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RESEARCH ARTICLE

Open Label Randomized Double-arm Clinical Trial to Evaluate the Efficacy of *Siddha Varmam* Therapy as a Non-pharmacological Intervention for Type II Diabetes Mellitus and Pre-diabetic Patients

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Abstract

Background: Non-pharmacological management in Type II Diabetes Mellitus (T2DM) is an important research field. *Siddha Varmam* Therapy (SVT) is one of the unique methods of physical manipulation used for various ailments. **Aim:** This study aims to investigate, if SVT will reduce blood sugar level in diabetes patients. **Methods:** This randomized open label clinical trial conducted in Siddha Clinical Research Unit, Tirupati, India, compared the effect of SVT with routine biomedicine in T2DM. Patients (n=30) were randomly allocated (1:1) either to *Varmam* arm (Arm 1) (n=15) or to Biomedicine and *Varmam* arm (Arm 2) (n=15) by simple randomization method with computer-generated random numbers. *Varmam* was manipulated for 3 days in a week for the period of 3 months. The primary outcome was reduction in Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS), Hemoglobin A1c (HbA1c). The secondary outcome was to access the safety of the trail through Liver Function Test (LFT), Renal Function Test (RFT). **Results:** The study revealed the highest incidence (53.4%) in the 45-50 age group, and mean ages of 49.31 years for males and 49.75 years for females. In the Arm 1 (15 patients), the FBS had a P value of 0.896 (Cohen's d = 0.034), PPBS 0.362 (d = 0.24), and HbA1c 0.515 (d = 0.17). In the Arm *2* (15 patients), the FBS showed a P value of 0.159 (d = 0.38), PPBS 0.199 (d = 0.35), and HbA1c 0.178 (d = 0.37). **Conclusion:** The study suggests SVT may modestly benefit diabetes patients, by reducing HbA1c levels in six patients in Arm 1 and eight patients in Arm 2, warranting further investigation.

Major Findings: Applying *Siddha Varmam* therapy to Type 2 diabetes mellitus patients on alternate days for three months resulted in modest improvements, pointing to potential reductions in FBS, PPBS, and HbA1c levels.

Keywords: Diabetes, Indian Medicine, Non-pharmacological Intervention, Traditional Medicine, *Varmam*

1. Introduction

Diabetes is a group of metabolic diseases in which an individual has high blood glucose either because insulin production is not adequate, or the body doesn't respond properly to insulin, or both[1]. In the past 3 decades the prevalence of Type 2 diabetes has risen dramatically in countries of all income levels. About 422 million people worldwide have diabetes, the majority living in low-and middle-income countries, and 1.5 million deaths are directly attributed to diabetes each year. Both the number of cases and the prevalence of diabetes have been steadily increasing over the past few decades[2]. Within India, 74 million people (of the total population of 1.4 billion) currently have diabetes. Furthermore, the diabetes epidemic in India is accelerating across all geographic and socioeconomic groups, and it is projected that there will be at least 124 million people with diabetes by 2045[3]. T2DM interacts with other major risk factors such as hypertension and dyslipidemia, increasing the risk for

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micro- and macrovascular morbidity such as Chronic Kidney Disease (CKD), End-Stage Renal Disease (ESRD), atherosclerosis, coronary heart disease and cerebral ischemia[4-6]. The management of T2DM and its complications are challenging in all medical systems, the medications for T2DM is causing side effects and the cost is not affordable for the patients. In order to tackle this scenario, the cost effective, safest treatment is obligatory[7,8].

In *Siddha* system of medicine *Varmam* is one unique method of physical manipulation used for various ailments. SVT specifies the therapeutic manipulation of certain points in which the life energy is found concerted. Handling on these points with a particular force for the definite time will release the life energy (*Vāci*), from these points and fetch relief to the affected individual by regulating the flow of life energy which is blocked due to attack on particular *Varmam* points or due to other causes[9]. The *Varmam* points are located on juncture of two bones or a muscle inserted into a bone or the blood vessels, nerves are prominent, these points are directly related to organs lying within. The therapy of physical manipulations either by applying pressure on the *Varmam* points or using massage therapy with a specific oil or blowing certain medicines in the nose or ear is called as *Varmam* treatment[10]. The text titled "*Varma Vilvicai*" mentions 8000 *varma* points in the body whereas author Thiyagarajan mentioned in his book "*Citta maruttuvaciṟappu*" is 108 points[11].

