

**AN OPEN CLINICAL STUDY OF SIDDHA DRUGS
“THIRUTHARATCHATHA CHOORANAM” (INTERNAL) AND
“ARUGAN VER THYLAM” (EXTERNAL) IN THE TREATMENT OF
“VIYAGULA UNMATHAM” (DEPRESSION)**

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ABSTRACT

Depression is a common mental disorder, characterised by sadness, loss of interest or pleasure, feeling guilt or low self-esteem, disturbed sleep, appetite, lethargy and poor concentration. A depressive disorder is a syndrome that reflects a sad and irritable mood exceeding normal sadness or grief. More specifically, the sadness mentality is characterized by a greater intensity, duration with severe symptoms and functional disabilities than normal. In this condition, anxiety and depression due to lack of courage, sorrow, grief, paleness, loss of wealth and crying with tears are the symptoms of the diseases. Depressive disorders are a huge public-health problem, due to its

affecting millions of people. About 10% of adults up to 8% of teens and 2% of preteen children experience some kind of depressive disorder. *Viyagula Unmatham* which mostly correlated with the symptoms of Depression in Modern science. *Thirutharakchatha chooranam* internally and *Aruganver thylam* externally, the ingredients are perfect combination for to treat *Viyagula unmatham* (Depression). The outcome of HAMILTON DEPRESSION (HAM-D) SCALE shows encouraging results of good improvement in 10 patients (33.3%) moderate improvement in 16 patients (53.3%), mild improvement in 04 patients (13.3%) and poor improvement in 00 patients (00%) of cases. In this clinical study reveals the efficacy of *Thirutharakchatha chooranam* internally and *Aruganver thylam*

externally in management of *Viyagula unmatham* (Depression) on positively. *Yogam* therapy is indicated for *udal* and *ulanoigal*. Hence the *Yogam* therapy also included in the study.

KEYWORDS: Depression, *Viyagula unmatham*, HAM-D scale, Siddha Medicine, *Yogam*.

INTRODUCTION

"*Marupa thudal noi marunthenalagum*

Marupa thulanoi marunthena saalum

Marupa thininnoi vaara thirukka

Marupathu saavaiyu marunthena laamae" -Thirumanthiram

In the view of *Siddhar Thirumoolar* definition of medicine, that one who ensures ailments of physical, mental, preventive and also postpone the death. Siddha system of medicine is a unique traditional system of medicine in the world. It is also called *Tamil Maruthuvam* and commonly followed by Tamil people since time immemorial. According to Siddha system of medicine, perfect health is maintained by three *uyirthatthukkal* (humours) namely *Vaatham*, *Pitham*, *Kabam*. Whenever there is derangement in these three *uyirthatthukkal*, the resultant will be diseases. The salvation is the ultimate aim of *Siddhars*, so they are maintained their health physically and mentally.

Siddha system has the wonderful principle which is *Panchapootham* theory. According to *Panchapootham* theory the universe and the human body both are formed by five elements i.e. Space, Air, Fire, Water, and Earth. Likewise, the diseases and the medicines are also based on the *Panchapootham* theory. Siddhars believed in the concept that a healthy soul can developed only from a healthy body. So, they developed methods and medications to strengthen their physical body and thereby their souls.

Siddhars have listed the diseases of mankind as 4448 based on the *Mukkutram* i.e., *Vali*, *Azhal*, *Iyyam*. Among the 4448 diseases, the Psychological related diseases are classified into 18 varieties by *Siddhar Agasthiyar*. The other imperative *Siddhars Yugi Munivar* and *Theraiyar* have also described the psychiatric diseases in their texts.

Viyagula Unmatham which mostly correlated with the symptoms of Depression in Modern science.

