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## Study on the Comparative Efficacy and Safety of Intellan, Poly Herbal Product (Test Group) with Vinpocetine (Control Group) to Treat Dementia

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**Abstract:** This study aimed to compare the efficacy and safety of Polyherbal product Intellan with Vinpocetine in managing dementia and subject them to analysis by Mini mental state examination (MMSE) score, which is the most broadly perceived formal intellectual test. The MMSE was a 30-point test. This study was conducted at the Department of Medicine, Civil Hospital, Karachi, for six months. Patients were dispensed to get the test drug Intellan or controlled drug Vinpocetine. Keeping in consideration for 20% dropout in the test drug arm, with full appliance in the vinpocetine treatment arm, 150 subjects were in each arm. A total of 300 patients of both genders aged between 30 and 75 years who met the inclusion criteria participated in the study. The patients were evaluated prospectively for 24 weeks. The patients were advised follow-up visits weekly. Data were entered and analyzed using SPSS 12.0 (statistical software). The study groups were compared with the baseline characteristic, clinical presentation and history. Mean comparison was done by independent t-test and dependent t-test as appropriate,  $p \leq 0.05$  was considered significant. No such study can be found that compare these drugs for treating dementia. In our study, mean MMSE before treatment, at 3 months and at 6 months was  $8.91 \pm 4.12$ ,  $10.78 \pm 4.41$ ,  $13.54 \pm 4.54$ , respectively, while in group B, mean MMSE before treatment, at 3 months and at 6 months was  $8.61 \pm 4.00$ ,  $10.74 \pm 4.18$ ,  $13.24 \pm 4.63$ , respectively. We found significant mean difference of MMSE before treatment with MMSE at 3 months, MMSE before treatment with MMSE at 6 months and MMSE at 3 months with MMSE at 6 months for both groups. An insignificant mean difference of MMSE at the 6th month s with study group ( $p=0.572$ ) was found. Mean comparison was also done according to the study group s for stratified categories of gender, age, socio-economic status, education status, family history of dementia, living area, Alzheimer, epilepsy, diabetes mellitus, hypertension and body mass index.

**Keywords:** Intellan, Vinpocetine, mini-mental state examination, dementia, efficacy.

## 英特兰、聚草本产品 ( 试验组 ) 与长春西汀 ( 对照组 ) 治疗痴呆的比较疗效和安全性研究

**摘要:** 本研究旨在比较多草产品英特兰与长春西汀治疗痴呆症的疗效和安全性, 并通过迷你金属状态检查(MMSE)评分对其进行分析, 这是最广泛认知的正式智力测试。MMSE 是一个 30 分的测试。这项研究在卡拉奇民间医院医学部进行了六个月。患者被分配获得测试药物英特兰或控制药物长春西汀。考虑到试验药物组有 20% 的辍学率, 长春西汀治疗组完全矫治器, 每组 150 名受试者。共有 300 名年龄在 30 至 75 岁之间且符合纳入标准

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的男女患者参与了该研究。对患者进行了为期 24 周的前瞻性评估。建议患者每周进行一次随访。使用 SPSS 12.0 (统计软件) 输入和分析数据。将研究组与基线特征、临床表现和病史进行比较。平均比较采用独立吨检验和依赖吨检验酌情进行,  $p \leq 0.05$  被认为是显著的。没有这样的研究可以比较这些治疗痴呆症的药物。在我们的研究中, 治疗前、3 个月和 6 个月的平均 MMSE 分别为  $8.91 \pm 4.12$ 、 $10.78 \pm 4.41$ 、 $13.54 \pm 4.54$ , 而乙组治疗前、3 个月和 6 个月的平均 MMSE 为  $8.61$  分别为  $\pm 4.00$ 、 $10.74 \pm 4.18$ 、 $13.24 \pm 4.63$ 。我们发现两组在 3 个月 MMSE 治疗前、6 个月 MMSE 治疗前 MMSE 和 3 个月 MMSE 与 6 个月 MMSE 治疗前 MMSE 的平均差异显著。发现研究组在第 6 个月时 MMSE 的平均差异不显著 ( $p=0.572$ )。还根据研究组对性别、年龄、社会经济地位、教育状况、痴呆家族史、生活区、阿尔茨海默病、癫痫、糖尿病、高血压和体重指数等分层类别进行了平均比较。

