sivi™
Passion Flower

SOUND AND GOOD QUALITY SLEEP

PASSIFLORA INCARNATA

Benefits of SIVI

- Helps to reduce stress and anxiety levels .
- Helps in the reduction of Serum Cortisol levels (stress bio- marker).
- Helps to improve sleep quality, sleep duration, time to sleep and sleep efficiency .
- Helps to reduce symptoms like fatigue and improve daytime mood, ability to function at work, concentration.
- Safe and does not produce any adverse effect as observed on clinical and laboratory tests for Kidney, Liver and Heart.
- Pesticide free with complete Traceability.
- Sustainable sourcing.

PASSIFLORA INCARNATA [SIVI]

INTRODUCING SIVI

- Research-based expertise and the generational knowledge passed down to the original owners of the land- the farmers, lies a lesser known yet striking wonder of nature - Passion flower herb. Out of all the varieties, our Passiflora Incarnata variety, is found to have the highest content of Vitexin, making it our variant of choice.
- SIVI is a well researched, standardised extract of Passion Flower, the marvel with diverse benefits.
- To ensure consistency in the quality of our produce, we use the roots of the existing plant and start the cycle for the new cultivation, to maintain its authentic sustainability.
- SIVI is manufactured under well experienced, scientifically trained personals, at a GMP certified, FDA approved, State of the Art manufacturing facility.
- SIVI is extracted with unique and standardised process to obtain Best Bio-active principles.

OUR CLINICAL STUDY

"A Randomized, Double blind, Placebo controlled, Multi-centric, Interventional, Prospective Clinical study to Evaluate Efficacy and Safety of Passiflora incarnata (Aerial Parts) Extract in participants with Stress and Insomnia."
Protocol No. PASSION/SI/JK/2022, Version 1.0, 2nd June 2022
(CTRI Registration no - CTRI/2022/07/043753)

OBJECTIVES

The main objective of the study was to evaluate efficacy and safety of Passiflora incarnata (Aerial Parts) Extract in participants with Stress and Insomnia.

PRIMARY OBJECTIVES

- Change in stress using perceived stress scale (PSS)
- Change in Patient reported total sleep time

SECONDARY OBJECTIVES

- Change in general psychological health using Short General Health Questionnaire (GHQ-12)
- Change in sleep efficiency (Total sleep time/ time in bed*100)
- Change in Patient-reported time to sleep onset
- Change in Patient- reported number of awakenings
- Change in Patient -reported wake time after sleep onset [Wake Time After Sleep Onset (WASO)
- Change in severity of insomnia using Insomnia Severity Index
- Post study change in serum cortisol (morning) level
- Change in daytime fatigue using Fatigue Severity Scale (FSS)
- Change in daytime mood, ability to function at work, concentration and memory on a graded scale
- Change in quality of sleep using Pittsburgh Sleep Quality Index (PSQI)
- Assessment of requirement of rescue medications
- Assessment of adverse events and vitals including BP, pulse rate, respiration rate and body temperature.
- Assessment of safety by assessing lab parameters.
- Global assessment for overall change by participants and by physician at the end of the study
- Assessment of post study tolerability of study product by participants and physician

RESULTS

A total of 65 participants were screened in the study and all of them were recruited and randomised to two groups (32 in Passiflora group and 33 in placebo group) as there were no screen failures. All the 65 participants completed the study (32 in Passiflora group and 33 in placebo group) as there were no dropouts.

Dosage : Passiflora group was given Passiflora extract (SIVI) 600 mg as dosage at night.

DEMOGRAPHY

Baseline Demography	Gender	Passiflora Group (32)	Placebo Group (33)
Age (in years)		38.63±11.86	40.06 ± 11.81 p<0.05)
Participants Numbers	Males	19	15 p<0.05)
	Females	13	18 p<0.05)

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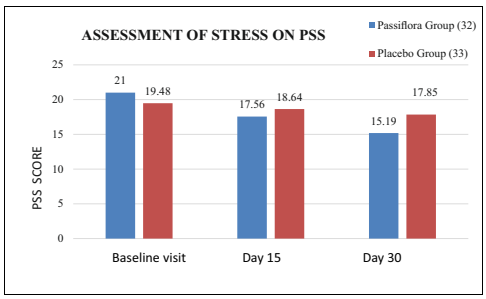
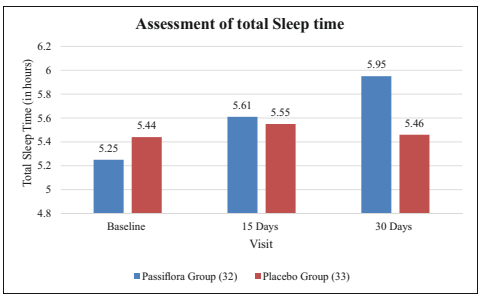