In recent years there are many clinical trials conducted on SVT to treat diseases such as osteoarthritis, periarthritis, cervical spondylosis, lumbar spondylosis, autism, Attention Deficit Hyperactivity Disorder (ADHD)[12-14]. However, to date, only a limited number of studies have been conducted to demonstrate SVT impact on T2DM. This study aims to evaluate the effect of the *Siddha Varmam* Therapy (SVT) on glycemic control in patients with T2DM and pre-diabetes by assessing reductions in FBS, PPBS, and HbA1c levels. The effectiveness of SVT is compared with *varmam* and conventional biomedicine treatment group. Additionally, the study assessed the safety of SVT through LFT and RFT.

2. Materials and Methods

This study protocol was approved by the IHEC, from Siddha Clinical Research Unit (SCRU), Tirupati, Andra Pradesh, India, Institutional Human Ethical Committee; IHEC no: IHEC/ SCRUT- CCRS-01/2020-21/03 and also registered in Clinical Trial Registry of India; CTRI, Registration no. CTRI/2021/02/031407. All patients provided written informed consent. This report adhered to the Consolidated Standards of Reporting Trials (CONSORT) guideline. This randomized clinical trial started in March 2021 and ended in August 2023, conducted at the Outpatient Department of SCRU, Tirupati, Andhra Pradesh, India.

2.1 Eligibility Criteria

The study included subjects aged between 30-60 years of both genders, patients with fasting blood sugar levels above 100 mg/dl, and those with HbA1C levels above 5.5%. Subjects below 30 years or above 60 years were excluded. Additionally, pregnant women, those planning to become pregnant within 6 months, and lactating mothers were also excluded. Other exclusion criteria include any known cases of malignancy, accelerated hypertension, coronary artery disease, Central Nervous System (CNS) disorders, Type I diabetes mellitus, acute infection or fever, chronic viral hepatitis, and HIV infection.

2.2 Intervention

Patients assigned to the *varmam* treatment group underwent *varmam* stimulation every 3 days for 3 months. Blood parameters were monitored for all patients on Day 0 (before treatment) and on Day 91 (after treatment). SVT manipulation was done by trained *Siddha Varmam* doctor on 3 days once for the period of 3 months. In this study, the *varmam* points utilized for addressing diabetes were derived from the book "Guidelines for practice of *Siddha Varmam* Therapy" by the Central Council for Research in Siddha (CCRS), Chennai[15]. This book outlines ten specific points for treating diabetes (Table 1) (Figure 1).

2.2.1 Intervention arm 1

Patients treated with SVT alone has undergone *Siddha Varmam* points manipulation on 3 days once for 3 months, all the selected *Varmam* points were manipulated for 30 Sec.

2.2.2 Intervention arm 2

Patients treated with both SVT and biomedicine. Biomedicine is a standard conventional medicine

Table 1. Standard operating procedure (SOP) of *Siddha Varmam* therapy (SVT)

S. No.	*Varmam* points	Location	Mode of application
1	*Uṟumi kalam*	5 fingers breadth below xiphisternum	Press and release the point with middle finger 3 times.
2	*Vāyu kalam*	At spinous process of T12 vertebrae	Press and release the point with middle finger 3 times.
3	*Kaṇapatimu ka`varmam*	2 fingers breadth below the lower border of patella	Place the thumb and apply pressure for 30–60 seconds, then perform a rotatory motion.
4	*Āmaikālam*	Center part of anterior thigh	Place the thumb, press and release the point 3 times
5	*Kākkaṭaivarmam*	Supraclavicular fossa on both sides	Place the middle 3 fingers on the supraclavicular fossa, then press and release 3 times.
6	*Pakkākaḻut tunāṭṭukkuvarmam*	Middle of lateral aspect of neck	Press and release on varmam point for 30 seconds, 3 times.
7	*Eḻurukkivarmam*	2 fingers breadths below the nipple	Press and release on varmam point for 30 seconds, 3 times.
8	*Cītākalām*	Medial side of great toe	Press downwards and hold for 5 seconds, repeat this twice.
9	*Pūmikalām*	Center of great toe	Press upward with thumb and hold for 5 seconds, repeat this twice.
10	*Kūrccavarmam*	Lower end of first metatarsal bone in plantar aspect	Press and release the point with thumb finger 3 times.

