Adv Ther
DOI 10.1007/s12325-014-0165-1

LONG TERM EFFECTS AND SAFETY OF SOY LECITHIN PHOSPHATIDYLSERINE (PS) TREATMENT IN COGNITIVELY IMPAIRED OUT-PATIENT GERIATRIC POPULATION

Study Progress Report , September, 2000.

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GENERAL.

Phospholipids are present in nerve cell membrane, and are essential for cell membrane functioning. The amount of Phospholipids in neuronal membranes declines with age, particularly of PS, which correlates with the level of cognitive impairment.

The Geriatric Institute for Education and Research in Kaplan Medical Center has performed in the past two studies on soy lecithin PS complex, one with normal aged patients, and the other with Alzheimer's Disease patients. The patients of these studies showed improvement.

This third study is an historical prospective study on out-patient, second opinion, geriatric clinic population for patients with cognitive complaints. The purpose of this study is to assess the long term influence and safety of soy lecithin phosphatidylserine (PS) complex usage, by reviewing records of patients that have been, or still are, under treatment with the Lipogen Ltd. soy lecithin PS complex.

In this stage of the study we can conclude the following:

Statistically significant positive clinical influence of PS treatment has been recorded in most categories with patients suffering from cognitive impairments.

The data could not allow relating any specific adverse effects to the soy lecithin PS complex treatment.

Except for a singular case, no cognitive deterioration was observed in the treatment group. This is in contrast to the natural cognitive deterioration, which is normally expected.

All patients had positive attitude towards the phosphatidylserine complex treatment and carried on with the treatment on their own expenses for more than a year.

The phosphatidylserine which was used in this study is vegetal and made of soy lecithin. Soy lecithin phosphatidylserine complex is considered a food supplement (lecithin and other phospholipids). The product is freely sold as an OTC product (Israel, Europe, USA, etc.).

This is a confidential study progres report. The information of this report is not to be disclosed in any publication nor be subjected to any public exposure whatsoever.

Study group population.

All the records of the patients who were registered between 1991-1999 in the geriatric clinics of the Geriatric Institute at the Kaplan Medical Center and the Assutah Hospital in Israel have been screened. The clinics include mainly second-opinion patients. Only patients that have been prescribed PS and assessed at least twice were included in this study. Data were collected by a physician in an historical prospective manner and gathered in a uniform instrument. Objective and subjective data from patients and families were collected as well. There were no exclusive criteria and there is no control group in the study. Further, there are concomitant other intervention in the patients due to the second-opinion visits, such as discontinuation of drugs and change in treatment regime that may interfere with the results. In the following tables the characteristics of the study group population are summarized.

Table 1a, Age distribution.

Mean ± S.D	Maximum age	Minimum age	No. of patients	
76 ± 8.74	92	44	68	Age

Gender. Table 1b,

%	Frequency	Gender
50.0	34	Male
50.0	34	Female
100.0	68	*TOTAL*

Table 1c, Patients place of residence.

% (recorded)	%	Frequency	Residence
91.8	82.4	56	Home
3.3	2.9	2	Kibbutz
4.9	4.3	3	Long term care
-	10.3	7	Missing
100.0	100.0	68	*TOTAL*

Table 1d, Patients diagnosis.

% (recorded)	%	Frequency	Diagnosis
76.1	75.0	51	Alzheimer's disease
14.9	14.7	10	Other dementia
8.9	8.8	6	Memory loss
-	1.5	1	Missing
100.0	100.0	68	*TOTAL*

Table 1e, Degree of dementia.

% (recorded)	%	Frequency	Degree of dementia
14.5	13.2	9	Mild
67.8	61.8	42	Moderate
17.7	16.2	11	Severe
-	8.8	6	Missing
100.0	100.0	68	*TOTAL*

DURATION OF CONTINUOUS PS TREATMENT.

The average duration of continuous treatment with the soy lecithin phosphatidylserine complex was 1.4 ± 1.8 years. The maximum length of treatment period was 13 years. The minimum treatment period was 2 months.

Table 2, Duration of continuos PS treatment.

% (recorded)	%	Frequency	Treatment's duration
38.9	33.8	23	Less than 6 months
10.2	8.8	6	6-12 months
50.9	44.1	30	More than a year
-	16.7	9	Missing

STATISTICAL METHODS AND RESULTS.

The Wilcoxon signed ranks test was used to test the hypothesis (Ho) that the cognitive state of patients before PS treatment and after 3-6 months or after more than 12 months have the same distribution.

