Post-COVID-19 Clinics: Improves Physical Status, Dyspnea, Fatigue, Anxiety, and Quality of Life

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Study Design:

A prospective pretest and posttest intervention study will be conducted at the post-Covid clinics in Riyadh, Saudi Arabia.

Study Setting and duration of study:

The study will be conducted at the post-COVID clinics in Riyadh region. The duration will be for 4-week, 3 sessions per week. Each session will last for 45 minutes.

Study subjects/participants:

Inclusion Criteria:

- The participants' ages from 18-45 years old
- Participants who are referred to the post-COVID clinics.
- Participants who are discharged from the hospitals between 3 to 6 months ago.

Exclusion Criteria:

- If they have any viral pneumonia, acute respiratory distress syndrome (ARDS), cardiovascular instability, pulmonary embolism, and disability or disorders.
- Musculoskeletal disorders
- Neurodegenerative diseases
- Patients unable to walk.

Recruitment:

- Participants who are referred to the post-COVID clinics.
- Each participant who is referring to the clinic will be asked if he/she willing to be part of the study.

Procedures:

The research team will provide a full explanation of the study design, methods, and protocols to each participant. Informed consent then will be signed by the participants before starting the study.

The following safety precautions will be observed when assessing and training the participants. A safety belt will be placed around the participants' hips if needed. The participants will be requested to place their arms around the therapist's hips if they need to stand or walk. Therapists should avoid lifting the participants unless they ask for additional assistance. The participants should be given time to stand using their own strength. The therapists should stay close to the participants during transfer and walking, and the participants' weight should be kept close to the therapist's center of gravity to avoid falling. When the participants feel fatigued, the assessment of their training should cease immediately, and the participants should be given the opportunity to take a rest. After each assessment and training session, the participants should be given a two-to-three-minute break. Furthermore, the therapists must be closely supervised by an investigator to ensure that all research activities are carried out in accordance with the approved study protocols.

After signing the informed consent, the participants will answer thise questionnaire.

Demographic questionnaire

After signing the informed consent form, subjects will be asked to complete a baseline demographic questionnaire that will record the following variables: age, gender, height (cm), weight (kg), educational level, job status, marital status, smoking status, and number of COVID-19 vaccine doses.

Surveys will be used before and after the intervention:

In addition, participants will complete the following validated questionnaires.

• The <u>BERG Balance Scale will be used</u> to assess participants' ability (or inability) to safely maintain their balance (static, dynamic, and fall risk) during a series of scheduled tasks. This is a 14-item objective measure list, with each item answered using a five-point ordinal scale ranging from 0 to 4, with 0 indicating the lowest level of function and 4 the highest level of function. The questionnaire takes approximately 20 minutes to complete. The participants should understand that they must maintain their balance

while attempting the tasks. The choice of which leg to stand on or how far to reach is left to the participants. Poor judgment will adversely influence their performance and scoring. A higher score indicates good functional balance.

- The <u>Modified Medical Research Council (mMRC) Dyspnea Scale</u> will be used to assess participants' degree of baseline functional impairment due to dyspnea from respiratory diseases. The mMRC 0–4 scale was developed by the American Thoracic Society as a modification of the dyspnea index originally proposed by the British Medical Research Council, which uses a 1–5 scale.
- The <u>Depression, Anxiety, and Stress Scale 21 Items (DASS-21)</u>. This is a set of three self-report scales designed to measure emotional states of depression, anxiety, and stress. Each of the three DASS-21 scales contains seven items, divided into subscales with similar content.
- The <u>Fatigue Assessment Scale (FAS)</u>. This is a 10-item scale used to evaluate symptoms of chronic fatigue. It is quick and easy for participants to complete and is not time-consuming.
- The <u>Quality of Life (QOL) short form SF-36.</u> This 36-item questionnaire uses eight subscales to measure physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. An Arabic version of the QOL questionnaire will be used.

Then, these measurements will used to measure physical status, endurance, and capacity.

- <u>6-min walk test (6-MWT)</u> will be assessed using two cones will be placed at 30 meters in an unimpeded walkway. The patients are instructed to walk as far as possible for six minutes (recorded on a timer) at a comfortable speed between the cones, with every turnaround, the cones being quick pivots. The total distance walked was recorded at the end of 6 minutes.
- <u>10-meter walk test (10MWT)</u> will be measured by a clear pathway of at least 10 m in length in a designated area over solid flooring is required. The pathway will be measured and marked at the start and end points of a 10-m walkway. A mark will be added at 2 m and 8 m (identifying the central 6-m, which will be timed). The patients will ask to walk comfortably until the end of the mark, then walk fast again until the of the mark. Two trails of each walk will be recorded, and the best score will be recorded.
- <u>A Time Up and Go (TUG) test</u> will be evaluated using a chair will be placed in a hallway, and tape will be used to mark 3-meters in front of the chair. The test starts with the patient will be sitting on a chair. Then the patient will be instructed to stand up from the chair on command, walk 3 meters, turn around, walk back to the chair, and sit down with the therapist recording the time taken from standing up from the chair to the point he sits back.
- <u>1-min sit-to-stand test (1-MSTST)</u> will be assessed by asking the patients to sit comfortably in the chair with both feet flat on the ground, and a timer will be set for one minute. Then the patients will be instructed to hold the hand close together loosely and stand up from the chair until the legs are completely extended, followed by sitting back down again, which counts as one. The patients will continue standing and sitting as many times as they can in one minute. The total number of sit-to-stand will be recorded at the end of one minute.

