# Indian Council of Medical Research (ICMR)

**Deptartment of Health Research**

(Ministry of Health and Family Welfare)

## CAR

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**Proposal Id:** CAR-2025-01-000349, () **Version Id:** F1, **Proposal Type:**Concept
**Proposal Title:**
Impact of Yoga Combined with Conventional Stroke Rehabilitation on Quality of Life in Stroke Survivors

**Personal details of Principle Investigator (PI)**

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| **Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation** | DR DEEPAK GOEL, Professor, deepakgoel.dg69@gmail.com,9557175025, Male, 16-10-1967, 16-10- |
| **Nature of Employment** | Permanent |
| **Institute** | Himalayan Institute of Medical Sciences, **Institute Type:** Private |
| **Advertisement** | Call for Centre for Advanced Research (CAR),under Extramural Research Progra 2025 (Concept) |

**Summary (up to 2000 words): Rationale:**
Stroke is one of the leading causes of acquired disability worldwide and has devastating personal, social, and economic consequences. It affects not functioning but also cognitive and psychological well-being, thereby severely impacting the quality of life of survivors and their caregivers. According t estimates, around 15 million people suffer a stroke annually, with nearly 5 million left permanently disabled. Approximately one in four of these cases individuals above 65 years of age. Stroke remains one of the foremost causes of mortality, morbidity, and disability-adjusted life years (DALYs). In 20 ranked as the second leading cause of DALYs in people aged 50 years and above, highlighting its disproportionate impact on the aging population.

The Indian context presents additional challenges. The incidence of stroke has risen substantially in the last decade, with estimates suggesting 105–100,000 individuals annually and a prevalence ranging from 44.29 to 559 per 100,000. This rising burden is worsened by delayed recognition, lack of comprehensive stroke centers, and limited rehabilitation resources. Even when patients survive the acute phase, residual impairments such as motor cognitive decline, depression, and anxiety remain highly prevalent, causing reduced independence and quality of life.

Standard rehabilitation—including physiotherapy, occupational therapy, speech therapy, and psychological support—is known to be beneficial. Yet, re incomplete, and caregiver burden remains high. Yoga, a traditional mind–body practice with physical postures, breathing, and meditation techniques, promise in neurological rehabilitation. Early studies suggest potential benefits in motor recovery, balance, mood, and stress reduction. However, the e weak due to small sample sizes, methodological flaws, and inconsistent yoga protocols. A recent Cochrane review noted yoga's potential role but cor robust, methodologically sound trials are urgently needed to establish efficacy and safety.

This project seeks to fill that gap by evaluating the integration of yoga with conventional stroke rehabilitation during the early recovery phase, when n plasticity is optimal.

**Novelty:**
Stroke rehabilitation protocols based on physical therapy are well established and standardized by the American Heart Association/American Stroke (2018). However, yoga as a therapeutic intervention in stroke rehabilitation lacks structured guidelines and scientific validation. Current evidence is lir fragmented, and inconclusive.

The latest Cochrane review (2021) analyzed only two randomized controlled trials (72 participants). These primarily assessed psychological outcome anxiety, depression, and overall quality of life. One study reported improvement in memory, while the other showed no significant impact. Only one ev disability outcomes, with inconsistent findings. Moreover, different quality-of-life tools were used, limiting comparability. Overall, the evidence was gra quality."

Swami Rama Himalayan University Director Research

A major limitation is the delayed timing of intervention, as participants were enrolled 4–6 years after stroke, when neuronal plasticity and recovery pot reduced.

The proposed project introduces novelty by targeting the early recovery phase (1–3 months post-stroke), when neuroplasticity is optimal. By combinir conventional rehabilitation, we hypothesize a synergistic benefit on motor recovery, cognition, psychological well-being, and quality of life. This will be rigorously designed, adequately powered randomized controlled trials in India to evaluate yoga's role using standardized protocols and validated outc measures.

**Objective:**
The overarching aim of this project is to determine whether yoga can enhance outcomes when added to conventional rehabilitation in stroke survivor:

**Specific objectives are:**

1. To assess the effect of yoga on **physical disability** among stroke survivors.
2. To evaluate the impact of yoga on **cognitive functions.**
3. To determine the role of yoga in reducing **psychological distress** (anxiety and depression).
4. To examine the overall impact of yoga on **stroke-related quality of life.**

This study will generate robust evidence that may guide clinical practice, shape rehabilitation strategies, and influence policy on integrative stroke car

**Methods:**

# Study Design

This will be a single-center, prospective, randomized controlled trial (RCT) with two parallel arms to evaluate the impact of yoga, in addition to conver rehabilitation, on stroke recovery.

