Comparative Study of Multimodal and Pharmacological Therapy in Treating School Aged Children with ADHD

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Abstract
The attention deficit hyperactivity disorder (ADHD), one of the most commonly diagnosed psychiatric disorders among school aged children, continues to create disputes between specialists, upon the best treatment to be used. The herby study aims to bring forward some differences that may exist between the efficacy of the multimodal treatment compared to the drug treatment of ADHD. The novelty component of this study, unfolded February 2010-July 2012, is that the children, their parents and also their teachers were included in the multimodality treatment. The children included in this research (n=63), aged 6-14 and ADHD diagnosed, were randomly assigned in two groups. In the medication (Med) group (n=32) the children only received the specific pharmacological treatment (Atomoxetine or Methylphenidate), and for the multimodality (MM) group (n=31) the therapy included psychosocial interventions besides the drug therapy. All children were evaluated, both pre and post intervention, with the Achenbach System of Empirically Based Assessment – ASEBA, for the 6-18 aged category. We have compared the influence of therapy on the core symptoms, on the adaptive functionality and academic performance and on the competences and social functioning of the children in the two groups. The multimodal intervention proved to be more effective (p<0.05) than medication alone, firstly in ameliorating the child's social behavior in both family and school environment, than in what concerns the main ADHD symptoms. The children's academic performance was little impacted by either of the two therapies.

Keywords: Child; Attention deficit hyperactivity disorder (ADHD); Multimodal therapy; Competences; Symptoms

Introduction

One of the most frequently diagnosed disorders among school aged children is the attention deficit hyperactivity disorder (ADHD) [1]. Although intensely studied in the last decades, there is still a continuous controversy regarding its etiology and the most adequate treatment. The specialists' attention to this disorder, as well as the public concern on the matter, is justified by its sizably negative impact on the child's life.

The efficacy of the medication with stimulants [2] and atomoxetine [3] was clearly proven so far, in what concerns diminishing the primary symptoms: inattention, impulsivity and hyperactivity [4,5]. In what concerns controlling the difficulties the child is faced with socially, as well as family and school wise, medication proved less useful. Other interventions were elaborated to address

these aspects as well, applied either combined with medication or on their own. Among these, the behavioral therapy shows sustained effectiveness [6].

The studies using combined therapy (multimodality) are fewer than the ones evaluating the effectiveness of one type of intervention, but when made their results proved positive [7,8]. More recently, there were a few major clinical trials designed (the most known being the one developed by MTA cooperative Group, 1999) to evaluate the effectiveness of the multimodality approach [9]. Although the results of this research are encouraging [10] their number remains still small, and the type of intervention associated to the medication, is most frequently behavioral, the other psychotherapy types being less studied.

The aim of this study was to investigate if there are any differences between the effectiveness of multimodal therapy and that of medication alone, in the case of school aged children diagnosed with ADHD.

The subsequent objectives were:
1. Comparative study of the influence of therapy on the disorder's symptoms
2. Evaluating the effectiveness of the multimodal / monomodal approach on the child's adaptive functioning and academic performance
3. Study of the impact of the treatment on the ADHD child's competences and social functioning

Material and Method

The design is that of a longitudinal, prospective study (unfolded February 2010- July 2012), with parallel groups.

Our research implies besides the children, their parents and teachers as well, in the treatment. In this study, by multimodal therapy we refer to combining medication with psychotherapy for the child and training of the parent and teacher.

Selection and Description of Participants

The study included 63 patients selected according to the following inclusion criteria: children, aged 6-14, in the school system (grades I-VIII), diagnosed with ADHD based on the ICD 10 and DSM IV-TR criteria.

Also attending were the children's parents and teachers (usually the class main teacher).

The agreement of parents and teachers to active participate at this study was an additional inclusion criteria.

The number of children included in this research was reached by convenience sampling; the children were selected among those who have sought help from the Pediatric Psychiatry Clinic Cluj-Napoca, The Mental Health Center or the Diagnose and Treatment Center Cluj-Napoca, considering the inclusion criteria listed above.

