



MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University u/s 3 of UGC Act, 1956)

Grade 'A' Accredited by NAAC

MGM SCHOOL OF PHYSIOTHERAPY

Sector-1, Kamothe, Navi Mumbai – 410209

APPLICATION FOR SEED MONEY/RESEARCH GRANT

Date: 11th March 2022

Name of Principal Investigator: Dr. Rajani Mullerpatan

Name of co-investigator/s: Dr. Bela Agarwal, Mr. Vijay Bhosale

Title of the project: Telemetric lifestyle intervention: for self-administration of a novel, prophylactic tool to delay disability caused by osteoarthritis of knee (MARK-1)-A longitudinal study

Name of Department: MGM School of Physiotherapy & MGM's College of
Engineering and Technology, Kamothe, Navi Mumbai

Name of the Institution: MGM Institute of Health Sciences, Kamothe, Navi Mumbai

Designation: Dr. Rajani Mullerpatan-Director-Professor, MGM School of Physiotherapy
Dr. Bela Agarwal-Professor-Cardiopulmonary Physiotherapy, MGM
School of Physiotherapy
Dr. Vijay Bhosale- Professor at MGM's College of Engineering and
Technology, MGM IHS

E-mail address: rajani.kanade@gmail.com

Mobile: +91-9920048476

List of important publications of last 5 years of the all the investigators in the relevant fields:

Dr. Rajani Mullerpatan:

1. **Mullerpatan R, Agarwal BM.** Early detection and therapeutic intervention to maximize functioning in children and adults with non-communicable diseases associated with disability: challenges & solutions. Critical Reviews™ in Physical and Rehabilitation Medicine. (Accepted for Publication)
2. **Mullerpatan R, Agarwal BM, Joshi A, Nayak A, Kulkarni S.** Health-Related Quality of Life of People with Chronic Kidney Disease in Low-and Middle-Income Countries: A



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- Literature Review. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2023;35(2):19-40
3. Agarwal B, Shah M, Sawant B, Bagwe H, Murkudkar P, **Mullerpatan R**. Predictive equation for six-minute walk test in Indian children, adolescents, and adults. *Lung India*. 2023 Mar 1;40(2):143-8.
 4. Kuttan V, Shetty T, Parab S, Agarwal B, **Mullerpatan R**. Evidence-base for effect of team sports on physical, psychological, and social function in children with neuro-motor impairment: A narrative review. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2023
 5. Parab S, **Mullerpatan R**, Puri V, Joseph MA, Kulkarni A. Review on physical signs, biochemical and radiological bio-markers for detection of Prodromal Parkinson's disease. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2023 35(2):59-73
 6. Akhila Natesan, Triveni Shetty, **Rajani Mullerpatan**, Shrutika Parab. Evidence – base for effect of dance therapy on functioning in children with Neuro-motor disorders – A review based on ICF framework”*Critical reviews in Physical and Rehabilitation Medicine*. 2023 35(2):75-104
 7. Shetty T, Ganesan S, Johari A, **Mullerpatan R**. Gross motor function profile of children with cerebral palsy in a low-resource setting: A call for reflection on the model of care. *Journal of Pediatric Rehabilitation Medicine*. 2023 Mar 3(Preprint):1-8.
 8. Agarwal B, Parab SD, Amberkar O, **Mullerpatan R**. Effect of 12-week sports intervention programme on physical fitness and sports performance in individuals with spinal cord injury. *Indian Journal of Physiology and Pharmacology* 6. 2023 Jan;67(1):50.
 9. Anisha Gulati, **Rajani Mullerpatan**, Karna Ratish. Comparison of Palmar Abduction In Three Wrist Positions Among Healthy Adults Using Conventional Goniometer. *International journal of current advanced research*. 2023 Jan 12(1):1774-1777
 10. Costanzo G, Misaggi B, Ricciardi L, AlEissa SI, Tamai K, Alhelal F, Alqahtani Y, Alsobayel HI, Arand M, Balsano M, Blatter TR, **Rajani Mullerpatan**. SPINE20 recommendations 2021: spine care for people's health and prosperity. *European Spine Journal*. 2022 Jun;31(6):1333-1342
 11. **Mullerpatan RP**, Bharnuke JK. Differences in Foot Characteristics Between Bharatanatyam Dancers and Age-Matched Non-Dancers. *Medical Problems of Performing Artists*. 2022 Mar 1;37(1):53-7.
 12. **Mullerpatan RP**. National Education Policy 2020: Call for reconfiguration of physiotherapy education and research in India. *Journal of Society of Indian Physiotherapists*. 2022 Jan 1;6(1):1.
 13. Desai P, Mullerpatan R. Functioning of Older Adults in Low and Middle Income Countries: A Literature Review. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2022;34(1):69-8234
 14. Patel G, **Mullerpatan R**, Agarwal B, Shetty T, Ojha R, Shaikh-Mohammed J, Sujatha S. Validation of wearable inertial sensor-based gait analysis system for measurement of