**关键词:** 英特尔兰, 长春西汀, 小型精神状态检查, 痴呆, 疗效。

## 1. Introduction

Dementia, is extracted from a Latin word meaning 'without mind', is a procured clinical disease of delayed range and is generally dynamic which is depicted by an expanding disintegration in the movement of little strokes and a conflicting course of deficiencies impacting a couple of capacities and not others. Side effects can be divided into three classes: weakness of wisdom, mental and social features, and brokenness related to activities of ordinary living [1]-[2]. This fuse perplexity, issues with progressing memory, wandering and becoming stirred up in conspicuous spots, loss of bladder or stomach control (incontinence), energetic issues for instance, laughing or crying inappropriately, inconvenience following headings, and issues with essential capacities, for instance, managing cash.

### 1.1. Herbal Treatment for Dementia

Herbal medicines have been used for managing dementia-like side effects for quite a long time and may provide reasonable treatments. Due to their multicomponent and multitarget approach herbal medications are hotspots for new treatments for dementia. For instance, galanthamine, a normally used cholinesterase inhibitor, is a natural subsidiary [3]. Huperzine isolation from the Chinese spice *Huperzia serrata*, additionally shows remarkable improvement in symptoms [4]-[5]. Concentrates of the herb *Ginkgo biloba* have got a lot of examination, consideration and are as of now in inescapable use [6]-[7]. Trial reports recommend that a few herbs might have neuroprotective impacts against beta-amyloid [8]-[9]. Vinpocetine is a manufactured ethyl ester of apovincamine, a vinca alkaloid extracted from the leaves of the Lesser Periwinkle (*Vinca minor*) is likewise used in dementia treatment.

Polyherbal detailing has been used all over the

globe because of its supportive and accommodating application. It has, in any case, called polyherbal treatment or herb-herb combination. Over the last few years, the relentless advancement of herbal medications promoted, especially in the western countries, has been exceptional earth shattering. INTELLAN, a polyherbal drug, is a compound, coordinated by Herbion Pakistan (Pvt) Ltd. As indicated by the makers, it is used to overhaul and redesign the psychological execution, memory work, sharpness, ease of disquiet, trouble [10]-[11].

### 1.2. Plant Constituents of Intellan

*Centella asiatica – Barhami booti:* *Centella asiatica* is native to the Indian subcontinent, Southeast Asia, and wetland areas of the Southeastern US [12]-[13]. Because the plant is oceanic, it is particularly delicate to natural and compound poisons in the water, which might be assimilated into the plant. It may develop in drier soils as long as they are watered routinely. In conventional home-grown medication, *C. asiatica* has been used trying to treat varicose veins, ongoing venous deficiency, psoriasis, minor wounds [14], strangury, and to urge lactation [15]. According to the American Cancer Society, despite the fact that something like one research facility investigation of growth cells showed decreased cell development with gotu kola, accessible logical proof does not uphold cases of its viability for treating malignant growth or some other sickness in people.

*Coriandrum sativum – Dhaniya Khushk:* *Coriandrum Sativum* has a place within the family Apiaceae and is a yearly filled spice tracked down generally in the Mediterranean nations. The spice loves to fill where the temperature is sufficiently hot. The seeds of *Coriandrum Sativum* are called seeds of coriander and their leaves are, for the most part, alluded to as Cilantro. All pieces of the plant are palatable, yet

the new leaves and the dried seeds are the parts most customarily used in cooking. Coriander is used in cooking styles all through the world.

*Amomum subulatum* – *Ilaichi kalan*: Dark cardamom, otherwise called slope cardamom, Bengal cardamom more noteworthy cardamom, Indian cardamom, Nepalian cardamom, winged cardamom, or earthy colored cardamom, comes from both species in the family Zingiberaceae. Its seed units have a solid camphor-like flavor, with a smoky people getting from the method for drying.

