BIOPSYCHOSOCIAL MODEL VERSUS BIOLOGICAL MODEL IN MANAGEMENT OF CHILDHOOD NEPHROTIC SYNDROME, SINGLE CENTER EXPERIENCE, EGYPT

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Abstract
There is a shortage in the evidence of application of Biopsychosocial in nephrotic syndrome. Objectives: to design a Biopsychosocial model for steroid sensitive nephrotic syndrome (SSNS) children 2-10 years old, in Zagazig university outpatient clinic, implement this model on the intervention group and to assess the difference between the Biopsychosocial model and the biological model regarding the outcome in those children. Methods: A Randomized controlled clinical trial-single blinded study was conducted in Zagazig university pediatric nephrology outpatient clinic on 86 child (divided randomly into intervention and control groups) Primary steroid sensitive nephrotic syndrome Aged 2-10 years. Data was collected through a sheet of three parts; biological, social and psychological, the Biopsychosocial model was formulated, structured and applied on the intervention group and the biological model on the control group for 6 months where their ideas and expectations about disease, the compliance with treatment and follow up visits and frequency of relapses between the two groups were compared. Results: There was statistically significant difference between intervention and control group in the number of relapses and compliance with treatment. Regarding compliance with follow up visits, there was a highly significant difference between intervention and control group.. There was statistically significant difference after application of the Biopsychosocial model regarding patients' ideas and expectations about the disease. Conclusion: The Biopsychosocial model is significantly more effective than the biological model in the management of (SSNS) children, so we recommend all physicians to adopt this model.

Introduction.
Nephrotic syndrome (NS) is classically defined as massive proteinuria (>40 mg/m^2/hr), hypoalbuminemia (<2.5 g/dL), generalized edema, and hyperlipidemia in most cases [1]. The incidence of nephrotic syndrome is estimated to be 2–7 cases per 100 000 children per year and its prevalence rate is 16 per 100 000 children below th age of 16 in Iran [2].

A significant proportion of children with nephrotic syndrome show feature of depressed, hyperactive, or aggressive behavior. Somatic complaints, social withdrawal, and poor school performance were also observed [3].

The majority (80–90%) of patients have steroid-sensitive nephrotic syndrome (SSNS), with a very high probability of final cure. However, the disease often runs a prolonged and recurring course, affecting young children during the

phase in their lives when they are growing physically as well as socially and intellectually. It is recognized to cause short- and long-term physical, behavioral and psychosocial morbidities, particularly in those severely affected with frequent relapses [4]. Relapses seemed to be triggered by infections, especially the common cold. However, school events, such as final examinations or entrance examinations, and domestic events, especially those that seemed to reflect their mental stress, also appeared to trigger relapses [5].

The Biopsychosocial model is a general model that manages the biological, psychological and social issues as systems of the body and believes that all these factors have an important role in the occurrence of disease and illness. It draws a distinction between the actual pathological processes that cause disease, and the patient's perception of their health and the effects on it, called the illness, This concept is in contrast to the traditional biomedical concept of medicine which states that every disease process can be explained by the presence of an underlying factor that causes deviation from normal function such as a pathogen, genetic or developmental abnormality, or injury [6].

The Biopsychosocial model gives great importance to the illness; therefore the family physician must have efficient skills to be able to gather information during a consultation. As well as the biological signs and symptoms, the family specialist must pay a great attention to the patient's psychological state, their feelings and beliefs about the illness, and social factors such as their relationship with families and the larger community in order to produce greater health outcome and to relieve the patient suffering [7].

In this study, our objectives were; to design a Biopsychosocial model for (SSNS) children 2-10 years in the Zagazig university outpatient clinic, implement this model on the intervention group and to assess the difference between the Biopsychosocial model and the hospital model regarding the outcome of (SSNS) in those children.

Materials and methods

Design and setting: Randomized controlled clinical trial- single blinded study was conducted over 13 months from the first January 2012 to the end January 2013 in Zagazig University pediatric nephrology outpatient clinic as; it acts as a first health care contact serving Zagazig district population and adjacent rural areas, it is the only free center with famous reputation specialized for management of nephrotic syndrome with expected minimal drop outs and finally, this clinic services around 120 patients per month around 90% of them are nephrotic.

Patients: patients attending nephrology outpatient clinic at Zagazig University hospital and having the following inclusion criteria were included in our study; Primary nephrotic syndrome (idiopathic; without underlying cause), Age 2-10 years (The peak age for the onset of nephrotic syndrome is 2-3 years of age), and Steroid sensitive i.e. responding to steroid therapy within 4 weeks.

