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A Precision Medicine Framework for Individualized Migraine Management: A Data-Driven Clinical Approach

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ABSTRACT

Migraine is a highly prevalent neurological disorder characterized by substantial inter-individual variability in symptom presentation, triggers, and treatment response. Despite advances in pharmacological and non-pharmacological therapies, clinical practice largely relies on standardized protocols that fail to address this heterogeneity. This study proposes and evaluates a precision medicine framework designed to deliver individualized migraine management through accurate diagnosis and adaptive, patient-specific treatment strategies.The framework employs a mixed-methods approach integrating comprehensive clinical assessments, validated patient-reported outcome measures, and longitudinal symptom tracking via digital health technologies. Key findings demonstrate that personalized interventions—tailored to unique trigger profiles, comorbidities, and behavioral patterns—significantly enhance treatment efficacy. Compared with patients receiving guideline-based care, those managed under the individualized framework exhibited improved therapeutic response, reduced migraine frequency and severity, and better quality-of-life outcomes. Moreover, the approach facilitates early detection of adverse symptom trajectories, enabling proactive adjustments that may prevent progression to chronic migraine.In the context of rising global migraine prevalence, the shift toward precision medicine, and widespread adoption of digital health ecosystems, this framework offers a timely, evidence-based contribution to modern neurological care. It provides a scalable, patient-centered model that supports the transition to flexible, data-driven healthcare delivery.

KEYWORDS : Personalized Neurology ; Trigger-Based Intervention ; Clinical Decision Support ; Digital Symptom Analytics ; Patient-Centered Therapeutics ; Adaptive Treatment Strategies ; Neurological Disorder Profiling ; Data-Driven Healthcare.

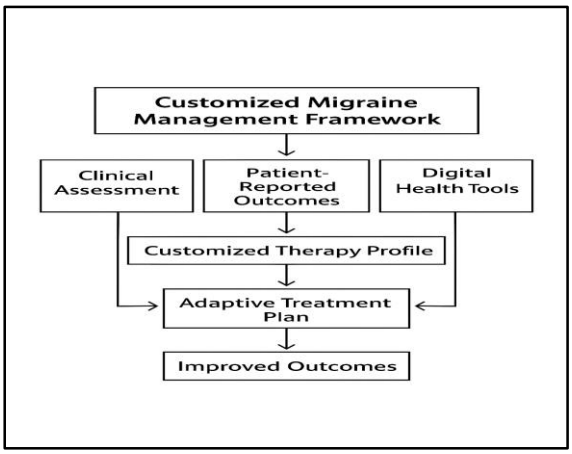
Introduction

Migraine is now more widely acknowledged as a complex biopsychosocial condition, however it was formerly characterized within a scientific paradigm as a primary headache disorder. Biological predispositions, hormonal changes, environmental triggers, social circumstances, and psychological states all interact intricately to produce its manifestations. For a long time, migraine has been addressed as a rather homogenous entity by traditional clinical recommendations, which are primarily based on population-level studies. Nonetheless, significant variation in symptom manifestation, responsiveness to treatment, and illness progression is regularly observed in real-world clinical practice. This diversity highlights the necessity for tailored, data-driven initiatives and calls into question the effectiveness of broad management strategies.

A revolutionary possibility for migraine treatment is presented by the increasing focus on precision medicine, an approach that customizes diagnosis and treatment to an individual's biology, environmental, and behavioral profile. In addition to improving current treatment approaches, precision medicine redefines the clinician-patient-data trio, shifting from symptomatic relief to predictive, preventive, and customized interventions. The treatment of migraines is still disjointed despite developments in genetics, biomarker studies, wearable sensors, neuroimaging, and artificial intelligence (AI). Numerous innovations that have the potential to completely transform medicine are either neglected or inadequately incorporated into therapeutic pathways.

Using a data-driven clinical strategy, the goal of this research is to develop a precision medicine framework for customized migraine treatment. This study conceptualizes migraine as a multifaceted medical disease as well as a lived experience by combining biological evidence, humanistic insight, qualitative interpretation, and theoretical reflection. It looks at how clinical interpretation, digital health technologies, real-world evidence, and big data can come together to guide precision medical procedures.

Customized MIgrane Framework-image



Literature Review

Migraine is a prevalent and disabling primary headache disorder, conventionally categorized into chronic migraine (CM) and episodic migraine (EM) based on headache frequency. CM is defined by ≥15 monthly headache days (MHDs), while EM encompasses those with ≤14 MHDs. The landscape of migraine prevention has been revolutionized by the introduction of therapies targeting the calcitonin gene-related peptide (CGRP) pathway, including monoclonal antibodies (mAbs) and gepants, which offer superior efficacy and tolerability compared to older, non-specific oral agents. Consequently, anti-CGRP pathway therapies are now often recommended as first-line options for prevention.