Table 3.1 Change of mental state by components of cognitive state after 3-6 months treatment.

Cognitive state after 3-6 months treatment				
p-value	Improved	No change	Deteriorated	
.025*	5	11	0	Judgement
.005*	19	29	0	Short term memory
.034*	7	35	1	Long term memory
.000	25	21	1	Organization
.004*	9	8	0	Drawing a clock
.001*	11	24	0	Calculating
.157	2	10	0	Actuality questions
.046	4	11	0	Counting backwards

Fig. 1

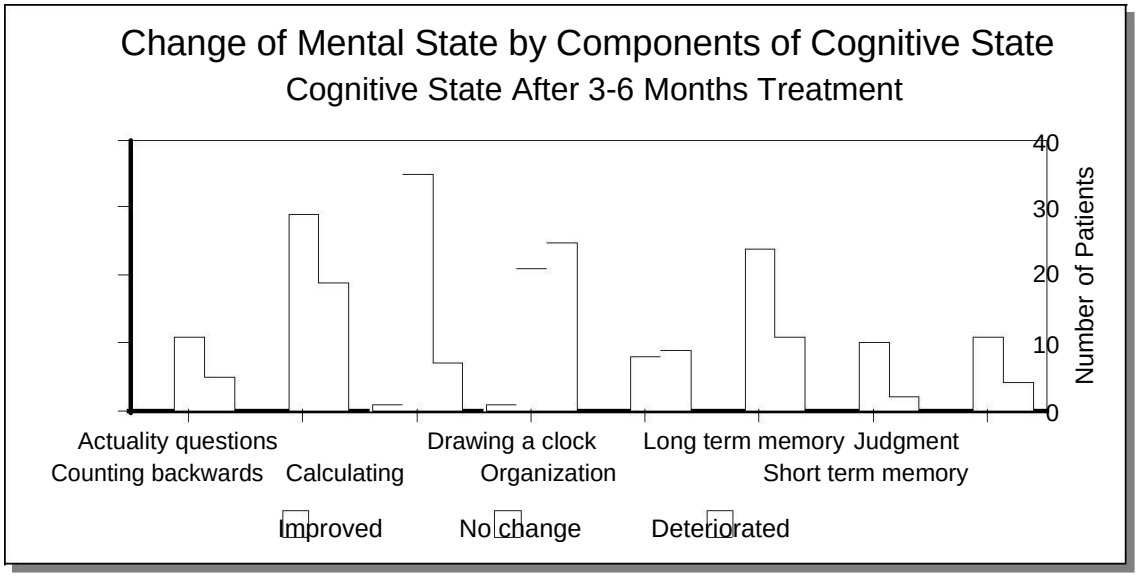


Table 3.2 Change of mental state by components of cognitive state after 12 months treatment.

Cognitive state after 12 months treatment				
p-value	Improved	No change	Deteriorated	
.046*	4	3	0	Judgement
.001*	12	10	0	Short term memory
.026*	4	13	0	Long term memory
.000	17	5	0	Organization
.083	3	6	0	Drawing a clock
.025*	5	10	0	Calculating
.317	1	3	0	Actuality questions
.157	2	2	0	Counting backwards