Sample size & sampling:

The sample size was calculated taking in consideration a significance level of 95%, power 80% and effect size 30%. Resulting in 90 children to be selected. A sample frame which consists of the files of all clinic attendants who fulfill the selection criteria was constructed from which the target population were chosen randomly, where only 86 children participated in our study (four patients refused to participate), then they were randomly allocated into two groups 1:1 (an intervention group and a control group).

Intervention (procedures) methods:

A. Data collection for this study was done by using a patient sheet which includes three parts social, biological and psychological.

a. _The social part_ includes: Personal data (name, age, sex, address, telephone,) and socioeconomic data.

b. _The biological part_ includes: _Clinical history;_ Age of 1st presentation, Duration of disease and Type of steroid sensitive nephrotic syndrome [a-frequent relapsing nephrotic syndrome ≥4 times per year or ≥ 2 times per 6 months. b-Infrequent relapsing nephrotic syndrome < 4 times per year or <2 times per 6 months c-Steroid dependent which relapse every time with the withdrawal of steroids]. _Clinical examination,_ e.g. weight, presence of edema, blood pressure, presence of any complication either of the disease or treatment, etc... and _Investigations_ (in the 1st visit) including: Boiling test for urine, serum albumin, kidney function.

c. *The psychological* part: The ideas and expectations of child or caregivers about the disease using the Illness perception questionnaire (child form_ modified) [8].
The sheets were filled through an interview with the child and the Caregiver, the questions were asked in lay language to the child if he was older than 6 years and to the caregiver if the child was ≤ 6 years. This was preceded by a pilot study conducted on 9 patients (i.e. 10% of the sample size) who were excluded from our sample, and needed modifications were done. The reliability of our questionnaire was 0.79 by cronbach's alpha Test.

B. Intervention tools: Both groups were managed by the routine protocol of management of nephrotic syndrome. A *personalized health education* to the child and/or caregiver (for intervention group only) was conducted in the form of message which was constructed depending on the concept of Biopsychosocial model ; a general knowledge about nephrotic syndrome (definition, causes, symptoms and signs, complications and how to deal with, triggers of relapse and how to avoid) , stressing on the importance of adherence to treatment protocol and follow up visits, adequate nutrition, guard against infections specially common cold, importance to avoid stress and how to reduce it and the importance of psychological and family support to the patients. This was conducted through interview with patients and their caregivers.

Outcome measures: outcome was measured at follow up visits and after 6 months of the intervention for the 2 groups to compare between; ideas and expectations about the disease their compliance with treatment (Compliance with treatment was assessed by counting pills [compliant if he took more than 80%of prescribed pills] [9], Compliance with follow up (we considered the patient complaint if he attended 5 visits or more out of 6). And frequency of relapses (Relapse is defined as recurrence of proteinuria [urine albumin dipstick ≥2+ on 3 consecutive days], most often in association with recurrence of edema [10].

Data management (statistics): Data was coded, entered and analyzed using SPSS program version 20 using chi square test, t-test, and Mcnemar test. Cochran's Q test which is an extension to the McNemar test for related samples was used to test for differences between three or more matched sets of frequencies or proportions within each group. In each study group individuals are observed under different times. The data are coded as dichotomous variables containing 0 to represent failure (or absence of follow visit), and 1 to represent success (or its presence). Logistic regression analysis was done to control for confounders that could affect the likelihood of relapses among the two study groups .The Odds of relapses in both study groups was calculated and Odds Ratio with 95% confidence interval with the relative estimate of risk. P value was set significant ≤ 0.05

Administrative and ethical design: Official permissions were obtained from the scientific, ethical committee of the collage "Institutional Review Board" (IRB), directors of the participated departments' family medicine division in community department, pediatric department, the director of the outpatient clinic. Also an informed written consent from the 2 groups of patient or their caregivers was taken.

Results
Table (1) shows that the sociodemographic characters of the intervention group were not statistically different from those of the control group.
Table (2) shows that there were no statistically significant differences between the intervention and control groups regarding their biological and disease related characters at the beginning of the study (p>0.05).
Table (3) shows that the baseline ideas and expectations of the patients /caregivers about the seriousness of disease were nearly the same with no significance difference before the application of BPS (p >0.05), while there is highly statistically significant difference regarding the patients' ideas after application of BPS in the intervention group in most of items, also there is a statistically significant difference after application of BPS between intervention and control group (p<0.05).
Table (4) shows that compliance of patients in the intervention group with treatment is significantly higher than those in the control group (p<0.05).
Figure (1) showed that the frequency of attendance at each scheduled visit (except the first) was significantly higher in the intervention group (p ≤ 0.05) , and also showed that there was a significant (p = 0.04) increase in the

proportions of those compliant to follow up visits in the intervention group. This was opposed by a non-significant change in compliance to follow up in hospital based model group (p = 0.75).