"*Mananalam mannuyirk kaakkam enanalam*

Ealla pugazhum tharum" -Thirukural

Depression is a common mental disorder, characterised by sadness, loss of interest or pleasure, feeling guilt or low self-esteem, disturbed sleep, appetite, lethargy and poor concentration. A depressive disorder is a syndrome that reflects a sad and irritable mood exceeding normal sadness or grief. More specifically, the sadness mentality is characterized by a greater intensity, duration with severe symptoms and functional disabilities than normal.

In this condition, anxiety and depression due to lack of courage, sorrow, grief, paleness, loss of wealth and crying with tears are the symptoms of the diseases.

Depressive disorders are a huge public-health problem, due to its affecting millions of people. About 10% of adults up to 8% of teens and 2% of preteen children experience some kind of depressive disorder.

It is the most common psychiatric disorder; its life time prevalence is 17%. It is twice as prevalent in women as in men and the mean age of onset is around 40 years. It is commonly in divorced and separated persons.

Depression is also responsible for maximum DAILYs (disability adjusted life years) amongst all the psychiatric disorders. It is also the most common cause of suicide.

A large population-based study from India to report on prevalence of depression and shows that among urban south Indians, the prevalence of depression was 15.1%. Age, female gender and lower socio-economic status are some of the factors associated with depression in this population. The overall prevalence of depression was 15.1% (age-adjusted, 15.9%) and was higher in females (females 16.3% vs. males 13.9%, $p < 0.0001$). The odds ratio (OR) for depression in female subjects was 1.20 [Confidence Intervals (CI): 1.12–1.28, $p < 0.001$] compared to male subjects. Depressed mood was the most common symptom (30.8%), followed by tiredness (30.0%) while more severe symptoms such as suicidal thoughts (12.4%) and speech and motor retardation (12.4%) were less common.

Yogam is a complete science of health, which deals with understanding of adequate functioning of all systems of the body and appropriate coordination between them, along with healthy functioning of our mind. The practice of *yogam* integrated the body with the mind and mind with the soul. *Yogam* prevents one from physical, mental and emotional imbalances due to various reasons in our day to day life. *Yogam* has the capacity to free the body from

most of the diseases, it not only operates on the physical level but also had great benefits on mental worries and tensions. The *Pranayamam* helps to reduce the intensity of mental stress.

Even though there are vast collection of medicines in *Siddha* to treat the *Mana noigal* but there is very minimum number of research has been carried out on depression. So, the *author* chosen *Thirutharakchatha chooranam* internally and *Aruganver thylam* externally, the ingredients are perfect combination for to treat *Viyagula unmatham*, cost effective and easily can be prepared too. *Yogam* therapy is indicated for *udal* and *ulanoigal*. Hence the *Yogam* therapy also included in the study.

MATERIALS AND METHOD

SELECTION CRITERIA

Patients between 20-55 years of age with classical features of depression from OPD of National Institute of Siddha, Chennai, India were selected for the present work, irrespective of their sex, religion, education, etc. Detailed research proforma was prepared incorporating all the signs and symptoms of disease.

SUBJECT SELECTION

Patients reporting with symptoms of inclusion criteria will be subjected to screening test and documentation.

INCLUSION CRITERIA

- Age: between 20 years and 55 years
- Sex: Male and female
- Depressed mood
- Reduced level of interest
- Considerable loss or gain of weight
- Insomnia or hypersomnia
- Psychomotor agitation or retardation
- Fatigue
- Thoughts of extreme guilt
- Diminished ability to think or concentrate
- Suicidal thoughts
- Willing to participate in trial and signing consent by fulfilling the conditions of proforma
- Willing to give blood sample for analysis for laboratory investigations

(If 8 – 10 criteria are positive, the patients will be included for the study).

EXCLUSION CRITERIA

- Pregnancy and lactation
- Diabetes mellitus
- Psychosomatic disorders
- Cardiac disease
- Any other serious systemic illness

INVESTIGATION

For the purpose of assessing the general condition of the patient and to exclude other pathologies, the following investigations were carried out.