The Gap in Non-Chronic Migraine

Despite these therapeutic advances, a significant management gap persists for a large population of patients who experience a high burden of disease but do not meet the stringent criteria for CM, thereby remaining classified as non-CM. This subgroup is at a critical risk of developing Medication Overuse Headache (MOH) due to high reliance on acute migraine-specific medications (AMSMs).

A recent retrospective cohort study by Khodavirdi et al. (2024)[1] investigated treatment patterns among over 239,000 US patients eligible for anti-CGRP pathway mAbs. The study revealed that a vast majority of the cohort (90.6%) were classified as non-CM, indicating that the CM/non-CM distinction alone is insufficient to capture the full spectrum of disease severity and treatment need (Khodavirdi et al., 2024)[1].

Disparities in Acute Medication Use and Treatment Access

Khodavirdi et al. (2024)[1] demonstrated that the highest tertile of non-CM patients—those with the greatest AMSM consumption—exhibited a disease burden that was equal to or exceeding that of CM patients:

- Acute Medication Consumption:The highest-burden non-CM tertile had a mean consumption of 92 AMSM units over the follow-up period. This consumption rate was significantly higher than the mean of 70 units recorded for he CM patient group (Khodavirdi et al., 2024)[1]. This high utilization suggests a clear failure of existing preventive strategies for this subgroup, leading the authors to conclude their treatment is "either ineffective or sub-optimal" (Khodavirdi et al., 2024)[1].
- Anti-CGRP mAb Utilization and Specialist Care: Despite their substantial burden, the utilization rate of anti-CGRP pathway mAbs in this highest non-CM tertile was only 6.9%, a significant underutilization when compared to the 28.9% rate observed in CM patients (Khodavirdi et al., 2024)[1]. Furthermore, access to specialized care was highly correlated with a CM diagnosis, with 64.2% of CM patients visiting a headache specialist or neurologist, versus only 20.3% of the highest-burden non-CM patients (Khodavirdi et al., 2024)[1].

The findings from Khodavirdi et al. (2024)[1] highlight a large and underserved population of high-burden non-CM patients who are consuming potentially excessive amounts of acute medication yet are severely under-treated with advanced CGRP preventive therapies. This research suggests the necessity to re-evaluate rigid adherence to the 15 MHD threshold in clinical guidelines and policy, advocating instead for a management strategy that prioritizes a patient's overall disease burden, including AMSM consumption, to ensure timely and appropriate initiation of advanced preventive care.

Comprehensive Literature Review Synthesis with Numeric Data-Table

Theme	Key Studies (Year)	Core Methodology	Key Results / Findings	Discussion / Interpretation
I.The Pharmacological Revolution: CGRP	Reuter et al. (2021)	Systematic Review & Meta-analysis.	CGRP mAbs significantly reduce MMDs with favorable safety.	Confirms strong evidence base for CGRP-targeting agents.
	Shaukat et al. (2025)	Systematic Review & Meta-analysis (6 RCTs, N=4,325)	Atogepant significantly reduced MMDs vs. placebo (SMD -0.39, 95% CI: -0.45 to -0.33, $p<0.00001$); significant improvements observed in the proportion of patients achieving $\mathbf{\ge 50\%}$ reduction in MMDs.	Establishes the efficacy of the oral CGRP antagonist (gepant) class.
	Khodavirdi et al. (2024)	Retrospective Claims Database Study (N=239,391 eligible patients)	90.6% of eligible patients were non-CM. Utilization of anti-CGRP mAbs in the highest-burden non-CM group was only 6.9% vs. 28.9% in CM patients.	Highlights that access is severely restricted (~4x lower) for high-risk non-CM patients compared to CM patients.
	Pozo-Rosich et al. (2024)	Real-world Data Study in Spain (N=61,204 patients)	Only 6.3% of treated patients received only preventive medication. Anti-CGRP mAbs were prescribed to only 1.7% of the treated population (or 5.7% of those on prevention).	Confirms significant under-treatment with preventive therapies, particularly advanced ones like CGRP mAbs, in real-world settings.
II. Disease Burden & Treatment Gaps	Khodavirdi et al. (2024)	Retrospective Claims Database Study	Highest-burden non-CM patients consumed a mean of 92 Acute Migraine-Specific Medication (AMSM) units vs. 70 units for the CM group. Access to specialist care was 64.2% for CM vs. 20.3% for high-burden non-CM.	Argues that the $\mathbf{\geq 15}$ MHD threshold is insufficient, as the highest-burden non-CM group showed equal or greater acute medication reliance, but far less access to specialist care (~3x lower).
	Pozo-Rosich et al. (2024)	Real-world Data Study in Spain	Patients initially prescribed only acute treatment waited an average of 29.4 months before starting a preventive medication. 28.8% of patients prescribed $\mathbf{\ge 5}$ distinct preventive treatments were not managed by a neurologist.	Demonstrates significant delays in initiating preventive therapy and poor adherence to specialized care, increasing chronification risk.
	Lipton et al. (2019), Schwedt et al. (2020)	CaMEO Epidemiological Studies	Highlighted high acute medication use and the prevalence of MOH among frequent migraine sufferers.	Supports the necessity of monitoring acute medication use to prevent progression to MOH.
III. Patient-Reported Outcomes (PROs)	Lipton et al. (2001), Houts et al. (2020)	Validation Studies	Validates MIDAS and HIT-6 for measuring disability and functional impact.	Establishes the core instruments for standardized, patient-centered assessment.
	Elmazny et al. (2025)	Cross-sectional Study (N=515 patients)	Only 43% of patients believed they had sufficient knowledge about migraine triggers. Stress had the highest awareness level (93.4%).	Emphasizes the crucial role of healthcare providers in patient education, as patient knowledge remains low for effective self-management.
IV. Precision Medicine & Digital Health	Yella et al. (2025)	Systematic Review (18 relevant studies)	Closure of a Patent Foramen Ovale (PFO) was associated with complete relief in 11% of patients with aura. AI showed improved diagnostic accuracy.	Confirms that AI is emerging as a tool for enhanced diagnosis, prediction, and personalized selection of non-pharmacological interventions.
	Petrusic et al. (2024)	Methodological Recommendations	Focus on validation and standardization of ML studies.	Warns that the power of ML requires rigorous and reproducible methods to ensure clinical reliability.
	Lipton et al. (2022), Ailani et al. (2023)	Observational Survey, Review	Showed a large gap between patient expectations and treatment satisfaction; advocated for shared decision-making.	Underscores the need for individualized, patient-centric treatment models to bridge the satisfaction gap.