Figure (2) showed a difference in frequency of relapses between study groups varied from visit to visit with significant difference between the two groups at 6th visit (p=0. 02). However, there was a significant decrease in the proportion of relapses from the first visit (16.3%) to the sixth visit (0.0%) in the intervention group, (p = 0.02) compared to non-significant drop in relapses in biological based model group (p = 0.98).

Table (5) shows multivariate logistic regression analysis in which the number of follow up visits as an independent variable significantly affects the occurrence of relapses. When it was less than 5 visits during the six months of follow up, it increases the odds of relapse 7.4 times in children with NS compared to those with > 5 visits with 95.0% C.I. of (2.5 – 22.3).

Discussion

An important aspect in nephrotic management is to support the patient in performing necessary self-care behavior by recommending effective self-care regimens and educating patients in their use. The effectiveness of the Biopsychosocial model might be due to the synchronizing effect of different factors such as patient education program, diet regimen and psychological intervention. All these factors lead to better control of disease **(7).** A Randomized controlled clinical trial- single blinded study was conducted in Zagazig University pediatric nephrology outpatient clinic. In our study the effectiveness of the model was calculated by the difference in the outcome by measurement of occurrence and frequency of relapse, compliance with treatment and follow up visits and improvement of some psychological complaints. The effect of the Biopsychosocial model of consultation on the outcome of nephrotic syndrome has never been evaluated owing to the latest available information on **PubMed** January 2014.

Our results revealed non-significant difference between intervention and control groups regarding their baseline data including; sociodemographic characters, duration of disease and relapses which is also reflected on the biological characters related to the disease. This was a good indicator for us about the effective randomization of patients between two groups.

On measuring compliance with treatment and follow up visits among our two groups there was a statistically significant difference between intervention and controls with high level of compliance (83.7%) in the intervention group, while (67.4%) came for 6 visits and this difference begins from 2nd visit till 6th one to reach 100% in intervention group opposite to 76.2% in the control group. These results are similar to those of the study conducted in Colombia, where the efficacy of a Biopsychosocial intervention program for hypertension patients was measured, where the post-intervention changes in adherence to treatment were (86.6%) which was also significantly different from non-intervention group [11]. This could be explained by the facts that health outcomes including adherence to treatment are much improved when patients are involved in managing their own chronic illness [12], also due to the effect of patient education included in our intervention which was directed to the parents as our results demonstrate that their ideas and expectations about the treatment and its effect in improving the health conditions of their children differs significantly after application of Biopsychosocial model compared to the control group who didn't receive an educational message based on BPS. This explanation is supported by the studies concluded that patient education and or parent education in the case of children regarding disease, medications, its benefits, and the potential side-effects can enhance compliance, this is especially true in children with chronic diseases [13]. Also it was an indication for us about the effective difference in application of education based on BPS model items.

Regarding relapses, our results show a statistically significant difference between intervention and control group in the occurrence of relapses, especially in the 6th visit where relapses were absent in the intervention group in relation to its occurrence in 14.3% of the control group. This result could be related to the compliance with treatment and follow up which was higher in the intervention group, also due to application of the Biopsychosocial approach to the intervention group, as the patients need beside medical treatment a person that can enter their life and make important changes in their thinking, lifestyle and reaction with chronic diseases. Our results show that, increasing follow up was very effective with the nephrotic patients in the intervention group (who receive patient education beside the normal biological management). This was supported by **Delamater et al.,** who proved that the application of social and

psychological interventions beside the biological ones, can improve the quality of life and adherence in diabetic children as an example of chronic diseases [14].

Conclusion and recommendations

The Biopsychosocial model is more effective than the biological model in control of the pediatric nephrotic syndrome. So we recommend the application of the BPS model in the control of nephrotic children through training of physicians to help them understanding the Biopsychosocial approach and reinforce their knowledge and skills. Also, we recommend further studies on different chronic diseases with different methodologies and sample sizes to prove the effectiveness of the BPS model in the management of other chronic diseases.

Limitations

Patients' unresponsiveness, short Consultation session time (around 15 minutes).

