Tele-rehabilitation for patients who have been hospitalised with Covid-19: a mixed-methods feasibility trial protocol

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Abstract

Background: Tele-rehabilitation has been proposed as a post-hospitalisation rehabilitation pathway for Covid-19 survivors, however patients' willingness and ability to engage with this online intervention remains unknown. **Objectives:** The aim of this study is to determine the feasibility of tele-rehabilitation in this population, specifically with regards to recruitment, intervention acceptability and adherence, data quality and primary outcome measure selection. **Methods:** A protocol for a single centre, fast-track (wait-list), randomised mixed-methods, feasibility trial of tele-rehabilitation for patients that have been hospitalised with Covid-19 is presented. The tele-rehabilitation programme is based on pulmonary rehabilitation principles and will encompass an initial assessment followed by twice-weekly exercise classes and education sessions for 6 weeks. Six educational sessions on the topics of rehabilitation from Covid-19; coping with breathlessness; exercise; nutrition; return to work; and fatigue management will be delivered by a multi-disciplinary team of healthcare professionals. A series of feasibility, clinical and safety outcomes will be quantitively described and patient experiences and opinions explored using thematic analysis of semi-structured interviews. **Discussion:** We anticipate that results from the study will inform a multi-centre randomised controlled trial for post-Covid-19 tele-rehabilitation and the results from the qualitative analysis may provide guidance to improve participant experience.

Key words:

Covid-19, tele-rehabilitation, pulmonary rehabilitation, long-Covid, post-Covid-19 syndrome

Introduction

The Coronavirus disease 2019 (Covid-19), due to the novel severe acute respiratory syndrome coronavirus-2 (SARS-Cov-2), has caused worldwide mass hospitalisation. Covid-19 has a clinical spectrum ranging from asymptomatic to multi-organ failure and death, with respiratory symptoms being the leading cause of hospitalisation (1). Hospitalisation rates for Covid-19 are higher amongst elderly individuals and those with underlying health conditions (2,3). Around 17% of hospitalisations require high dependency or intensive care input (1).

There are likely to be on-going rehabilitation needs following a period of hospitalisation with Covid-19, particularly in vulnerable patients and those who require prolonged ICU input (4). Indeed, many patients report persistent health problems (e.g., fatigue, breathlessness and chest and joint pain, amongst others) lasting beyond 12 weeks post-infection, which has been labelled post-Covid-19 syndrome or 'long-Covid' (5-7). Both patients who require hospitalisation and those who recovered from infection in the community have reported significant symptom burden from post-Covid-19 syndrome (5-7).

Proposals for post-hospitalisation rehabilitation for Covid-19 survivors have been presented and are based around the principles of pulmonary rehabilitation, albeit delivered remotely to facilitate social distancing (4,8). Indeed, The World Health Organisation (WHO) recommends that tele-rehabilitation should be used to deliver rehabilitation wherever feasible during the Covid-19 pandemic [17] and guidance from respiratory societies propose that rehabilitation should be based on the principles of pulmonary rehabilitation, [10,18], which has some limited evidence for being beneficial in outbreaks of viral pneumonias (9). Additional benefits of tele-rehabilitation that may make it appropriate in the

Covid-19 pandemic include; i) reduced treatment costs, ii) improved accessibility, and iii) enhanced scalability, which would likely far exceed that of in-person rehabilitation services.

The principle function of pulmonary rehabilitation is to improve symptoms of patients with chronic respiratory conditions. A standard multidisciplinary pulmonary rehabilitation programme consists of 12 face-to-face group sessions, over 6-12 weeks, featuring educational, social and physical elements, which aim to improve numerous outcome measures (i.e., exercise capacity, quality of life, respiratory symptoms and anxiety and depression) (10). Whilst the body of evidence for pulmonary rehabilitation for respiratory conditions such as COPD is strong (10), the extent to which a Covid-19 population would benefit from pulmonary rehabilitation is currently unknown. Furthermore, the body of evidence for remotely delivered pulmonary rehabilitation or tele-rehabilitation is much smaller, with heterogeneity surrounding the rehabilitation protocols (11).

