Research Protocol

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Physiotherapy Section

Supervised Tele-rehabilitation versus Unsupervised Home-based Pulmonary Rehabilitation in Individuals with COPD: A Randomised Controlled Trial Protocol

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ABSTRACT

Introduction: Chronic Obstructive Pulmonary Disease (COPD) is a major global health concern characterised by irreversible airflow limitation due to airway and alveolar abnormalities. Many individuals diagnosed with mild to moderate COPD often experience reduced independence and functional capacity, for which Pulmonary Rehabilitation (PR), the evidence-based program, is the only primary non pharmacological treatment approach for the treatment of COPD, which reduces progression of the disease and improves overall Quality of Life (QoL) of the patient.

Need of the study: However, access to centre-based PR programs is frequently limited by distance, cost, and resources. Tele-rehabilitation offers a feasible and accessible alternative for delivering PR remotely. Despite its potential benefits, further research is needed to establish its effects on functional outcomes in patients with COPD.

Aim: To evaluate the effectiveness of supervised tele-PR versus home-based PR on pulmonary function, balance, cognition, and functional performance in individuals with mild to moderate COPD.

Materials and Methods: A randomised controlled trial will be conducted at MM Super Speciality Hospital, Mullana, Ambala, Haryana, India, from August 2025 to June 2026. A total of 60 participants (Forced Expiratory Volume in one second/Forced Vital Capacity (FEV_1/FVC) <0.7 and FEV_1 >50%), aged 45-85 years, will be included and randomly allocated to supervised Tele-PR (Group 1) and unsupervised home-based PR (Group 2). The six-week tele-rehabilitation program will include supervised exercise, breathing techniques, and educational sessions via video conferencing. Pre and post intervention assessments will include pulmonary function tests (FEV_1 and FVC), the Berg Balance Scale (BBS) for balance, the Montreal Cognitive Assessment (MoCA) for cognitive function, and the Londrina Activities of Daily Living (ADL) Protocol for functional performance. Within-group and between-group comparisons will be performed using paired and unpaired t-tests, respectively. For non-normally distributed data, the Wilcoxon signed-rank test and Mann-Whitney U test will be used. Statistical significance will be set at $p<0.05$.

Keywords: Chronic obstructive pulmonary disease, Physical performance, Videoconferencing, Vital capacity

INTRODUCTION

The 2023 Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy defines COPD as a progressive respiratory condition characterised by persistent symptoms like cough, sputum production, and frequent exacerbations. These symptoms result from irreversible structural changes in the airways and alveoli, leading to chronic and progressive airflow limitation [1].

Persistent symptoms of COPD include fatigue, wheezing, chest tightness, mucus hypersecretion, persistent coughing, increased dyspnoea, and decreased exercise tolerance. These symptoms collectively impair ADLs, reduce QoL, and affect sleeping, causing obstructive sleep apnea [2]. In addition to pulmonary dysfunctions, systemic co-morbidities such as peripheral muscle weakness, cardiovascular diseases, osteoporosis, depression, and cognitive impairment often aggravate due to COPD. These effects result in reduced muscle strength, cognition, and independence, and a higher risk of falls in affected individuals [3].

The diagnosis can be confirmed using spirometry, which demonstrates a reduced ratio of FEV_1 to FVC [4]. The severity of COPD can be classified according to the post bronchodilator FEV_1 expressed as a percentage of the predicted value. As FEV_1 declines across these stages, disease severity and associated functional impairment progressively worsen.

The symptoms of the disease can be modified through appropriate lifestyle modifications, which form a cornerstone of comprehensive disease management alongside pharmacological management. These non pharmacological management programs include, but are not limited to, structured exercise programs in PR, increased physical activity to improve exercise tolerance, breathing control techniques to reduce dyspnoea, and complete smoking cessation often accompanied by counselling, effective management of anxiety and depression through cognitive behavioural therapy and medication adherence [5,6]. Pharmacological management of COPD involves a multimodal approach aimed at reducing airflow limitation, chronic inflammation, and exacerbations. Inhaled bronchodilators are the cornerstone of treatment and help slow the decline in lung function. In severe cases (FEV_1 <50% predicted), the phosphodiesterase-4 inhibitor roflumilast may be used as an adjunct to reduce airway inflammation. Macrolides such as azithromycin exert anti-inflammatory and immunomodulatory effects, thereby decreasing exacerbation frequency in high-risk patients. Corticosteroids further help control airway inflammation, while antioxidant therapies target oxidative stress to restore redox balance within lung tissues [7]. The goal of both approaches is to improve QoL, reduce hospitalisation risks, and slow functional decline.