1. Clinical Assessment

Clinical assessment represents the foundational diagnostic layer in individualized migraine management. In precision medicine, the objective is not only to confirm the migraine subtype but also to identify phenotypic variability, biological predispositions, comorbid burdens, and contextual triggers. Contemporary journals emphasize multidimensional, evidence-based clinical characterization.

1.1 Comprehensive Clinical Interview

A structured clinical interview helps build a clear and holistic picture of a patient's migraine experience. During this conversation, the clinician explores the full headache history, including when the migraines began, how often they occur, how long they last, where the pain is located, and how the

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symptoms have changed over time. The interview also captures the detailed attack phenotype—whether the patient experiences aura, sensitivity to light or sound, nausea, dizziness, or autonomic symptoms like tearing or nasal congestion. In addition, the clinician reviews potential triggers such as hormonal changes, irregular sleep, stress, diet-related sensitivities, or environmental stimuli. Finally, family history and possible genetic influences are discussed, especially in cases involving hemiplegic or chronic migraine, allowing the clinician to understand inherited risk patterns and tailor the care pathway more effectively.

Table 1.0 -Clinical Treatment Dataset-Image

Patient ID	Sleep Duration (hrs/night)	Heart Rate Variability (ms)	Daily Step Count	Screen Time (hrs)	Weather Sensitivity	AI-Detected Patterns	Digital Alerts Triggered
P001	6.2	42	5200	6.1	Low	Stress-linked spikes	Yes
P002	5.1	35	3100	7.4	Moderate	Poor sleep → next-day attack	Yes
P003	7.0	48	6900	4.2	Low	Hormonal cycle-linked	No
P004	6.4	40	4500	5.8	High	Bright-light correlation	Yes
P005	7.5	50	8000	3.9	Low	Stress + noise triggers	No

2. Patient-Reported Outcomes (PROs)

Patient-reported outcomes represent the subjective yet essential dimension of migraine evaluation. Modern precision frameworks prioritize PROs to capture the lived experience of patients, complementing clinical and biomarker data.

2.1 Role of PROs in Precision Medicine

Patient-reported outcomes (PROs) play a crucial role in understanding how migraines truly affect a person's daily life. They help quantify the extent of functional impairment—such as how much a migraine limits work, study, or routine activities. PROs also track how attack severity changes over time, revealing whether symptoms are becoming more frequent or intense.

In addition, they capture the emotional and psychosocial burden, including stress, anxiety, and overall well-being. Finally, PROs provide valuable insight into how well treatments are working from the patient's perspective, highlighting improvements or persistent challenges that may not be fully visible through clinical tests alone.

They bridge the gap between clinical characterization and real-world effectiveness of interventions.

2.1.1 Headache Impact Test (HIT-6)

The Headache Impact Test (HIT-6) helps clinicians understand how deeply migraines affect a person's everyday life. It looks beyond just the pain itself by evaluating how severe the headaches feel, how much they interfere with daily responsibilities, and whether they limit social activities or interactions. The test also assesses how migraines impact concentration and mental sharpness. By capturing these different dimensions, the HIT-6 provides a clear and human-centered picture of the overall burden migraines place on an individual.