# Study Setting

The trial will be conducted in the Department of Neurology at Swami Rama Himalayan University (SRHU), Dehradun, in close collaboration with the D Physical Medicine & Rehabilitation and Yoga Sciences, ensuring a multidisciplinary approach.

# Participants

**Inclusion Criteria:**

- Adults (≥18 years) with a confirmed ischemic or hemorrhagic stroke, documented by neuroimaging.
- Presence of residual motor, cognitive, or psychological impairment.
- Modified Rankin Scale (mRS) ≤ 3 at enrollment.
- Recruitment between 1–6 months after the acute stroke event.

**Exclusion Criteria:**

- Patients with severe comorbidities making yoga unsafe (e.g., unstable cardiac conditions, severe orthopedic limitations).
- Stroke duration >6 months.
- Severe aphasia or cognitive impairment precluding consent or participation.

# Study Groups

- **Control group (n ≈ 75):** Standard medical treatment + conventional rehabilitation.
- **Intervention group (n ≈ 75):** Standard medical treatment + conventional rehabilitation + yoga therapy.

# Standard Medical Treatment

All participants will receive evidence-based pharmacological management and preventive care as per AHA/ASA guidelines, including:

- Antiplatelet or anticoagulant therapy, statins, antihypertensives, and diabetes management where appropriate.
- Lifestyle modification counseling, including dietary advice and secondary stroke prevention strategies.

- Supportive care, including psychological counseling and caregiver education.

# Conventional Rehabilitation

Rehabilitation will follow AHA/ASA 2018 protocols, delivered by trained physiotherapists and rehabilitation specialists. This will include:

- **Motor rehabilitation:** Limb mobilization, strengthening, gait training, and balance exercises.
- **Cognitive rehabilitation:** Structured exercises targeting memory, attention, and executive functioning.
- **Psychological support:** Stress management techniques, counseling, and caregiver guidance to aid recovery.

# Yoga Intervention

The yoga program will be supervised by certified instructors from the Department of Yoga Sciences. It will run for **12 weeks**, with sessions of 40–65 n

**Weeks 1–4 (40–60 minutes/session):**

- Breathing practices (10–12 cycles, 5 min).
- Joint loosening exercises (Sukshma Vyayama, 20 min).
- Pranayama: Nadishodhan (9 rounds) and Bhramari (9 rounds, 10 min).
- Breath-focused meditation (5 min).
- Yoga Nidra (Swami Rama Technique, 20 min, twice weekly).

**Weeks 5–12 (45–65 minutes/session):**

- Breathing practices (3 min).
- Sukshma Vyayama (5 min).
- **Asanas**: Tadasana, Trikonasana, Katichakrasana, Hasthauttanasana, Vrikshasana, Bhujangasana, Makarasana, and Shavasana (15–20 min)
- Pranayama: Nadishodhan (5 min), Bhramari (3 min).
- Breath meditation (5 min).
- Yoga Nidra (20 min, twice weekly).

This structured, progressive approach is designed to enhance motor recovery, promote psychological well-being, and improve quality of life.

# Outcome Measures

Assessments will be performed at baseline, after the 12-week intervention, and at 3-month follow-up.

- **Motor recovery:** Muscle strength (Medical Research Council scale), balance (Berg Balance Scale), mobility (Timed Up and Go Test).
- **Cognitive function:** Montreal Cognitive Assessment (MoCA).
- **Psychological parameters:** Hamilton Anxiety Rating Scale (HAM-A) and Hamilton Depression Rating Scale (HAM-D).
- **Quality of life:** Stroke-Specific Quality of Life (SS-QOL) scale.

# Sample Size

Based on a moderate effect size (Cohen's d = 0.5) for quality-of-life improvements, with $\alpha = 0.05$ and power = 80%, a minimum of 64 participants per required. Allowing for a 15% attrition rate, at least 150 participants will be enrolled (75 per arm). To ensure robustness, the recruitment target will be s participants.

# Randomization

Participants will be randomized in a 1:1 ratio using a computer-generated sequence, with allocation concealment ensured through sealed opaque en

# Statistical Analysis

Data will be analyzed using **SPSS v25** and **R**.