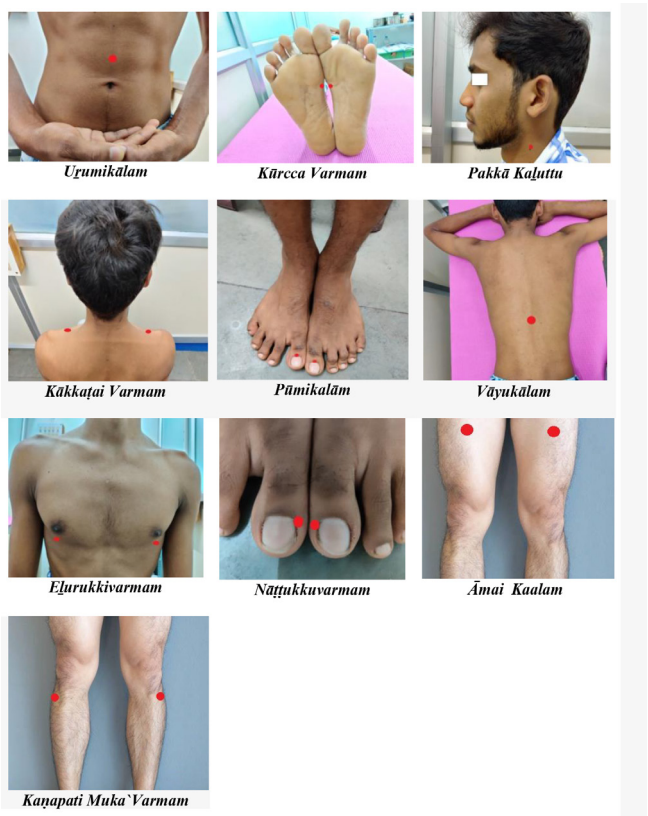


Figure 1. *Siddha Varmam* Therapy (SVT) points manipulated in this trial.

used by patients, including their routine anti-diabetic medication and any other medications they are taking regularly for comorbidities such as hypertension, dyslipidemia, hypothyroidism, *etc.*

2.3 Randomization and Allocation

Participants were randomly assigned to Arm 1 and Arm 2 in a 1:1 ratio. In this study 45 patients were screened and 30 were enrolled. Among the remaining 15 patients, 13 were excluded, and 2 declined participation. Consequently, the study included 15 participants in arm 1 and 15 participants in arm 2 (Figure 2).

2.4 Sample Size

As there is no prior work on this research question, no assumptions for the sample size calculation could be made. This study served as a pilot trial, involving 30 patients, with 15 participants in each of the two groups.

2.5 Statistical Analysis

Statistical analysis was done with IBM SPSS (Statistical Package for the Social Sciences, Version 29.0) as statistical program. The study used a paired

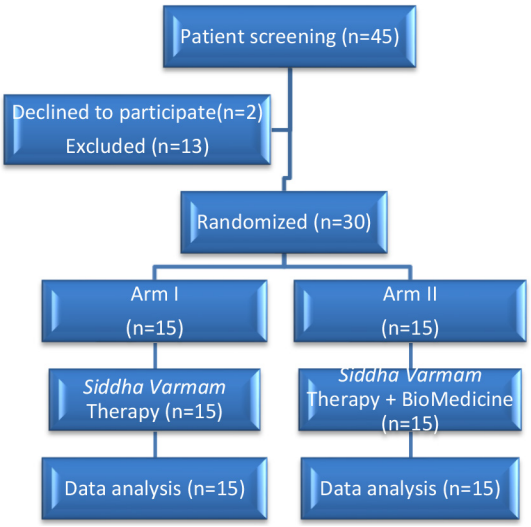


Figure 2. CONSORT flow diagram shows this workflow of enrollment, allocation, and analysis.

