FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI No	**CTRI/2024/01/061987** [Registered on: 29/01/2024] **Trial Registered Prospectively**
Acknowledgement Number	REF/2024/01/077243
Last Modified On:	11/01/2024
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug Physiotherapy (Not Including YOGA)
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Physiotherapy for Post-COVID-19 Conditions
Scientific Title of Study	Comparing Effectiveness of Physiotherapy versus Drug Management on Fatigue, Physical Functioning, and Episodic Disability for Myalgic Encephalomyelitis in Post-COVID-19 Condition
Trial Acronym	PCCPT

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)
Clarification(s) with Reply
Modification(s)

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Source of Monetary or Material Support

Physiotherapy unit, BRB Hospitals Ltd, Panthapath, Dhaka-1205, Bangladesh

Primary Sponsor

Name	Jashore University of Science and Technology
Address	Jashore University of Science and Technology Jashore-7408 Bangladesh
Type of Sponsor	Government funding agency

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

Bangladesh

Sites of Study
Clarification(s) with Reply
Modification(s)

No of Sites = **1**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Tofajjal Hossain	BRB Hospital Limited and Specialized Physiotherapy Hospital Ltd	Room No 202, Department of Physiotherapy, BRB Hospital Limited,77A Panthapath, Dhaka 1215, Bangladesh	01715560669 yousufraju6423@gmail.com

Details of Ethics Committee

No of Ethics Committees= **1**

Name of Committee	Ethics Committee registered with DHR /CDSCO or not	Ethics Committee Registration No.	Approval Status	Date of Approval	Approval Document	Is IEC?
Institute of Physiotherapy, Rehabilitation & Research	Yes	BPA-IPRR/IRB/19/01/2023/69	Approved	13/02/2023	Approval File	Not Available

Regulatory Clearance Status from DCGI

Status	Date	Aproval Document
Not Applicable	No Date Specified	No File Uploaded

Health Condition / Problems Studied

Health Type	Condition
Patients	**(1) ICD-10 Condition:** J984||Other disorders of lung,

Intervention / Comparator Agent
Clarification(s) with Reply
Modification(s)

Type	Name	Details
Intervention	Adapted physical activity and therapeutic exercise through telemedicine (APTE-T)	3 Months. APTE-T the interventions will be provided by a consultant physiotherapist through digital media Such as Zoom, WhatsApp, Facebook Messenger, or the personalized app of the Department of Physiotherapy and Rehabilitation at Jashore University of Science and Technology. It will be a 45-minute session with a one-to-one approach. The patient will be performing exercises or advice at home. The physiotherapist will explain and demonstrate procedures through cameras, and the patient will perform. There will be

			continuous communication with the patients to ensure that the interventions provided are performed accordingly and is safe.
	Comparator Agent	Drug Management (DM)	3 Months. Participants of the drug management group will receive the drug interventions as azithromycin, remdesivir, favipiravir, infliximab, tocilizumab, siltuximab, hydrocortisone, rituximab, rintatolimod, intravenous immunoglobulin [15, 16]. The drug interventions will be directly prescribed by a physician specialized in treating PCC cases. A single brand name will be prescribed for each drug. We will communicate with the patients to ensure no adverse effects of the medications. The patient will be given a choice if they are willing to join the exercise programs; they have full liberty to join the programs even after the completion of the trial.
	Intervention	Institute-based adapted physical activity and therapeutic exercise (APTE-I)	3 Months. APTE-I will be provided under the consultation of a consultant physiotherapist specializing in Post-COVID-19 Condition rehabilitation. Interventions will be provided for 45-minute sessions in a one-to-one approach. There might be some home exercises or advice to follow at home. There will be continuous communication with patients. To ensure that the treatment does not deteriorate the symptoms.

Inclusion Criteria

Age From	20.00 Year(s)
Age To	70.00 Year(s)
Gender	Both
Details	1) Diagnosis of long COVID according to who working group criteria1, 2) Diagnosis of chronic fatigue syndrome(CFS) according to the 2006 Canadian consensus criteria5, 3) Respondents meeting with persistent or relapsing chronic fatigue and post exertion malaise or fatigue criteria of the Canadian consensus guideline, and 4) willing to participate with the trail with a consent of adherence with the intervention

Exclusion Criteria

Details	(1) any preexisting post-exertion symptoms exaggeration, (2) any preexisting clinical condition with fatigue as cardiovascular or neurological disability, (3) any red flags or signs that are explained as contraindication according to safe Post-COVID-19 condition rehabilitation guideline, and (4) patient drop-out within the 1st week of inclusion

Method of Generating Random Sequence

Computer generated randomization

Method of Concealment

Sequentially numbered, sealed, opaque envelopes

Blinding/Masking

Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	TimePoints
Chalder fatigue Scale (CFS)	At baseline, 12 weeks and 6 months

Secondary Outcome

Outcome	TimePoints
Physical Functioning sub-domain of SF-36	At baseline, 12 weeks and 6 months
Disability Adjacent Life Years (DALYs)	At baseline, 12 weeks and 6 months

Target Sample Size

Total Sample Size="124"
Sample Size from India="124"
Final Enrollment numbers achieved (Total)= "Applicable only for Completed/Terminated trials"
Final Enrollment numbers achieved (India)="Applicable only for Completed/Terminated trials"

Phase of Trial
Clarification(s) with Reply
Modification(s)

Phase 4

Date of First Enrollment

10/05/2024

(India) Clarification(s) with Reply Modification(s)	
Date of Study Completion (India)	Applicable only for Completed/Terminated trials
Date of First Enrollment (Global)	20/05/2024
Date of Study Completion (Global)	Applicable only for Completed/Terminated trials
Estimated Duration of Trial	**Years=**"0" **Months=**"6" **Days=**"0"
Recruitment Status of Trial (Global) Clarification(s) with Reply Modification(s)	Not Yet Recruiting
Recruitment Status of Trial (India)	Not Applicable
Publication Details	N/A
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - YES 1. What data in particular will be shared? **Response** - All of the individual participant data collected during the trial, after de-identification. 2. What additional supporting information will be shared? **Response** - Study Protocol **Response** - Statistical Analysis Plan **Response** - Informed Consent Form **Response** - Clinical Study Report 3. Who will be able to view these files? **Response** - Anyone 4. For what types of analyses will this data be available? **Response** - For individual participant data meta-analysis. 5. By what mechanism will data be made available? **Response** - Proposals should be directed to [*altafhossainsarker272@gmail.com*]. 6. For how long will this data be available *start date provided 31-05-2024 and end date provided 31-12-2028*? **Response** - Immediately following publication. No end date. 7. Any URL or additional information regarding plan/policy for sharing IPD? **Additional Information** - NIL
Result Disclosure	**Do you wish to upload results?** **Response** - Summary results have not yet been disclosed
Brief Summary	ME/CFS patients will be recruited and treated in three specialized Hospitals. The study will be conducted in BRB Hospital Limited and Specialized Physiotherapy Hospital Ltd in the Dhaka division. In the Khulna division, the treatment center will be the Department of Physiotherapy and Rehabilitation at Jashore University of Science and Technology. The APTE-I, APTE-T, and DM groups will be recruited from any centers. However, the DM group will have respondents from the participants who are not willing to take any exercise interventions and only accept to take drug management. To prevent cross-contamination of the data,

	different treatments set up will be arranged in each study setting, and separate personnel will be employed for each treatment group.