Excluded from this study, were the children presenting comorbidities such as mental retardation, severe depression, autolytic tentatives, substance abuse, autistic spectrum disorders, schizophrenia or schizophrenic disorders, cerebral syndromes; incompatibility or allergies to medication, refusal of pharmacological treatment. Also, since the collaboration with the parents was very important, we could not include children whose parents presented themselves significant psychiatric disorders such as mental retardation, severe mood disorders, schizophrenia or schizophrenic disorders.

Methods

The work stages as follows:

1. Selecting of the eligible patients. The children were first evaluated by a pediatric psychiatrist according to the ICD 10 criteria (the one commonly used in the Romanian medical system). There were five physicians that put the diagnosis of ADHD to the children. To improve the accuracy of the diagnose, before submission in the study, all children previously diagnosed with ADHD by

different physicians, were clinically evaluated by another pediatric psychiatrist (the same for all patients) and verified under the DSM-IV TR criteria as well.

2. Obtaining the informed consent of the parents and teachers;

3. Deciding on the medical treatment by the attending physician

4. Random repartition of the children in the 2 groups;

5. Applying the pre-intervention evaluation questionnaires;

6. Administration of the medication and delivering the psychosocial interventions;

7. Final evaluation (both clinical and through questionnaires) of all participants (approximately 14 weeks from the initial evaluation).

In the case of the group under just pharmacological treatment (Med), the only intervention was the administration of the specific medication by the attending physician. As specific treatment it was concurred to use atomoxetine or methilphenidate (Strattera[R], Concerta[R] or Medikinet[R]).

For the group under multimodal therapy (MM) we have combined the drugs (the same as in the Med group, atomoxetine or methilphenidate) with a package of psychosocial interventions. They consisted in training and counseling program for the parent and the teacher and child psychotherapy.

For the intervention in the school domain, a guide for the teachers was drawn up. This was accompanied by periodical individual meetings with the purpose of approaching specific school problems the children were faced with and of properly observing the children's evolution.

The parent's training was organised in 14 weekly meetings. During these meetings, besides presenting some basic information about ADHD, and understanding parent-child relations we have also used behavioral management techniques (improving parental methods of attending to child behavior, establishing a token/point system, using time out, managing behavior in public places).

The child's psychotherapy unfolded during weekly meetings, with common objectives for all children, but overall it was less structured than the other interventions, allowing a specific approach based on each child's issues.

We have not used a witness lot that has not received any treatment or that was administrated placebo, because on one hand, the effectiveness of the ADHD medication was already proven in numerous studies, and on the other hand, we found it would be unethical for some patients not to benefit of any treatment, considering the negative influence of this disorder on the life of both the child and his family.

Instruments

For the demographical aspects of the participants we have used a data gathering record.

The evaluation was both clinically and through rating scales.

The Achenbach System of Empirically Based Assessment - ASEBA, for the age range 6-18 is a set of scientific validated scales, adapted and published in Romanian [11]. From this system we have used 3 categories of rating scales: I. Child behavior checklist-CBCL (the child behavioral assessment questionnaire addressed to their parents), II. Teacher's report form-TRF (child assessment made by their teachers, III. Youth self-report-YSR (self-evaluation questionnaire for 11-18 aged children).

From each category of scales we have selected the subscales that were compatible with the specific objectives previously established (12 scales and subscales in total).

From CBCL: 1. The competences rating scale; 2.The syndromes rating scale, IV-social problems and 3.The syndromes rating scale, VI-attention problems; 4.The DSM derived rating scale 4-ADHD problems.

From TRF: 1. The adaptive functioning rating scale; 2.The academic performance assessment subscale; 3.The syndromes rating scale VI-attention problems; 4.The DSM derived rating scale 4-ADHD problems.