*Emblica officinalis* – *Amlao*: Indian conventional arrangement of medication, the Ayurveda. The organic product, otherwise called Indian gooseberry or Amla, has been a natural part of Thai conventional plans accepted to dial back the aging process [16] but at the same time is utilized to treat numerous diseases like normal cold and fever, as a diuretic, purgative, liver tonic, refrigerant, stomachic, helpful, alterative, antipyretic, anti-inflammatory, hair tonic, to forestall peptic ulcer and dyspepsia, and as a digestive.

*Canscora decussata* – *Sankha Holi*: Each plant part, yet basically, the juice, is applied in herbal medication used in Ayurveda, Sidha and Unani. The spice helps metabolic rates and treat anxious disorders. The scope of conditions in which the herb is applied incorporates scrofula, nervous debility, sanity, and epilepsy. Sankh Pushpi is believed to be compelling in treating nervous issues, similar to cerebrum conditions and others, giving better and longer memory, furthermore being a metabolic sponsor. Herbal drugs produced from the plant are known to further improve memory.

### 1.3. Clinical Diagnosis

The clinical disorder of dementia, portrayed by new functional reliance based on moderate intellectual decay, can be because of an assortment of hidden pathophysiological processes. The most widely recognized of these is Alzheimer's illness (AD; 50%-75%) trailed by vascular dementia (VaD; 20%), dementia with Lewy bodies (DLB; 5%) and frontotemporal lobar dementia (FTLD; 5%) [17]. The critical clinical and neurotic crossover between these cycles means their overall frequencies are gauges at best [18]-[19]. Less normal causes (3%) incorporate Huntingdon's infection, Creutzfeldt-Jakob sickness, HIV/AIDS and various sclerosis.

Cognitive impairment vital to the diagnosis of dementia can be ordered into five fundamental categories: memory; executive capacity; language; visuospatial capacities; personality and conduct.

#### 1.3.1. The Scales Used for the Diagnosis of Dementia

Physical assessment is needed to analyze for central neurological or extrapyramidal signs, Cognition. Presumably, the most broadly perceived formal intellectual test is the Mini Mental State Examination (MMSE), first proposed in 1975. The MMSE is a 30-

point test.

#### *Advantages:*

- Relatively fast and simple to perform
- Requires no extra hardware
- Can give a technique for checking crumbling over the long run

#### *Disadvantages:*

- Biased against individuals with poor education because of components of language and numerical testing
- Bias against visually impeding
- Limited assessment of visuospatial cognitive capacity
- Poor sensitivity in identifying mild/early dementia

## 2. Materials and Method

### 2.1. Study Area

The study was conducted in the department of medicine Dr. Ruth KM Pfau Civil Hospital, Karachi, Pakistan.

*Duration:* From 25<sup>th</sup> September 2020 to 24<sup>th</sup> March 2021.

*Sample size:* 300 subjects were enrolled, 150 patients in each group.

*The sample technique:* non-probability of consecutive sampling was used for this study.

*Study Design:* Randomized controlled trial.

### 2.2. Sample Selection

#### 2.2.1. Inclusion Criteria

- Dementia diagnosed or possibly patients with dementia and Alzheimer's
- Patients who have hypertension, diabetes, heart illness, or stroke that have been steady or controlled by medication for no less than multi-month.

#### 2.2.2. Exclusion Criteria

- Subjects with different types of dementia, insanity, schizophrenia, intense sickness, or inadequately perpetual infections
- Medications that influence psychological capacity that include Ginkgo biloba, psychotropic medications, hypnosedatives.
- Medications, for example, warfarin that has critical medication communications with the herbs in the equation.

### 2.3. Data Collection Procedure

This study was conducted at the Department of Medicine, Civil Hospital, Karachi for six months. The research was a double-blind, randomized study. A statistician created adjusted subject allocation without providing data to patients and officer. After the subject allocation, patients were dispensed Intellan or controlled drug Vinpocetine. Considering the 20%

dropout in the test drug arm, with full appliance in the vinpocetine treatment arm, 150 subjects in each arm, Randomization happened as near the beginning of treatment as would be prudent and the following management was apportioned undistinguished before the commencement of trial.