For patients with symptomatic COPD, exercise-based PR evidently has a role as an evidence-based treatment, both in stable phases and during acute exacerbations. It mainly consists of exercise training tailored to individual patient limitations, which addresses both ventilatory and circulatory impairments, improves respiratory, cardiovascular, neurological, and muscular function, and enhances

movement efficiency [8]. PR approaches to maximise physical capacity and improve symptoms like dyspnoea and exercise intolerance include whole body low- and high-intensity training, endurance training, interval training, resistance training, balance training, and inspiratory muscle training [9]. PR is essential for improving exercise tolerance, enhancing QoL, and reducing symptoms, thereby supporting comprehensive disease management alongside pharmacological treatment. Exercise training programs have been shown to improve dyspnoea, exercise capacity, cognition, balance, strength, Central Nervous System (CNS) functioning, and health-related QoL in individuals with COPD.

Despite the established effectiveness of PR, several barriers limit access to these programs. Such barriers to rehabilitation participation include issues with cost, travel, and transport to attend programs, which are typically undelivered in remote areas [10]. To address these barriers, alternative models of rehabilitation, such as home-based PR programs and Tele-rehabilitation programs, have been demonstrated to be clinically and cost-effective, where supervision while performing the exercises plays a critical role in ensuring the patient's adherence to the treatment protocol, which is difficult to monitor when the patient has no contact with the therapist. In remote areas, telecommunication can help to bridge this gap [11].

Primary objectives:

- To assess the impact of supervised tele-PR on pulmonary functions, balance, cognition, and functional outcomes in individuals with COPD.
- To assess the impact of unsupervised home-based PR on pulmonary functions, balance, cognition, and functional outcomes in individuals with COPD.

Secondary objective:

- To compare the impact of supervised tele-PR versus unsupervised home-based PR on pulmonary functions, balance, cognition, and functional outcomes in individuals with COPD.

Null hypothesis:

- There will be no significant effect of supervised tele-PR versus unsupervised home-based PR on pulmonary functions, balance, cognition, and functional outcomes in individuals with COPD.

Alternate hypothesis:

- There will be a significant effect of supervised tele-PR versus unsupervised home-based PR on pulmonary functions, balance, cognition, and functional outcomes in individuals with COPD.

REVIEW OF LITERATURE

COPD presents significant challenges in receiving PR due to associated barriers to achieving centre-based rehabilitation. In recent years, tele-rehabilitation has emerged as a promising approach to address these barriers. Tele-rehabilitation uses telecommunications technology to deliver rehabilitation services remotely. The growing acceptance of tele-rehabilitation has provided an effective management of COPD [12].

Paneroni M et al., conducted a multicentre, prospective, controlled, non randomised pilot feasibility study to assess the safety, adherence, and patient satisfaction of a home-based Tele-rehabilitation Program (TRP) by comparing an Outpatient Rehabilitation Program (ORP). The comparison was done among 18 TRP and 18 ORP participants, conducted 28 sessions of strength and cycle training, which showcased that TRP patients completed all the sessions without any side effects and showed improvements in the 6-Minute Walk Test (6MWT), enhancing the functional capacity, which matched with the ORP patients, which validated that tele-rehabilitation is a secure and viable option [13].

In a parallel-group randomised controlled trial, Toldo de Graham BL et al., compared two PR protocols delivered via videoconferencing. Group 1 received breathing exercises along with health education, while Group 2 received health education alone. Following the 8-week intervention, Group 1 demonstrated greater improvements in functional capacity. The authors concluded that tele-rehabilitation-based PR is effective in enhancing functional capacity in individuals with COPD [14].