Randomised clinical trials of tele-rehabilitation for Covid-19 patients are required. However, before a full clinical trial can be developed, it is important to determine; i) the symptom burden of people after being discharged from hospital for Covid-19; ii) patient's willingness and ability to perform tele-rehabilitation in their own home using video-link to connect with their therapist in a group situation; iii) the most appropriate outcome measures to assess intervention efficacy, and iv) patients' perspectives of a tele-rehabilitation programme. This protocol for a single centre, fast-track (wait-list), randomised, mixed-methods, feasibility trial of tele-rehabilitation for patients who have been hospitalised with Covid-19 is designed to answer these questions in order to inform the design of a full clinical trial.

Methods

Research Governance

Health Research Authority (HRA) and NHS Research Ethics Committee approval was obtained (reference number; 20/IEC08/0017) and the trial registered with clinicaltrials.gov (reference; 285205).

Research Design

A single centre, fast-track (wait-list), randomised, mixed-methods, feasibility trial of tele-rehabilitation for patients who have been hospitalised with Covid-19.

Study Population

Patients discharged from Castle Hill Hospital, Cottingham, and Hull Royal Infirmary, Hull, both part of Hull University Teaching Hospitals NHS Trust, will be recruited to this study. This trial aims to recruit forty individuals who have been hospitalised with Covid-19 within the last 6 months, that suffer ongoing persistent breathlessness (MRC dyspnoea grade 2 or more) and/or functional limitations compared with pre-Covid-19 illness at the time of recruitment. The study start date is July 2020 and is due to conclude July 2021. Full inclusion and exclusion criteria are presented in Table 1.

Participant identification

Participants will be identified by their clinical team during routine tele-consultation, 4-6 weeks following hospital discharge. Eligible participants will be contacted by a research physiotherapist (MN, AG, JS), who will provide the participant information sheet and answer and queries. Willing eligible participants will provide full informed consent.

Randomisation

Participants will be randomised in a 1:1 ratio to fast-track or wait-list groups, using a commercial web-based randomisation system (Sealed Envelope Ltd, London, UK). Randomisation will occur after eligibility has been established, informed consent obtained, and baseline measurements collected from patients to reduce initial attrition. Patients randomised to the fast-track group will receive intervention 14 ± 7 days after randomisation. Patients randomised to the wait-list group will receive the intervention 56 ± 7 days after randomisation (Figure 1).

Study Intervention

The tele-rehabilitation programme will be delivered by trained therapists (MN, AG, JS, AS , LH) and will be structured using conventional pulmonary rehabilitation principles (i.e., twelve core sessions of group exercise, with additional opportunities of educational sessions and peer support) (9).

The tele-rehabilitation programme will be delivered via a video conferencing application. It will comprise of an initial assessment, followed by 12 sessions delivered via video link over a 6-week period. Participants will be advised to undertake exercises on up to 3 additional days of the week, resulting in 5 days of exercise participation a week, where applicable. Usual care will continue throughout the study to all participants

Exercise programme

Prior to commencing any exercise, a physiotherapist will conduct a virtual consultation to check eligibility, accessibility and safety to exercise with remote supervision. The exercise programme was developed in consultation with physiotherapists (MN, JS, AG) and an accredited strength and conditioning coach and lecturer (PM). A particular emphasis was placed on functional movement

patterns. Participants will receive an individualised exercise programme based on their goals, current levels of exercise tolerance and functional activity level.

Twice a week participants will be invited to join a virtual exercise class in a group of approximately 5 people. The classes will be led by a physiotherapist and will include a structured warm-up, guidance/demonstration and observations of exercises, consisting of cardiovascular, flexibility, strength based movements, balance work and a cool down with structured relaxation element. At each session, the patients' individual exercise programme will be reassessed and progressions/regressions to the exercises modified as appropriate.