From YSR: 1. The competences rating scale; 2. The syndromes rating scale IV-social problems; 3. The syndromes rating scale VI- attention problems; 4.The DSM derived rating scale 4-ADHD problems.

The scales were applied twice, before and after the intervention, using the same instruments for all patients.

Statistical Methods

The data was logged in a SPSS data base, version 17, and analyzed using suitable statistical methods.

Initially, we have described the characteristics of the 2 groups and of the initial results on the rating scales in order to verify the homogeneity of the groups (independent-samples t test).

The second stage was applying the paired-samples t test on pair samples for all the score sets, from all the participants, in order to discover to what extent there were changes registered between the initial and final evaluations.

As a last stage, the two-way mixed ANOVA, was used to evaluate the difference between the changes appeared in time in the two groups.

The Student and ANOVA tests were applied after verifying data normality.

In order to eliminate the selection bias and to balance the arms of the study, we assigned randomly the patients in the two groups, using a block randomization method.

The established threshold of the statistical significance was $p < 0.05$.

Results

Sample Description

Out of the 63 participants (53 boys and 10 girls), 31 were randomly distributed in the multimodal therapy group, and 32 in the one under medication only. Initially the children count was somewhat higher (68), but 5 of them were excluded from the study either because of poor compliance to the medication treatment or they have voluntarily abandoned the project (due to incompatibility between the family schedule and the weekly meetings schedule included in this research).

From the children included in the MM group 25 were boys (80.65%, 95%CI [62.53%-92.55%]) and 6 girls (19.35%, 95%CI [7.45%-37.47%]) and in the Med lot 28 were boys (87.5%, 95%CI [71.01%-96.49%]) and 4 girls (12.5%, 95%CI [3.51%-28.99%]). There was no significant correlation between the group and the gender of children: Fisher's Exact Test Significance (2-sided) p=0.51.

In what concerns their age, the mean age in the 2 groups was very similar, t=0.41; Mean Difference=2.03, 95%CI [-7.69 - 11.76] (Table1).

Table1. Mean age in years of the children in the two groups

Group	N children	Mean age (years)	SD	Minimum	Maximum
MM	31	9.3	1.42	7.3	11.9
Med	32	9.1	1.76	7.1	14

The medication received by the patients was either methilphenidate - 10 children from the MM group and 8 children in the Med group and atomoxetine - 21 children from the MM group and 24 children from the Med group.

There was no significant correlation between the group and the type of medication, meaning, the groups (Med and MM) were homogenous in what concerns the medication received by the children (Pearson Chi-Square=0.41, df=1, p=0.52)

Comparison of the Scores Rated by the Participants in Both Groups

Mean scores were not significantly different, following the analysis of the two groups characteristics, in regards to the equality of means and variances, at the initially applied rating scales, (tables 2a, 2b, 2c).

Table2a. Independent Samples Test results, pre-intervention. Competences and social problems rating scales.

Scale	Group	Nchildren	M	SD	T	df	p-value	95%CI	
1. CBCL competences total	MM	31	15.45	4.54	0.09	61	0.92	-1.88	2.09
	Med	32	15.39	3.31					
2. YSR competences total	MM	7	9.28	2.92	-1.30	11	0.22	-5.96	1.53
	Med	6	11.5	3.20					
3. CBCL social problems	MM	31	8.85	2.84	1.18	61	0.24	-5.93	2.03
	Med	32	8.00	2.90					
4. YSR social problems	MM	7	5.14	1.95	-1.65	11	0.12	-4.32	0.61
	Med	6	7.00	2.09					

M=mean score; SD=standard deviation; 95% CI=95% Confidence Interval

Table 2b. Independent Samples Test results, pre-intervention. Adaptive functioning and academic performance.

