



## Development, Validation and Verification of a Self-Assessment Tool to Estimate Sadhaka Pitta (Mental Strength)

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### ABSTRACT

The holistic approach of Ayurveda, treating the patient as a whole, meaning intervention targeted toward complete physical, psychological, and spiritual well-being. Sadhaka Pitta is the factor responsible for mental health and mental strength (weak and strong Sadhaka Pitta functions) assattva. It is the sub-dosha of pitta among the five types. The primary objective of the study was to develop and validate a self-assessment tool to estimate Sadhaka Pitta. The developed tool was evaluated for its reliability and validity by administering to 50 healthy volunteers of either gender belonging to 21 to 50 year age groups. Besides confirming the statistical validity and reliability, the applied utility of the newly developed tool was evaluated by mental health based on Sadhaka Pitta functions parameters of all the volunteers. The results show that the mental functions controlled by brain, vary significantly according to functions of Sadhaka Pitta. The tool therefore can be used to screen normal population to look for possible susceptibility to certain behaviours.

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## INTRODUCTION

### What is Sadhaka Pitta / Mental Strength?

The three types of dosha, Vata, Pitta and Kapha are called Tridosha (Astanga Hrudaya, 2005). Sadhaka Pitta is one of the five types of Pitta associated with certain mental functions and behaviours (Hss

Paradakara, 2005). The word Sadhaka derived from the root word "Sadha" – which means "to accomplishment" (Williams, 2007). The Sadhaka Pitta helps to achieve for the determination of intelligence, memory power and self-esteem. By this, individuals can accomplish the Chaturvidha-Purusharthasviz- Dharma (righteous behaviour), Artha (Wealth), Kama (Fulfilment of desires), and Moksha (Freedom from bandages) (Sharma, 2008a). Sadhaka Pitta Always prevents the covering of heart by Kapha and Tamoguna which depresses the Hridaya. Hence Hridaya becomes more active by the effect of Sadhaka pitta. Pitta Dosha in normal state acts for proper digestion, healthy appetite, thirst, happiness and intelligence. Out of its five types, Sadhaka Pitta is called Medha-Krita (promoting knowledge), which is situated in Hridaya and is a regulator of intellect, grasping power, and self-respect (Susrutha Samhita, 2003). Thus it is likely to be disturbed in mental functions.

Acharya Charak had said that Aapta persons were having all their senses in excellent conditions, so the process of perception of all senses becomes accurate. In Ayurveda, the Hridaya is considered the home of Chetna (consciousness), thus ultimately connecting the Hridaya (heart) and mana (functional brain). Sadhaka Pitta is supposed to govern all the senses, called as AbhiprarthitaManorathaSiddhikrita means fulfilment of all desire. The functions of Sadhaka Pitta can be correlated with the features of different parts of the brain carried by hormones & neurotransmitters.

### Location of sadhaka pitta

All the authors stated that the location of Sadhaka Pitta is in the Hridaya (heart) and responsible for intelligence (Buddhi), memory (smriti), intellect (Medha), self-esteem (Abhimana), enthusiasm (Utsaaha) and the achievement of all desires (abhiprarthitmanoratha) (Sharma, 2008b).

The term 'hrid', in all except the first five (5 sensory organs) inflexions, thought to be connected with the hridaya (heart- as the seat of feelings & emotions), soul (consciousness), mind (brain-seat of feelings & intellectual/mental operation). There are so many correlated structure & functions are related to hridaya.

According to MM. William, synonyms and the meanings of hridaya are interiors of the body/ centre/ core/ essence/ best/ most secret part of anything/ true/ and divine knowledge. The hridaya, like heart, internal ward, innermost, pleasing, beloved, cherished, grateful, charming and lovely (Williams, 2006).

### Functions of sadhaka pitta

According to Acharya Charaka, natural (Avikrita) Pitta is responsible for the promotion of vision, causes digestion, generation of body heat, causes hunger & thirst, maintenance of body elasticity, confers lustre, clarity of mind and contributes to intelligence & intellect.

According to Acharya Sushruta, the Sadhaka pitta enables one to achieve one's aspirations, i.e. So-abhiprarthita-manorath-sadhanakrita (fulfilment of all the desires).