sample t test for comparison of FBS, PPBS, HbA1c, LFT, RFT before and after treatment within a group. Cohen's d effect sizes were calculated on the mean change scores before and after treatment, with the following formula (MMBCT - MTAU) / σ pooled. A Cohen's d between 0.2 and 0.5 indicates a small effect, between 0.5 and 0.8 a moderate effect, and larger than 0.8 a large effect.

3. Results

3.1 Baseline Characteristics

Among 30 cases, 22 cases (73.3%) were Male, 8 cases (26.7%) were Female. Among 30 cases high age incidence 53.4% was between 45-50 years, the next highest 30% is between 51-55 years, Mean age of males is 49.31 years. The female mean age is 49.75 years (Table 2). Of these 30 patients, 15 were randomized to the Arm 1 *Varmam* alone, 15 to Arm 2, *Varmam* and Biomedcine.

3.2 Primary Outcome

In the *Varmam* alone arm (Figure 3), the initial FBS was 128.2 ± 29.83 before treatment and 128.87 ± 34.1 after treatment, with a non-significant p value of 0.896. The effect size was 0.034, indicating a very small effect. PPBS levels were 180.13 ± 58.98 before treatment and 171.47 ± 48.91 after treatment, with

Table 2. Baseline characteristics of the patients

S. No	Variable n (%)		Varmam alone (n=15)	Varmam and Biomedicine (n=15)
			n (%)	
1	Sex	Male	11 (73.3)	11 (73.3)
		Female	4 (26.7)	4 (26.7)
2	Mean age, years	Male	49.31 years	
		Female	49.75 years	

a non-significant p value of 0.362 and a small effect size of 0.24. HbA1c levels were 6.94 ± 1.27 before treatment and 7.11 ± 1.29 after treatment, with a non-significant P value of 0.515 and a very small effect size of 0.17. In the *Varmam* and Biomedicine arm (Figure 4), initial FBS was 168.27 ± 53.52 before treatment and 157.2 ± 42.85 after treatment, with a non-significant p value of 0.159 and a small effect size of 0.38. PPBS levels were 255.8 ± 82.07 before treatment and 233.87 ± 86.71 after treatment, with a non-significant p value of 0.199 and a small effect size of 0.35. HbA1c levels were 8.92 ± 2.22 before treatment and 8.42 ± 2.03 after treatment, with a non-significant P value of 0.178 and a small effect size of 0.37.

When comparing both arms, in Arm-1, the mean FBS was 128.2 ± 29.83, compared to 168.27 ± 53.52 in Arm-2 (t = -2.532, p = 0.017). The mean PPBS was 180.13 ± 58.98 in Arm-1 and 255.8 ± 82.07 in Arm-2 (t = -2.900, p = 0.007). For HbA1c, Arm-1 had a mean of 6.94 ± 1.27, while Arm-2 had a mean of 8.92 ± 2.22 (t = -2.997, p = 0.006) (Table 3).

3.3 Secondary Outcome

The paired samples statistics indicate that neither the *Varmam* only arm nor the arm receiving both treatments showed significant changes after treatment (Table 4). In the *Varmam* only group, total bilirubin (p = 0.722), direct bilirubin (p = 0.751), SGPT (p = 0.227), SGOT (p = 0.860), urea (p = 0.457), and creatinine (p = 0.613) did not exhibit statistically significant differences. Similarly, in the group receiving both treatments, total bilirubin (p = 0.758), direct bilirubin (p = 0.751), and Serum Glutamic Pyruvic Transaminase (SGPT) (p = 0.197), Serum Glutamic Oxaloacetic Transaminase (SGOT) (p = 0.242), urea (p = 0.984), and creatinine (p