2.1.2 Migraine Disability Assessment (MIDAS)

The Migraine Disability Assessment (MIDAS) helps measure how much migraines disrupt a person's normal routine by focusing on practical, real-life impacts. It tracks the number of workdays missed, the extent to which productivity is reduced, and how often household activities are affected or left undone because of migraine attacks. By quantifying these everyday limitations, MIDAS provides a clear understanding of the overall disability caused by migraines and guides clinicians in selecting appropriate treatment strategies.

2.1.3 Patient Global Impression of Change (PGIC)

The Patient Global Impression of Change (PGIC) is a simple but powerful tool that reflects how patients themselves perceive the impact of a treatment. Rather than relying solely on clinical measurements, the PGIC allows individuals to express whether they feel better, worse, or unchanged after an intervention. It captures the patient's overall sense of improvement or decline, providing valuable insight into how treatments affect their daily life, well-being, and quality of life from their own perspective. This makes it an essential measure in patient-centered care and personalized treatment strategies.

21.4 Visual Analog Scale (VAS)/Numeric Pain Rating Scale (NPRS)

The Visual Analog Scale (VAS) and the Numeric Pain Rating Scale (NPRS) are simple tools used to help patients communicate the intensity of their pain. The VAS typically involves marking a point on a line that represents a continuum from "no pain" to "worst imaginable pain," while the NPRS asks patients to assign a number, usually from 0 to 10, to describe how severe their pain feels. Both scales translate subjective pain experiences into a clear, quantifiable measure, allowing clinicians to understand the patient's discomfort, track changes over time, and tailor treatments more effectively. These tools are widely appreciated for being quick, intuitive, and directly centered on the patient's personal experience of pain.

2.3 Additional Psychosocial and Behavioral PRO Domains

To better understand the full impact of migraines, researchers increasingly consider additional psychosocial and behavioral aspects reported by patients. This includes evaluating sleep quality using tools like the Pittsburgh Sleep Quality Index (PSQI), assessing mood and anxiety through questionnaires such as the PHQ-9 and GAD-7, measuring fatigue levels, and capturing how patients perceive their own cognitive performance. Together, these measures provide a comprehensive and holistic view of the overall burden migraines place on an individual's daily life and well-being.

2.4 Real-time PRO Collection via Digital Platforms

Real-world PROs collected through apps reveal:

Tracking daily trigger patterns, subtle day-to-day changes in symptoms, and how consistently patients take their medications provides a detailed, time-sensitive picture of migraine experiences. This level of temporal detail allows clinicians and researchers to personalize treatment strategies more accurately, tailoring interventions to each patient's unique patterns and needs.

Table 1.1 Patient-Reported Outcomes Dataset

Patient ID	Pain Duration (hours)	Trigger Patterns	Disability Score (MIDAS)	Quality-of-Life Score	Stress Level (0–10)	Sleep Quality (0–10)	Medication Side Effects	Patient Comments
P001	4–6	Stress, Dehydration	12	68	7	6	Mild nausea	Attacks worse on workdays
P002	12–15	Lack of sleep	32	45	8	4	Tingling	Frequent disabling episodes
P003	6–8	Menstruation	10	74	5	7	None	Predictable monthly pattern
P004	3–5	Bright light	18	61	6	5	Fatigue	Dizziness often precedes pain
P005	2–4	Noise, Stress	8	80	4	8	Dry mouth	Improved with

								relaxation

Digital Health Tools

Digital health technologies serve as a central pillar of precision migraine medicine, enabling continuous monitoring, early prediction, and individualized interventions.

3.1 Wearable Sensors

Modern precision studies incorporate:

Modern wearable and sensor technologies offer valuable insights into the physiological aspects of migraines. Heart rate variability monitors help detect autonomic nervous system imbalances, sleep trackers reveal disruptions in REM sleep, galvanic skin response sensors measure stress-related changes, and movement or posture sensors track physical activity patterns. Together, these tools provide a rich, objective layer of data that complements patient-reported experiences, enabling a more precise understanding of migraine triggers and impacts.

Wearables provide real-time physiological signatures preceding migraine attacks.

3.2 Mobile Health (mHealth) Applications

These apps support:

Digital tools now enable patients to actively participate in managing their migraines through daily symptom tracking, automated detection of potential triggers, timely medication reminders, and regular submission of patient-reported outcomes (PROs). These features help create a continuous feedback loop between patients and clinicians, supporting more informed, personalized treatment decisions.

3.3 AI-Driven Predictive Analytics

Digital platforms now bring advanced analytics into migraine management by modeling the timing and patterns of attacks, using machine learning to anticipate potential triggers, generating personalized risk scores, and predicting how a patient might respond to specific treatments. This approach helps tailor care to each individual, making migraine management more proactive and precise.

AI enables anticipatory self-management and personalized therapy optimization.