Acharya Vriddha Vagbhata stated that Sadhaka Pitta is responsible for Buddhi (Intelligence), Medha (Intellect), Abhimana (Pride), Utsaha (Enthusiasm) and Abhipretartha (achievement of one's aspirations).

### Mansik or psychological functions

i) Prakrita or Normal characteristics- Shaurya- courage, Harsha- Cheerfulness, Prasada-purity of

mind.

ii) Vaikrita or Abnormal characteristics- Bhaya- Fear, Krodha-anger or rage, Moha- attachment, confusion, clouding of mind, thinking and reasoning.

The characters of an individual derived from mana (functional brain) are Bhakti (desire), Sheel (conduct), Shauch (purity), Dwesha (hatred), Moha (attachment), Tyaga (detachment), Matsarya (strong desire), Shaurya (valour/courage), Bhaya (fear), Krodha (anger), smriti (memory), Utsaha (enthusiasm), Tandra (drowsiness), Tikshna (sharpness), Mardava (softness), Gambheer (seriousness) and Anavastha-tattva (un-stability) (Sharma, 2008a)

### Clinical significance of evaluation of sadhaka pitta

Today Modern science agrees that emotional imbalances (i.e., stress) are the primary component in health problems both mental and physical. The mental diseases are depression, rages, anxiety and bipolar disorders; all are considered as the symptoms of weak Sadhaka Pitta. Without strong Sadhaka Pitta, Dhi (ability to learn) and Dhriti (ability to recall) can result in weakening the channels of the body, especially between the heart and brain (hridaya & mastulunga).

The scientific evaluation of Sadhaka Pitta suit essential in surroundings of conduct (vichara) directions, mental health associated guidance by non-pharmacological methods, and needy of therapeutic interventions (Sharma, 2008b). Sadhaka Pitta is the factor responsible for mental health and mental strength. Furthermore, since the status of Sadhaka Pitta (mental functions) is expected to vary concerning the independent organisation, age groups, situation, repetitive rhythms together with et al., it becomes even new chief to accurately to estimate the power of Sadhaka Pitta is independent of the perspective of Ayurveda.

### No tools available for the of sadhaka pitta

There is no tool available on Sadhaka Pitta based on subjective parameter.

A tool for assessment of Sadhaka Pitta based on objective parameter like Intelligence Quotient & memory scale was conducted by Deepika S et.al. The Sadhaka Pitta with its location as Hridaya can act as an instrumental tool for achieving Intelligence, Discrimination, self- esteem and enthusiasm.

It is the one whose functions are very much similar to the tasks of higher centres of the brain carried out by different neurotransmitters. So there is a vast scope for the assessment Sadhaka Pitta with

**Table 1: The sadhaka pitta assessment tool**

S.N	Questions	Avara Sattva (1)	Pravara Sattva (2)
A.	Smriti(Memory)		
1.	Does your memory is affected by stressful events or environments?		
2.	Do you remember routine events for long time?		
3.	Do you remember matter immediately after listening carefully?		
4.	Do you need frequent revision of study matter in examination/competitive events/Interviews?		
5.	Do you feel your memory is better than other people of your age group?		
B.	Bhaya (Fear)		
1.	Do you feel stressed while performing any task?		
2.	Do you afraid of dark place?		
3.	Do you feel fear travelling alone during night?		
4.	Are you afraid of loneliness?		
5.	Do you afraid of participation in competitive events?		
C.	Shaurya(Courage)		
1.	Do you have capability to face any unexpected situation?		
2.	Do you have good tolerance power to any type of pain?		
3.	Do you feel yourself capable to handle any type of adverse situation?		
4.	Do you have tendency to surrender before completion of task in adverse situation?		
5.	You are never afraid of in any unexpected event?		
D.	Krodha(Anger)		
1.	Do you get easily anger on provocation?		
2.	Do you use harsh words when people are not convinced with your opinion?		
3.	Do you have tendency to anger on not getting attention?		