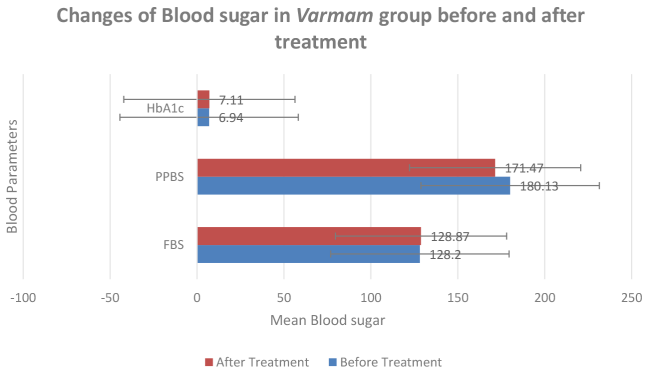


Figure 3. Arm 1 patients efficacy outcome (Glycemic outcome).

Patients showed small improvement in (FBS) Fasting Blood sugar (mg/dl), (PPBS) Post prandial Blood Sugar (mg/dl), Hemoglobin A1c (HbA1c) (Percentage %) from baseline; P value equals p<0.05 represents statistically insignificant, Cohen's *d* <0.2 shows small effect. Effect of *Siddha Varmam* therapy on FBS, p-value 0.896 (Effect size d = 0.034) PPBS, p-value 0.362 (Effect size d = 0.24), HbA1c, p-value 0.515 (Effect size d = 0.17) from baseline. Data are presented as means.

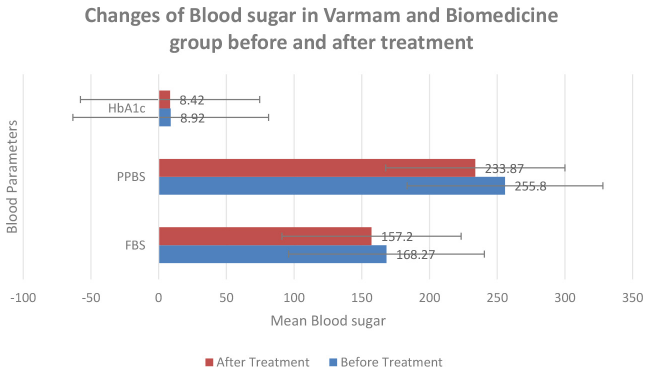


Figure 4. Arm 2 patients efficacy outcome (glycemic outcome).

Patients showed small improvement in Fasting Blood sugar (FBS) (mg/dl), Post prandial Blood Sugar (PPBS)(mg/dl), Hemoglobin A1c (HbA1c) (Percentage%) from baseline; P value equals p<0.05 represents statistically insignificant, Cohen's *d* <0.2 shows small effect. Effect of *Siddha Varmam* therapy and biomedicine (Arm 2), FBS, p-value, 0.159 (Effect size d = 0.38), PPBS, p-value 0.199 (Effect size d = 0.35), HbA1c p-value 0.178 (Effect size d = 0.37) from baseline. Data are presented as means.

Table 3. Paired samples t test-baseline characteristics in both arms

Variables	Group	Mean ±SD	t test	P value
FBS_BT	Arm-1	128.2 ± 29.83	-2.532	0.017
	Arm-2	168.27 ± 53.52		
PPBS_BT	Arm-1	180.13 ± 58.98	-2.900	0.007
	Arm-2	255.8 ± 82.07		
HbA1c_BT	Arm-1	6.94 ± 1.27	-2.997	0.006
	Arm-2	8.92 ± 2.22		

Paired samples t-test. Where p>0.05 represents statistically significant. Before Treatment- BT; After Treatment- AT. Fasting Blood Sugar-FBS (mg/dl); Postprandial Blood Sugar-PPBS (mg/dl); Hemoglobin A1c-HbA1c (Percentage %).

= 0.434) showed no significant changes in post-treatment. Thus, the non-significant changes of LFT and RFT before and after treatment show the safety of the trial[16].