Educational sessions and peer support

Once a week, participants will be invited to an educational session on relevant topics (Table 2), and will be afforded time to share experiences and ask questions of their peers and physiotherapy staff, to encourage a sense of community and peer support. We are not able to provide psychological counselling as part of the intervention. However, patients will be sign-posted to relevant services where applicable.

Outcome measures

Due to the multidisciplinary nature of the intervention and the novel nature of the disease, numerous outcome measures will be collected to capture potential patient benefit. We have selected conventional clinical outcome measures that reflect a change in exercise capacity, quality of life, symptoms and levels of anxiety and depression. Further, multiple feasibility and safety outcomes will be measured at various time points, as described below and detailed in the schedule of procedures (Table 3).

Feasibility outcomes

Recruitment: contact to consent ratio; screen failure rate; recruitment rate; retention/follow-up rates will be measured at each time point. Data quality will be assessed by the completion of clinical outcomes (questionnaires and other assessments) at each contact point. Intervention adherence will be recorded by attendance at each rehabilitation session.

Clinical outcomes

Exercise capacity will be measured using the one-minute sit-to-stand test (12). Participants will undertake this assessment in their own homes while observed via an audio or video link.

Respiratory symptoms will be measured using; the modified Medical Research Council dyspnoea scale (mMRC) (11); Numerical Rating Scale (NRS) / Visual Analogue Scale (VAS) (scored 0-10 where 0 = no breathlessness and 10 = worst possible breathlessness) (13) and the modified Functional Assessment of Chronic Illness Therapy: Fatigue (version 4) (14).

Quality of life will be measured by the EQ-5D-5L (15) and the EQ visual analogue scale (EQ VAS). The EQ-5D-5L will measure 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) using 5 levels (no problem, slight problem, moderate problems, severe problems and extreme problems).

Mood will be assessed using the hospital anxiety and depression scale (HADS) (16). The EQ-5D-5L will also provide insight to the participants' mood as anxiety and depression domains will be measured.

Safety monitoring

The adverse events (AE) reporting period for this trial begins at screening and ends at the participant's final study visit. Each trial participant will be questioned about adverse events at each visit. The investigator will record all directly observed AEs and all serious adverse events (SAEs) spontaneously reported by the trial participant. A pre-existing condition (i.e. a disorder present before the AE reporting period started and noted on the pre-study medical notes), will not be reported as an AE unless the condition worsens, or episodes increase in frequency during the AE-reporting period.

Service evaluation questionnaire and semi-structured interviews

Following the tele-rehabilitation programme, all patients will be asked to complete a service evaluation survey using an online survey provider [Joint Information Systems Committee (JISC), Bristol, UK], on the topics of; programme content, satisfaction with therapy staff and satisfaction with the video platform.

Following completion of the rehabilitation programme a sub-set of patients (n=12) will be asked to participate in an interview to further explore their experience of the tele-rehabilitation programme. As part of this exploration, patients will be asked to write down their expectations for the rehabilitation programme before it begins. The interviews will be led by a physiotherapist who is independent to the delivery of the rehabilitation programme, with extensive qualitative research experience (CK). The topic guide for the semi-structured interview and example questions are provided in Table 4.

Data analysis plan

Descriptive statistics

For the primary outcomes, the feasibility criteria will be recruitment rate, retention rate, adverse events, compliance and acceptability of the intervention. The recruitment rate, consisting of the eligibility and consent rate will be calculated with 95% confidence intervals. Tables showing baseline demographic and clinical characteristics for each of the groups will be presented to indicate differences between the groups. Medians will be reported for ordinal data, mean for continuous data and raw count for nominal data.