*Continued on next page*

<i>Table 1 continued</i>			
S.N	Questions	Avara Sattva (1)	Pravara Sattva (2)
4.	You do not have much friends or good relations due to your temperament?		
5.	Do you accept failures easily?		
<b>E. Abhimana (Self Esteem/Pride)</b>			
1.	Are your friends/colleague considered you as a dignified person?		
2.	Do you realize that you and your opinion is always right?		
3.	Do you consider yourself always overall superior than other?		
4.	Do you react immediately on not being treated properly?		
5.	On disputes do you make effort to continue with the same feeling with friends/relatives?		
<b>F. Medha(Intellect)</b>			
1.	Are you able to handle the adverse situations intelligently?		
2.	Do you prefer analysing the things critically before accepting it?		
3.	Do you make opinion about the people without much thinking?		
4.	Do you get rewarded as per efforts you make?		
5.	Are you considered all-rounder by others?		
<b>G. Harsha(Happiness)</b>			
1.	Do you feel that your life is rewarding?		
2.	Are you optimistic even in unfavourable situations?		
3.	Do you enjoy even in small events?		
4.	Do you easily forget bad experiences?		
5.	Are you not bothered with criticism by others?		
<b>Total Score</b>		..... /35	...../35
<b>Percentage%</b>			

Percentage of Sadhaka Pitta = Score obtained for individual class of Sadhaka Pitta x100 Total Scores allotted to that class of Sadhaka Pitta

**Table 2: Results of Analysis of Variance Applied to Compare Mean Scores Obtained in Each Group for Each Question.**

Questions	Sadhaka Pitta	Mean	Std. Deviation	F	P	Post-Hoc Bonferroni Significant pairs	Pearson correlation (r)
Memory-Q1	Avarasattva	1.21	.426	26.81	< .000	All pairs	.577
	Pravarasattva	2.00	.000				
Q2	Avarasattva	1.43	.514	624.00	< .000	All pairs	.356
	Pravarasattva	2.00	.000				
Q3	Avarasattva	1.43	.514	624.00	< .000	All pairs	.529
	Pravarasattva	2.00	.000				
Q4	Avarasattva	1.43	.514	624.00	< .000	All pairs	.529
	Pravarasattva	2.00	.000				
Q5	Avarasattva	1.43	.514	624.00	< .000	All pairs	.579
	Pravarasattva	2.00	.000				
Fear-Q6	Avarasattva	1.43	.514	624.00	< .000	All pairs	.422
	Pravarasattva	2.00	.000				
Q7	Avarasattva	1.43	.514	624.00	< .001	All pairs	.468
	Pravarasattva	2.00	.000				
Q8	Avarasattva	1.43	.514	146.25	< .000	All pairs	.637
	Pravarasattva	2.00	.000				
Q9	Avarasattva	1.43	.514	12.48	< .000	All pairs	.544
	Pravarasattva	2.00	.000				
Q10	Avarasattva	1.43	.514	12.48	< .000	All pairs	.544
	Pravarasattva	2.00	.000				
Courage-Q11	Avarasattva	1.50	.514	12.48	< .001	All pairs	.519
	Pravarasattva	2.00	.000				
Q12	Avarasattva	1.50	.519	12.48	< .000	All pairs	.544
	Pravarasattva	2.00	.000				
Q13	Avarasattva	1.36	.519	146.25	< .000	All pairs	.690
	Pravarasattva	2.00	.000				
Q14	Avarasattva	1.50	.519	62.00	< .000	All pairs	.637
	Pravarasattva	2.00	.000				
Q15	Avarasattva	1.36	.497	146.25	< .000	All pairs	.690
	Pravarasattva	2.00	.000				
Anger-Q16	Avarasattva	1.36	.519	30.86	< .003	All pairs	.637
	Pravarasattva	2.00	.000				
Q17	Avarasattva	1.14	.363	12.48	< .000	All pairs	.544
	Pravarasattva	2.00	.000				
Q18	Avarasattva	1.14	.363	57.77	< .000	All pairs	.637
	Pravarasattva	2.00	.000				
Q19	Avarasattva	1.14	.363	12.48	< .000	All pairs	.529
	Pravarasattva	2.00	.000				
Q20	Avarasattva	1.14	.363	624.00	< .000	All pairs	.529
	Pravarasattva	2.00	.000				
Pride-Q21	Avarasattva	1.50	.519	146.25	< .000	All pairs	.422
	Pravarasattva	2.00	.000				
Q22	Avarasattva	1.43	.363	146.25	< .000	All pairs	.468
	Pravarasattva	2.00	.000				
Q23	Avarasattva	1.14	.363	624.00	< .000	All pairs	.529
	Pravarasattva	2.00	.000				