As per the Food and Drug Administration FDA, US[17]. The change from baseline in A1C has been recognized as the main endpoint in clinical trials aimed at obtaining a glycemic-control indication. A1C serves as a validated surrogate marker for reducing the risk of microvascular disease, making it a suitable endpoint for this indication. FBS, PPB are also considered

Table 4. Safety outcome in both Arm1 and Arm2

Arm1 (Only Varmam)	Mean ± SD	t test	P value	Arm2 (Both Varmam and Biomedcine)	Mean ± SD	t test	P value
T_Bil_BT	0.82 ± 0.32	-0.364	0.722	T_Bil_BT	0.79 ± 0.23	0.315	0.758
T_Bil_AT	0.85 ± 0.32			T_Bil_AT	0.78 ± 0.25		
D_Bil_BT	0.18 ± 0.09	0.323	0.751	D_Bil_BT	0.13 ± 0.05	-0.323	0.751
D_Bil_AT	0.17 ± 0.06			D_Bil_AT	0.14 ± 0.06		
SGPT_BT	25.66 ± 10.05	1.264	0.227	SGPT_BT	21.56 ± 5.26	-1.356	0.197
SGPT_AT	21.83 ± 9.19			SGPT_AT	24.41 ± 9.9		
SGOT_BT	22.76 ± 9.58	0.179	0.860	SGOT_BT	24.11 ± 5.99	-1.222	0.242
SGOT_AT	22.43 ± 6.86			SGOT_AT	27.16 ± 10.3		
Urea_BT	22.25 ± 6.66	-0.764	0.457	Urea_BT	23.96 ± 8.71	0.021	0.984
Urea_AT	23.2 ± 8.78			Urea_AT	23.92 ± 6.17		
Cre_BT	0.85 ± 0.15	0.517	0.613	Cre_BT	0.87 ± 0.24	-0.806	0.434
Cre_AT	0.83 ± 0.18			Cre_AT	0.91 ± 0.19		

Confidence Interval (C. I): 95%; Paired samples t-test. Where p<0.001, p<0.05 represents the statistical insignificant. Before Treatment- BT; After Treatment- AT; T. Bil-total bilirubin (mg/dl); D. Bil-direct bilirubin (mg/dl); SGPT- Serum Glutamic Pyruvic Transaminase (IU/L); SGOT- Serum Glutamic Oxaloacetic Transaminase (IU/L); Urea (mg/dl), Cre- creatinine (mg/dl).

an additional measure of glycemic control. In this study 3 patients (20%) in *Varmam* alone arm and 6 patients (40%) in both *Varmam* and biomedicine arm showed significant reduction in blood sugar of more than 0.5%. In the *Varmam* alone arm, 8 patients showed significant improvement in FBS, 10 patients had notable improvements in PPBS, and 6 patients saw their HbA1c levels improved. In the combined *Varmam* and Biomedicine arm, 8 patients experienced considerable improvement in FBS, 8 patients showed better PPBS levels, and 8 patients had improved HbA1c levels (Figure 5).

4. Discussion

This study's main objective was to test the effectiveness of *Varmam* in reducing sugar levels of diabetic patients. To the best of our knowledge, this is the first randomized trial to find the efficacy of SVT in T2DM. Recent literature reveals limited studies employing SVT for T2DM.

The study on managing Diabetes Mellitus (*Matumēkam*) using *Siddha* medicine and *Varmam* points involved stimulating specific points (*Tācavāyupiṉṉal, nērvarmam, untivarmam, muṇṭalvarmam, īralvarmam, vastivarmam, tuṉṉalmuṭiccuvarmam*) either every 15 days (3 patients) or every 2 days (2 patients) for 3 months. All 5 patients received both *Siddha* internal medicine and *Varmam* treatment, leading to significant reductions in FBS, PPBS, and HbA1c. Improvements were noted