Fig. 2

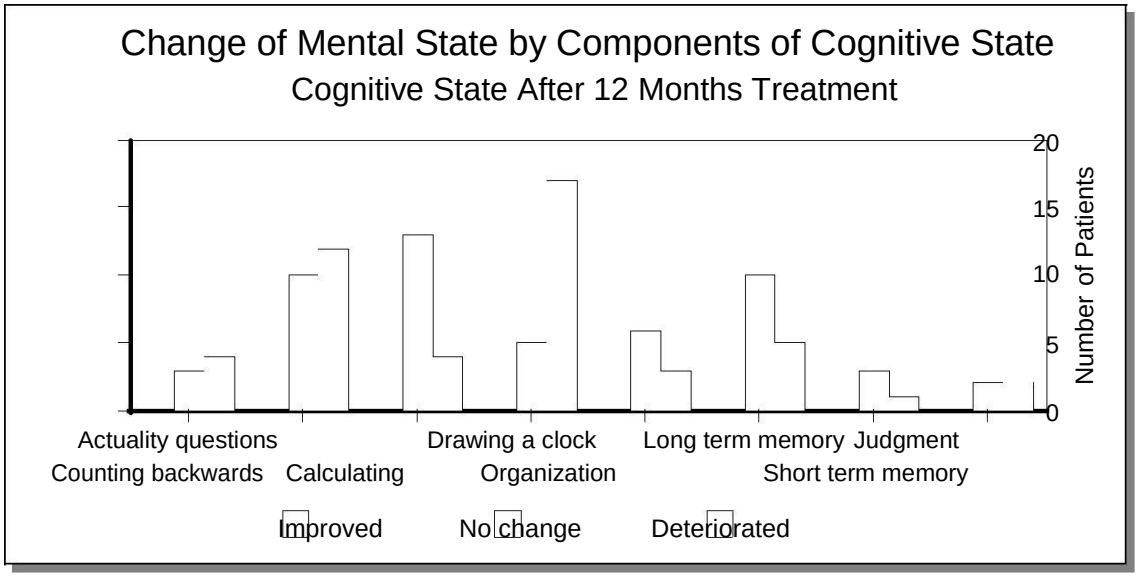
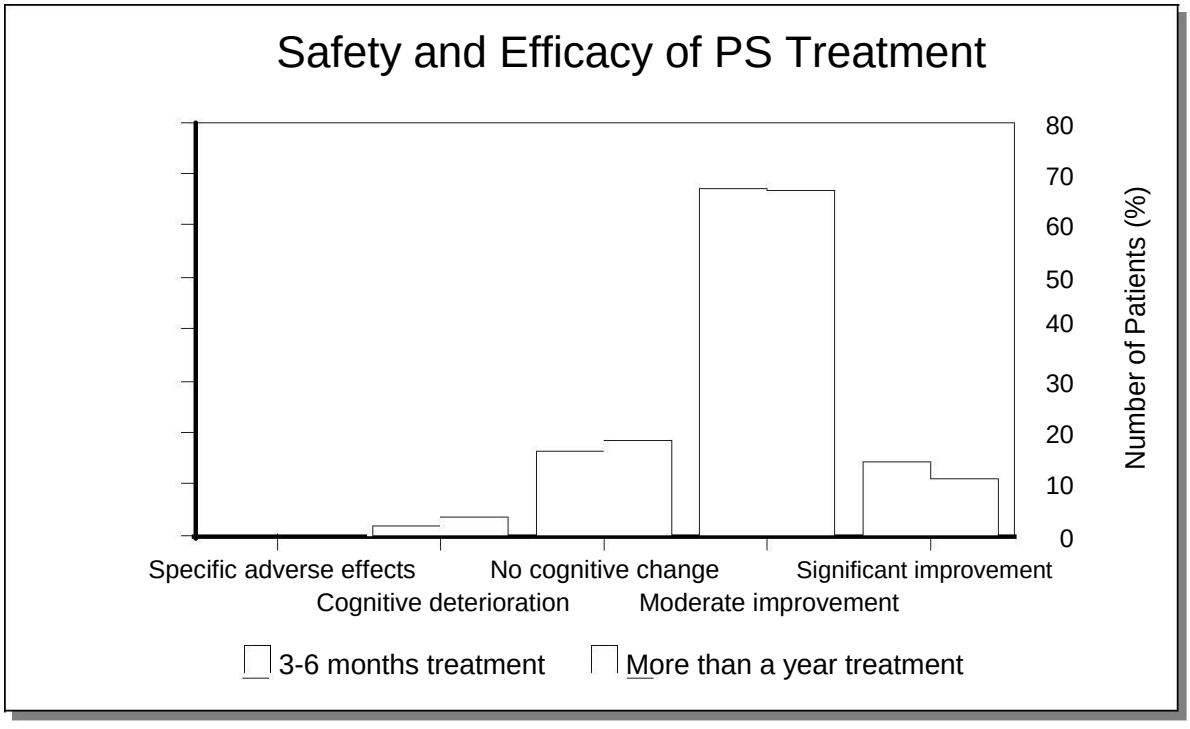


Table 4, Summary – Safety and efficacy of PS treatment

More than a year treatment		3-6 months treatment		Effect
%	Number of Patients	%	Number of Patients	
0	0	0	0	Safety - (specific adverse effects)
3.7	1	2.0	1	Cognitive deterioration
18.5	5	16.3	8	No cognitive change
66.7	18	67.4	33	Moderate improvement
11.1	3	14.3	7	Significant improvement
100.0	27	100.0	49	*TOTAL*

Fig. 3



Conclusions

Statistically significant positive clinical influence of PS treatment has been recorded in most categories with patients suffering from cognitive impairments.

The data could not allow relating any specific adverse effects to the soy lecithin PS complex treatment.

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