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- spatiotemporal parameters and lower extremity joint kinematics in sagittal plane. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 2022 Jan 8; 236(5):686-696.:09544119211072971.
15. Lubna Khan, Mamta Shetty, Shifa Kherada, Reema Kava, Mubina Kazi, Prachita Walankar, **Rajani Mullerpatan**. Dough Kneading exposure at kitchen workstation: its Influence on handgrip strength and implications for therapy in hand rehabilitation. Work: A Journal of Prevention, Assessment & Rehabilitation.(Accepted for Publication)
 16. **Mullerpatan R**, Shetty T, Singh Y, Agarwal B. Lower extremity joint loading during Bounce rope skip in comparison to run and walk. Journal of Bodywork and Movement Therapies. 2021 Apr 1;26:1-6.
 17. Pahade AJ, Wani SK, **Mullerpatan RP**, Elizabeth Roach K. Indian (Marathi) version of the Shoulder Pain and Disability Index (SPADI): Translation and validation in patients with adhesive capsulitis. Hong Kong Physiotherapy Journal. 2021 Dec 19;41(02):139-46.
 18. Agarwal BM, van Deursen R, **Mullerpatan RP**. Electromyographic evaluation of spine and lower extremity muscles during repeated and sustained bodyweight deep-squat. Trends in Sport Sciences, 2021, 28(1): 19-27.
 19. Scott Haldeman, Margareta Nordin, Patricia Tavares, **Rajani Mullerpatan** et al. Distance Management of Spinal Disorders During the COVID-19 Pandemic and Beyond: Evidence-Based Patient and Clinician Guides from the Global Spine Care Initiative. JMIR Public Health Surveill. 2021 Feb 17;7(2): 25484.
 20. Jinny P Kanjirathingal, **Rajani P Mullerpatan**, Girish Nehete, Nagarathna Raghuram. Effect of Yogasana intervention on standing balance performance among people with diabetic peripheral neuropathy: A pilot study. 2021; 14 (1) 60-70.
 21. **Rajani Mullerpatan**, Triveni Shetty, Yuvraj Singh, Bela Agarwal. Lower extremity joint loading during Bounce rope skip in comparison to run and walk. Journal of Bodywork & Movement Therapies. 26 (2021) :1-6.
 22. Dharod R, Shetty T, Shete R, **Mullerpatan R**. Effect of Plyometric Training on Explosive Power, Agility, Balance, and Aerobic Performance of Young Adult Male Kabaddi Players. Critical Reviews™ in Physical and Rehabilitation Medicine. 2020;32(3).
 23. **Rajani P Mullerpatan**, Bela M Agarwal, Triveni V Shetty. Exploration of muscle activity using surface electromyography while performing Suryanamaskar. International Journal of Yoga; 2020 13 (2): 137-143.
 24. **Mullerpatan R**, Nahar S, Singh Y, Cote P, Nordin M. Burden of spine pain among rural and tribal populations in Raigad District of Maharashtra State of India. European Spine Journal. 2021 Apr;30:1004-10.
 25. Mohanty T, Mehta D, **Mullerpatan R**, Agarwal B. Cardiorespiratory Endurance, Flexibility and Lower-Extremity Muscle Strength in Children and Adolescents with Cerebral Palsy. Critical Reviews™ in Physical and Rehabilitation Medicine. 2020;32(2)