Graph 1: Assessment of stress using perceived stress scale (PSS)

Assessment of stress using perceived stress scale (PSS):

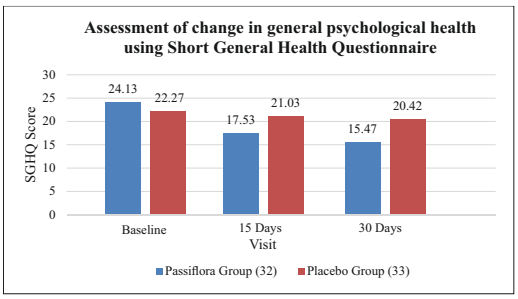
Statistically significant **(27.6%)** reduction ($p<0.05$) in stress levels were observed with the use of Passiflora at the end of 30 days ($p=0.0413$)



Graph 2: Assessment of total sleep time:

Assessment of change in subject-reported total sleep time:

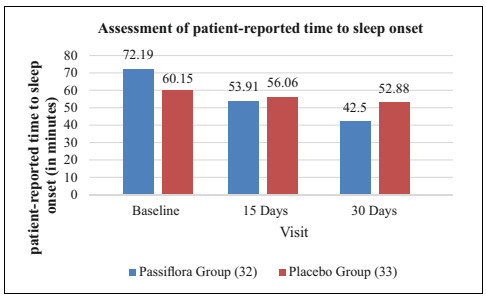
Significant increase **(13.3%)** in total sleep time was observed with the use of passiflora as compared to placebo at the end of 30 days ($p=0.0254$)



Graph 3: Assessment of change in general psychological health:

Assessment of change in general psychological health using Short General Health Questionnaire (GHQ-12):

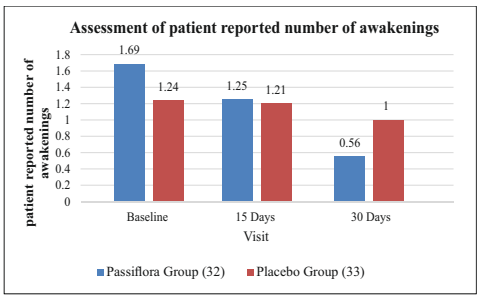
Significant reduction **(35.8%)** in GHQ-12 was obsereved in Passiflora as compared to placebo at the end of 30 days ($p<0.0001$)



Graph 4: Assessment of patient - reported time to sleep onset

Assessment of change in patient-reported time to sleep onset:

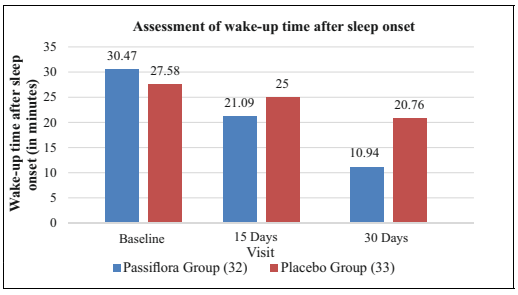
Statistically significant reduction **(41.1%)** in patient-reported time to sleep onset was observed in Passiflora as compared to the placebo at the end of 30 days ($p=0.0199$).



Graph 5: Assessment of patient reported number of awakenings

Assessment of change in patient reported number of awakenings:

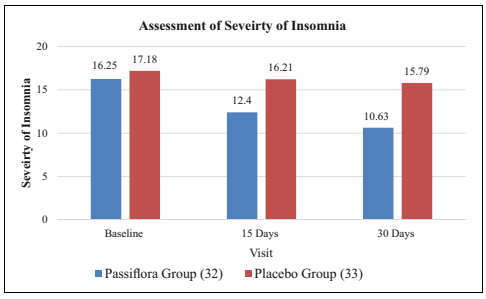
Statistically significant reduction **(66.8%)** in patient-reported number of awakenings was observed in Passiflora as compared to placebo at the end of 30 days ($p=0.0189$).



