Clinical Trial Details

CTRI Number	CTRI/2021/11/038207 [Registered on: 23/11/2021] - **Trial Registered Prospectively**
Last Modified On	22/11/2021
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Physiotherapy (Not Including YOGA)
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Teleheath impact on post delivery females after cesarean section on fitness and mental health in covid-19 pandemic duration.
Scientific Title of Study	â€œ Impact of Telehealth on Physical Fitness and Overall Body Conditioning in Women with Post Cesarean Section Delivery During COVID-19 Pandemic â€“ Randomized Controlled Trialâ€•

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator

Details of Principal Investigator	
Name	Shreya Agarwal
Designation	student of post graduation
Affiliation	Dr.D.Y.Patil college of Physiotherapy
Address	4th Floor,Physiotherapy department at Dr. D. Y. Patil college of physiotherapy, sant tukaram nagar, pimpri, Pune. Dr. D. Y. Patil college of physiotherapy, sant tukaram nagar, pimpri, Pune. Pune MAHARASHTRA 411018 India
Phone	9636959607
Fax	
Email	shreyasinghalajmer@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Manisha Rathi
Designation	Professor
Affiliation	Dr.D.Y.Patil college of Physiotherapy
Address	4th Floor, Physiotherapy department, Dr. D. Y. Patil college of physiotherapy, sant tukaram nagar, pimpri, Pune. Pune MAHARASHTRA 411018 India
Phone	9850418712
Fax	
Email	manisha.rathi@dpu.edu.in

Details Contact Person (Public Query)

Details Contact Person (Public Query)

Name	Manisha Rathi
Designation	Professor
Affiliation	Dr.D.Y.Patil college of Physiotherapy
Address	4th Floor, Physiotherapy Department at Dr. D. Y. Patil college of physiotherapy, sant tukaram nagar, pimpri, Pune. Pune MAHARASHTRA 411018 India
Phone	9850418712
Fax	
Email	manisha.rathi@dpu.edu.in

Source of Monetary or Material Support

Source
Shreya Agarwal

Primary Sponsor

Primary Sponsor Details	
Name	shreya agarwal
Address	Dr. D. Y. Patil college of physiotherapy, sant tukaram nagar, pimpri, Pune.
Type of Sponsor	Other [self funded]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Principal Investigator	Site Name	Address	Contact
shreya agarwal	Dr. D. Y. Patil College of Physiotherapy	4th Floor, Physiotherapy Department at Dr. D. Y. Patil college of physiotherapy, sant tukaram nagar, pimpri, Pune. Pune, MAHARASHTRA	9636959607

Details of Ethics Committee

Name	Approval Status
Institutional Ethics Committee	Approved

Regulatory Clearance Status from DCGI

Status
Not Applicable

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Post Natal Females

Intervention / Comparator Agent

Type	Name	Details
Intervention	online mode of exercises during covid-19 pandemic	exercises targeting physical fitness and overall body conditioning in post cesarean delivery females, 3 days a week for 6 weeks.
Comparator Agent	unsupervised home exercises during covid-19 pandemic	Exercises targeting Physical fitness and overall body

		conditioning in post cesarean delivery females, 3 days a week for 6 weeks.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	35.00 Year(s)
Gender	Female
Details	1) Post-partum with cesarean section women within age group 18 â€“ 35 years. 2) Post 12 weeks after surgery up to 1 year post delivery. 3) Women using digital mode or device for online video consultation or conferencing.

Exclusion Criteria

Exclusion Criteria	
Details	1) Mother or child tested positive for covid -19. 2) Death of fetus due to any medical complication. 3) Any form of exercise more than once per week for at least past 6 months. 4) Chronic heart and lung disease (except controlled hypertension). 5) Poorly controlled diabetes, hypertension, epilepsy, hyperthyroidism. 6) Severe anemia (hematocrit value 7) Orthopedic conditions like any hip joint (articular) pathology including pain, fracture, instability, Lumbar spondylosis, Ankylosing spondylitis, Lumbar spinal stenosis. 8) Recent fractures or fracture since past 2 years

Method of Generating Random Sequence

Computer generated randomization

Method of Concealment

Alternation

Blinding/Masking

Participant Blinded

Primary Outcome

Outcome	Timepoints
For Physical fitness: 1) Sit and reach test for Flexibility of hamstring and trunk muscles. 2) Modified knee pushups for muscle strength. 3) Sit Ups in 1 minute, to measure Muscle endurance. 4) Six minute walk test to measure Cardiovascular endurance. For Mental health: 1) Edinburgh Postnatal Depression Scale (EPDS) for Depression. 2) State-Trait Anxiety Inventory Scale (STAI) for Stress.	Pre and Post intervention for 6 weeks

Secondary Outcome

Outcome	Timepoints
BMI, Weight measurement	Pre and Post intervention

Target Sample Size

Total Sample Size: **38**
Sample Size from India: **38**
Final Enrollment (Total): **Applicable only for Completed/Terminated trials**
Final Enrollment (India): **Applicable only for Completed/Terminated trials**

Phase of Trial

N/A

Date of First Enrollment (India)

01/12/2021

Date of First Enrollment (Global)

No Date Specified

Date of Study Completion (India)	No Date Specified
Date of Study Completion (Global)	No Date Specified
Estimated Duration of Trial	Years: 1, Months: 1, Days: 0
Recruitment Status (Global)	Open to Recruitment
Recruitment Status (India)	Not Yet Recruiting
Publication Details	
Brief Summary	Exercise Intervention of thrice in a week for total 6 weeks will be given to Post Cesarean delivery females from age group of 18-35 years through Online video conferecing application to check impact of teleheath during covid-19 pandemic .