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26. Bharnuke JK, **Mullerpatan RP**, Hiller C. Evaluation of Standing Balance Performance in Indian Classical Dancers. *Journal of Dance Medicine & Science*. 2020 Mar 15;24(1):19-23.
27. Preface: Rehabilitation with a Focus on Pathologies that Significantly Impact the Quality of Life. **Mullerpatan R**, Kamath MV. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(4).
28. Shetty M, Balasundaran S, **Mullerpatan R**. Grip and pinch strength: Reference values for children and adolescents from India. *Journal of pediatric rehabilitation medicine*. 2019 Jan 1;12(3):255-62
29. **Mullerpatan R**, Shetty T, Ganesan S, Johari A. Review of lower extremity function following SEMLS in children with cerebral palsy. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(2)
30. **Mullerpatan R**, Girdhar P, Singh Y, Salgotra KR, Wilkey A, Nordin M. Evidence-Based Rehabilitation of Spine-Pain Disorders among Underserved Individuals in Navi Mumbai, India: A Two-Year— Observational Report. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(2)
31. **Mullerpatan R**, Sonkhia M, Thomas B, Mishra S, Gupta A, Agarwal B. Review of Contextual Factors Influencing Function Following Lower Extremity Amputation in Low to Middle Income Countries. *Crit Rev PhysRehabil Med*. 2019;31(2)
32. Shah T, Shetty M, Bose M, **Mullerpatan R**. A Study of Fine and Manual Hand Dexterity in People with Parkinson's disease. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
33. **Mullerpatan R**, Bharnuke J, Hiller C. Gait kinematics of Bharatanatyam dancers with and without low back pain. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
34. Agarwal B, Advani M, van Deursen R, **Mullerpatan R**. Influence of varying squat exposure on knee pain and function among people with knee osteoarthritis. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
35. Nair S, Agarwal B, Chatla J, **Mullerpatan R**. Health-related physical fitness of people with type 2 diabetes mellitus. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
36. Naryanan G, Bose M, Parab S, Agarwal B, **Mullerpatan R**. Energy expenditure using three different walking techniques in individuals with spinal cord Injury. *Crit Rev Phys Rehab Med*. 2019;31(1):35-41
37. Amberkar O, Agarwal B, Singh Y, Shete R, **Mullerpatan R**. Level of sports participation and performance among people with spinal cord injury. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
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39. **Mullerpatan R**, Thanawala M, Agarwal B, Ganesan S. Development of the Deep Squat Milestone in Typically Developing Children. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
 40. Shetty T, Parab S, Ganesan S, Agarwal B, **Mullerpatan R**. Lower extremity muscle strength and endurance in ambulatory children with cerebral palsy. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
 41. Iyer P, Shetty T, Ganesan S, Nair S, Rao N, **Mullerpatan R**. Exploration of sports participation in children with mild intellectual disability. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)
- Agarwal B, Advani M, van Deursen R, **Mullerpatan R**. Influence of varying squat exposure on knee pain and function among people with knee osteoarthritis. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1)

Dr. Bela Agarwal:

1. Mullerpatan R, Agarwal BM. Early detection and therapeutic intervention to maximize functioning in children and adults with non-communicable diseases associated with disability: challenges & solutions. *Critical Reviews™ in Physical and Rehabilitation Medicine*.
2. **Agarwal B**, Shah M, Sawant B, Bagwe H, Murkudkar P, Mullerpatan R. Predictive equation for six-minute walk test in Indian children, adolescents, and adults. *Lung India*. 2023 Mar 1;40(2):143-8.
3. Mullerpatan R, **Agarwal BM**, Joshi A, Nayak A, Kulkarni S. Health-Related Quality of Life of People with Chronic Kidney Disease in Low-and Middle-Income Countries: A Literature Review. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2023;35.
4. Kuttan V, Shetty T, Parab S, Agarwal B, Mullerpatan R. Evidence-base for effect of team sports on physical, psychological, and social function in children with neuro-motor impairment: A narrative review. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2023
5. **Agarwal B**, Parab SD, Amberkar O, Mullerpatan R. Effect of 12-week sports intervention programme on physical fitness and sports performance in individuals with spinal cord injury. *Indian Journal of Physiology and Pharmacology*. 2023 Jan;67(1):50.
6. Bhosale DA, **Agarwal B**, Murkudkar P, Bagwe H. Incentive Spirometer to Improve Lung Function in Patients with Chronic Lung Disease: A Patient Guide. *Archives of Physical Medicine and Rehabilitation*. 2023 Apr 13.
7. Murkudkar P, **Agarwal BM**, Mullerpatan R. Factors Influencing Health-Related Quality of Life, Return to Work, and Optimal Utilization of Cardiac Rehabilitation in