The members and exploring staff were blinded to the treatment distribution until the point of completion of the trial. Just statistician, also the information checking board saw unblinded information, yet none had the contact information of participants. All considered members and exploring staff were not informed about treatment allotment until the completion of the study.

Patients aged between 30 years and 75 years of both sexes attending Medical outdoor patients (OPD), diagnosed to have dementia were included in this study. Approved international criteria for diagnosis MMSE is a criterion for diagnosis.

The drugs which were used and their dose ranges are given below:

1. Vinpocetine at a dose of 30 mg once daily.
2. Intellan 500 mg once daily.

The patients were assessed tentatively for a considerable length of time that is 24 weeks. Patients were suggested for follow-up visits weekly. Data were entered and analyzed using SPSS 12.0. Study groups were compared with the baseline characteristic, clinical presentation and history. We used an independent t-test while comparing the study groups to look at the effectiveness of the drug regimens at each follow-up when the dose was given.

### 3. Results

In total, 300 patients of both sexes, male and female, aged between  $\leq 30$  and  $\geq 75$  years, meeting inclusion criteria of study, participated in the study to compare efficacy and safety of polyherbal product Intellan with Vinpocetine to manage dementia. Patients were divided into two treatment groups, Group A (poly herbal product Intellan) and Group B (Vinpocetine) with 150 patients in each arm. Descriptive statistics were calculated using SPSS. Qualitative variables are presented in terms of frequency and percentages. The qualitative variables are presented in terms of mean and standard deviations. Mean comparison was done by independent t-test and dependent t-test as appropriate,  $p \leq 0.05$  was considered significant.

The results showed 68.7% male and 31.3% female patients in group A. In group B, there were 50.7% male and 49.3% female patients, as presented in Table 1.

Table 1 Frequency distribution of gender (n = 300)

	Frequency (%)	
	Group A	Group B
Male	103 (68.7)	76 (50.7)
Female	47 (31.3)	74 (49.3)
Total	150	150

The mean age of patients in groups A and B was  $52.76 \pm 11.47$  years and  $52.98 \pm 10.87$  years, respectively. The descriptive statistics of age are presented in Table 2. Age was further stratified in the groups. Frequencies of patients in age groups are presented in Fig. 1.

Table 2 Descriptive statistics of age (years) (n = 300)

	Group A (n = 150)	Group B (n = 150)
Mean	52.76	52.98
SD	11.47	10.87
Median	51.00	53.00
Range	39	38
Minimum	34	34
Maximum	73	72

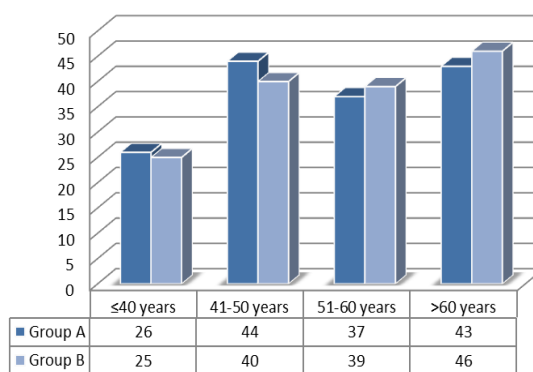


Fig. 1 Frequency of patients according to age groups

In group A, 57.3% participants were from low class and 42.7% were from middle class, while in group B, 62.7% participants were from low class and 37.3% were from middle class, as presented in Table 3. In both groups majority (63.3% and 72.7%) had an educational till matric while 95.3% of patients having dementia family history in group A and 93.3% in group B. Detailed frequency distributions are presented in Table 4 and Table 5.