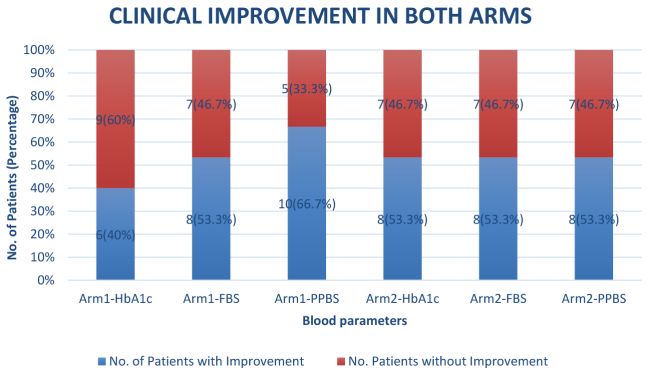


Figure 5. Arm I (*Varmam* alone), Arm II (both *Varmam* and Biomedicine) patients showing clinical improvement in FBS, PPBS, HbA1c.
Fasting Blood Sugar- FBS Postprandial; Blood Sugar- PPBS; Hemoglobin A1c- HbA1c; No. -Number.

in glycemic control, urinary incontinence, bowel movements, stomach issues, joint restrictions, stress, hair loss, fatigue, and dryness in the mouth[18].

Another study examined the effect of SVT on diabetes mellitus using points like *urumikālam, tum'mikālam, aṭappākālam, āmaikālam, vāyukālam, naṅkaṉappūtu, poḻivarmam*. Five patients with hyperglycemia showed significant recovery and stable glycemic levels after receiving *Varmam* therapy twice a week for 4 weeks to 2 years. The study did not report initial or final sugar levels or include statistical analysis[19].

A study on the effect of combining yoga with SVT on FBS and triglyceride levels in middle-aged T2DM. *Varmam* points included *vāyukālam, tum'mikālam, oṭṭuvarmam, jaṭappiriyalvarmam, piṭārikālam, āmaikālavarmam, aṇṇākālavarmam, puṉalvarmam, mūṭṭuvarmam, kalliṭaikālavarmam, nērvarmamandaṭappakālam*. The experimental group practicing both therapies showed significant reductions in FBS and triglycerides compared to the control group, who were on active rest. Therapy was administered 6 days a week for twelve weeks[20].

A study investigated the effect of SVT on 30 Diabetic Peripheral Neuropathy (DPN) patients, who were divided into 3 groups: Group I received *Varma* therapy with Silambam practice, Group II had only Silambam, and Group III had no practice. Over 12 weeks (3 days per week), Group I showed significant improvements in systolic and diastolic blood pressure, resting heart rate, gait posture, energy levels, and reduced neuropathy compared to the other groups. The *Varmam* points were *koṇṭaikkollivarmam, tilarttavarmam, ōṭṭuvarmam, maṇipantavarmam, kompērikālam, kutiraikaḻvarmam and uḻḻaṅkālvellaivarmā*[21].

In a study examining the effects of 12 weeks of SVT on 30 men with DPN. The therapy significantly normalized systolic and diastolic blood pressure, reduced body mass index, improved nerve function, and decreased DPN levels. It also enhanced gait posture, energy levels, stability, and overall nerve function. The therapy, conducted six days a week, involved various *Varmam* points including *koṇṭaikkolli (ucci) varmam, tilarttavarmam, ōṭṭuvarmam, kākkaṭṭai, pakkākaḻuttunaṭukkuvarmam, nērvarmam, ellārukkivarmam, pallavarmam, urumikālam, naṅkaṉappūṭṭu, maṇipantavarmam, āmaikkāḷam, āmaikkāmkutikaḻvarmam, kaṇpukaiccalvarmam, uḻḻaṅkālveḻḻaivarmam*[22].

Siddha varmam points are commonly linked with acupressure points[23]. Researchers suggest that acupressure triggers the release of neurochemical mediators, which helps regulate blood sugar by influencing glandular functions, particularly the pituitary-hypothalamus-adrenal axis. Furthermore, acupressure alleviates stress and promotes relaxation, which is why stress management treatments have been found to benefit diabetic patients. According to acupressure, applying pressure to specific points stimulates endorphin release in the brain, relaxing muscles and enhancing the patient's overall comfort[24].