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- Adults with Cardiac Disorders– A Literature Review. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2023;35(2).
8. **Bela Agarwal**, Nikita Jagtap, Hiranmayee Bagwe, Payal Murkudkar. Awake repositioning/proning protocol: A Guide for ICU patients and caregivers. *Archives of Physical Medicine and Rehabilitation*. Accepted for publication(2022)
 9. Bagwe H, **Agarwal BM**, Mullerpatan R. Evaluation and Physiotherapy Management of Diaphragm Dysfunction in Patients Admitted to the Medical Critical Care Unit: A Review of the Literature. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2022;34(4).
 10. Mullerpatan R, Waingankar P, Parab S, **Agarwal B**, Nagrale O, Dalvi S. Pilot implementation of rural rehabilitation services, India. *Bulletin of the World Health Organization*. 2022 Nov 1;100(11):662-8.
 11. Kanojia AK, Bagwe HS, **Agarwal BM**. A review of the physiological effects of Suryanamaskar in children. *MGM Journal of Medical Sciences*. 2022 Jul 1;9(3):410-8.
 12. Patel G, Mullerpatan R, **Agarwal B**, Shetty T, Ojha R, Shaikh-Mohammed J, Sujatha S. Validation of wearable inertial sensor-based gait analysis system for measurement of spatiotemporal parameters and lower extremity joint kinematics in sagittal plane. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*. 2022 Jan 8:09544119211072971.
 13. Aglawe DR, **Agarwal BM**, Sawant BD. Physical Function in Critically Ill Patients during the Duration of ICU and Hospital Admission. *Indian Journal of Critical Care Medicine: Peer-reviewed, Official Publication of Indian Society of Critical Care Medicine*. 2022 Mar;26(3):314.
 14. **Agarwal BM**, Aglawe D, Sawant B. Physical function assessment tools in the intensive care unit: a narrative review. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2022;34(1).
 15. **Agarwal BM**, Yadav RP, Tambe SD, Kulkarni CC, Mullerpatan RP. Evaluation of Early Knee Osteoarthritis Using Biomechanical and Biochemical Markers. *Critical Reviews™ in Biomedical Engineering*. 2021;49(6).
 16. Vaidya SS, **Agarwal B**, Singh Y, Mullerpatan R. Effect of Yoga on Performance and Physical Fitness in Cricket Bowlers. *International Journal of Yoga Therapy*. 2021 Sep 22.
 17. Mullerpatan R, Shetty T, Singh Y, **Agarwal B**. Lower extremity joint loading during Bounce rope skip in comparison to run and walk. *Journal of Bodywork and Movement Therapies*. 2021 Apr 1;26:1-6.
 18. **Agarwal BM**, van Deursen R, Mullerpatan RP. Electromyographic evaluation of spine and lower extremity muscles during repeated and sustained bodyweight deep-squat. *Trends in Sport Sciences*, 2021, 28(1): 19-27.
 19. Swaminathan N, Jiandani M, Surendran PJ, Jacob P, Bhise A, Baxi G, Devani P, **Agarwal B**, Kumar VS, Pinto NM, Damke U. Beyond COVID-19: Evidence-Based