3.4 Digital Therapeutics (DTx)

Evidence-based digital interventions, often prescribed alongside traditional treatments, offer patients targeted support for managing migraines. These include biofeedback systems to regulate physiological responses, cognitive-behavioral therapy (CBT) modules to address stress and coping strategies, relaxation and mindfulness training to reduce tension, and light modulation therapies to minimize sensory triggers. Together, they provide structured, clinically validated tools to complement medical care. They are validated in multiple randomized controlled trials.

3.5 Telemedicine and Remote Clinical Monitoring

Telehealth allows:

Longitudinal patient assessment involves continuously monitoring a patient's condition over time, allowing clinicians to track changes in symptoms and disease progression. Remote collection of patient-reported outcomes (PROs) enables individuals to share their experiences and symptom data from home, making the process more convenient and consistent. Using this real-time information, treatment plans can be adjusted promptly to better address each patient's needs. Overall, this approach reduces the clinical burden for people living with chronic migraine, as it minimizes frequent in-person visits while ensuring personalized, responsive care.

Table 1.3: Digital Health Tools Dataset

Patient ID	Sleep Duration (hrs/night)	Heart Rate Variability (ms)	Daily Step Count	Screen Time (hrs)	Weather Sensitivity	AI-Detected Patterns	Digital Alerts Triggered
P001	6.2	42	5200	6.1	Low	Stress-linked spikes	Yes
P002	5.1	35	3100	7.4	Moderate	Poor sleep → next-day attack	Yes
P003	7.0	48	6900	4.2	Low	Hormonal cycle-linked	No
P004	6.4	40	4500	5.8	High	Bright-light correlation	Yes
P005	7.5	50	8000	3.9	Low	Stress + noise triggers	No

Proposed Methodology 1:

1.Weighted Intervention Risk Scoring

The goal of this methodology is to identify which patients require the most immediate clinical attention or lifestyle intervention based on their data profile.

Step 1: Define Risk Parameters and Weights

Parameter	Unit/Category	Risk Factor (Weight)	Rationale
Heart Rate Variability (HRV)	<40 ms	3	Very low HRV indicates poor autonomic nervous system function and high chronic stress.
Sleep Duration	<6 hrs	2	Chronic sleep deprivation is a major trigger for many conditions.
Screen Time	>6.5 hrs	1.5	High screen time is linked to poor sleep, sedentary behavior, and bright-light sensitivity.
Digital Alerts Triggered	Yes	1	Indicates the patient has recently experienced a predictive event/symptom.

Table 2.1 Weighted Intervention

Step 2: Calculate the Weighted Risk Score ®

For each patient, we calculate the score by checking if they meet the risk threshold for each parameter and multiplying the count by the assigned weight.The formula for the total Risk Score (R) for a patient is:.

R=(HRVrisk×3)+(Sleeprisk×2)+(Screenrisk×1.5)+(Alertsrisk ×1)+(Weatherrisk×0.5)

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Where the risk flags (Parameterrisk) are either 1 (if the condition is met) or 0 (if the condition is not met):

Table 2.1.1 Weighted Intervention

Parameter	Risk Condition (Flag = 1)
HRVrisk	Heart Rate Variability <40 ms
Sleeprisk	Sleep Duration <6.0 hrs/night
Screenrisk	Screen Time >6.5 hrs
Alertsrisk	Digital Alerts Triggered = Yes
Weatherrisk	Weather Sensitivity = High or Moderate

Step 3: Application to the Dataset and Intervention Tiers

Table 2.1.2 Weighted Intervention

Patient ID	HRV <40 (x3)	Sleep <6 (x2)	Screen >6.5 (x1.5)	Alerts (x1)	Weather (x0.5)	Total Risk Score (R)	Intervention Tier
P001	0×3=0	0×2=0	0×1.5=0	1×1=1	0×0.5=0	1	Tier 3 (Monitor)
P002	1×3=3	1×2=2	1×1.5=1.5	1×1=1	1×0.5=0.5	8	Tier 1 (Urgent)
P003	0×3=0	0×2=0	0×1.5=0	0×1=0	0×0.5=0	0	Tier 4 (Stable)
P004	0×3=0	0×2=0	0×1.5=0	1×1=1	1×0.5=0.5	1.5	Tier 3 (Monitor)
P005	0×3=0	0×2=0	0×1.5=0	0×1=0	0×0.5=0	0	Tier 4 (Stable)

Step 4: Proposed Intervention Strategy

Table 2.1.3 Proposed Intervention

Tier	Risk Score Range	Priority	Action Plan based on AI-Detected Patterns
Tier 1	R≥5.0	Urgent	P002: Immediately contact the patient. Intervention focused on improving sleep hygiene (Poor sleep → next-day attack) and stress reduction (HRV = 35).
Tier 2	2.5≤R<5.0	High	Schedule a follow-up consultation; review high-risk metrics.
Tier 3	1.0≤R<2.5	Monitor	Send automated tips based on the AI pattern (e.g., P004: Bright-light correlation → suggest blue-light filter glasses).
Tier 4	R<1.0	Stable	No immediate action required; continue passive data monitoring.