- **Continuous variables:** Independent t-test or ANOVA.
- **Categorical variables:** Chi-square test.
- **Longitudinal analysis:** Mixed-model ANOVA for repeated measures.
- **Multivariate regression:** To adjust for confounding factors (age, sex, stroke type, baseline disability).
  A two-tailed $p < 0.05$ will be considered statistically significant.

# Ethical Considerations

The study will be approved by the Institutional Ethics Committee (IEC) of SRHU. Informed consent will be obtained from all participants or their legal representatives. Confidentiality and safety monitoring will be ensured throughout the trial.

# Significance

This study addresses critical gaps in current stroke rehabilitation research. Most prior yoga trials recruited participants years after stroke, when recov limited. By intervening within the **early recovery phase (1–6 months post-stroke),** this trial aims to leverage heightened neuroplasticity. The combir and conventional rehabilitation may provide synergistic benefits, improving not only motor and cognitive recovery but also psychological resilience an of life.

Furthermore, the trial's methodological rigor, standardized yoga protocol, and validated outcome measures will enhance the reliability of results. If suc findings could inform structured guidelines for incorporating yoga into stroke rehabilitation, particularly in resource-constrained settings like India.

**Expected Outcome:**
We expect yoga, when integrated with conventional rehabilitation, to provide measurable improvements across physical, cognitive, psychological, an domains of stroke recovery.

**Motor disability:** Yoga postures and breathing practices will enhance postural stability, neuromuscular coordination, and muscle strength, thereby im and balance. Patients in the intervention group are expected to demonstrate superior performance in functional mobility tests compared to controls.

**Cognitive function:** Meditation and pranayama practices emphasize concentration, memory, and attentional control, which may lead to improved Mo Cognitive Assessment (MoCA) scores. Enhanced neuronal plasticity in the early recovery phase could further amplify these benefits.

**Psychological well-being:** Yoga fosters relaxation and emotional regulation. We anticipate lower anxiety and depression scores (HAM-A, HAM-D) a participants compared to controls. This could translate into reduced stress levels and better coping mechanisms for both patients and caregivers.

**Quality of life:** By simultaneously addressing physical, cognitive, and psychological impairments, yoga is expected to improve overall health-related as measured by SS-QOL scores. Patients may report better independence in daily activities, reduced fatigue, and enhanced self-efficacy.

**Long-term implications:**

1. Reduced stroke-related disability and dependency.
2. Lower caregiver burden through improved patient autonomy.
3. A culturally relevant, low-cost, and scalable adjunct for stroke rehabilitation.
4. Evidence to inform policy for integrating yoga into standard post-stroke care.

If successful, this project will be one of the first large-scale trials to establish yoga as a validated adjunct in stroke rehabilitation, shaping future guidel clinical practice both in India and globally.

**Evidence for expertise:**

- **Prof. Dr. Deepak Goel (PI):** Overall supervision, neurological assessments, patient recruitment, coordination with regulatory/funding agencies, authorship of publications.
- **Dr. Manish Mittal (Co-I):** Clinical neurology follow-up assessments, monitoring adverse events, and stroke outcome evaluations.
- **Dr. Ashwani Bhat (Co-I):** Oversight of cognitive assessments, data interpretation related to memory and dementia, contribution to manuscript
- **Dr. Subodh (Co-I, Yoga Sciences):** Development of standardized yoga protocol, training of instructors, ensuring intervention fidelity, and scier yoga components.
- **Dr. Manish Jha (Co-I, Neurorehabilitation):** Supervision of physiotherapy protocols, integration of yoga with conventional rehab, and patient monitoring.
- **Dr. Deepika Khanduja (Stroke Coordinator):** Day-to-day coordination, recruitment, patient follow-up, data entry, and maintaining trial records

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| **Priority Area/Priority Area diseases** | Non-Communicable Diseases / Neurological conditions |

**Narrative description of skills and expertise of research team in the proposed area of research:**
**Principal Investigator (PI) Dr. Deepak Goel** has over 30 years of extensive teaching and research experience. He has successfully led three ICMR-projects in addition to several intramural studies. Currently, he is the Principal Investigator for the ICMR-funded **Hospital Based Stroke Registry (HE** has been directing for more than a year. His consistent scholarly contributions and publications on stroke reflect his long-standing commitment to adv research and patient care.