Furthermore, Ora J et al., conducted a systematic review and meta-analysis to evaluate the clinical effectiveness of tele-rehabilitation in patients with COPD. The analysis included eight studies comparing tele-PR with no rehabilitation and with centre-based rehabilitation. Outcomes assessed included the 6MWT, modified Medical Research Council (mMRC) dyspnoea scale, and COPD Assessment Test (CAT). The findings indicated that tele-PR was non-inferior to centre-based rehabilitation in improving exercise tolerance and symptom control, supporting its effectiveness in the management of COPD [15]. These studies supported the effectiveness of tele-rehabilitation as a safe and viable alternative to centre-based rehabilitation.

Thus, the current study aims to find the effectiveness of the tele-rehabilitation program in improving pulmonary functions, functional capacity, cognition, and balance in individuals with COPD.

MATERIALS AND METHODS

A prospective, parallel-group randomised controlled trial will be conducted at MM Super Speciality Hospital in Ambala district of Haryana (India) from August 2025 to June 2026, with informed consent obtained from the participants. The study has been approved by the Institutional Ethical Committee with IEC no: IEC-3462 and registered with CTRI India with ID: CTRI/2025/09/095364.

Inclusion criteria:

- Men and women, aged between 45-85 years;
- Spirometric value of $FEV_1/FVC < 0.7$ and $FEV_1 > 50\%$;
- Individuals who are near normal or have mild cognitive impairment with a MoCA score more than 24 [16];
- Consent to participate.

Exclusion criteria:

- Individuals with neurological disorders, musculoskeletal disorders, unstable cardiovascular disease;
- Recent Myocardial Infarction (MI) (<6 months), uncontrolled arrhythmias;
- Individuals with severe hypoxaemia requiring continuous oxygen, recent exacerbation (<4 weeks);
- Videoconferencing technology not available;
- Severe mobility limitations;
- Active smokers or recent cessation (<3 months).

Sample size calculation: Sample size calculation was based on six minute walk distance from a previous study with an effect size of 0.8, α=0.05, and power (1-β)=0.80 were used [17]. Using the "Formula"

$n=2(Z_{1-}\alpha_{/2} + Z_{1-\beta})^2 / d^2$

where n=number of participants per group

$Z_{1-\alpha/2}=1.96$

$Z_{1-\beta}=0.84$

d=0.8

$n=2(1.96 + 0.84)^2 / 0.8^2$

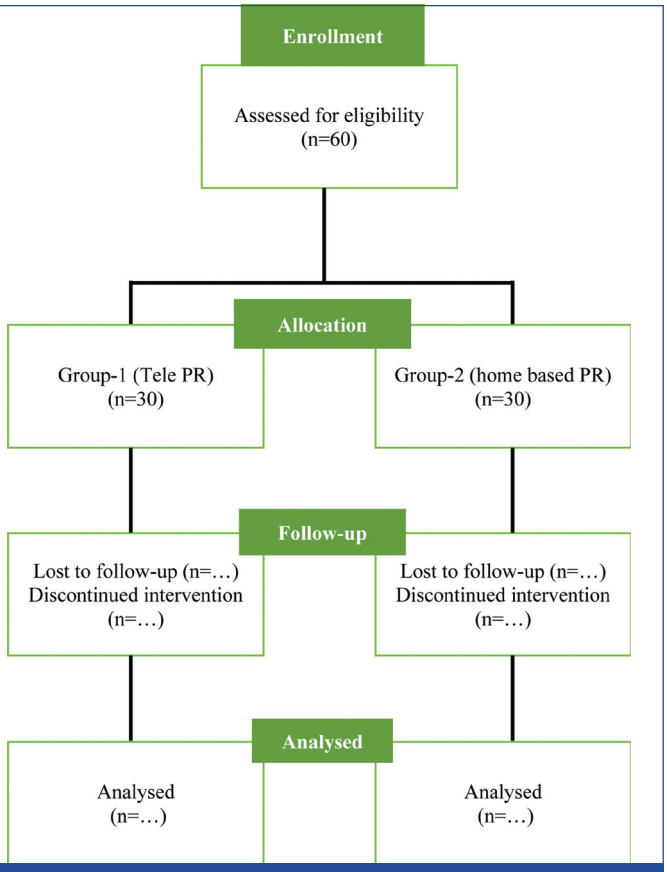
$n=2(2.8)^2 / 0.64$

n=25

Therefore, the total number of participants per group is to be 25, with a total sample size of 50. Considering 20% dropout rate, the total sample size was adjusted to 60, with 30 participants per group. Participants will be recruited from the respiratory medicine outpatient department. Patients with confirmed COPD will be screened for eligibility based on age, diagnosis, disease stability, and willingness to participate. Written informed consent will be obtained from eligible individuals before

enrollment. Participants who meet the inclusion and exclusion criteria will then undergo baseline assessments of balance, cognition, and ADL, followed by spirometry to confirm the diagnosis of COPD.