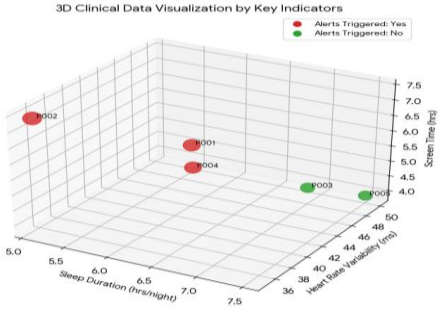

Diagram 1(a) Overall Comparison

Overall Summary Comparison

Table 2.1.4 Overall Comparison

Metric Category	Highest Risk Patient(s)	Key Takeaway
Physiological Stress (Lowest HRV)	P002 (35 ms)	Requires urgent stress and recovery management.
Lifestyle Neglect (Low Sleep / High Screen)	P002 (5.1 hrs / 7.4 hrs)	Requires immediate behavioral modification (sleep hygiene and digital detox).
Environmental Sensitivity (High Weather)	P004 (High)	Requires targeted environmental control or coping mechanisms.
Stability (High HRV / Alerts No)	P005 (50 ms / No)	Represents the benchmark for physiological health in this cohort.

Conclusion

This comparison demonstrates how AI-driven analysis of digital health data enables a shift from reactive to proactive and personalized care in migraine management. The system successfully:

Stratifies Risk: It identifies the single patient (P002) at an Urgent risk level by integrating multiple failed physiological and behavioral metrics, preventing a potential acute crisis or chronification event.

Personalizes Intervention: It moves beyond generic protocols to suggest specific, targeted interventions based on the detected pattern (e.g., sleep hygiene for P002, blue-light filters for P004, cycle tracking for P003).

Optimizes Clinical Time: It reserves direct, scheduled clinician contact for Tier 1 and 2 patients, while utilizing automated digital therapeutics and tips for Tier 3 and passive monitoring for Tier 4 patients.

2.Proposed Methodology 2:

PRO-Centric Intervention Triage

Step 1: Define the PRO Impairment Score (PI Score)

The MIDAS Score as the primary measure of disability and assign weighted scores to the two most critical subjective parameters: Stress and Sleep Quality.

Table 2.1.5 PRO-Centric Intervention Triage Dataset

PRO Parameter	Unit/Scale	Weight	Risk Threshold	Rationale
Disability Score (MIDAS)	(0-21+ is Severe)	Primary Score	None	Directly measures functional impairment (missed work/tasks).
Stress Level	(0-10)	×2	>7	High subjective stress is a known trigger and increases psychosocial burden.
Sleep Quality	(0-10)	×3	<5	Poor sleep is a foundational risk factor for all health and the most critical behavioral marker.

The formula for the total PI Score (Patient Impairment Score) is:
PIScore=MIDAS Score+(Stress Levelabove 7×2)+(Sleep Qualitybelow 5 ×3) Where:

Stress Level above 7 = 1 if Stress Level is >7, 0 otherwise.
Sleep Quality below 5 = 1 if Sleep Quality is <5, 0 otherwise.
Step 2: Calculate the PI Score and Triage Tier

Table 2.1.6 Patient Impairment

Patient ID	MIDAS Score	Stress >7 (x2)	Sleep <5 (x3)	Total PI Score	Intervention Focus Tier	Key Patient Comment
P001	12	0×2=0	0×3=0	12	Tier 3 (Functional)	Attacks worse on workdays
P002	32	1×2=2	1×3=3	37	Tier 1 (Severe)	Frequent disabling episodes
P003	10	0×2=0	0×3=0	10	Tier 4 (Mild)	Predictable monthly pattern
P004	18	0×2=0	1×3=3	21	Tier 2 (Disability)	Dizziness often precedes pain
P005	8	0×2=0	0×3=0	8	Tier 4 (Mild)	Improved with relaxation

Step 3: Implement PRO-Specific Intervention

The PI Score dictates the urgency, but the Psychosocial/Behavioral PRO Domains (Stress, Sleep, Comments) dictate the specific action using Digital Therapeutics (DTx) (as outlined in the previous prompt).