Table 3 Frequency distribution of the socio-economic status (n = 300)

	Frequency (%)	
	Group A	Group B
Low	86 (57.3)	94 (62.7)
Middle	64 (42.7)	56 (37.3)
Total	150	150

Table 4 Frequency distribution of education (n = 300)

	Frequency (%)	
	Group A	Group B
Illiterate	23 (15.3)	9 (6)
Matric	95 (63.3)	109 (72.7)
Inter	32 (21.3)	32 (21.3)
Total	150	150

Table 5 Frequency distribution for family history of dementia (n = 300)

	Frequency (%)	
	Group A	Group B
Yes	143 (95.3)	140 (93.3)
No	7 (4.7)	10 (6.7)

Continuation of Table 5		
Total	150	150

There were 49.3% patients from urban and 50.7% from rural areas in group A while 46.7% were from urban and 53.3% were from rural areas, as presented in Table 6.

Table 6 Frequency distribution of living area (n = 300)

	Frequency (%)	
	Group A	Group B
Urban	74 (49.3)	70 (46.7)
Rural	76 (50.7)	80 (53.3)
Total	150	150

In group A, 89.3% patients were found with Alzheimer, 96.7% with epilepsy, 24.7% with diabetes mellitus and 17.3% with hypertension, while in group B, 88.7% of patients were found with Alzheimer, 98% with epilepsy, 17.3% with diabetes mellitus and 14% with hypertension, respectively. Most patients (38.7%) were overweight in group A while in group B, Majority (32.7%) were found with normal weight, as presented in Tables 7 and 8, respectively.

Table 7 Frequency distribution of comorbidities (n = 300)

	Frequency (%)	
	Group A	Group B
Alzheimer	134 (89.3)	133 (88.7)
Epilepsy	145 (96.7)	147 (98)
Diabetes Mellitus	37 (24.7)	26 (17.3)
Hypertension	26 (17.3)	21 (14)

Table 8 Frequency distribution of the body mass index group (n = 300)

	Frequency (%)	
	Group A	Group B
Underweight	21 (14)	34 (22.7)
Normal	50 (33.3)	49 (32.7)
Overweight	58 (38.7)	44 (29.3)
Obese	21 (14)	23 (15.3)
Total	150	150

In our study, mean MMSE values before treatment (Table 9), at 3 months (Table 10) and at 6 months (Table 11) were  $8.91 \pm 4.12$ ,  $10.78 \pm 4.41$ ,  $13.54 \pm 4.54$ , respectively, while in group B, mean MMSE before treatment, months and at 6 months was  $8.61 \pm 4.00$ ,  $10.74 \pm 4.18$ ,  $13.24 \pm 4.63$ , respectively.

Table 9 Descriptive statistics of the MMSE score before treatment (n = 300)

	Group A	Group B
	(n = 150)	(n = 150)
Mean	8.91	8.61
SD	4.12	4.00
Median	11.00	10.00
Range	13	13
Minimum	1	1
Maximum	14	14

Table 10 Descriptive statistics of the MMSE score at the 3rd month (n = 300)

	Group A	Group B
	(n = 150)	(n = 150)
Mean	10.78	10.74
SD	4.41	4.18
Median	12.00	12.00
Range	16	16
Minimum	2	2
Maximum	18	18

Table 11 Descriptive statistics of the MMSE score at the 6<sup>th</sup> month (n = 300)

	Group A	Group B
	(n = 150)	(n = 150)
Mean	13.54	13.24
SD	4.54	4.63
Median	15.00	14.00
Range	20	19
Minimum	2	3
Maximum	22	22

We found a significant mean difference in MMSE before treatment with MMSE at 3 months, MMSE before treatment with MMSE at 6 months and MMSE at 3 months with MMSE at 6 months for both groups as presented (Table 12).