1. Hematological investigations: The routine hematological examination was carried out which included total leukocyte count, differential count, hemoglobin, packed cell volume, and Erythrocyte Sedimentation Rate (ESR).
2. Liver function test like, Serum total bilirubin, Direct bilirubin, Indirect bilirubin, Serum Alkaline phosphatases, SGOT, SGPT, GGT.
3. Lipid profile
4. Routine urine analysis
5. Thyroid profile test.

FOLLOW UP

A follow-up study was carried out for 6 months after completion of treatment.

STATISTICAL ANALYSIS

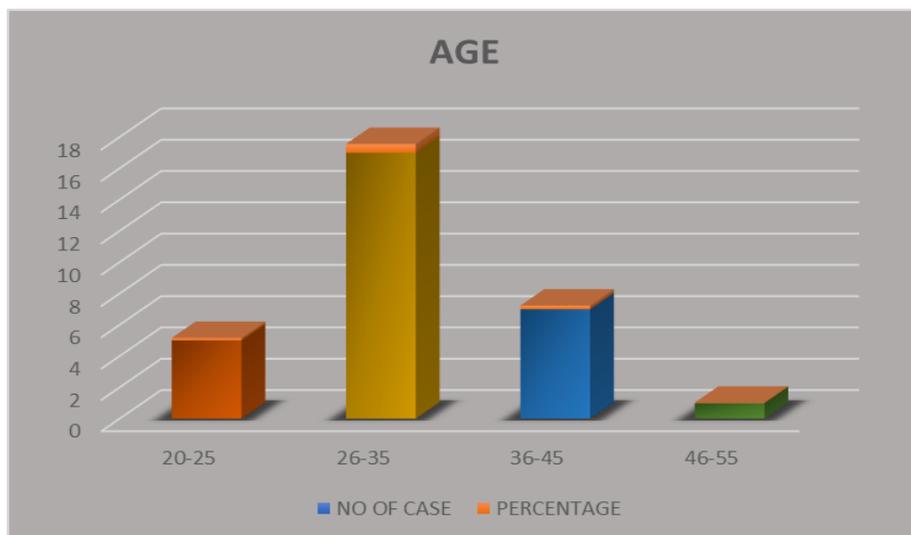
All collected data were entered into MS Excel software using different columns as variables and rows as patients. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean \pm Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

Table 1: Paired sample statistics (ham-d score before treatment and after treatment).

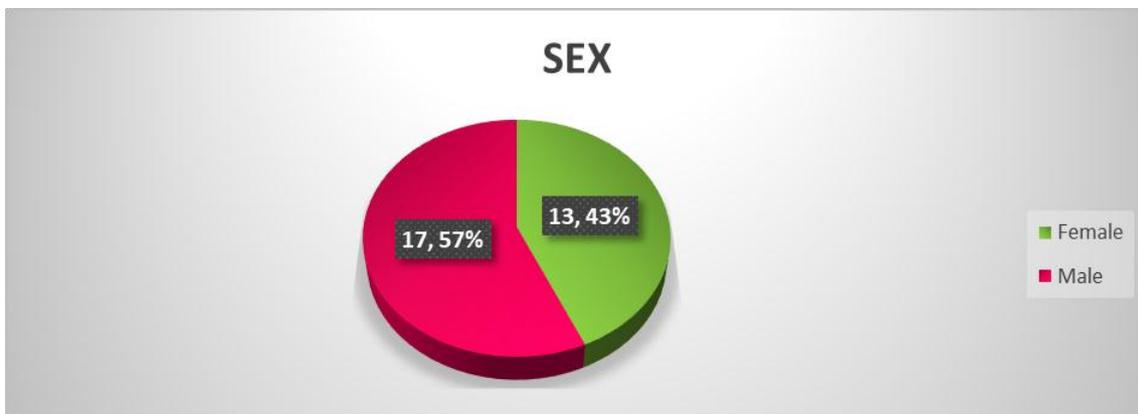
Variable	Frequency	Mean \pm SD	t Value	p Value
Before treatment	30	15.60 \pm 2.54	t= 11.4698	p >0.0001
After treatment	30	8.63 \pm 3.36		

Observation The mean± standard deviation of HAM-D score at before and after treatment were -15.60 ± 2.54 and 8.63 ± 3.36 respectively which is statistically significant ($p > 0.0001$). There is a significant difference between before and after treatment on HAM-D Score i.e. 44.68% reduction in HAM-D Score after the trial.