Table 2.1.7 Patient Impairment Score

Patient ID	MIDAS Score	Stress >7 (x2)	Sleep <5 (x3)	Total PI Score	Intervention Focus Tier	Key Patient Comment
P001	12	0×2=0	0×3=0	12	Tier 3 (Functional)	Attacks worse on workdays
P002	32	1×2=2	1×3=3	37	Tier 1 (Severe)	Frequent disabling episodes
P003	10	0×2=0	0×3=0	10	Tier 4 (Mild)	Predictable monthly pattern
P004	18	0×2=0	1×3=3	21	Tier 2 (Disability)	Dizziness often precedes pain
P005	8	0×2=0	0×3=0	8	Tier 4 (Mild)	Improved with relaxation

Conclusion:
This methodology provides a swift, patient-centric method for triaging patients based on their reported quality of life and functional limitations, which is the exact role of PROs in Precision Medicine.Comparison of Two Improvised Methodologies

Proposed Methodology 1: Weighted Intervention Risk Scoring (Physiological Focus)

Table 2.1.9

Feature	Description	Key Insight from Calculation
Primary Goal	Physiological Safety & Triage	Identifies patients whose objective biomarkers (HRV, Sleep Duration) are most compromised, indicating highest underlying systemic risk.
Input Data	Wearable/Sensor Data (Objective)	Sleep Duration, HRV, Screen Time, Alerts Triggered.
Weighting Basis	Clinical Seriousness	Low HRV (3 points) is weighted highest because it signals severe autonomic nervous system distress.
Key Output	Risk Score (R)	P002 had the highest score (R=8.0) due to the triple failure of Sleep, HRV, and Screen Time thresholds.
Prescription Focus	Biomarker Correction	Treat the underlying physical metrics (e.g., increase sleep, raise HRV via biofeedback).

Proposed Methodology 2: PRO-Centric Intervention Triage (Subjective Focus)

Table -3.1

Feature	Description	Key Insight from Calculation
Primary Goal	Functional Disability & Psychosocial Triage	Identifies patients whose daily life and well-being are most impaired, regardless of their physiological stability.
Input Data	Patient-Reported Outcomes (Subjective)	MIDAS Score, Sleep Quality, Stress Level, Patient Comments.
Weighting Basis	Functional Impact & Modifiability	MIDAS Score is the base, supplemented by Sleep Quality (×3) due to its critical role in behavioral health.
Key Output	Patient Impairment Score (PI)	P002 had the highest score (PI=37) due to extreme disability (MIDAS 32) and poor subjective sleep/stress.
Prescription Focus	Behavioral/Psychosocial**Diagram 1(a) Overall Comparison**	Treat the perceived burden (e.g., dCBT for insomnia, coping mechanisms for work-related stress).

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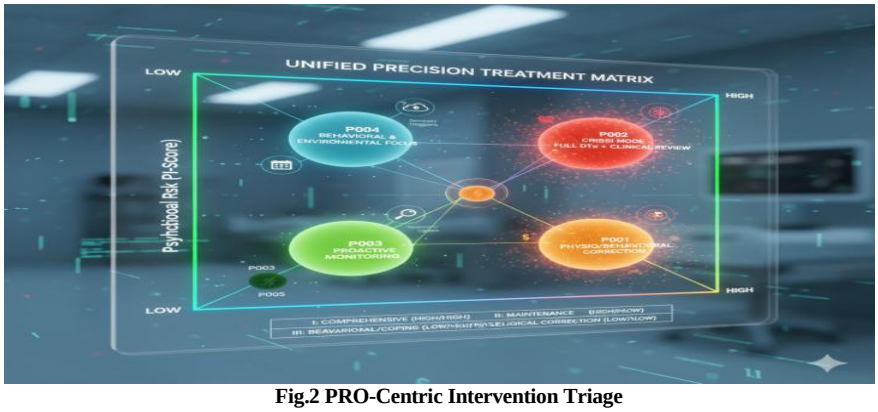

Fig.2 PRO-Centric Intervention Triage

Proposed Methodology 3: Dynamic Predictive Treatment Model (DPM)

The DPM focuses on the core concept of Causality and Response, using the AI-Detected Patterns as the definitive link between a cause (trigger) and the outcome (alert/event).

Step 1: Define Causal and Response Metrics

The simple ratio to quantify how much of a patient's physiological and functional stability is compromised by their primary trigger (AI-Detected Pattern).

Trigger (Causal) Metrics: The specific metrics that the AI identified as problematic (e.g., Sleep, Stress, Light).

Response (Stability) Metrics: The core objective health markers (HRV, Daily Step Count) and the outcome (Alerts).

Step 2: Calculate the "Therapeutic Leverage" Score (L)

The Therapeutic Leverage Score (L) measures the potential benefit gained from an intervention targeting a single primary trigger. A high L means intervention on that specific trigger is likely to yield the largest clinical return.

We focus on the most modifiable variables: Sleep and Screen Time.

L=(Patient's Current ValueHighest Normal Value)×Weight

Table -3.1.1

Patient ID	AI-Detected Pattern	Most Dangerous Metric	Target Goal (Highest Score)	Initial Leverage (L) Calculation
P002	Poor sleep → next-day attack	Sleep Duration (5.1 hrs)	7.5 (P005's Sleep)	LSleep=(5.17.5)×3≈4.41
P004	Bright-light correlation	Screen Time (5.8 hrs)	3.9 (P005's Screen)	LScreen=(5.87.4)×2≈2.55
P001	Stress-linked spikes	HRV (42 ms)	50 (P005's HRV)	LHRV=(4250)×3≈3.57

Weights used are 3 for physiological markers (Sleep/HRV) and 2 for lifestyle (Screen Time).