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- Consensus Statement on the Role of Physiotherapy in Pulmonary Rehabilitation in the Indian Context. *The Journal of the Association of Physicians of India*. 2020 Dec 1;68(12):82-89.
20. Jiandani MP, **Agarwal B**, Baxi G, Kale S, Pol T, Bhise A, Pandit U, Shetye JV, Diwate A, Damke U, Ravindra S. Evidence-based National Consensus: Recommendations for Physiotherapy Management in COVID-19 in Acute Care Indian Setup. *Indian Journal of Critical Care Medicine: Peer-reviewed, Official Publication of Indian Society of Critical Care Medicine*. 2020 Oct;24(10):905-913.
 21. Mohanty T, Mehta D, Mullerpatan R, **Agarwal B**. Cardiorespiratory Endurance, Flexibility and Lower-Extremity Muscle Strength in Children and Adolescents with Cerebral Palsy. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2020;32(2):75-83.
 22. Mullerpatan RP, **Agarwal BM**, Shetty TV. Exploration of muscle activity using surface electromyography while performing surya namaskar. *International Journal of Yoga*. 2020 May;13(2):137-143.
 23. Mullerpatan RP, **Agarwal BM**, Shetty T, Nehete GR, Narasipura OS. Kinematics of suryanamaskar using three-dimensional motion capture. *International journal of yoga*. 2019 May;12(2):124.
 24. Mullerpatan R, Sonkhia M, Thomas B, Mishra S, Gupta A, **Agarwal B**. Review of Contextual Factors Influencing Function Following Lower Extremity Amputation in Low to Middle Income Countries. *Crit Rev Phys Rehabil Med*. 2019;31(2):173-183.
 25. **Agarwal B**, Advani M, van Deursen R, Mullerpatan R. Influence of varying squat exposure on knee pain and function among people with knee osteoarthritis. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1):11-22.
 26. Nair S, **Agarwal B**, Chatla J, Mullerpatan R. Health-related physical fitness of people with type 2 diabetes mellitus. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1):23-33.
 27. Naryanan G, Bose M, Parab S, **Agarwal B**, Mullerpatan R. Energy expenditure using three different walking techniques in individuals with spinal cord Injury. *Crit Rev Phys Rehab Med*. 2019;31(1):35-41.
 28. Amberkar O, **Agarwal B**, Singh Y, Shete R, Mullerpatan R. Level of sports participation and performance among people with spinal cord injury. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1):43-51.
 29. Mullerpatan R, Thanawala M, **Agarwal B**, Ganesan S. Development of the Deep Squat Milestone in Typically Developing Children. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1):63-73.
 30. Shetty T, Parab S, Ganesan S, **Agarwal B**, Mullerpatan R. Lower extremity muscle strength and endurance in ambulatory children with cerebral palsy. *Critical Reviews™ in Physical and Rehabilitation Medicine*. 2019;31(1):75-84.



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Duration of the project: 3 years

Approval from Scientific Advisory Committee: Yes/No

Ethics committee Clearance: Yes/No

Budget requirements (as per the format as Annexure 1B)

Consumables	Item	Justification	Quantity	Cost in INR
Consumables	X Ray, MRI /CT scan	For screening participants	3000 x 100	300000
Miscellaneous	Printing questionnaires	Data collection	-	10,000
Total				3,10,000

Signature
Principal Investigator

Signature
Co-Investigator

Signature
Head of Department





MAHATMA GANDHI MISSION'S DENTAL COLLEGE & HOSPITAL
INSTITUTIONAL ETHICS COMMITTEE
Junction of NH-4 and Sion Panvel Expressway,
Sector-1, Kamothe, Navi Mumbai- 410 209
E-Mail ID :iercmgmdch@gmail.com

MGM/DCH/ IEC / 002 / 22

Date: - 11/3/2022

To,
Dr. Rajani Mullerpatan
Faculty,
MGM School of Physiotherapy,
Kamothe, Navi Mumbai

Reference:

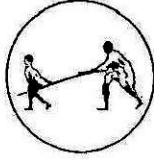
1. Your submission of study protocol
2. Study Title: "Telemetric lifestyle intervention- for SELF administration of a novel, prophylactic tool to delay disability caused by osteoarthritis of knee (MARK-1) – A longitudinal study"
3. IEC-MGMDCH reference no. **MGM/DCH/IEC/002/22**