The main results are inconclusive, because our sample size calculation was not based on any previous study, there was no studies conducted in this field. The study did not show statistical significance, and while reductions in FBS, PPBS, and HbA1c were observed, the effect sizes were small. The past three decades have seen a dramatic shift towards reporting effect sizes, such as Cohen's d, that convey information about the magnitude of the relationship between variables[25]. Particularly in the field of public health, small effects scaled across an entire population can be very relevant and impactful when supported by empirical evidence or strong, falsifiable lines of reasoning. Other authors have made similar arguments that small effect sizes when applied to an entire population may scale up to be impactful. Another study, argued that small effect sizes are the norm in psychological sciences and can be highly relevant[26]. There were no alterations observed in LFT and RFT in either arm post-treatment. The non-significant P-value indicates the absence of changes before and after treatment, suggesting the safety of SVT. Additionally, there were no adverse reactions noted.

When comparing the both arms, statistically significant differences in baseline FBS, PPBS, and HbA1c levels suggest that the randomization process may have been compromised. This discrepancy may be attributed to the small sample size. Small sample sizes increase the likelihood of random variations affecting the results, leading to imbalances between groups. Larger sample sizes generally provide more reliable and generalizable results by reducing the impact of random variation and ensuring that the groups are more comparable.

5. Recommendations for Future Research

It is imperative that future trials meticulously document the following key parameters. First, the rationale in *Varmam* point selection, which involves the scientific basis in selecting *Varmam* points. Conducting randomized controlled trials or foundational research will help identify the right *Varmam* points for specific diseases. Secondly, the number of treatment sessions administered over a specified duration should be carefully recorded. Thirdly, the frequency of SVT application at individual *Varmam* points within each session should be noted. Additionally, the length of time each *Varmam* point is stimulated during SVT sessions, expressed in seconds or minutes, should be documented. The duration between successive SVT sessions, known as the time interval, is also a crucial parameter to be recorded. Lastly, the magnitude of pressure exerted during *Varmam* point stimulation, quantified in suitable units, should be measured meticulously. By documenting these parameters, future research can ensure a more thorough understanding and evaluation of the *Varmam* treatment's efficacy.

6. Limitations

Small sample size, short observation period, and open study design. Other issues are the unequal gender distribution among participants and the lack of pre-planned or adequately powered analyses for subgroups. This encompasses individuals with varying baseline glycemic levels, different durations of diabetes, and prior use of diabetes medications. Additionally, treatment success should not be solely evaluated through glycemic metrics, highlighting the need for Quality-of-Life (QOL) which is currently missing in the trial.

7. Conclusion

This clinical trial aimed to assess the impact of SVT on patients with diabetes. Although the P values between the 2 groups did not show significant changes, it is encouraging to note the positive outcomes observed in both the arms. In both treatment groups, about half the patients improved their FBS, PPBS, and HbA1c

levels, with a small but positive effect size that could be significant in larger population studies. Safety parameters such as liver and renal function tests were within normal limits, and no adverse events were observed during the trial. Various *Varmam* techniques hold potential in diverse clinical settings, suggesting the need for careful consideration of the most feasible and practical approach for diabetic management. While the study suggests that *Varmam* could be an effective and safe non-pharmacological method for managing diabetes, offering notable benefits in terms of safety, simplicity, and being pain-free, further research is needed. Future trials involving larger populations in well-established settings are essential to confirm its efficacy.

8. Acknowledgement

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9. Author Contribution

Rajalakshmi Shanmugavelan served as the Principal Investigator, performed the Varmam point stimulations, conducted the trial throughout its duration, and led the manuscript writing. Samraj Karunanithi supervised the trial, provided critical insights, and contributed to manuscript preparation. Nandhagopal Kannaiyan, as Co-Investigator, assisted in Varmam point stimulation and selection. Vinod Nalupalil Purushothaman contributed to data analysis and statistical interpretation. N. J. Muthukumar supervised the overall conduct of the trial. All authors have read and agreed to the published version of the manuscript.

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