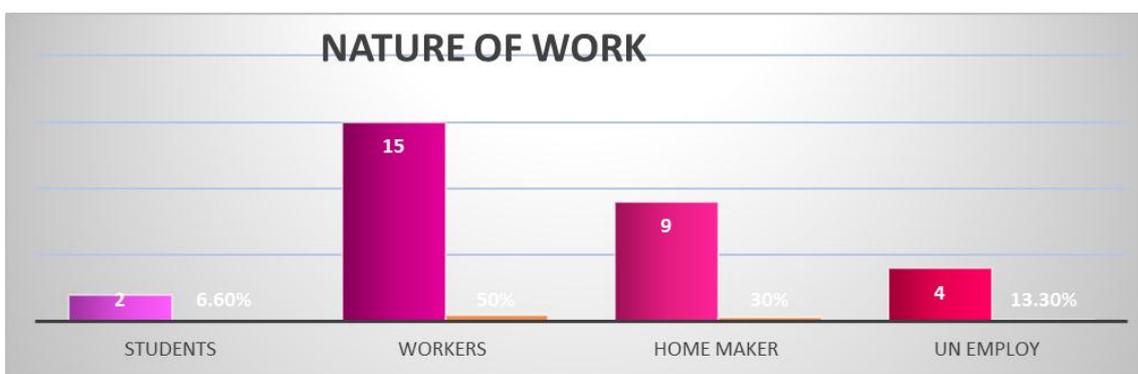
RESULTS AND OBSERVATIONS



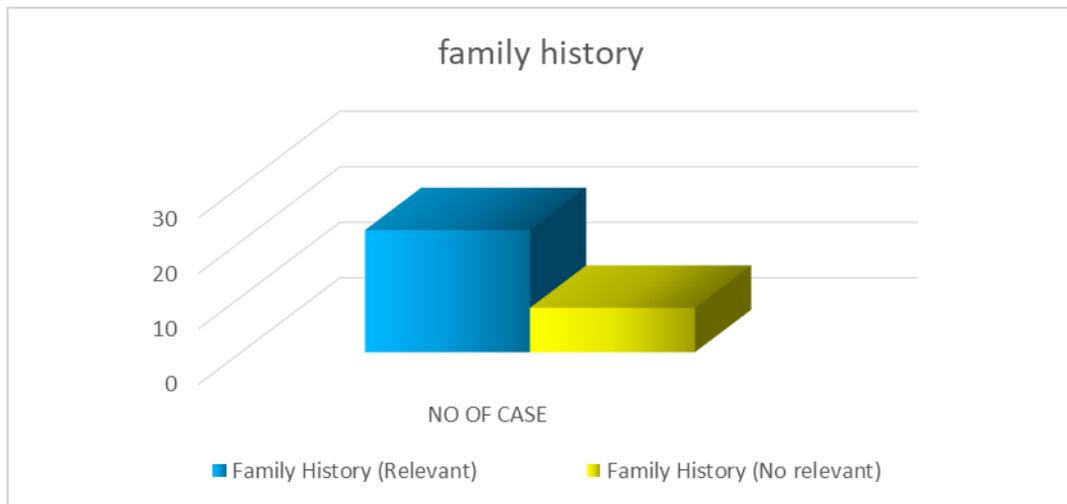
Bar diagram 1: Observation of Age Group.