Scale	Group	Nchildren	M	SD	T	df	p-value	95%CI	
5. TRF adaptive functioning	MM	31	14.12	1.76	0.75	61	0.45	-0.67	1.49
	Med	32	13.71	2.47					
6. TRF academic performance	MM	31	3.01	0.59	0.93	61	0.35	-0,16	0.45
	Med	32	2.86	0.64					

M=mean score; SD=standard deviation; 95% CI=95% Confidence Interval

Table 2c. Independent Samples Test results, pre-intervention. ADHD symptoms.

Scale	Group	N	M	SD	T	df	p-value	95%CI	
7. CBCL syndromes attention problems	MM	31	11.40	1.88	-0.41	45.67	0.67	-1.83	1.2
	Med	32	11.71	3.80					
8. CBCL DSM ADHD problems	MM	31	10.29	1.86	-0.27	61	0.78	-1.23	0.94
	Med	32	10.43	2.41					
9. TRF syndromes attention problems	MM	31	33.38	6.67	0.70	61	0.48	-2.48	5.19
	Med	32	32.03	8.44					
10. TRF DSM ADHD problems	MM	31	18.67	6.17	0.33	55.24	0.73	-2.28	3.20
	Med	32	18.21	4.57					
11. YSR syndromes attention problems	MM	7	10	1.15	1.49	11	0.16	-0.47	2.47
	Med	6	91.26	1.26					
12. YSR DSM ADHD problems	MM	7	8.14	0.89	-0.66	11	0.52	-1.54	0.83
	Med	6	8.5	1.04					

M=mean score; SD=standard deviation; 95% CI=95% Confidence Interval

The statistical analysis shows that in the MM group there were significant changes on 10 out of 12 scales. The scales on which there were no significant changes were: YSR social problems and TRF academic performance rating scales.

In the Med group there were significant changes seen on 6 out of 12 scales. The scales showing a lack of significant changes were: CBCL total competences, YSR total competences, YSR social problems, TRF adaptive functioning, TRF academic performance and YSR syndromes attention problems rating scales (Tables 3 a and b).

Table 3a. Paired-Samples T Test results: Multimodal group

Scale	Pre intervention			Post intervention			MD	SD MD	95%CI		t	df	p-value
	Freq	M	SD	Freq	M	SD							
1.	31	15.45	4.45	32	19.74	4.49			-5.32				0.00
2.	31	8.84	2.84	32	7.32	2.74			0.70				0.001
3.	7	9.28	2.92	6	17.21	2.44	-7.92	2.54	-10.27	-5.57	-8.25	6	0.00
4.	7	5.14	1.95	6	4.57	1.13	0.57	1.61	-0.92	2.06	0.93	6	0.38
5.	31	14.12	1.76	32	16.14	2.41	-2.01	2.22	-2.83	-1.20	-5.05	30	0.00
6.	31	3.01	0.59	32	3.07	0.68	-0.06	0.60	-0.29	0.15	-0.61	30	0.54
7.	31	11.40	1.88	32	8.70	3.55	2.69	3.50	1.40	3.97	4.27	30	0.00
8.	31	10.29	1.86	32	8.69	3.08	1.59	3.15	0.43	2.75	2.81	30	0.009
9.	31	33.38	6.67	32	22.77	8.25	10.61	8.68	7.42	13.80	6.80	30	0.00
10.	31	18.67	6.17	32	13.19	4.84	5.48	4.66	3.77	7.19	6.55	30	0.00
11.	7	10.00	1.15	6	6.85	1.21	3.14	0.69	2.50	3.78	12.05	6	0.00
12.	7	8.14	0.89	6	5.14	0.69	3.00	0.57	2.46	3.53	13.78	6	0.00

1. = CBCL competences total; 2. = CBCL social problems; 3. = YSR competences total; 4. = YSR social problems; 5. = TRF adaptive functioning; 6. = TRF academic performance; 7. = CBCL syndromes attention problems; 8. = CBCL DSM ADHD problems; 9. = TRF syndromes attention problems; 10. = TRF DSM ADHD problems; 11. = YSR syndromes attention problems; 12. = YSR DSM ADHD problems