Conflict of interest: Authors declare there is no conflict of interest regarding the publication of this paper.

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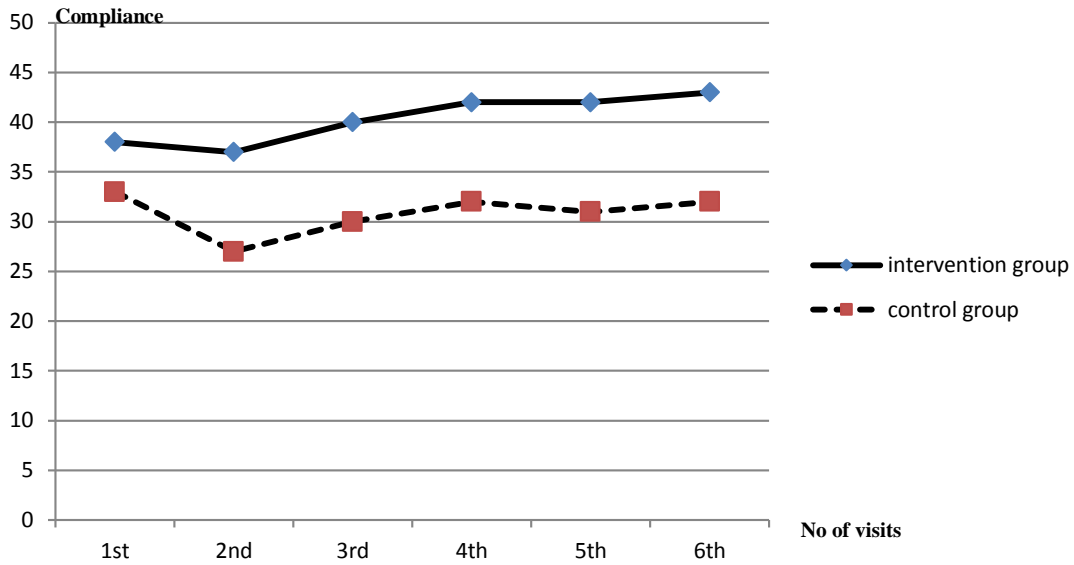
Figures

Figure (1) compliance of the patients in intervention and control groups with the follow up visits
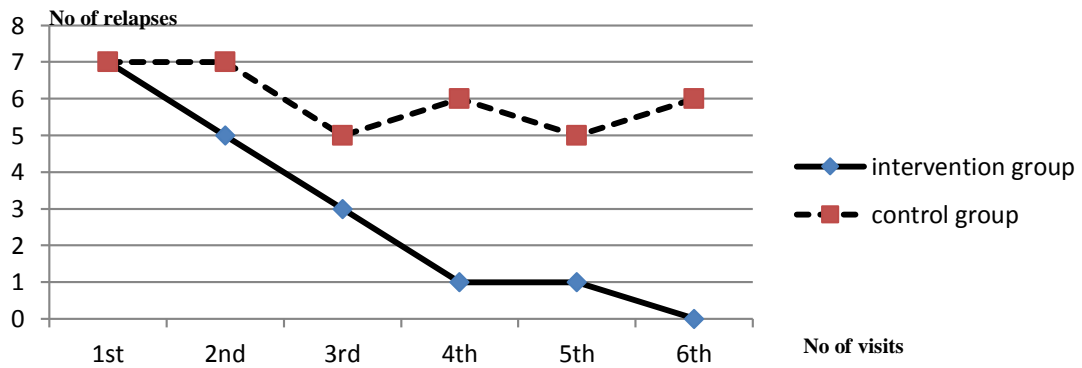

Figure (2) Relapses in relation to the visits in both intervention and control groups.

Table (1): Socio demographic characteristics of the intervention and control groups

	Intervention (N =43)		Control (N=43)		x^2	p-value
	n	%	n	%		
Gender:						
Male	28	65.1	27	62.8	0.05	0.82
female	15	34.9	16	37.2		
Address:						
Urban	23	53.5	21	48.8	0.18	0.66
rural	20	46.5	22	51.2		
Father education:						
Illetrate						
Read&write	21	48.8	20	46.5	0.16	0.99
Primary	2	4.7	2	4.7		
Moderate	5	11.6	5	11.6		
high	12	27.9	12	27.9		
	3	7	4	9.3		
Mother education:						
Illetrate						
Read&write	14	32.6	15	34.8	0.46	0.97
Primary	5	11.6	5	11.6		
Moderate	2	4.7	2	4.7		
high	21	48.8	19	44.2		
	1	2.3	2	4.7		
Father occupation:						
Farmer						
Worker	6	14	7	16.3	0.13	0.99
Skilled	20	46.5	20	46.5		
Official	9	20.8	8	18.5		
Professional	6	14	6	14		
	2	4.7	2	4.7		
Mother occupation:						
Not work						
work	40	93	40	93	0.00	1.00
	3	7	3	7		
Income:						
Not enough	15	34.9	16	37.2	0.05	0.97
Enough	23	53.5	22	51.2		
Enough&more	5	11.6	5	11.6		