Dear Dr. Rajani Mullerpatan

The IEC- MGMDCH has received and reviewed your submission

Following documents were reviewed in the meeting held on date 21/1/2022

1. Application to IERC MGMDCH dt. **24/9/21**
2. Summary of research protocol
3. Research protocol (Version ..., dt. **24/9/2021**)
4. Amendments to research protocol (No 4 Dt. //2022) **NA**
5. Informed consent document (ICD) in English (Versiondt. **24/9/2021**)
6. ICD in Hindi language translated from English (Version dt. **24/9/2021**)
7. ICD in Marathi language translated from English (Versiondt. **24/9/2021**)
8. Back translations of ICD from Hindi to English (Versiondt. **24/9/2021**)
9. Back translations of ICD from Marathi to English (Versiondt. **24/9/2021**)
10. Amendments to the ICD (Version, dt. /...../2022)
11. Case Record Form (CRF) / Study Questionnaire / Study Proforma ✓
12. Principal investigators Current Curriculum Vitae (signed and dated) ✓
13. Subject recruitment procedures: advertisement, letters to doctors, notices **NA**
14. Investigator Brochure (IB) – applicable for investigational new drugs (IND) **NA**
15. Ethics Committee clearance of other study centers (Total No.) **NA**
16. Insurance policy if any **NA**
17. Drugs Controller General (India) [DCG(I)] clearance if applicable **NA**
18. Investigator's undertaking to DCG(I) if applicable **NA**
19. Health Ministry Screening Committee (HMSC) approval if applicable **NA**
20. Bhabha Atomic Research Centre (BARC) approval if applicable **NA**
21. Genetic Engineering Advisory Committee (GEAC) approval if applicable **NA**
22. Director General of Foreign Trade (DGFT) approval if applicable **NA**
23. FDA marketing/manufacturing license for herbal drugs. if applicable **NA**
24. Other Documents (specify



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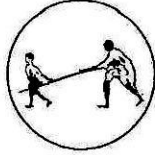
Date: - 11/3/2022

The following members of the Ethics committee discussed the study documents and voted at the meeting:

Sr.	Name	Role and Responsibility
1.	Dr. Deepak Langade	Chairman, Scientific
2.	Dr. Prakash Khandelwal	Co-chairperson
3.	Dr. Shilpa Patel	Member Secretary
4.	Adv. Dr. Sheela Hosamani	Legal Expert
5.	Mrs. Sabitha Praveen	Biostatistician
6.	Dr. Usha Asnani	Clinician
7.	Dr. Ravindranath VK	Clinician
8.	Dr. Sumanthini MV	Scientific Member
9.	Dr. Ashvini Padhye	Scientific Member
10.	Dr. Jyoti Nadgere	Scientific Member
11.	Dr. Rajesh Goel	Scientific Member
12.	Ms. Nithya Eldho Varghese	Lay person
13.	Mrs Rupali Gujar	Social worker

DECISION *approved*

Page No.2



MAHATMA GANDHI MISSION'S DENTAL COLLEGE & HOSPITAL
INSTITUTIONAL ETHICS COMMITTEE
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E-Mail ID :iercmgmdch@gmail.com

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Date: - 11 / 13 / 2022

Based on the discussion of the submitted documents for the scientific and ethical review, we approve the research protocol to be conducted and its presented form subject to the following conditions:

1. Applicable and mandatory regulatory permissions to be obtained prior to commencement of the study i.e. registration at clinical trial registry of India. (www.ctri.nic.in)
2. The investigators and other participants should be adequately trained on the protocol and its related procedures, the Good Clinical Practices (GCP) guidelines prior to commencing the study.
3. Participating subjects should be adequately enlightened about the protocol during informed consent process and under insurance coverage in an event of any trial related injury/accident.
4. Participating subjects should not be put to additional financial burden related to the study protocol.

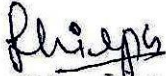
The validity of this approval is for two years from date of approval. Within this period, the Institutional Ethics Committee expects to be periodically informed about the following:

- The progress of the study
- Any Serious Adverse Event (SAE) occurring in the course of the study
- Any significant changes in the protocol/patient information/ informed consent
- Update on safety of the investigating product or procedure

To provide an abridge copy of the final report after completion of the study.

Thanking You,

Yours Sincerely


Dr. Shilpa Patel
Member Secretary