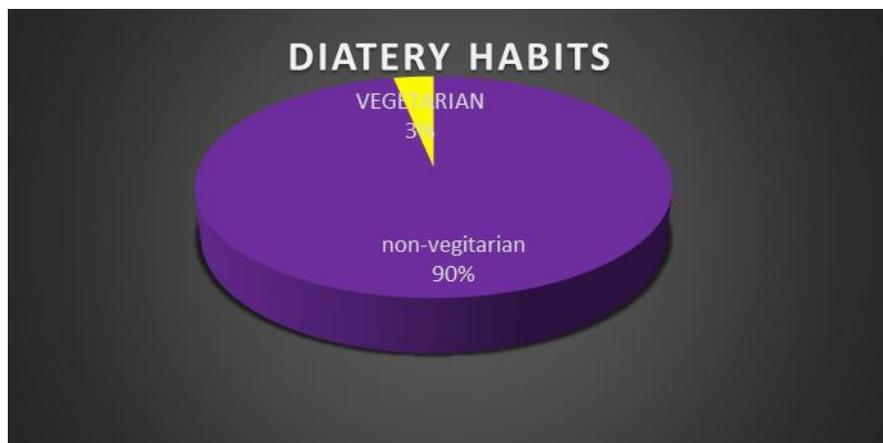
Bar diagram 2: Observation of Se.



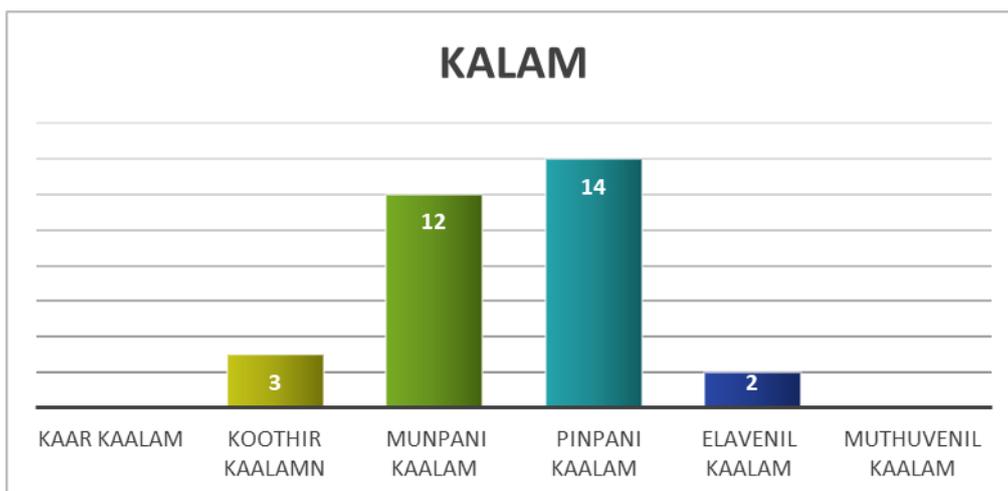
Bar diagram 3: Observation Of Nature of Works.



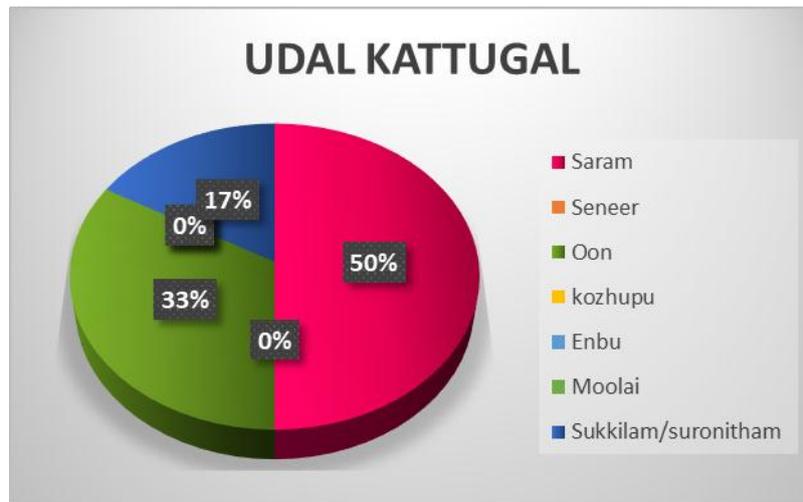
Bar diagram 4: Observation Of Family History.