The proposed project will be supported by a strong **multidisciplinary team. Dr. Manish Mittal** and **Dr. Ashwani Bhat**, both neurologists, are actively various research initiatives. Dr. Bhat, notably, is a member of the **National Cognitive Neurosciences Group** and is deeply involved in research on v dementia. **Dr. Subodh**, Professor of Yoga Sciences, brings significant expertise in yoga research and doctoral mentorship; his role in developing a st protocol for stroke rehabilitation will be crucial.

**Dr. Manish Jha**, faculty in the Neurorehabilitation Unit, Department of Physical Medicine and Rehabilitation, strengthens the team with his innovative a patent titled *"Vibrator Strap for Chest Physiotherapy"* (Application No. 202411103162A, published 10/01/2025). **Dr. Nikku Yadav** provides expertise methodology and clinical drug trials. She has extensive experience in conducting **Department of Health Research (DHR) Good Clinical Practice (( trainings**, ensuring methodological rigor and regulatory compliance. **Dr. Deepika Khanduja**, stroke coordinator in the Department of Neurology, offe operational support and currently manages the HBSR project efficiently.

The team's strength is reflected in their collective publications, patents, and research experience. All members are permanent faculty of the Universit continuity, stability, and sustained commitment throughout the project. This diverse expertise and collaborative structure provide a strong foundation f the proposed objectives successfully.

**Impact of PI and/ investigator's publication/ patents on clinical or public health:**
The Principal Investigator (PI), **Dr. Deepak Goel**, has made sustained contributions to stroke neurology and public health through impactful research critical clinical challenges.

His recent narrative review on **oral anticoagulant use in stroke patients (2025)** provides essential clarity on guideline-based practice, enabling clini manage complex anticoagulant regimens more effectively and thereby reducing risks of recurrent stroke and hemorrhage. In a collaborative study (2( and colleagues demonstrated the strong association between **poor drug adherence and recurrent stroke**, highlighting the urgent need for structure family education. This work carries direct implications for secondary prevention strategies in India, where non-adherence remains a major cause of tr His research on **endogenous defense mechanisms for neuroprotection (2024)** has also opened new avenues for innovative therapies in large-ve

A pivotal randomized study (2022) on the **surgical management of deep supratentorial intracerebral hemorrhage (SICH)** reinforced the principle harm," showing that clot removal surgery in certain cases may worsen outcomes. This evidence has reshaped neurosurgical decision-making, guidin evidence-based practices. Earlier, his hospital-based study on **atrial fibrillation in ischemic stroke (2020)** influenced screening strategies in resour settings, while a population-based survey on **hypertension in rural India (2012)** informed cardiovascular risk reduction interventions.

Beyond publications, the investigative team has significantly contributed to **neurorehabilitation innovations**. Co-Investigator **Dr. Manish Jha's pate Strap for Chest Physiotherapy" (2025)** introduces a novel, low-cost rehabilitation tool with wide application potential. Additionally, Co-PI **Dr. Nikku** developed a specialized **"Rehabilitation Module (RehabMo)" for improving functional disability and impaired cognition in post-stroke patient** been granted **copyright registration (Application No.: LD-26166/2025-CO)**.

Collectively, these contributions have influenced stroke care pathways, prevention strategies, neurosurgical practices, and rehabilitation approaches, bridging the gap between clinical research and real-world public health outcomes.

**Investigator Details**

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## Publication Details

| # | Publications arising from ICMR grants of the following types | Title of publication | Impact factor of journal | Citation | Year of Publication | Author type | Citation in Vancouver style | Remarks | Creat By |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Original research article View | Knowledge, Attitude and Practice of Epilepsy in Uttarakhand, India | 3 | 10 | 2012 | First | Goel D, Agarwal A, Dhanai JS, Mehrotra V, Saxena V. Knowledge, Attitude and Practice of Epilepsy in Uttarakhand, India.Ann Indian Aced Neurol 2011; 14: 116-9. | This publication is outcome of ICMR project entitled: To find out Prevalence and Patterns of seizure cases in Chakrata Block of Uttarakhand 2008 | - |
| 2 | Original research article View | Neurocysticercosis and its impact on crude prevalence rate of epilepsy in an Indian community. | 1 | 15 | 2012 | First | Goel D, Agarwal A, Dhanai JS, Mehrotra V, Saxena V. Neurocysticercosis and its impact on crude prevalence rate of epilepsy in an Indian community. Neurology India 2012; 59: 37-40. | This publication is outcome of ICMR project entitled: To find out Prevalence and Patterns of seizure cases in Chakrata Block of Uttarakhand 2008 | - |
| 3 | Any Systematic review View | Dealing with oral anticoagulants in stroke patients: A narrative review | 4.8 | 16 | 2025 | First | Goel D, Singh P. Dealing with oral anticoagulants in stroke patients: A | | - |