Following baseline assessment, participants will be randomly allocated in a 1:1 ratio to either the supervised Tele-PR group or the unsupervised home-based PR group [Table/Fig-1]. Randomisation will be performed using computer-generated block randomisation (block size=4) by the primary researcher, with allocation concealed in sealed opaque envelopes.



[Table/Fig-1]: CONSORT flow diagram.

Study Procedure

Participant enrollment will be conducted by the principal investigator, who will remain unaware of group assignment until the envelope is opened after baseline assessment. Outcome assessors and statistical analysts will be blinded to group allocation. Participant confidentiality will be maintained throughout the study, and access to study data will be restricted to the research team. After outcome measure assessment all the participants will provide an educational session comprises of correct medication use, follow structured rehabilitation plan, cessation of smoking, lifestyle modification to minimise dyspnea.

Participants in Group 1 will receive supervised PR through tele-rehabilitation (Tele-PR), while those in Group 2 will undertake an unsupervised home-based PR program. Group 1 will attend exercise sessions via videoconferencing using Google Meet, with meeting links shared directly with participants. Group 2 will perform the same exercise protocol independently at home [Table/Fig-2]. To enhance adherence, all participants will receive an exercise booklet and be instructed to maintain a logbook documenting their exercise sessions. Regular telephone reminders will be provided to encourage compliance with the prescribed program.

In Group 1, sessions will be conducted in real time under supervision. Participants will be grouped based on recruitment time and similar progression rates; if more than three patients per day demonstrate comparable progress, they will be assigned to group sessions; otherwise, sessions will be conducted individually. Missed sessions will be compensated using the remaining day of the week. The program will be conducted for six days per week over six weeks, with one rest day. Each session will last approximately 55 minutes and include a warm-up (10 minutes), endurance training (target 10 minutes), strength training (20 minutes with 30-second rest intervals between sets), and respiratory training (15 minutes). Walking duration will be standardised to 10 minutes per session, irrespective of track. Exercise intensity will begin at 50% of HR_{max} to minimise dyspnoea and will be progressively increased by 10%, with progression stabilising after the fourth week. Baseline assessment will include measurement of 1RM, and further progression will follow standard training principles. Any adverse event during a session will lead to immediate termination for that day, and caregivers will be advised to closely monitor the patient and ensure the availability of transport to a hospital if required.

Warm up			
Exercises	**Frequency**	**Duration**	**Repetitions**
Neck rotations	6D/Week	10 minutes	1 set of 10 repetitions
Neck tilts			
Trunk rotations			
Static march			
Endurance training	**Procedure**	**Intensity**	**Frequency**
Brisk walking	Walk on flat ground for 10 minutes	50% of the maximum heart rate (HR_{max}), the intensity will be gradually increased by 10% of HR_{max} every week till 4th week.	6D/Week
Strength training			
Dynamic quads	While sitting on the bed with legs touching the ground, raise the legs.	50% of 1RM	2 sets of 10 repetitions each. 30-secs interval 6D/Week
Dynamic hams	While lying on your stomach on the bed, fold the legs.	50% of 1RM	2 sets of 10 repetitions each. 30-secs interval 6D/Week
Arm curl	Hold the weight in your hands and curl your hands toward your shoulders.	50% of 1RM	2 sets of 10 repetitions each. 30-secs interval 6D/Week
Shoulders front raise	Hold the weights in your hands and raise the arm forward.	50% of 1RM	2 sets of 10 repetitions each. 30-secs interval 6D/Week
Shoulders lateral raise	Hold the weights in your hands and raise the arm laterally.	50% of 1RM	2 sets of 10 repetitions each. 30-secs interval 6D/Week
Respiratory training			
Active Cycle of Breathing Technique (ACBT)	3 cycles of controlled breathing, following 3 deep breaths, holding it for 5 secs, then last forceful expiration with coughing the secretions out.		1 set of 3 cycles
Pursed-lip breathing	Inhale through the nose and blow the air out through the mouth as if you are trying to blow out the candle.		2 sets of 10 breaths. 30-second interval 6D/Week
Exhalation on effort	Stand and inhale while raising your arms above your head, and blow the air as you bend down.		2 sets of 10 breaths. 30-second interval 6D/Week

[Table/Fig-2]: Intervention protocol to be administered in both study groups.