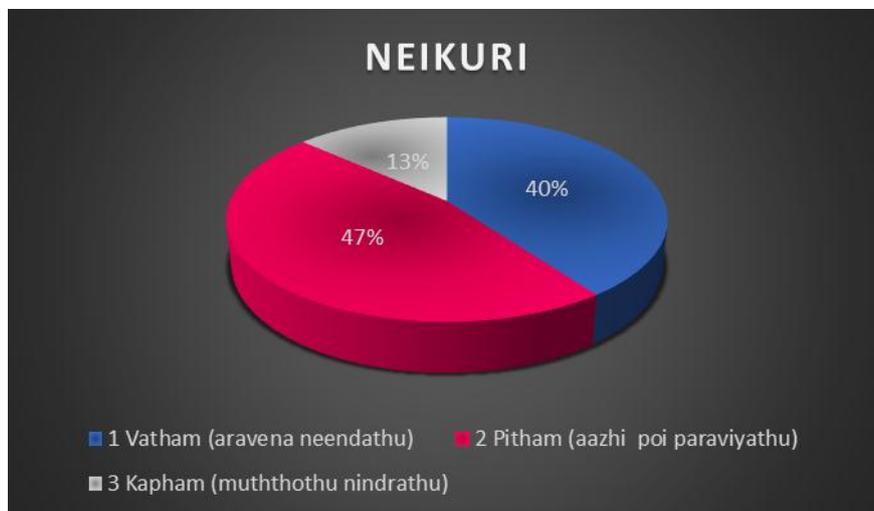
Bar diagram 5: Observation Of Diatery Habits.



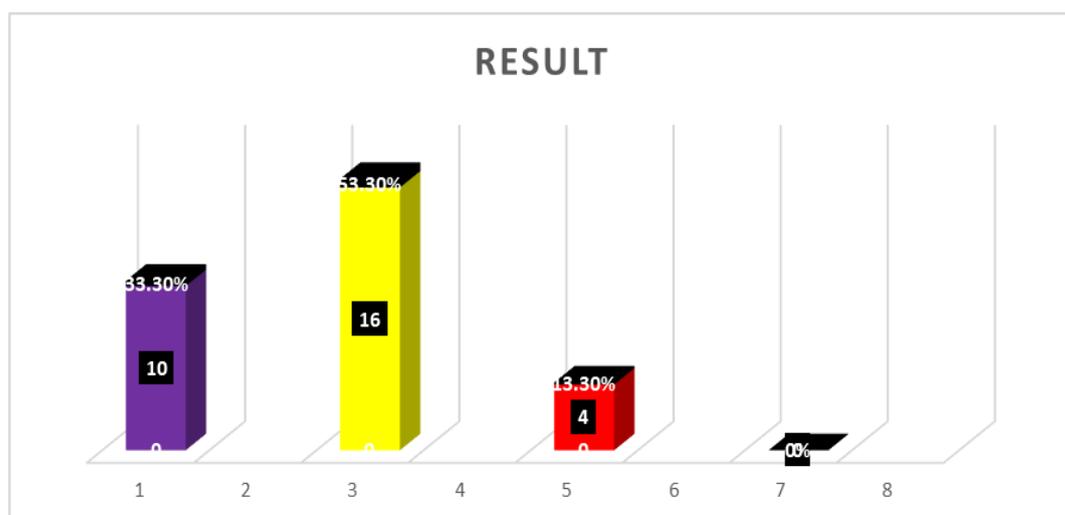
Bar diagram 6: Observation Of Seational Changes.