Intervention

The intervention will be based on a rehabilitation program approved by the MOH. (24) The rehabilitation sessions will include breathing techniques, aerobic exercises, strength training, and education. As part of the regular rehabilitation protocol, each participant will undergo the following rehabilitation program with a specialized licensed clinician.

1. <u>Respiratory Exercises</u>

- Active cycle of breathing technique (ACBT)

The participants will start with exercises 1-3 at least twice a day and increase the frequency to four to six times a day. The exercises will include three stages: breathing control, chest expansion, and exhalation. Breathing control will be achieved by asking the participants to breathe in and out gently through the nose if possible. If the breath is exhaled through the mouth, the participant will be instructed to purse their lips as if they were blowing out a candle. The participant will be asked to try to gradually make their breathing slower. Following that, the participant will be instructed to take a long, slow, deep breath in through their nose if they can while keeping their chest and shoulders relaxed, then breathe out gently without forcing the air out and relax, as if sighing. Finally, they will be asked to "huff", which is exhaling through an open mouth and throat instead of coughing. This helps move sputum up the participant's airways so that they can be cleared in a controlled way. To "huff," they must quickly squeeze air from their lungs and let it out through their open mouth and throat, as if they were trying to mist up a mirror or their glasses. They will be asked to use their abdominal muscles to help them squeeze the air out, but not to force it so much that they cause wheezing or tightness in their chest. If huffing clears their sputum, then they should not need to cough. They should only cough if the sputum can be cleared easily. They should continue the breathing exercises for about 10 minutes, ideally until their chest feels clear of sputum.

2. Aerobic exercises

The aerobic exercises will include walking up and down stairs, walking at home, cycling, and dancing. Each session should last for 30–60 minutes per day and start with low-intensity exercise. The intensity will be increased by 10% every week. A limit of 70% of the maximum heart rate will be set. (25)

3. <u>Progressive strengthening training</u>

Strengthening exercises are designed to improve muscle strength and endurance. The frequency and intensity will be adjusted for each participant individually. The participants will be requested to perform the following strengthening exercises. Standing heel raise: the participant should hold on to a chair, reach overhead while standing on their toes and bring their hands together. This should initially be repeated two to three times, increasing gradually to eight times (for one set). Mini squats should be performed while holding onto a chair and breathing. Wall push-ups should be held for eight seconds. Core exercises should start with 10–15 repetitions and then repetitions should slowly be increased. Participants should perform sit to stand

exercises for one minute. All these exercises should initially be repeated two to three times per day and frequency should be increased gradually to 10 times a day.

4. <u>Mobility training or gait training to increase endurance.</u>

Every day, participants will be asked to walk for at least 30 minutes without stopping as part of a mobility training program to improve endurance. Participants will also begin walking on flat surfaces before progressing to uneven surfaces. As the participants' mobility progresses and they gain endurance, they will be asked to challenge themselves by walking on hills and inclines for 10 minutes, increasing the frequency of this exercise to three times a day. They will be asked to walk five times per week, ascending and descending stairs with assistance if needed.

5. <u>Home-exercise program (HEP)</u>

All the activities, including a walking program, resistance exercises, and breathing techniques, should be continued at home.

Data analysis

Sample size

The required sample size was estimated from the percentage of the total population referred to the post-COVID centers using a confidence level of 95% and a confidence interval of 5%, resulting in an estimate of 60 participants with a 30% dropout rate.

Statistical analysis

The data will be analyzed using multivariate statistics to compare more than two variables at baseline and afterward. Continuous variables will allow a mean to be obtained with standard deviation (normal data) or a median with an interquartile range (skewed data), while categorical variables will be obtained as numbers and percentages. The score data from the 6MWT, 10MWT, TUG, and STS tests will be examined using a paired t-test or a Wilcoxon signed rank test to facilitate comparison of matched pretest and post-test scores, in addition to observations of the behavior and differences in the survey data.

Ethical approval:

The study was approved by King Fahad Medical City (KFMC) in Riyadh, Saudi Arabia under IRB Log Number: 22-472E.