Outcome Measures

- **Pulmonary functions:** FEV1, FVC, and FEV1/FVC, will be measured using spirometry, RMS Helios 401 software will be used following American Thoracic Society (ATS) / European Respiratory Society (ERS) guidelines [18].

- **Cognition:** To measure the cognition of the participants, the H-MoCA scale, a validated adaptation of the original MoCA (ICC: 0.87), will be used [19]. It is a translated and culturally adjusted version for Hindi-speaking populations to screen for mild cognitive impairment. MoCA score threshold (>24) was used as part of the participant screening and eligibility criteria. This threshold was applied to ensure that participants had sufficient cognitive function to understand instructions, engage effectively in tele-rehabilitation sessions, and participate safely in the intervention. At the same time, cognition remained one of the study outcome variables, and MoCA was additionally used to evaluate changes in cognitive performance following the intervention. Thus, serving the dual function.
- **Balance:** The BBS (ICC: 0.99) will be considered to assess the participants' balance [20]. It is a 14-item performance-based measure evaluating static and dynamic balance through functional tasks such as sit-to-stand, reaching forward, tandem stance, and single leg stance, each bearing a score of 0-4 with a total of 56 as a higher score.
- **Functional outcomes:** The Londrina ADL Protocol (ICC: 0.91) will be used as an outcome measure to assess the functional outcomes of the participating individuals [21]. It is a validated, performance-based test designed to assess functional capacity in COPD patients, preferred over the 6MWT because of the inclusion of realistic daily tasks, comprising five different stations, i.e., arranging objects on a table, walking while carrying bags, hanging clothes on a clothesline, arranging items on shelves, and a final 6m walk. The total time taken to complete all the tasks is recorded.

The outcomes will be assessed at baseline, after the allocation and post intervention at six weeks. Patients will come back after the session for follow-up.

STATISTICAL ANALYSIS

Data will be analysed using Statistical Package for Social Sciences (SPSS) version 30.0. Data normality will be assessed using the Kolmogorov-Smirnov test. Normally distributed data will be presented as mean±standard deviation and analysed using paired t-tests for within-group comparisons and independent t-tests for between-group comparisons. Non-normally distributed data will be presented as median (interquartile range) and analysed using the Wilcoxon signed-rank test for within-group comparisons and the Mann-Whitney U test for between-group comparisons. A p-value <0.05 will be considered statistically significant.

REFERENCES

[1] Agustí A, Celli BR, Criner GJ, Halpin D, Anzueto A, Barnes P, et.al. Global Initiative for Chronic Obstructive Lung Disease 2023 Report: GOLD Executive Summary. Am J Respir Crit Care Med. 2023;207(7):819-37. Doi:10.1164/rccm.202301-0106PP.

[2] Lareau S, ZuWallack R, Nici L. Increasing quality and quantity of life in individuals with chronic obstructive pulmonary disease: A narrative review with an emphasis on pulmonary rehabilitation. Life (Basel). 2025;15(5):750. Published 2025 May 7. Doi: 10.3390/life15050750.

[3] Tounsi B, Acheche A, Lelard T, Tabka Z, Trabelsi Y, Ahmaidi S. Effects of specific inspiratory muscle training combined with whole-body endurance training program on balance in COPD patients: Randomized controlled trial. PLoS One. 2021;16(9):e0257897.

[4] Johns DP, Walters JA, Walters EH. Diagnosis and early detection of COPD using spirometry. Journal of Thoracic Disease. 2014;6(11):1557-69.

[5] Joyce A, Fair N, Fongeh T. An overview of the non-pharmacological and non-surgical management of chronic obstructive pulmonary disease. Med Res Arch. 2020;8(6):01-23. Available from: https://esmed.org/MRA/mra/article/view/2178. Doi: 10.18103/mra.v8i6.2178.