For patient clinical outcome data, descriptive statistics: mean for continuous outcomes, medians for ordinal data and raw count for categorical outcomes will be reported. This will be presented for each group at each time point. These sizes will be used to inform the selection of the primary endpoint, primary outcome measure and the sample size for the definitive randomised controlled trial. Safety data will be summarised using descriptive statistics.

Qualitative analysis

The semi-structured interviews will be recorded, transcribed verbatim, and will undergo thematic analysis (17) by an experienced qualitative researcher, who is independent to the delivery of the programme (CK).

Computer assisted qualitative data analysis software (NVivo 12) will be used to ensure transparency and provide an audit trail of the data analysis process (18). Each interview will be read and re-read multiple times to allow immersion and gain familiarity with the depth and breadth of the data. Data will then be coded inductively to express the data as forms of concepts. These initial codes will subsequently be sorted into potential themes which will be refined, defined, and then reported as

themes (17). A second member of the research team will independently cross-check sections of the qualitative data analysis by comparing the codes and themes to the transcripts. Any discrepancies with the themes or coding will be resolved through discussion with the wider research team to reach consensus.

Discussion

The global Covid-19 pandemic has led to mass hospitalisation of patients often requiring respiratory support. There is an evident need for a post-hospitalisation rehabilitation pathway for Covid-19 patients (4). Guidance from The WHO and several respiratory societies propose that rehabilitation should be provided remotely (19) and based on the principles of pulmonary rehabilitation (11,20). However, the efficacy of tele-rehabilitation for Covid-19 survivors is currently unknown. Prior to a full clinical trial, it is important to conduct a feasibility study to identify uncertainties regarding study design (i.e., recruitment, intervention adherence / preference, data quality and outcome measure selection). Here we present a protocol for a single centre, fast-track (wait-list), randomised, mixed-methods, feasibility trial of tele-rehabilitation for patients who have been hospitalised with Covid-19, in accordance with the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) statement (21), CONSORT 2010 statement on feasibility trials (22) and the Template for Intervention Description and Replication (supplementary material).

Whilst adhering to the standard pulmonary rehabilitation model of 12 supervised sessions over 6 weeks, our rehabilitation programme offers several features. Firstly, we opted for synchronised (live) group exercise sessions twice per week. This approach allows for regular contact with participants and for continued review of safety aspects and adjustments to their individualised exercise

programme, based on patient feedback and direct observation. Further, the group approach facilitates a sense of community, which itself is identified as a valuable aspect of pulmonary rehabilitation (23). A multidisciplinary team of physiotherapists, exercise physiologists and a strength and conditioning coach developed the exercise programme. The programme was designed for completion at home, without additional equipment, and the exercises intended to improve functional movement patterns. Progressions, regressions and alternatives to each functional movement pattern can be prescribed as appropriate on an individual basis. This means that all patients will complete similar movements and activate similar muscle groups, but will work at a level appropriate for their ability.

The characteristics of Covid-19 patients discharged from the participating NHS Trust during wave one have been analysed (24). Based on these data, we do not anticipate the number of eligible participants to be a significant issue, however the recruitment rate of these participants to tele-rehabilitation is yet to be established. Further, it is now apparent that patients who avoided hospitalisation are also suffering post-Covid-19 syndrome (7) and may benefit from tele-rehabilitation. Their inclusion in a full randomised controlled trial should therefore also be considered.

Adherence to pulmonary rehabilitation is low in COPD (25). However, adherence to rehabilitation programmes in a Covid-19 population is unknown. We will assess adherence to exercise sessions, both live and prescribed, and education sessions to inform a randomised controlled trial. Further, we have incorporated a service evaluation questionnaire and semi-structured interviews to facilitate feedback with regards to patients' experiences, preferences, facilitators and barriers to the rehabilitation programme. The strength of this mixed-method approach is likely a better depth of understanding into the patients' lived experience of tele-rehabilitation, which will inform the

randomised controlled trial and ensure it better meets participant needs. Further, in light of a dearth of knowledge on the topic, these insights may facilitate better patient centred care in the short-term management of Covid-19 survivors.