*Continued on next page*

Table 2 continued

Q24	Avara-sattva	1.43	.497	146.25	<.000	All pairs	.637
	Pravara-sattva	2.00	.000				
Q25	Avara-sattva	1.43	.363	624.00	<.000	All pairs	.529
	Pravara-sattva	2.00	.000				
Intellect-Q26	Avara-sattva	1.36	.363	146.25	<.001	All pairs	.422
	Pravara-sattva	2.00	.000				
Q27	Avara-sattva	1.43	.524	12.48	<.001	All pairs	.544
	Pravara-sattva	2.00	.000				
Q28	Avara-sattva	1.43	.497	624.00	<.000	All pairs	.314
	Pravara-sattva	2.00	.000				
Q29	Avara-sattva	1.36	.497	624.00	<.001	All pairs	.690
	Pravara-sattva	2.00	.000				
Q30	Avara-sattva	1.14	.363	624.00	<.000	All pairs	.468
	Pravara-sattva	2.00	.000				
Happiness Q31	Avara-sattva	1.43	.514	57.77	<.003	All pairs	.529
	Pravara-sattva	2.00	.000				
Q32	Avara-sattva	1.93	.267	146.25	<.000	All pairs	.468
	Pravara-sattva	2.00	.000				
Q33	Avara-sattva	1.14	.363	12.48	<.000	All pairs	.544
	Pravara-sattva	2.00	.000				
Q34	Avara-sattva	1.14	.363	26.81	<.000	All pairs	.693
	Pravara-sattva	2.00	.000				
Q35	Avara-sattva	1.29	.469	57.77	<.001	All pairs	.637
	Pravara-sattva	2.00	.000				

its structural and functional location and its activity in future \$.

### Objectives of the present study

The concept of mental health is essential at every stage of life, from infancy, preteens, and young persons through middle age. So we assure to establish an instrument to evaluate Sadhaka Pitta that observes the particular characteristics designated to on the foundation about two status of sattva (mental strength). The prime intention of the analysis was to develop and validate the Sadhaka Pitta estimation instrument. Besides the acceptable probability analysis preowned validation, to ensure that the instrument is practically useful. For this purpose, we distributed the Sadhaka Pitta Questionnaire to 50 healthy volunteers to show the sattva (mental strength) individual difference. Hence we presumed certain sattva (mental strength) variables would fluctuate as per Sadhaka Pitta. Whether the comparable association is shown, the instrument could be used for diverse mental functions protecting purpose.

### Methodology

**Study design:** This study utilises a random sampling experimental design.

### Citizens and representative (Population and sample)

The citizens for conduction of the current work was interpreted as faculty students, faculty and non-teaching staff of anyone familiar, pertaining to 21 to 50 age groups recorded from different events of Banaras Hindu University. Declarations were constructed in the department of Rachana Sharir and lecture hall concerning the work for recruitment of healthy participants. Every single participant who has given the written consent willingly was assessed entirely. After this process, we had 50 volunteers in the study.

### Ethical clearance letter

The committee of institutional ethics from IMS, BHU, Varanasi has given the ethical clearance approval letter. The number of letters is dean/2018/ethical committee/325. The consent has been taken from healthy participants before starting the questionnaire's.

### Preparation of the preliminary tool

Regarding the deficiency and restrictions observed in the new procedures of Sadhaka Pitta evaluation, we planned a "self-evaluating personality inventory" (Table 1 ) for monitoring the power of sattva (mental strength). This personality inventory is mainly designed on the foundation of

Sadhaka Pitta functions as described in Charaka sutra sthana 12/14, and 18/52 (Sharma PV, Charak Samhita, 2008), Astanga hridaya sutra sthana 12/13-14 (Astanga Hrudaya, 2005), and, SushrutaSharirsthana 4/33, and sutra sthana 21/10 (Acharya, 2003). These verses depict the seven function of Sadhaka Pitta of component Smriti (memory), Bhaya (fear), Shaurya (courage), Krodha (anger), Abhimana (self-esteem/pride), Medha (intellect) and Harsha (happiness). Further qualities of sattva are constructed on this mode of grouping were also collected from other traditional texts of Ayurveda, and an introductory question naire was expanded in a method mentioned above that simple opinions or statements were designed to evaluate each feature of Sadhaka Pitta. The instrument prescribed that the suspected data their agreement (harmony) or disagreement (disputed) with the question in suitable columns by labelling a check mark (ü) against the specific statement/questions that best described their physiology on the base of the structure. One score was designated for the determined reply if start to have existed in that independent. Total ratings were deliberated in particular columns, and afterwards, the scores were converted into a percentage for further statistical investigation. The status of sattva (mental strength) in an individual was pronounced based on highest percentage scores prevailed supported the different class.