Graph 6: Assessment of patient-reported wake time after sleep onset

Assessment of change in patient-reported wake time after sleep onset:

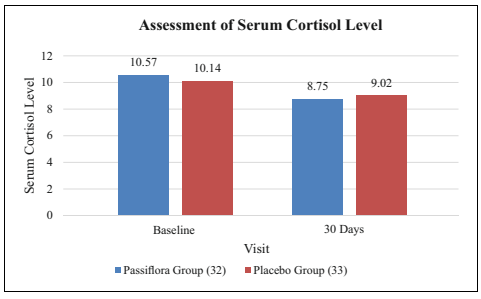
Significant reduction **(64%)** in wake time after sleep onset (based on subject diary) was observed in Passiflora as compared to placebo at the end of 30 days ($p=0.0466$)



Graph 7: Assessment of severity of insomnia assessed using Insomnia Severity Index

Assessment of change in severity of insomnia assessed using Insomnia Severity Index:

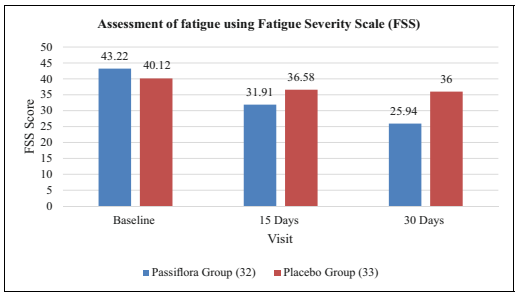
Statistically significant reduction **(34.5%)** in severity of insomnia was observed in Passiflora as compared to Placebo at the end of 30 days ($p<0.0001$).



Graph 8: Assessment of serum cortisol level:

Assessment of post study change in serum cortisol (morning) levels:

Intergroup analysis showed non-significant difference between the two groups at the end of 30 days ($p=0.7502$). A higher percentage reduction of **17.21%** was observed in Passiflora compared to 11.04% reduction in Placebo. Serum Cortisol levels were observed to be within normal limits at baseline and end of the study.



Graph 9: Assessment of Fatigue on FSS:

Assessment of change in daytime fatigue using Fatigue Severity Scale (FSS) :

Intergroup analysis showed significantly higher reduction **(39.9%)** in FSS levels in Passiflora as compared to Placebo at the end of 30 days ($p=0.0007$)

Assessment of change in daytime mood, ability to function at work, concentration & memory:

Significantly lesser interference of sleep on day time mood, ability to function at work, concentration and memory in Passiflora group as compared to Placebo group

Parameter	Passiflora Group (32)			Placebo Group (33)			Between group analysis	
	Baseline	15 days	30 days	Baseline	15 days	30 days	15 days	30 days
Daytime mood	3.22 ± 0.42	2.19 ± 0.47	1.50 ± 0.84	3.09 ± 0.29	2.64 ± 0.60	2.48 ± 0.83	p<0.0040	p<0.0001
Ability to function at work	3.22 ± 0.42	2.19 ± 0.47	1.50 ± 0.84	3.00 ± 0.00	2.70 ± 0.64	2.58 ± 0.83	p<0.0019	p<0.0001
Concentration	2.97 ± 0.18	2.19 ± 0.47	1.50 ± 0.84	3.00 ± 0.25	2.70 ± 0.64	2.58 ± 0.83	p<0.0019	p<0.0001
Memory	2.97 ± 0.18	2.19 ± 0.47	1.50 ± 0.84	2.97 ± 0.17	2.64 ± 0.60	2.48 ± 0.83	p<0.0040	p<0.0001

Assessment of change in quality of sleep using PSQI

Between group analysis showed significantly better quality of sleep in Passiflora as compared to Placebo at the end of 30 days (p=0.0020)

	Standard Group (n=32)			Placebo Group (n=33)		
	Baseline	15 days	30 days	Baseline	15 days	30 days
Mean ± SD	14.72 ± 5.02	13.47 ± 5.22	9.00 ± 5.11	15.09 ± 4.33	14.45 ± 5.06	13.15 ± 4.15
p Value	–	0.0007,	< 0.0001,	–	0.0574,	0.0032,
15 days	p=0.2533, not significant.					
30 days	p=0.0020, significant.					

PASSIFLORA AUTHENTICITY:

- While many plant extracts contain amino acids, Passiflora extracts were found to have the highest GABA content of 21 examined plants. Gamma-aminobutyric acid (GABA) is an amino acid that functions as the primary inhibitory neurotransmitter for the central nervous system (CNS). GABA helps to lower the hyperactivity of some brain cells, which helps to reduce anxiousness and improve calm sleep. ***[Phytomedicine. 2010 October; 17(12): 940–949.]***
- Shortening of sleep latency and increasing in the amount of SWS (Slow way Sleep) produced by the extracts of Passiflora incarnata suggest that this plant possesses adequate properties to be considered as sleep inducer. These characteristics could be profited in the treatment of insomniac patients complaining about problems related to sleep onset. ***[Ref: Sleep Sci. 2017;10(3):96-100]***
- SIVI is mainly standardised to Vitexin, Iso-vitexin, Orientin, Homoorientin as its Active priniciples – Scientific study says Vitexin is an apigenin flavone glycoside & has a variety of pharmacological effects, including antioxidant, pain relief, and neuroprotective calming effects. ***[Ref: Food Sci Nutr. 2020;8:2569–2580.]***

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