Table 3b. Paired-Samples T Test results: Medication group

Scale	Pre intervention			Post intervention			MD	SD MD	95% CI		t	df	p-value
	Freq	M	SD	Freq	M	SD							
1.	32	15.39	3.31	32	15.95	3.79	-0.59	1.90	-1.28	0.09	-1.76	31	0.08
2.	32	8.00	2.90	32	7.15	3.30	0.84	1.95	0.13	1.54	2.44	31	0.02
3.	6	11.5	3.20	6	13.7	0.67	-2.20	3.68	-6.07	1.66	-1.46	5	0.20
4.	6	7.00	2.09	6	6.50	1.87	0.50	1.04	-0.60	1.60	1.16	5	0.29
5.	32	13.71	2.47	32	14.00	2.87	-0.28	1.78	-0.92	0.36	-0.89	31	0.37
6.	32	2.86	0.64	32	2.95	0.57	-0.08	0.46	-0.25	0.07	-1.09	31	0.28
7.	32	11.71	3.80	32	8.81	3.78	2.96	2.31	2.07	3.74	7.08	31	0.00
8.	32	10.43	2.41	32	8.54	3.01	1.89	1.96	1.18	2.59	5.43	31	0.00
9.	32	32.03	8.44	32	24.68	6.96	7.34	6.09	5.14	9.54	6.81	31	0.00
10.	32	18.21	4.57	32	14.53	4.36	3.68	3.25	2.51	4.86	6.40	31	0.00
11.	6	9.00	1.26	6	8.66	0.81	0.33	1.21	-0.93	1.60	0.67	5	0.53
12.	6	8.50	1.04	6	7.66	1.36	0.83	0.75	0.04	1.62	2.71	5	0.04

M=mean score ; SD=standard deviation
MD=mean difference; SD MD=standard deviation mean difference
95% CI=95% Confidence Interval
1. = CBCL competences total; 2. = CBCL social problems; 3. = YSR competences total; 4. = YSR social problems; 5. = TRF adaptive functioning; 6. = TRF academic performance; 7. = CBCL syndromes attention problems; 8. = CBCL DSM ADHD problems; 9. = TRF syndromes attention problems; 10. = TRF DSM ADHD problems; 11. = YSR syndromes attention problems; 12. = YSR DSM ADHD problems

The final results have shown the existence of significant differences in some areas between the 2 lots, and subsequently between the 2 types of used interventions.

The difference between the changes appeared in time in the two groups is significant in the case of the competences rating scales (from CBCL and YSR), the adaptive functioning rating scales (from TRF) and the ADHD symptoms from YSR. The rest of the scales showed no significant difference (Table 4).

Table 4. Two-way mixed ANOVA results. Comparison of the changes appeared in time in the two groups.

Scale	F	p-value	Partial Eta Squared
1. CBCLcompetences total	37.38	0.000	0.38
2. CBCL social problems	1.67	0.200	0.02
3. YSR competences total	10.89	0.007	0.49
4. YSR social problems	0.01	0.920	0.001
5. TRF adaptatative functioning	11.71	0.001	0.16
6. TRF academic performance	0.02	0.870	0.00
7. CBCL syndromes attention problems	0.08	0.770	0.001
8. CBCL DSM ADHD problems	0.19	0.650	0.003
9. TRF syndromes attention problems	3.00	0.080	0.04
10. TRF DSM ADHD problems	3.16	0.080	0.04
11. YSR syndromes attention problems	27.52	0.000	0.71
12. YSR DSM ADHD problems	34.51	0.000	0.75

Discussion

The resulted groups after randomization were relatively homogeneous in what concerns the studied characteristics and with a boy / girl proportion (4.1:1 in the MM lot and 7:1 in the Med lot) similar to the one reported by most epidemiological studies [12].