Table (2): Biological and disease related characters of the Intervention and control groups at the beginning of the study.

	Intervention (N=43)		Controls (N=43)		t-test	p-value
	mean	SD	mean	SD		
Age (in years)	5.85	2.18	5.9	2.25	0.10	0.91
Age of 1st presentation	3.25	1.54	3.51	1.86	0.70	0.48
Disease duration	2.58	2.08	2.34	2.03	0.54	0.58
	n	**%**	**n**	**%**	x^2	**p-value**
Type : Frequent relapsing In frequent relapsing Steroid dependent	12 29 2	27.9 67.4 4.7	10 31 2	23.3 72.1 4.7	0.24	0.88
Events associated with relapses: Common cold Infection School event Domestic event Stop medicine Tapering medicine	37 12 0 0 4 9	86 27.9 0.0 0.0 9.3 20.9	34 10 0 0 3 6	79.1 23.3 0.0 0.0 7 14	0.72 0.24 0.15 0.72	0.39 0.62 0.69 0.39
Complications: Infection Moon face Obesity Ascitis Hypertention	7 14 21 9 6	16.3 32.6 48.4 20.9 14.0	9 14 19 6 3	20.9 32.6 44.2 14.0 7.0	0.30 0.00 0.18 0.72 1.11	0.57 1.00 0.66 0.39 0.29
Edema: Patients in relapse (edematous). Patients in remission (not edametous).	16 27	37.2 62.8	17 26	39.5 60.5	.049	0.82

Table (3) Ideas and expectations of the patients and/or their caregivers in the studied groups before and after BPS model application.

	Intervention group				Control group				p-value	
	Before (n=43)		After (n=43)		Before (n=42)		After (n=42)		#P3	##P4
	n	%	n	%	n	%	n	%		
Serious disease	26	60.5	15	34.9	28	66.7	27	64.2	0.552	0.006
	*P1: 0.723				*P2: 0.060					
Has a big effect on life.	12	27.9	11	25.6	15	35.7	16	38.1	0.439	0.215
	P1: 0.002				P2: 0.093					
Others see the child differently	7	16.3	4	9.3	13	30.9	17	40.5	0.110	0.000
	P1: 0.000				P2: 0.076					
Difficult for family and friends.	32	74.2	19	44.2	23	54.7	22	52.4	0.057	0.449
	P1: 0.144				P2: 0.639					
Can do a lot to control symptoms.	33	76.7	40	93.0	28	66.7	27	64.2	0.302	0.001
	P1: 0.000				P2: 0.060					
Will get better with time.	25	58.1	40	93.0	26	61.9	24	57.1	0.723	0.000
	P1: 0.003				P2: 0.205					
Treatment will help	27	62.8	40	93.0	26	61.9	25	59.5	0.932	0.000
	P1: 0.001				P2: 0.159					
Nothing can help	12	27.9	5	11.6	13	30.9	16	38.1	0.758	0.004
	P1: 0.000				P2: 0.052					

Total number of controls 42 only due to death of one patient

*Mac nemare test was used

Chisquare test between between before intervention in both groups.

Chisquare test between between after intervention in both groups.

Table (4): Compliance with treatment in both Intervention and control groups for the six visits:

	Intervention (n=43)		Controls (n=42)#		x^2	p-value
	n	%	n	%		
Yes	36	83.7	23	54.8	7.93	.005
No	7	16.3	19	45.2		

#total number of controls 42 only due to death of one patient

Table (5): Logistic regression analysis showing likelihood of relapses with number of follow up visits .

	B	S.E.	p value	Odds ratio (OR)	95.0% C.I. for OR	
					Lower	Upper
FU visits ≤4	2.001	0.564	0.00	7.400	2.451	22.345
Constant	-0.520	0.269	0.053	.595		

B = regression coefficient, SE = standard error, p value is significant <= 0.05