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Protocol for a Cross-Sectional Study to Validate the Role of *Viharaja Hetu* in *Pratishyaya* Through Questionnaire Development

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Abstract

Introduction:

Pratishyaya, a prevalent respiratory condition, is influenced by various factors, notably lifestyle factors (*Viharaja hetu*). In Ayurveda, it is primarily associated with *Vata* and *Kapha dosha* and is considered a precursor to diseases like *Kasa* and *Rajyakshma*. While *Viharaja hetu* has been acknowledged in classical texts, modern medicine often overlooks its impact. This protocol outlines a study aimed at validating a questionnaire to assess the role of *Viharaja hetu* in the pathogenesis of *Pratishyaya*.

Methods:

This is a cross-sectional study protocol designed to develop and validate a questionnaire that evaluates lifestyle-related risk factors contributing to *Pratishyaya*. The questionnaire will be developed based on a review of classical Ayurveda texts, contemporary literature, and research on *Viharaja hetu*. Subject experts will validate the content, and statistical methods will be applied to test its reliability and

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consistency.

Results:

The study anticipates the development of a validated tool that can assess the role of *Viharaja hetu* in *Pratishyaya*. The results will help identify significant lifestyle factors contributing to the disease, promoting awareness and preventive care strategies based on Ayurveda principles.

Discussion:

This study aims to bridge the gap between classical Ayurveda knowledge and modern research methods by creating a reliable, standardized tool to assess *Viharaja hetu* as a risk factor for *Pratishyaya*. Through expert validation and statistical testing, the study will provide valuable insights into the prevention and management of *Pratishyaya* through lifestyle modifications aligned with Ayurveda practices.

Keywords:

Pratishyaya, Viharaja hetu, Ayurveda, Lifestyle factors, Questionnaire validation, Pathogenesis

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Introduction

Pratishyaya is a frequently occurring respiratory condition, affecting individuals across all age groups and both genders. Although it is often self-limiting, if left untreated or inadequately managed, it can lead to serious complications such as Kasa, Kshaya, and Rajyakshma. Classical Ayurveda texts, particularly the Caraka Samhita, regard Pratishyaya nidanarthak (disease-inducing) disorder of Kasa (cough) and as a precursor (purvaroop) to Rajyakshma (tuberculosis), highlighting its significant role in the pathogenesis of more severe conditions.

In Ayurveda, the emergence of *Pratishyaya* is strongly linked to lifestyle factors, known as *Viharaja hetu*, which include exposure to extreme temperatures, allergens, irregular daily routines, and the

suppression of natural urges. These factors are believed to disrupt the balance of the Vata and Kapha doshas, contributing to the onset and exacerbation of the Nidan condition. *parivarjan*—the avoidance of causative factors—is a fundamental approach in Ayurveda medicine for both the prevention and management of *Pratishyaya*.

This study aims to design and validate a comprehensive questionnaire to evaluate the role of *Viharaja hetu* in the development of *Pratishyaya*. By developing a standardized tool, the study seeks to enhance our understanding of the lifestyle-related risk factors that contribute to this condition, thereby promoting better preventive strategies and management based on Ayurveda principles.

Table: 1: Viharaja Hetu for Pratishyaya According to Various Acharya

Viharaja Nidana (lifestyle factors)	Caraka samhita	Sushruta samhita	Yoga ratnakar a	Ashtanga hridayam/ Ashtanga sangraha	Kashyapa samhita	Madhava nidana
Raja (Exposure to Dust particles)	+	+	+	+		+
Dhumasewana (Inhalation of smoke)	+	Dhuli				Dhuli
Avashaya (Exposure to frosty conditions/ cold dew)	+		+	+		+

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Shirasoabhitapa (Injury or secondary causes	+	+	+			
related to head)						
Baashpa (Excessive tears)	+		+			
Vaashpa nigrah (Forceful Suppression of tears)				+		
Neecha-Atyuccha upadhana (use of too low or too high leveled pillow)				+		
Anupahitashayano, atiparshava shayan, apavrata mukha shayan (Sleeping covering the mouth or sleeping on either side)					+	
Sandharana (suppression Of natural urges)	+	Mutra Purisha	+		Nirantara vegadhar ana	Purishadi
Atiswapna (excessive Sleeping/ Day time sleeping)	+		+	+		Diwaswa pna
Prajagarana (being awake/ being awake at night)	+		+			
Atibhashya (excessive talking)	+		+	+		
Atimaithuna (excessive sexual intercourse)	+	Ati nariprasanga	+			
Krodha (excessive anger)					+	
Chhardinigraha (forceful Suppression of vomiting)				+		

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Aim and Objectives

Aim:

To develop and validate a questionnaire for assessing the role of Viharaja hetu as a risk factor in *Pratishyaya*.

Objectives:

- 1. To design and validate a comprehensive questionnaire for assessing *Viharaja hetu*.
- 2. To validate the questionnaire with the help of subject experts.

Research Question

What is the role of Viharaja hetu in the pathogenesis of Pratishyaya, and how can it be assessed effectively using a validated tool?