The outcome measure selection includes recording of safety aspects (i.e., adverse events) and many clinical outcomes that are routinely captured during pulmonary rehabilitation (10). Some variations were required due to logistical constraints with remote delivery, for example the one-minute sit-to-stand test was favoured over the six-minute walk test (6MWT). The one-minute sit-to-stand test has been shown to be a reliable, valid and responsive test for measuring functional exercise capacity and is comparable to the 6MWT in a large population of COPD patients (12), however its validity in a Covid-19 population is still unknown. Further, we have included several additional clinical outcomes which were deemed appropriate for a Covid-19 population (i.e., a health-related quality of life questionnaire and a fatigue related questionnaire).

A proposal for a multidisciplinary tele-rehabilitation service for the assessment and rehabilitation of Covid-19 survivors has been proposed by members of the research team (AG, MGC) (24). In short, the Covid-19 pandemic has caused i) an unprecedented case load of patients discharged with residual rehabilitation needs, ii) restrictions in terms of movement and social distancing, and iii) reduced capacity of community rehabilitation services. Tele-rehabilitation may address these problems by offering a means to deliver remotely supervised therapy to patients within their homes. Further, the added convenience of tele-rehabilitation may facilitate better adherence and satisfaction (26). Tele-rehabilitation is not a new concept and has been shown to be effective and safe in COPD (27,28), the novelty here is its application to a new disease.

The protocol has some limitations, for example it will be performed in only one centre and will include a mixed profile of participants, including some which require prolonged hospital stay, ventilator support, and other organ support. To address these aspects, the rehabilitation programme is designed to be flexible to patients' needs, with regards to the exercise prescription and educational content. Another cofounding variable is that patients' pre-Covid-19 functional capacity will be collected subjectively on a screening questionnaire, which has not been validated against an objective measure of functional capacity.

In summary, we provide a protocol for a single centre, fast-track (wait-list), randomised, mixed-methods, feasibility trial of tele-rehabilitation for patients who have been hospitalised with Covid-19. We anticipate that the findings from this study will be used to directly inform the design of a randomised control trial and may help improve the rehabilitation of Covid-19 survivors. If successful, this intervention would be inexpensive and could be implemented on a large scale.

Disclosure Statement

The authors report no conflict of interest

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Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria

- Males and females aged ≥ 18 years
- Suspected or confirmed Covid-19 requiring hospitalisation within 6 months of study recruitment. Requirement for either: non-invasive respiratory support [CPAP, HFNO, NIV], or invasive mechanical ventilation will be recorded but is not necessary for enrolment in the trial.*
- >4 weeks since hospital discharge/ first positive Covid-19 swab (whichever is later) at time of screening
- mMRC dyspnoea grade 2 or more
- Perceived limitation of activities compared with pre-Covid-19 hospitalisation (patient or investigators perception)
- Internet connection and access to a device that supports video calling
	- Unwilling or unable to consent or complete study measures
	- Significant comorbid physical or mental illness considered by the investigator to:
	  - prevent engagement in modified exercise
	  - impair the participant's ability to follow instructions
	  - place the participant at undue risk during exercise training
	  - adversely affect the recovery or rehabilitation trajectory
	- Current involvement in other interventional clinical trials relating to Covid-19 (e.g. clinical trial of an investigation medicinal product)

CPAP, Continuous Pulmonary Airways Pressure; HFNO, High Flow Nasal Oxygen; NIV, Non-Invasive Ventilation; mMRC- modified Medical Research Council Dyspnoea Scale. * Originally only patients receiving respiratory support were eligible for inclusion, however the inclusion criteria were amended early in the course of the study to expand eligibility to all hospitalised Covid-19 patients.