The ADHD symptoms significantly diminished in a similar amount through both approaches (multimodal and medication only) from the point of view of the parents and the teachers. The decreased symptoms are more visible in the multimodal lot from the point of view of the children over 11. These results are generally consistent with those reported by the first major clinical trial conducted by the National Institute of Mental Health, the Multimodal Treatment of Attention-Deficit Hyperactivity Disorder (MTA). Effect sizes associated with combined stimulant-behavioral interventions are about the same as for stimulants alone, when impact on ADHD symptoms is examined. Another intensive multimodal treatment study, the New-York-Montreal study (NYM) [13] which included 103 children with ADHD, age 7-9 years, conflicted the MTA findings concerning the benefits of combined treatment over medication alone, but there are some methodological disadvantages of this study compared to the MTA study (NYM focused exclusively on stimulant responsive children responsive children with less comorbidity and more attention was given to the medication compared to the psychosocial treatment)

When focusing on functioning of children at home, results were different for the multimodal versus the medication group. The competence level has significantly improved after the multimodal intervention, but not after receiving the medication alone. This effects of combined treatments are sustained by other researches [14,15,16] which reveal the fact that combined stimulant-behavioral treatment protocols lead to larger effects than for medication alone for a wide range of associated difficulties, such as conduct problems, oppositional behavior, social skills and disruptive behaviors at home and recreational peer settings.

When comparing this study with those mentioned above, in some specific areas, like social difficulties, the level of social problems decreased in a similar amount in both groups from the parents' perspective. The children over 11 presented a minor improvement in this area, regardless of the used treatment method.

In what concerns the adaptive functioning in the educational environment on its whole, its level only increased significantly as a consequence of the multimodal intervention.

The level of academic performance registered minimal changes, regardless the therapy used, suggesting need of taking on new measures which would aim this area.

Although, the general results of the research were positive, there are some certain limitations that can have an influence on the study outcomes.

These are mainly related to the small size of the sample and the low number of children over 11, which may result in reduced statistical power of the research.

Another limitation of this study is the short time interval during which the research was developed (14 weeks for each participant), not allowing a long term monitoring of the subjects' evolution and maintenance of those gains in time.

Despite the advantages of not interfering to much with the usual evaluation and treatment protocol (similarity with a natural setting) the lack of rigorously might reduce the importance of the reported results.

Also, because the study involved counseling and psychotherapy, it is difficult to appreciate how much of the outcome is due to specific therapeutic components, and how much is due to general non-specific factors, such as the therapist attention, maturation, or the confidence of the participants in the expected benefits following the intervention.

Conclusions

The combined treatment proved to be more effective than the administration of medication alone, mainly in diminishing the social and family environment difficulties and in correcting the child's behavior in class than in diminishing the symptoms of ADHD. The exception are the children aged over 11 who clearly show a more visible decrease of the symptoms level as a result of the multimodality intervention.

The academic performance was little impacted by both therapy methods.

Although, there are some benefits when combining treatments, drawing clear conclusions remains difficult and further research on larger samples is needed.

Optimal treatment is likely to involve a combination of approaches for maximal effectiveness, but the extent to which combined treatments are superior to medication alone is a controversial issue.

List of abbreviations

ADHD= Attention Deficit Hyperactivity Disorder
MM= multimodality group
Med= medication only group
ICD-10= International Classification of Diseases -10th Revision
DSM-IV= Diagnostic and Statistical Manual of Mental Disorders, fourth edition
ASEBA= Achenbach System of Empirically Based Assessment
CBCL= Child Behavior Checklist
TRF= Teacher's Report Form
YSR= Youth Self-Report
MTA= Multimodal Treatment of Attention-Deficit Hyperactivity Disorder
NYM= New-York Montreal study

Ethical Issues if any

The hereby study received approval from the Ethics Committee of "Iuliu Haţieganu" University of Medicine and Pharmacy Cluj-Napoca, and it was carried in accord with the good clinical practice rules.

Conflict of Interest

The authors declare that they have no conflict of interest.

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