[6] Janssens W, Verleden GM. Nonpharmacological interventions in COPD. European Respiratory Review. 2023;32(167):230028.

[7] Vu SP, Veit K, Sadikot RT. Molecular approaches to treating chronic obstructive pulmonary disease: Current perspectives and future directions. International Journal of Molecular Sciences. 2025;26(5):2184.

[8] Wouters EF, Posthuma R, Koopman M, Liu WY, Sillen MJ, Hajian B, et al. An update on pulmonary rehabilitation techniques for patients with chronic obstructive pulmonary disease. Expert Review of Respiratory Medicine. 2020;14(2):149-61.

[9] Ammous O, Feki W, Lotfi T, Khamis AM, Gosselink R, Rebai A, et al. Inspiratory muscle training, with or without concomitant pulmonary rehabilitation, for chronic obstructive pulmonary disease (COPD). The Cochrane Database of Systematic Reviews. 2023;2023(1):CD013778.

[10] Rochester CL. Barriers to pulmonary rehabilitation. Respiratory Care. 2024;69(6):713-23.

[11] Burge AT, Cox NS, Holland AE, McDonald CF, Alison JA, Wootton R, et al. Telerehabilitation Compared with Center-based Pulmonary Rehabilitation for People with Chronic Respiratory Disease: Economic Analysis of a Randomized Controlled Clinical Trial. Annals of the American Thoracic Society. 2025;22(1):47-53.

[12] Promsarn S, Rattanasaengloet K. Telerehabilitation in Chronic Obstructive Pulmonary Disease (COPD) management: Exploring experiences and effectiveness. Journal of Health Science and Medical Research. 2024;42(5):20241057.

[13] Paneroni M, Colombo F, Papalia A, Colitta A, Borghi G, Saleri M, et al. Is telerehabilitation a safe and viable option for patients with COPD? A feasibility study. COPD: Journal of Chronic Obstructive Pulmonary Disease. 2015;12(2):217-25.

[14] Graham BL, Steenbruggen I, Miller MR, Barjaktarevic IZ, Cooper BG, Hall GL, et al. Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. Am J Respir Crit Care Med. 2019;200(8):e70-e88. Doi: 10.1164/rccm.201908-1590ST. PMID: 31613151.

[15] Ora J, Prendi E, Attinà ML, Cazzola M, Calzetta L, Rogliani P. Efficacy of respiratory tele-rehabilitation in COPD patients: Systematic review and meta-analysis. Monaldi Archives for Chest Disease. 2022;92(4):2249.

[16] Villeneuve S, Pepin V, Rahayel S, Bertrand JA, de Lorimier M, Rizk A, et al. Mild cognitive impairment in moderate to severe COPD: A preliminary study. Chest. 2012;142(6):1516-23.

[17] Galdiz JB, Gómez A, Rodriguez D, Guell R, Cebollero P, Hueto J, et al. Telerehabilitation Programme as a Maintenance Strategy for COPD Patients: A 12-Month Randomized Clinical Trial. Arch Bronconeumol (Engl Ed). 2021;57(3):195-204. Doi: 10.1016/j.arbres.2020.03.034.

[18] Rajdeep P, Poorey K, Patel RK, Oommen ER. A pilot study for development of a pulmonary function test induction jacket to automate effort in performing the forced vital capacity manoeuvre. Sci Rep. 2023;13(1):8004. Published 2023 May 17. Doi: 10.1038/s41598-023-34930-1.

[19] Gupta M, Gupta V, Buckshee RN, Sharma V. Validity and reliability of hindi translated version of Montreal cognitive assessment in older adults. Asian Journal of Psychiatry. 2019;45:125-28.

[20] Viveiro LA, Gomes GC, Bacha JM, Junior NC, Kallas ME, Reis M, et al. Reliability, validity, and ability to identity fall status of the Berg Balance Scale, Balance Evaluation Systems Test (BESTest), Mini-BESTest, and Brief-BESTest in older adults who live in nursing homes. Journal of Geriatric Physical Therapy. 2019;42(4):E45-E54.

[21] Paes T, Belo LF, da Silva DR, Morita AA, Donária L, Furlanetto KC, et al. Londrina activities of daily living protocol: Reproducibility, validity, and reference values in physically independent adults age 50 years and older. Respiratory Care. 2017;62(3):298-306.

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