Table 12 Mean comparison of the MMSE scores for each group (n = 300)

MMSE	MMSE	Mean $\pm$ SD		P-Value
		Mean	SD	
Group A	Before Treatment	8.91	4.12	0.000*
	At 3 months	10.78	4.41	
	Before Treatment	8.91	4.12	
	At 6 months	13.54	4.54	
Group B	At 3 months	10.78	4.41	0.000*
	At 6 months	13.54	4.54	
	Before Treatment	8.61	4.00	
	At 3 months	10.74	4.18	
Group B	Before Treatment	8.61	4.00	0.000*
	At 6 months	13.24	4.63	
	At 3 months	10.74	4.18	
	At 6 months	1.48	0.67	

Notes: Dependent t-test was applied; P-value  $\leq 0.05$  is considered significant; \* Significant at 0.05 levels

We found an insignificant mean difference in MMSE at the 6th month with the study group ( $p=0.572$ ) as presented in Table 13. Mean comparison was also performed according to a study group for stratified categories of gender, age, socio-economic status, education status, family history of dementia, living area, Alzheimer, epilepsy, diabetes mellitus, hypertension and body mass index (Tables 14-24).

Table 13 Mean comparison of MMSE at 6 months according to the study group (n = 300)

	Mean $\pm$ SD		P-Value
	Mean	SD	
Group A	13.54	4.54	0.572**
Group B	13.24	4.63	

Notes: An independent t-test was applied; P-value  $\leq 0.05$  is considered significant; \*\* Insignificant at 0.05 levels

Table 14 Mean comparison of MMSE at the 6th month according to the study group for gender (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Male	Group A	13.54	4.66	0.975**
	Group B	13.56	4.59	
Female	Group A	13.53	4.33	0.739**
	Group B	12.90	4.67	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 15 Mean comparison of MMSE at the 6th month according to the study group for the age group (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
≤ 40 years	Group A	16.92	2.03	0.499**
	Group B	16.48	2.58	
41-50 years	Group A	16.59	2.19	0.823**
	Group B	16.47	2.54	
51-60 years	Group A	14.24	2.88	0.659**
	Group B	13.92	3.39	
> 60 years	Group A	7.76	2.73	0.607**
	Group B	8.08	3.07	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 16 Mean comparison of MMSE at the 6th month according to the study group for socio-economic status (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Low	Group A	13.39	4.72	0.594**
	Group B	13.39	4.72	
Middle	Group A	13.73	4.32	0.865**
	Group B	13.58	4.99	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 17 Mean comparison of MMSE at the 6th month according to the study group for education status (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Illiterate	Group A	13.65	4.95	0.469**
	Group B	15.00	3.80	
Matric	Group A	13.51	4.44	0.607**
	Group B	13.18	4.72	
Inter	Group A	13.53	4.69	0.609**
	Group B	12.93	4.52	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 18 Mean comparison of MMSE at the 6th month according to the study group for a family history of dementia (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Yes	Group A	13.63	4.52	0.586**
	Group B	13.34	4.53	
No	Group A	11.57	4.85	0.934**
	Group B	11.80	5.86	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 19 Mean comparison of MMSE at the 6th month according to the study group for living area (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Urban	Group A	13.62	4.56	0.439**
	Group B	13.01	4.82	
Rural	Group A	13.46	4.55	0.975**
	Group B	13.43	4.47	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 20 Mean comparison of MMSE at the 6th month according to the study group for Alzheimer (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Yes	Group A	13.43	4.65	0.973**
	Group B	13.41	4.61	
No	Group A	14.43	3.48	0.087**
	Group B	11.88	4.68	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 21 Mean comparison of MMSE at the 6th month according to the study group for epilepsy (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Yes	Group A	13.48	4.57	0.597**
	Group B	13.19	4.63	
No	Group A	15.20	3.56	0.965**
	Group B	15.33	4.72	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 22 Mean comparison of MMSE at the 6<sup>th</sup> month according to the study group for treatment of diabetes mellitus (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Yes	Group A	14.13	4.68	0.375**
	Group B	13.07	4.54	
No	Group A	13.34	4.50	0.906**
	Group B	13.27	4.66	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 23 Mean comparison of MMSE at the 6th month according to the study group for hypertension (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Yes	Group A	12.88	4.28	0.125**
	Group B	14.85	4.31	
No	Group A	13.67	4.60	0.229**
	Group B	12.97	4.64	

Notes: An independent t-test was applied; P-value ≤ 0.05 is considered significant; \*\* Insignificant at 0.05 levels