Bar diagram 7: Observation Of Udal Kattugal.



Bar diagram 8: Observation Of Neikuri.



Bar diagram 9: Result Of Clinical Improvement.

1. Good Improvement 2. Moderate Improvement 3. Mild Improvement 4. Nil improvement.

DISCUSSION

The Depression is one of the most affected psychological problems more common among the population. Majority of them are not seeking the help to proper health care providers due to social stigma in related with psychological illness. Large numbers of patients perceive even the natural physiological function as abnormal. The Depression is rampant among the Indian population and leads to large number of physical and psychological symptoms. Majority of these individuals visit self-claimed psychiatrist and traditional faith healers. The contact with these health providers not only strengthen their misconception and false beliefs, but also compel the patients to pay huge cost of investigations and drugs which are not only non-effective but also hazardous. This may lead them as a patient in physically and mentally. In many hospitals both modern and Siddha medical practitioners daily attending some of cases who try to share their private matters related to their psychological problems. Many times, it was missed by the doctors due to their heavy workload and a think that it was not a serious issue. Hence these kinds of patients get more worsened with their problems and become a mentally affected patient.

The trial drugs were prepared in *Gunapadam* lab of National Institute of Siddha after the authentication of the raw drugs by Assistant professor of Medicinal botany NIS, Chennai. The trial drug was prepared by Standard Operating Procedure as mentioned in the Protocol.

The Bio chemical analysis was done at the biochemistry lab of NIS and the results were documented. The Bio-chemical analysis of *Thirutharakchatha chooranam* had shown the presence of sulphate, chloride, phosphate, carbonate, calcium, aluminium, zinc, magnesium, reducing sugars, iron, tannic acid, starch and alkaloids. The clinical study was conducted with a well-defined protocol and a proper proforma after the approval of Institutional Ethical Committee. For this dissertation study, 30 patients were selected and patients were treated in the OP Department of *Sirappu Maruthuvam*, in Ayothidoss Pandithar Hospital - National Institute of Siddha, Tambaram Sanatorium, Chennai –600 047.

Based on various criteria, the data were collected and tabulated. The criteria were family history, age distribution, occupation, dietary habits and incidence of the disease with reference to *thinai*, seasonal variation, clinical manifestations and assessment of the improvement in the prognosis of the disease with the trial drug.

In Siddha System, it is necessary to bring the vitiated humours to equilibrium. Hence before the treatment *Meganatha Kulikai* with *Inji charu* (*Zingiber officinale*) juice was given for *Viresanam* (Purgation) in the early morning to normalize the vitiated humours. During the treatment, the patients were advised to follow *pathiyam* (Dietary regimen).

Internal Drug: *Thirutharakchatha chooranam* - 2gm two times per day with ghee.

External Drug: *Aruganver Thylam* for external application for oil bath 2 times per week.

Duration of Drug: 48 days

30 patients were enrolled for this study, among 30 patients, age group 20 to 25 years were in number 5 (16.6%), patients between 26 to 35 were in number 17 (56.6 %), patients between 36 to 45 years were in number 7 (23.3 %), patients between 45 to 55 years, 1 (3.3%). *Viyagula unmatham*(Depression) commonly appears at young and middle age. In this present study, considerable numbers of patients were reported (17 patients) between the age of 26-35 among study sample.

Among the 30 patients, male cases were reported in number 17(56.6%) and female cases were reported in number 13(43.3%). Usually the studies carried out on depression, proves that female were affected sex. But the study carried out in NIS, proves that males are commonly affected. The inference of this study is still female sex is lacking awareness about their mental health and considering themselves as social stigma.

The majority of patients in this study were common workers 15 (50 %), homemakers 9(30%), unemployed 4(13.3%) and students 2(6.6%). Inference of this study shows that, in current scenario employed people are highly exposed to stress often, which is the root cause of depressive disorders.