410 Table 2. Educational session content

Education session	**Indicative content**
Rehabilitation of Covid-19	Disease anatomy, physiology and pathology; rehabilitation process; expectations.
Principles of exercise	Management of atrophy; exercise programming; goal setting; cycles of activity/inactivity; functional movement; musculoskeletal problems.
Managing breathlessness	Pacing; breathing techniques; managing functional breathing; long-term oxygen therapy (where applicable).
Managing fatigue	Sleep hygiene, pacing strategies, energy conservation, graded exercise therapy, gradual resumption of activities, mitigation of the development of chronic fatigue.
Return to work / social issues	Returning to work; return to driving; relationships; isolation/loneliness.
Nutrition	Education on diet enrichment; healthy weight management.

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412 Table 3. Schedule of procedures

Visit	Eligibility and baseline assessment	Randomisation (Day 0) Fast-Track Group Receive Intervention (Day 14±7 - 56±7)	Fast Track Start-of-treatment	Fast Track End-of-treatment	Wait-List Group Receive Intervention (Day 56±7 - 98±7)	Wait List Start-of-treatment	Wait List End-of-treatment / End of Study	Post-study survey and qualitative assessment
Day	**0**		**14 ± 7**	**56 ± 7**		**56 ± 7**	**98 ± 7**	
Procedure								
Inclusion/exclusion criteria	x							
Informed consent	x							
Medical history	x							
Medication history	x							
Covid-19 history	x							
AE monitoring			x	x		x	x	
Questionnaires	x		x	x		x	x	
One-minute sit-to-stand test	x		x	x		x	x	
Assessment of intervention adherence				x			x	
Health care utilisation	x		x	x		x	x	
Service evaluation survey								x
Semi-structured interviews								x

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415 Table 4. Semi-structured interview guide

Topic	**Example questions [and prompts]**
Expectations of the rehabilitation programme	Tell me about the expectations you wrote down before joining the exercise programme.
Experience of rehabilitation programme	How would you describe your experience of the rehabilitation programme? [What was your favourite part? What did you find most challenging?] How do your experiences compare to the expectations you had prior to the programme? If you missed any of the sessions, what were the reasons? [Time, diary conflict, health, not motivated] How does participating in the sessions make you feel? [Physical health (muscle strength, level of breathlessness, ability to do jobs around the house); mental health (mood); social aspects]
Attitudes towards exercise / physical activity	What were your attitudes towards exercise prior to Covid-19? How have these changed since contracting Covid-19? Has the rehabilitation programme affected these attitudes in any way? Have you participated in other exercise programmes in the past? What's the difference between this programme and your past experiences? If there was an opportunity to keep exercising together is this something you would be keen to do? Would you prefer ongoing exercise in a group or individual setting?
Specific comments on the exercise components	How would you describe your relationship with exercise during the programme? Tell me about how the specific exercises have been for you. [Have any been particularly easy or difficult?] How do you feel after the class? [Tired, energetic, motivated] Tell me about any exercise you completed outside of the group session. [Did you engage in any? Did you find it easy or

	difficult? Did your engagement differ between the online sessions and the prescribed exercise outside of the classes?]
Specific comments on the education and social elements	Tell me about the social aspects of the group. How have you found the educational aspects of the sessions? [Which ones have been most helpful? Which ones have not been as relevant for you? Is there a topic you would have liked to have been included?]
Role of the instructor	How did you find the delivery method/s employed in the programme? Is there anything about the way that the group is led that is helpful for you? Anything that makes it challenging for you?
Experience with technology	How did you find the delivery platform / technology used in this project? Have you any previous experience of using this type of technology? Is there an alternative platform / delivery method you feel would work better / be more effective? [Preferences regarding face-to-face or online delivery] If you experienced any problems / issues with the technology what were these? How do you feel these could best be overcome?

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Figure caption

Figure 1. Study flow chart: the left side of the diagram illustrates the time frame for the fast-track group, and the right illustrates the time frame for the wait-list group.