Hypothesis

Null Hypothesis (H₀): The designed questionnaire does not significantly assess the role of Viharaja hetu in Pratishyaya.

Alternate Hypothesis (H_a): The designed questionnaire significantly assesses the role of Viharaja hetu in Pratishyaya.

Materials and Methods

Study Design:

A cross-sectional study focused on questionnaire development and validation.

Sources of Data:

- 1. Clinical Source: Participants will be recruited from the college campus to validate the questionnaire.
- 2. Literary Source: Classical Ayurveda texts like Carakasamhita, Sushrutasamhita,

Ashtangahridayam, Ashtangasangraha, Madhavnidana, Yogratnakara, Kashyapasamhita, commentaries, modern literature, research articles, and online portals.

Methodology:

1. Literature Review:

An extensive review of classical Ayurveda texts like Carakasamhita, Sushrutasamhita, Ashtangahridayam, Ashtangasangraha, Madhavanidana, Yogratnakara, Kashyapasamhita, modern literature, and research articles to identify Viharaja hetu contributing to *Pratishyaya*.

2. Questionnaire Design:

- A 5-point Likert-scale questionnaire will be prepared, addressing key *Viharaja hetu* identified from the literature.
- The questionnaire will include questions related to lifestyle factors such as exposure to extreme temperatures, irregular routines, suppression of natural urges, and environmental conditions.

3. Validation of the Questionnaire:

- Expert Review: 10 Subject experts will review the questionnaire to ensure content validity.
- Focal group discussions with experts in Ayurveda will refine the

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- questionnaire by suggesting corrections till validation.
- Pre-testing and Reliability Testing:
 The validated questionnaire will be distributed to selected participants.
- Statistical tools will be used to assess reliability and consistency.
 Chi-square test for association and Mann Whitney U test for differentiation will be applied.
- 4. Data Collection and Analysis:
 - Responses will be collected through Google Forms .
 - Statistical analysis will determine
 the effectiveness of the
 questionnaire in assessing Viharaja
 hetu. Chi-square test for
 association and Mann Whitney U
 test for differentiation will be
 applied.

Inclusion Criteria:

- 1. Participants aged 18–60 years, irrespective of gender, caste, or socio-economic status.
- 2. Participants willing to provide informed consent for the study.

Exclusion Criteria:

- 1. Structural abnormalities like deviated nasal septum, nasal polyps, or sinusitis.
- 2. Functional abnormalities like smell and taste disorders.
- 3. Infectious diseases like tuberculosis and

- systemic diseases like bronchial asthma.
- 4. Participants below 18 years or above 60 years.
- 5. Participants unwilling to participate.

Materials Required:

- 1. Ayurveda classical texts and commentaries.
- 2. Questionnaire designed on *Viharaja* hetu.
- 3. Statistical tools for validation and reliability testing.

Data Analysis

- The responses to the questionnaire will be analyzed using statistical methods, such as Cronbach's alpha for reliability and factor analysis for validation.
- Results will help establish the questionnaire as a standardized tool for assessing Viharaja hetu in Pratishyaya.

Anticipated Outcomes:

- 1. A validated questionnaire for assessing the role of Viharaja hetu in Pratishyaya.
- 2. Identification of key lifestyle-related risk factors contributing to the disease.
- 3. Insights into preventive measures aligned with Ayurveda principles.

Expected outcomes:

Primary Outcomes:

1. Development and validation of a reliable, standardized questionnaire to

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assess Viharaja hetu in the pathogenesis of Pratishyaya.

2. Systematic identification and categorization of significant Viharaja hetus contributing to the onset and progression of Pratishyaya, based on classical Ayurveda texts and expert inputs.

Secondary Outcomes:

- 1. Creation of a practical assessment tool for clinicians to evaluate lifestyle-related risk factors and their role in Pratishyaya, aiding in preventive care strategies.
- 2. Strengthening the scientific foundation of Ayurveda principles by integrating classical knowledge with modern research

methods through questionnaire validation.

3. Promoting awareness among patients and the general public about the importance of avoiding *Viharaja hetu* and adopting healthier lifestyle practices to prevent *Pratishyaya* and its complications.

Significance of the Study:

This study emphasizes the importance of lifestyle factors (*Viharaja hetu*) in the development of *Pratishyaya*. By developing a validated questionnaire, it bridges the gap between theoretical understanding and practical assessment, aiding in better disease prevention and management strategies.

Table 2: Timeline of the Proposed Research Work

Name	■Date	∺ Status	Remarks
Phase 1 Literature Review & Questionnaire Preparation	April 1, 2024 - August 31, 2024	Complete	Conduct literature review, draft questionnaire, plan validation process.
Phase 2 Questionnaire Development and Validation Recruitment & Initial Assessment Phase 3 Data Analysis	September 1, 2024 - June 30, 2025	In progress	Validate and statistically test the questionnaire. Clean, validate, and analyze data statistically.
Phase 4 Writing and Submission	July 1, 2025 - October 1, 2025	Upcoming	Draft, revise, and finalize thesis, prepare for defense.

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