The bulk of patients in this study were Non-vegetarian 27 (90%) remaining 3 (10%) patients were vegetarian. Inference of this study, shows that people who are consuming high non-vegetarian diet, gets antagonistic behaviour which leads to psychiatric disorders.

Highest number of patients 14 (46.6%) were studied during *Pinpani Kaalam*, 12 patients (40%) were studied during *Munpani Kaalam*, 3 patients (10%) were studied during *Koothir kaalam* and 2 patients were studied during *Ilavenil kaalam*.

Most of patients 9(30%) were affected in duration of below one year and above 2 to 3 years, 8 (26.6%) patients were affected by the illness from 1 to 2 years, above 3 years were in same number 5 (12.5%). Laboratory investigations were done for all the cases before and after treatment. There were no variations in hepatic, renal and other parameters. The outcome of this study was clinically observed by HAM-D Score, which showed encouraging results of good improvement in 10 patients (33.3%), moderate improvement in 16 patients (53.3%) and mild improvement in 4 cases (13.3%).

Among the 30 patients randomized selected 15 patients received *yogam* along with trial medicines (internally & externally). This *yogam* results shown 20 % (3 patients) is good improvement, 73.3%(11 patients) shown moderate improvement and 6.6%(1 patient) shown poor improvement. Patients who have lot of sadness, lack of concentration and sleep exposed to very poor result and respond, may be this is the effect of *thoorkaminmai* (Insomnia) and more stressful life style. Based on Siddha Literature the one who not maintain the *Naal ozhukkam* (Daily regimen) haven't maintain their good health, this may reflect in this patient.

Remaining 15 patients received only trial medicines (internally & externally), without *yogam*. This trial medicine shown results as 33.33%(5 patients) shown good improvement and 66.66% (10 patients) shown moderate improvement.

Patients who were received both treatments (*yogam* & trial medicine) had revealed good result and quick revilement than the only trial medicine taken group. Based on this it is shown Medicine combined with *Yogam* therapy is more effective and appropriate to treat the *Viyagula Unmatham* (Depression).

In this study, no adverse events were observed during the course of the treatment. After the study period, all the patients were advised to attend Out Patient Department of *Sirappu Maruthuvam* of NIS for further follow-up of 6 months.

CONCLUSION

The present clinical study confirms the efficacy of the trial drug *Thirutharakchatha chooranam* (internal medicine) and *Aruganver thylam* (external medicine) which is Siddha poly herbal formulation. It was found to be good resulting on *Viyagula unmatham* patients in reducing clinical symptoms like depressive mood, loss of sleep and appetite, weight loss, lack of concentration, anhedonia, suicidal thoughts etc. The literature evidence for this drug

Agathiyar Vaithiya Ratna Surukam page no 45, Publication of *Tanjavur Magaraja Sarabojini Saraswathy Mahal Noolagam*. The quantitative outcome of HAM-D score shows significant reduction between before and after treatment. The qualitative outcome shows there is 33.3 % of cases had shown good improvement and the rest 53.3 % of cases had shown moderate improvement and 13.3% of cases mild improvement. Further the *Yogam* had shown more impressive result of reduction of symptoms of *Viyagula unmatham* (Depression). It shows the better improvement more than 50 % was 26 (86.6 %) patients.

According to this result it could be observed that *yogam* therapy is further given as support to improve the condition of *Viyagula unmatham* (Depression). The Modern Medical concept of Anxiety related somatic complaints or Culture bound syndrome also has to be proven. The clinical trial conducted in selected patients was satisfactory and the results were encouraging. However, a study with large number of patients is required to find out the ideal dose response.

From the above results, the trial drugs “*Thirutharakchatha chooranam*” (Internal Medicine) and “*Aruganver Thylam*” (External Medicine) are responded well in the treatment of *Viyagula unmatham*. The costs of the trial medicines are comparatively low. These drugs are easily available and the dosage is also convenient.

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