



YENEPOYA

(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Details of the Collaborative Activity

2020-21

Name of the Collaborating Institute: Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust, UK

Name of the Collaborating Department from YDU: Yenepoya Physiotherapy College

Activities:

Joint Research:

- Dr. Mudassir Baba, Assistant Professor, Yenepoya Physiotherapy College collaborated with Dr. Jayanti Rai, Extended Scope Physiotherapist, Maidstone Hospital and Dr. Jeevan Pereira, Dr. Y Nishanth Shetty from Department of Orthopedics and Traumatology, Yenepoya Medical College and Hospital for two research projects.

Project details:

- Project 1: 'Health care workers' perceptions of their low back pain: a qualitative approach
- Project 2: How effective is home based kinetic chain exercises as compare to targeted shoulder exercises in the management of overhead athlete's shoulder pain: A pilot and feasibility randomized control trail with the nested qualitative study.
- Yearly study report was prepared and submitted

Collaborative agreement: Collaborative agreements were signed between Dr. Mudassir Baba and Dr. Jayanti Rai for both the projects.

ATTESTED

Dr. Angadhara Somayaji K S
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore 575 018, Karnataka.

08/07/2020

From

Jayanti Rai

Extended Scope Physiotherapist

Maidstone Hospital

Maidstone and Tunbridge Wells NHS Trust

ME16 9QQ, United Kingdom

Email- j.raai@nhs.net

Tel: +447540700138

To

Mudasir Rashid

Assistant Professor, College of physiotherapy

Yenepoya University

Deralakatte

Mangalore , 575018

India

Dear Mudasir

Re: Health care workers' perceptions of their low back pain : a qualitative approach

I, Jayanti Rai, Extended Scope Physiotherapist, as a chief investigator at Maidstone and Tunbridge Wells NHS Trust-would like to invite you, (Mudasir Rashid) of Yenepoya University for collaborating on the above mentioned research proposal. Each clinicians at the participating organisation will be principle investigator at their site for this research project and will be recognised for their contribution/authorship in the published documents.

We will also register the research study on <https://clinicaltrials.gov/>, each members of the research team, their roles, responsibilities and contact details will be mentioned on the website upon ethics approval from Yenepoya University, Mangalore, India.

The investigators and all the members of the research team shall comply with all the current regulations as amended from time to time for performance of the project, including but not limited to:

- UK policy framework for health and social care research 2017 or relevant Governance Framework
- The Principles of the World Medical Association Declaration of Helsinki
- Data Protection Act (2018)
- ICH Good Clinical Practice Guidelines (1996)
- Human Tissue Act (2004)
- The Mental Capacity Act (2005)

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Dr. Gangadhara Somayaji K S
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka.

During the project it is the responsibility of the Investigators to ensure that :

- The project is conducted in accordance with the approved version of the protocol and subsequent amendments
- Delegation of any responsibilities are clearly documented on the Delegation of Authority and Signature Log before study activity commenced, and the Sponsor kept informed of personnel changes
- All participants are consented using the correct version of the consent form as well as using the process agreed and documented in the application

Research and Development Department

Above Breast Unit, First Floor, Maidstone Hospital, Hermitage Lane, Maidstone, Tel: 01622 225340

Consent forms is facilitated where necessary to

- Access by Research Governance staff to all c perform audits during the course of the study submission to the relevant authorities i.e.
- Amendments are submitted to the Sponsor prior to ittee. Evidence of approval must be Health Research Authority, Research Ethics Commn – unless in emergency circumstances, provided to the Sponsor prior to their implementatio
- Reporting of Urgent Safety Measures and sub sequent management in line with Regulatory
- **A TMF Master File (TMF) is created, including individual sections for additional sites where required**
- **All relevant Standard Operating Procedures and policies have been made available to the research team and a 'read record' retained in the study team training file**
- Annual progress on the anniversary of the Ethics Favourable Opinion and where relevant, Development Safety Update Reports (DSUR) on the anniversary of the Clinical Trials Authorisation are produced and sent to the Sponsor prior to submission to relevant agencies
- All communication to the REC and other regulatory bodies are copied to the Sponsor representative for authorisation and processing where relevant
- Quality control systems for data handling are in place and all data stored on computers which are not part of the local network are adequately encrypted and secure as agreed in the application
- Quality control systems for the validation of data when using 'self-built' software programmes rather than preparatory software are in place
- In the case of studies deemed to be of higher risk, an annual meeting between study staff and Sponsor is facilitated
- The terms of any data sharing agreement are agreed with the Head of R&D.

At the end of the project, the Investigators must ensure that:

- End of trial notification is completed and sent to the Sponsor for review and processing
- Documents relating to the project are archived in accordance with the organisations Archiving policy
- The Sponsor is notified of any outputs, publications or changes in service as a result of the project

Thank you for your contribution and support. We are delighted to collaborate and look forward to hear from you. If you have any query or concerns, please do not hesitate to contact me.

With regards

Jayanti

Your's Sincerely
Jayanti Rai, Extended Scope Physiotherapist

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Email- j.rai@nhs.net
Tel: +447540700138

To
Mudasir Rashid
Assistant Professor, College of physiotherapy
Yenepoya University
Deralakatte
Mangalore , 575018
India

Dear Mudasir

Re: How effective is home based kinetic chain exercises as compare to targeted shoulder exercises in the management of overhead athletes shoulder pain: A pilot and feasibility randomised control trial with a nested qualitative study

I, Jayanti Rai, Extended Scope Physiotherapist, as a chief investigator at Maidstone and Tunbridge Wells NHS Trust would like to invite you, (Mudasir Rashid) of Yenepoya University for collaborating on the above mentioned research proposal. Each clinicians at the participating organisation will be principle investigator at their site for this research project and will be recognised for their contribution/authorship in the published documents.