### Content validity

The Contended validity concerns somewhat the independent objects in the estimated instrument communicable to the idea of what is being sustained. We have to go along with a generally employ the procedure of supporting contended validity, i.e., alongside measuring the consensus between concern's authority as regards how the specific fragment was essential (Bannigan and Watson, 2009). The instrument (tool) was assessed by Ayurvedicsconcern's authority through the meeting with discussion and sent to each expert. All of the concerns authority on the deciding committee answered to the successive cross-examine related to Sadhaka pitta for all objects (item):Is the feedback obtained by this item all questions are essential, may be deleted, may be modified in this form or not relevant, in the calculation of mental functions of the Sadhaka pitta? After the expert's checklist of questions for assessing Sadhaka Pitta it was found that majority of the experts recommended that an object (item)was necessary, comparable unit (item) were employed after it was supposed to have content validity. Consequently, the preparatory Sadhaka Pitta instrument accommodated seven objects as smriti, Bhaya, shau-

**Table 3: Depicting reliability of Sadhaka Pitta proforma**

Questions	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Total Correlation	Item-Cronbach's Alpha if Item Deleted
Memory-Q1	60.46	102.825	.765	.970
Q2	60.38	105.342	.550	.971
Q3	60.40	104.612	.617	.971
Q4	60.40	104.612	.617	.971
Q5	60.38	103.914	.727	.971
Fear-Q6	60.40	104.653	.612	.971
Q7	60.38	105.179	.570	.971
Q8	60.40	103.143	.794	.970
Q9	60.44	102.986	.766	.970
Q10	60.44	102.986	.766	.970
Courage-Q11	60.36	105.011	.617	.971
Q12	60.44	102.986	.766	.970
Q13	60.38	102.975	.845	.970
Q14	60.40	104.531	.627	.971
Q15	60.38	102.975	.845	.970
Anger-Q16	60.40	104.041	.686	.971
Q17	60.44	102.986	.766	.970
Q18	60.40	102.898	.824	.970
Q19	60.40	104.612	.617	.971
Q20	60.40	104.612	.617	.971
Pride-Q21	60.40	104.735	.602	.971
Q22	60.38	104.444	.661	.971
Q23	60.40	105.184	.549	.972
Q24	60.40	103.184	.789	.970
Q25	60.40	104.327	.651	.971
Intellect-Q26	60.40	104.939	.578	.971
Q27	60.44	102.986	.766	.970
Q28	60.40	105.592	.500	.972
Q29	60.38	103.914	.727	.971
Q30	60.38	105.098	.580	.971
Happiness Q31	60.40	103.755	.720	.971
Q32	60.38	104.444	.661	.971
Q33	60.44	102.986	.766	.970
Q34	60.42	102.412	.856	.970
Q35	60.42	102.575	.836	.970
Cronbach's Alpha	.989			
Cronbach's Alpha based on Standardized Items	.964			
No. of Items	35			



rya, krodha, Ahankara, Medha and Harsha.

### Construct validity

Establish validity is the suitability of concludes on the base of measurement: i.e., whether an experiment estimates the planned established or not (Rat-tray and Jones, 2007). The Established validity in plotting the Sadhaka Pitta assessment tool concluded in the continuous mode: Fifty (50) healthy participants exist gradually subjected to the experiment inside the full introductory questionnaire accommodating seven objects with 37 questions were conducted. Following analysing the outcomes, individually found that two questions certainly not tried by most of the participants as these characteristics were not generally set up as agree and disagree based on healthy participants. Consequently, we ended with releasing these two question repeatedly arranged questionnaire with seven objects with 35 questions, which were then issued to 50 participants. After the current tool is "Self-Evaluation" variety, the interrogation of inter-rater variance and multiple squared correlations was not considered (Saw and Ng, 2001).