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| | | based on current practice guidelines. | | | | | narrative review based on current practice guidelines. Brain Circulation, June 2025; Ahead of publication. (Impact factor = 4.8, First and Corresponding author) | | |
| 4 | Original research article View | Goel D, Mittal M, Bhat A. Association of Poor Drug Adherence and Recurrent Stroke. An Alarm for better patient's and Family education. | 3.8 | 13 | 2024 | First | ii) Goel D, Mittal M, Bhat A. Association of Poor Drug Adherence and Recurrent Stroke. An Alarm for better patient's and Family education. ARC Journal of Neuroscience 2024; 7: 1-7. (impact factor = 3.824, First and Corresponding author) | | - |
| 5 | Original research article View | Goel D, Shangari S, Mittal M, Bhat A. Endogenous defense mechanism-based neuroprotection in large-vessel acute stroke: A hope for future. | 4.8 | 17 | 2024 | First | Goel D, Shangari S, Mittal M, Bhat A. Endogenous defense mechanism-based neuroprotection in large-vessel acute stroke: A hope for future. Brain Circulation 2024; 10: 51-59. | | - |
| 6 | Original research article View | SMortality in Ischemic stroke score: A predictive score of mortality for acute ischemic stroke. | 4.8 | 16 | 2017 | First | Somaya H, Mittal, Deepak Goel. Mortality in Ischemic stroke score: A predictive score of mortality for acute ischemic stroke. Brain Circ. 2017; 3: 29-34. (Impact factor 4.8, Co-author) | | - |
| 7 | Original research article View | A case of recurrent stroke with underlying adenocarcinoma: Pseudo-cryptogenic stroke. | 4.8 | 27 | 2020 | First | Goel D, Sharma V, Pran MM, Gupta R, Keshri T, Shettigar U. A case of recurrent stroke with underlying adenocarcinoma: | | - |

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| | | | | | | | Pseudo-cryptogenic stroke. Brain Circulation 2020; 6: 126-9. (Impact factor = 4.8, First and Corresponding author) | | |
| 8 | Original research article View | . Prevalence of atrial fibrillation in acute ischemic stroke patients: A hospital-based study from India. | 4.8 | 23 | 2020 | First | Goel D, Gupta R, Keshri T, Rana S. Prevalence of atrial fibrillation in acute ischemic stroke patients: A hospital-based study from India. Brain Circ 2020; 6: 19-25. | | - |
| 9 | Original research article View | x) Bansal SK, Saxena V, Kandpal SD, Gray WK, Walker RW, Goel D. The prevalence of hypertension and hypertension risk factors in a rural Indian community: A prospective door-to-door study. | 13.3 | 60 | 2012 | Any Position | x) Bansal SK, Saxena V, Kandpal SD, Gray WK, Walker RW, Goel D. The prevalence of hypertension and hypertension risk factors in a rural Indian community: A prospective door-to-door study. J Cardiovasc Dis Res 2012;3:117-23. | | - |

## Patent Details

| # | Title | Patent file or granted | Patent No. | Patent Agency | Patent da |
|---|---|---|---|---|---|
| 1 | VIBRATOR STRAP FOR CHEST PHYSIOTHERAPY | Filed | 202411103162A | Indian Patent Office | 2025-01- |

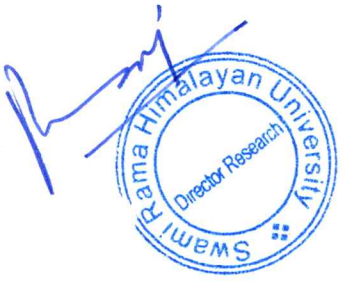
**Documents consideration**

| # | Document Name | Uploaded Document | Remarks |
|---|---|---|---|
| No record found | | | |

**Declaration**

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

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