone groups. Although after the first 3 weeks, the mean



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Figure 1: Study design flow chart

Table 1: Demographics and clinical characteristics of subjects (*N*=87)

Characteristics	Risperidone+BT N=42	BT <i>N</i> =45	P value
Sex (number [%])			
Male	22 (52.3)	26 (57.7)	0.631
Female	20 (47.7)	19 (42.3)	
Age	5.3±1.1	4.9±1.1	0.14
Period of suffering from masturbation	3.4±1.2	3.8±1.7	0.22
Frequency of masturbation	2.7±0.9	2.6±0.9	0.781

All variables are mean ( $\pm$ SD) unless otherwise indicated, BT=Behavioral treatment

frequency of masturbation was approximately the same in both groups, but at the end of  $4^{th}$  week there was a more significant reduction in the risperidone group (P=0.01). Gender and the period of the illness had no significant effect on the effectiveness of treatment in either group; however, age and the frequency of masturbation at the beginning of the study had a significant impact on the effectiveness of the treatment. Lower the age and the frequency of masturbation at the beginning of the study, the more effective is the treatment for both groups [Table 3].

No drug side-effects were observed in the risperidone group.

Table 2: Summarized mean and standard deviation of the frequency of masturbation per day in the 4 weeks follow-up period in children aged 3-7

Study groups characteristics	Control		Risperidone	
	Number	Mean±SD	Number	Mean±SD
At the beginning	46	2.6±0.9	44	2.7±0.9
At the end of 1st week	46	2.3±0.6	44	2.2±0.6
At the end of 2 <sup>nd</sup> week	45	1.9±0.6	44	1.8±0.5
At the end of 3 <sup>rd</sup> week	45	1.7±0.6	43	1.5±0.5
At the end of 4 <sup>th</sup> week	44	1.4±0.5	43	1.1±0.4

#### **DISCUSSION**

The results of the present study showed that by some interventions, the frequency of masturbation would be decreased and over continuous weeks showed to have a meaningful process. Both of the behavioral treatment alone and combining it with risperidone result in the lowering the frequency of masturbation.

As Nguyen and Murphy study with Mirtazapine showed, [18] after the 4th week the reduction of the

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Table 3: Summarized results of ANCOVA repeated measure analysis of the effect of characteristics on the frequency of masturbation per day in the 4 weeks follow-up period in children aged 3-7

Effect of characteristics	F test	df	P value
Time (study period)	8.5	(3.82)	<0.001
Study groups	6.9	(1.84)	0.010
Interaction (time*group)	22.4	(3.84)	< 0.001
Age	5.5	(1.84)	0.022
Sex	0.13	(1.84)	0.150
Duration of masturbation (months)	2.6	(1.84)	0.112
Number of daily masturbation at the beginning	0.16	(1.84)	<0.001

ANCOVA=Analysis of covariance, df=degree of freedom

frequency of masturbation in the risperidone group was more effective and statistically more significant than the control group, leading to a more rapid control of masturbation in children in order to avoid it continuing to adulthood. [12] In addition while the child is initially showing an insufficient response to the behavioral treatment, use of risperidone can be acceptable. In the current study, the addition of risperidone to the behavioral treatment was effective in both genders with no statistically significant difference.

In contrast to the behavioral treatment which was only effective in younger ages in the control group, the addition of risperidone to the behavioral treatment was effective in all ages. The effectiveness of the behavioral treatment, which was consisted of distracting the child during the masturbation would decrease probably by the aging and increasing of the child's attention and concentration about his/her atmosphere, whereas using drug therapy with the behavioral treatment can be considerably influential in all ages.<sup>[19,20]</sup>

A meaningful relationship was observed between the frequency of masturbation at the beginning of the study and the effectiveness of the interference. This finding indicates that the effect of treatment is much more if it occurs while the frequency of masturbation has yet to increase.<sup>[13]</sup> Therefore, we could understand how necessary it is for parents to realize the importance of the interference at the initial stages of their child's masturbation regarding the reduction of the problem.

According to the results of this study, risperidone can be used for rapidly controlling masturbation in children in order to avoid its continuation to adulthood and also when the child is not responding suitably to the behavioral treatment. This drug with

the behavioral treatment on its side will probably reduce more effectively the frequency of masturbation in children in comparison to the general behavioral treatment alone.

It is recommended that researches with a larger sample size, containing a control group which uses placebo and also researches regarding the effects of risperidone alone (without behavioral treatment) to be designed.

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#### **AUTHORS' CONTRIBUTION**

Dr. Omranifard contributed in concepts, design, definition of intellectual content, literature search, data acquisition, manuscript preparation and review. Dr. Najafi contributed in concepts, design, definition of intellectual content, data acquisition, and correspondence. Dr. Sharbafchi contributed in concepts, design, definition of intellectual content, literature search, and manuscript preparation. Dr. Emami contributed in concepts, design, definition of intellectual content, and clinical studies. Dr. Maracy contributed in concepts, design, definition of intellectual content, data analysis and statistical analysis.

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