### Collection of data and data entry

The participants who have given the consent form, exist afterwards described regarding particular character in work. Every single participant was then issued with a Sadhaka Pitta evaluation tool which included some introductory details associated with the independent to be fill up. After fulfilment of the pattern, the determining of scores was concluded. The details acquired occur first entered in internet-based structure to keep away from details discrepancy throughout its item. We collected data items to define the role of each variable in and subsequently was transferred to a spreadsheet besides in addition to analysis (Scott, 2019).

### Statistical validation of sadhaka pitta assessment tool

While entering the details, the immediate results were contribution for proper categorisation of Sattva: 1= Avara sattva (Strongly disagree), 2= Pravara sattva (Strongly agree). This type of mental strength (sattva) was done because of categories of Sadhaka pitta like extending from reduction to accent. Subsequently entering the details, Mean and Standard deviation results prevailed for all subject was deliberated for all variety of Sadhaka Pitta. These methods were differentiated applying 1-way analysis of variance found on the categorisation of Sadhaka Pitta.

Table 3 suggests the difference between the mean scores were statistically significant from each other

( $p < .001$ ) in almost all cases, indicating that each item in the tool is efficient in differentiating each category of Sadhaka Pitta.

### Experiment for the reliability of the instrument

The authenticity of the questionnaire was once more completed utilising descriptive analysis and by using Cronbach's alpha that recommends inside ethical stability of the items in the scale. A little value of alpha suggests defective inter-relatedness among things or the diverse setup. In the study, a high value of Cronbach's alpha, i.e., 0.96 was acquired for a large scale. A value of Cronbach's alpha higher than 0.7 is a grasp as allowable for validation of questionnaire (Bland and Altman, 1997). Moreover eliminating some items did not significantly expand the value of Cronbach's alpha, and hence all the details were retained in the questionnaire. Individually further deliberated the total Sadhaka Pitta scores secured by all individual and compared the mean total Sattva scores between a different group of Sadhaka Pitta by using 1-way analysis of variance (ANOVA). As Table 2 submits the differences between the means score of all categories were statistically highly significant ( $p < .001$ ) manifesting once again that the instrument (tool) is effective in transforming the individual groups.

## DISCUSSION

Different IQ (Intelligence Quotient) test (Wechsler Intelligence scale for children/ adults, Stanford-Binet Scale, Bhatia's Scale etc.) and Memory test (Wechsler Memory Scale) are available to measure the intelligence and memory of a person. By measuring the IQ and Memory levels in a person, it may be possible to assess the functioning of Sadhaka Pitta. So objective parameter for the assessment of Sadhaka Pitta functioning may be considered as Intelligence Quotient tests and Memory tests (wikipedia.org/wiki/wechslermemory scale). Abhimana (pride) and Utsaaha (enthusiasm) are also functions of Sadhaka Pitta, and they are more of subjective entities so, assessment cannot be done with the help of objective tools. Still, individually one can feel the functioning of Sadhaka Pitta in his body. Sadhaka Pitta should be considered as a factor or a factor complex that facilitates the above functions, especially intelligence, memory, self-esteem, enthusiasm and other emotional states. The substance or substances, either produced by or associated with the Mastishka (brain), with functions similar to those described to Sadhaka Pitta, may be considered as various neurotransmitters. For example, acetylcholine, norepinephrine, dopamine, serotonin, glutamic acid, etc., of the Central nervous sys-

tem (Shastri, 2002).

## CONCLUSIONS

The principal purpose of the analysis was to establishment and endorsement a self-questioning instrument to evaluate Sadhaka Pitta to test the tool for its validity and reliability. The objective beyond such a project was to formulate an instrument (tool) based on the traditional illustrations found in Ayurveda literature while contemporary surrendering them empirical and applicable in the circumstances of regular objective implementation. While generating the items was taken as a criterion by consulting experience Ayurveda physicians and academicians. Hence the language of these seven items with thirty-five question was kept as uncomplicated as possible. As the solution of the work show, the current tool may be supposed to be reasonably valid and reliable based on statistical inspection. However, this requires further assessment in a large sample. Whether equivalent a probability is shown, the tool may be distributed in the middle of the common public so they may be motivated to evaluate their Sadhaka Pitta functions and can be inspired to know the mental health, mental strength and openness for particular situations.

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## Conflict of interest

The authors declare that they have no conflict of interest for this study.

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