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- All participants are consented using the correct version of the consent form as well as using the process agreed and documented in the application
- Access by Research Governance staff to all consent forms is facilitated where necessary to perform audits during the course of the study
- Amendments are submitted to the Sponsor prior to submission to the relevant authorities i.e. Health Research Authority, Research Ethics Committee. Evidence of approval must be provided to the Sponsor prior to their implementation – unless in emergency circumstances, where retrospective approval is acceptable
- Reporting of Urgent Safety Measures and subsequent management in line with Regulatory requirements
- A Trial Master File (TMF) is created, including individual sections for additional sites where required
- All relevant Standard Operating Procedures and policies have been made available to the research team and a 'read record' retained in the study team training file
- Annual progress on the anniversary of the Ethics Favourable Opinion and where relevant, Development Safety Update Reports (DSUR) on the anniversary of the Clinical Trials Authorisation are produced and sent to the Sponsor prior to submission to relevant agencies
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With regards

Jayanti

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Jayanti Rai, Extended Scope Physiotherapist

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225340

Date: 20 August 2020

From
Mudasir Rashid baba
Assistant professor,
Yenepoya Physiotherapy College
Yenepoya Deemed to be University

To,
The Head of department
Orthopaedic and traumatology, YMCH
Yenepoya Deemed to be University

Sub: Approval to involve 2 faculty from your department as CO-PI in multicentre research project in collaboration with Maidstone hospital, NHS, UK

Respected sir,

As I have received two multicentre research projects as PI from India in collaboration with Maidstone hospital, NHS, UK, entitled as follows:

1. How effective is home based kinetic chain exercises as compare to targeted shoulder exercises in the management of overhead athletes shoulder pain: A pilot and feasibility randomised control trial with a nested qualitative study
2. Health care workers' perceptions of their low back pain : a qualitative approach

As per our previous discussion and verbal approval from your side, 2 faculty from your department named Dr. Jeevan Pereira and Dr. Y. Nishanth Shetty agreed upon to be a part of the above mentioned research projects as CO-PI. I hereby request you to give us an official approval for the same. I am glad to inform that we shall sign MOU soon to start our work.

Thanking you

Mudasir Rashid Baba
Assistant Professor,
Yenepoya Physiotherapy College,
Yenepoya Deemed to be University

Approved

cc

- ① Dr Nishanth
- ② Dr Jeevan.

Prof. Dr. Y. Nishanth Shetty
20/08/2020
M.D. of Orthopaedics
YENEPLOYA MEDICAL COLLEGE
DERALAKATTE
MANGALORE-575018

ATTESTED

Dr. Gangadhara Somayaji K S

Registrar

Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018, Karnataka.

YENEPLOYA PHYSIOTHERAPY COLLEGE

Status of the work

Collaborating multi centre Research proposal: Maidstone Hospital

Maidstone and Tunbridge Wells NHS Trust ME16 9QQ, United Kingdom

1. How effective is home based kinetic chain exercises as compare to targeted shoulder exercises in the management of overhead athletes shoulder pain: A pilot and feasibility randomised control trial with a nested qualitative study
2. Health care workers' perceptions of their low back pain : a qualitative approach

I, Mudasir Rashid Baba, Assistant Professor at Yenepoya Physiotherapy College received above mentioned collaborative multicentre research projects from Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust ME16 9QQ, United Kingdom .I have been invited as principle investigator from India, whereas Yenepoya university shall be recognised for their contribution/authorship in the published documents. I am glad to inform that I have happily agreed upon the above mentioned research proposal.

Work done till date:

1. MOU documents received from Maidstone Hospital Maidstone and Tunbridge Wells NHS Trust ME16 9QQ, United Kingdom, and same has been discussed with Dr. ArunBhagwat and as per his instructions some amendments in the MOU has been incorporated by the Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust ME16 9QQ, United Kingdom .
2. Research team: Yenepoya Deemed to be University
 - Mudasir Rashid Baba (Principle Investigator from India)
Assistant Professor, YPC
 - Prof. S Padma Kumar (Co-PI from India)
Principal YPC
 - Dr. RM Shenoy (Co-PI from India)
HOD, Department of Orthopaedics, YMCH,
 - Dr. Jeevan Pereira
Assistant Professor, Dept. of Orthopaedics, YMCH
 - Dr. Y. Nishanth Shetty
Senior Resident, Dept. of Orthopaedics, YMCH

 **ATTESTED**

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3. Discussion on research projects was held with HOD, department of Orthopaedics, Dr. Jeevan Pereira and Dr.Y. Nishanth Shetty ,Department of Orthopaedics, YMCH on 15/7/2020
4. On 16/7/2020, PI had telephonic discussion with the United Kingdom research team members.
5. Obtained approval letter from the department of Orthopaedics and traumatology, YMCH

Proposed work:

1. MOU from Yenepoya deemed to be university shall be signed by Honourable Registrar Dr. K.S.Gangadhara Somayaji and PI Mudasir Rashid Baba, Assistant Professor, Yenepoya Physiotherapy College, Yenepoya Deemed to be University.
2. Further work shall be carried out as per the norms of the Yenepoya Deemed to be university.

Principle Investigator:

Mudasir Rashid Baba

Assistant Professor, Yenepoya Physiotherapy College

CO-PI

1. Prof S Padma kumar
Principal, Yenepoya Physiotherapy College
2. Dr. RM Shenoy
Prof & HOD, Department of Orthopaedics, YMCH
3. Dr. Jeevan Pereira
Assistant Professor, Department of Orthopaedics, YMCH
4. Dr.Y. Nishanth Shetty
Senior Resident, Department of Orthopaedics, YMCH

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