Table 24 Mean comparison of MMSE at the 6th month according to the study group for body mass index (n = 300)

		Mean ± SD		P-Value
		Mean	SD	
Underweight	Group A	13.57	4.52	0.869**
	Group B	13.38	3.84	
Normal	Group A	13.54	4.97	0.353**
	Group B	12.55	5.56	
Over Weight	Group A	13.82	4.01	0.919**
	Group B	13.90	3.94	
Obese	Group A	12.71	5.11	0.739**

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Group B    13.21    4.81

Notes: An independent t-test was applied; P-value  $\leq 0.05$  is considered significant; \*\* Insignificant at 0.05 levels

#### 4. Discussion

This study was conducted to compare the efficacy and safety of polyherbal product Intellan with Vinpocetine in managing dementia as there is no such study found that compare the Intellan and Vinpocetine safety and efficacy, and majority of the studies have been conducted on animals. We have discussed the mechanism by which Intellan improves brain activity and cited a few studies related to Vinpocetine. The literature survey has revealed that the therapeutic efficacy of the herbal products/drugs is not only based on the chemical and proximal composition but also on the protein and amino acid content. Ample data are available, which depict that proteins and amino acids are used in the therapy of many diseased conditions of mental disorder.

It is an established fact that amino acids, particularly the non-essential amino acids (NEAA) along with other chemical mediators, act as neurotransmitters within the central nervous system (CNS) involved in the memory and learning abilities of the brain. The literature citation reveals that deficiency of amino acids, especially glutamic and aspartic acids lead to decreased brain function, including numerous abnormalities, such as impaired memory function, IQ and mental performance, abnormal behavioral pattern, autism, lack of concentration and decreased cognitive ability. The drug Intellan contains 11.0% protein. Thus, the presence of protein in the drug tries to provide not only the amino acid units needed for the synthesis of new tissues but also compensates for the system which results in loss of weight, marked weakness, strain, stress, mental emotional changes. In contrast, a study had demonstrated that vinpocetine is a safe drug in patients but failed to demonstrate efficacy. Vinpocetine may also function as a cerebral vasodilator and a vasodilator may not be effective in AD because other cerebral vasodilators have been ineffective in this disorder. In our study, mean MMSE before treatment, at 3 months and at 6 months was  $8.91 \pm 4.12$ ,  $10.78 \pm 4.41$ ,  $13.54 \pm 4.54$ , respectively, in group A, while in group B mean MMSE before treatment, at 3 months and at 6 months was  $8.61 \pm 4.00$ ,  $10.74 \pm 4.18$ ,  $13.24 \pm 4.63$ , respectively. We found a significant mean difference in MMSE before treatment with MMSE at 3 months, MMSE before treatment with MMSE at 6 months and MMSE at 3 months with MMSE at 6 months for both groups. We also observed an insignificant mean difference in MMSE at the 6<sup>th</sup> month with the study group.

#### 5. Conclusion

Herbal medicine implies the usage of plants to treat illness and improve general wellbeing and prosperity.

Currently, consideration is being centered around the examination of the adequacy of plants in the traditional medication since they are economical and have minimal side effects. For centuries, cultures worldwide have depended on plant drugs to meet their medical care needs. Despite therapeutic and mechanical progression of the advanced era, the worldwide interest in plant prescriptions is expanding as they are more reasonable and open than conventional medicines and many individuals favor using them. In this study, both herbal drugs Intellan that is an herb-herb combination from *Centella asiatica* Linn, *Herpestis monniera* H.B.K., *Corriander sativum* Linn., *Amomum aromaticum*, Roxb., *Embllica officinalis*, Linn., *Glycyrrhiza glabra*, Linn, and Vinpocetine, which is a synthetic compound obtained from vincamine, an alkaloid found in the *Vinca minor* L. plant, were used to treat dementia. Both are found to be equally effective and safe for treating dementia. We recommend dementia clinics in every tertiary care hospital to administer these herbal drugs so that poor patients may get uninterrupted treatment of their disease.

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