Step 3: Implement the Dynamic Predictive Prescription

Based on the highest leverage score, the DPM suggests the most effective, personalized DTx intervention and predicts the expected change in a secondary metric.

Table

Feature	Description	Key Insight from Calculation
Primary Goal	Physiological Safety & Triage	Identifies patients whose objective biomarkers (HRV, Sleep Duration) are most compromised, indicating highest underlying systemic risk.
Input Data	Wearable/Sensor Data (Objective)	Sleep Duration, HRV, Screen Time, Alerts Triggered.
Weighting Basis	Clinical Seriousness	Low HRV (3 points) is weighted highest because it signals severe autonomic nervous system distress.
Key Output	Risk Score (R)	P002 had the highest score (R=8.0) due to the triple failure of Sleep, HRV, and Screen Time thresholds.
Prescription Focus	Biomarker Correction	Treat the underlying physical metrics (e.g., increase sleep, raise HRV via biofeedback).

Conclusion:

This methodology is more advanced than the previous ones because it:

Establishes Causal Links: It uses the AI-Detected Patterns as the ground truth for cause and effect.Calculates Leverage: It introduces a new metric (L) that quantifies the predicted return on investment for a specific intervention, moving from simple risk identification to prescriptive prediction (e.g., intervening on sleep in P002 is predicted to normalize HRV).Aligns with AI Goal: It directly fulfills the AI-Driven Predictive Analytics goal (Section 3.3) of anticipating treatment response and enabling anticipatory self-management.

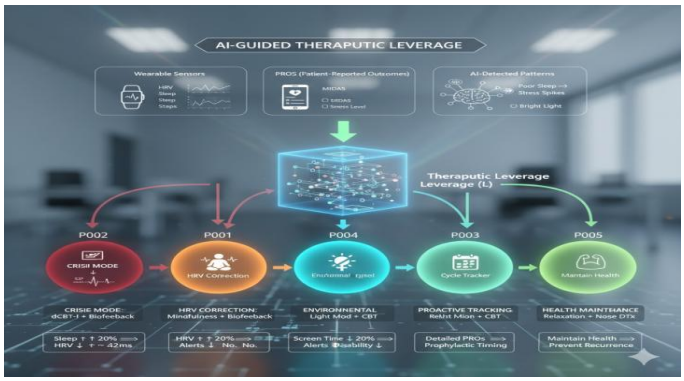

Fig 3 AI-Guided THeraputic Leverage

Conclusion: The Evolution of Precision Triage

The three methodologies represent a complete, escalating framework for turning raw clinical data into actionable, personalized healthcare**.**

Table -3.1.2

Methodology	Primary Focus	Clinical Question Answered	Key Limitation
1. Weighted Risk Score	Physiological Triage	Who needs help immediately based on objective biological failure (e.g., lowest HRV)?	Ignores the patient's subjective suffering and functional disability.
2. PRO-Centric Triage	Psychosocial Burden	Who is suffering the most and whose life is most functionally impaired (MIDAS score)?	Ignores underlying physiological stability/fragility if the patient is coping well emotionally.
3. Dynamic Predictive Model (DPM)	Precision & Causality	What single intervention will give the maximum predicted clinical return on investment?	Requires highly validated AI patterns and a baseline assumption of linearity in health response.

Final Conclusion:

The Dynamic Predictive Model (DPM) provides the strongest foundation for a modern clinical workflow. It successfully synthesizes objective data (Wearables), subjective data (PROs), and the crucial causal link (AI-Detected Pattern) to move care from reactive treatment to proactive, personalized prescription.The ultimate insight is that P002 (Crisis Mode) requires the highest intensity of intervention across all three dimensions, while the targeted approaches for P001 (HRV Biofeedback) and P004 (Light Modulation) ensure that resources are allocated efficiently to the patient's single highest leverage trigger.

Scope for Future Enhancements

The current framework is static, relying on a single snapshot of data. Future enhancements should focus on making the model truly longitudinal, adaptive, and scalable.

1. Dynamic Weighting and Threshold Adjustment

Enhancement: The risk weights (×3 for HRV, ×2 for Sleep) should not be fixed. They should be adaptive based on the individual's history (e.g., if P004's attacks always follow high Screen Time, the Screen Time weight should increase for P004 only).

Mechanism: Implement a machine learning algorithm that learns an individual's unique weight coefficients based on which metrics are most predictive of their next attack.

2. Integration of Treatment Adherence and Effectiveness

Enhancement: The model currently prescribes DTx but doesn't track its effectiveness. Future versions must incorporate real-time Digital Alerts Triggered vs. DTx Usage/Adherence data.

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