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Evaluating a new model of rehabilitation for individuals recovering from COVID-19

Submission date
21/08/2020

Recruitment status
No longer recruiting

Registration date
02/10/2020

Overall study status
Completed

Last Edited
09/06/2023

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Those recovering from COVID-19 are likely to experience high levels of physical, cognitive, and social impairments. In the UK, approximately 50% of survivors will require additional rehabilitation within the community to help them recover. Despite this, there is currently no evidence-based guideline available in England and Wales that addresses how best to rehabilitate these individuals. It is now important to rapidly develop and evaluate a new rehabilitation service to support patients and health services at large. Nuffield Health, the UK's largest not-for-profit healthcare charity have responded by configuring a multi-disciplinary team to create a rehabilitation pathway addressing the immediate requirements for those recovering from COVID-19 in the community.
This study aims to investigate the immediate and long-term impact of a new rehabilitation programme on quality of life as well as symptoms relating to COVID-19. The cost-effectiveness and overall experience of those completing the rehabilitation programme will also be evaluated.

Who can participate?
Adults who have been discharged from hospital care following treatment for COVID-19 are eligible for this rehabilitation programme. Specifically, individuals that can walk independently for at least 20 meters, have access to the internet and smartphone/tablet/personal computer (with adequate technological literacy) and have access to transport to attend rehabilitation are eligible.

What does the study involve?
The rehabilitation programme is split into two distinct phases:
Weeks 1-6 will consist of 3 exercise sessions per week. Session 1 will be an online live-streamed activity conducted by 2 Nuffield Health trained rehabilitation specialists. One practitioner will run the exercise session and the second will answer questions via the online chat function. The stream will be a 1-way stream, meaning that whilst multiple patients will access the stream at any given time, they will not be recorded/filmed nor will their personal details be visible to the group. A maximum of 10 patients will join a stream at any time. The live stream will last up to 45 minutes followed by a 15-minute period for questions via the secure online chat function or alternatively spoken questions can be provided should the patient have microphone functionality.

The second session of the week during phase 1 will be self-directed. The patient will be directed to a pre-recorded guided exercise session located on a dedicated online platform (Vimeo, New York, USA). This will be a 45-minute activity which the patient completes at their leisure. All exercises are designed such that they can be carried out with ease at home.

The third exercise session of the week is described as 'build your own'. The patient's workbook provides the patient with a menu of activities suitable for them, which they may select to populate an exercise session commensurate with their personal threshold.

Each week the patient will be provided with a phone call that will last up to 45-minutes with the rehabilitation specialist. The aim of the phone call is to listen to any patient queries but to also offer support on themes such as exercise selection, symptom management and emotional wellbeing. Nuffield Health specialists have comprehensive training in each of these areas. Prior to progressing to Phase 2 patients will receive a remote mid-point review by the rehabilitation specialist. Progress will be discussed in detail and the patient will be asked if they feel ready and willing to progress to phase 2. If their progress is deemed insufficient, the patient will be recommended to complete another 6-week digital programme in full, before moving into a gym-based setting. Progress will be reviewed weekly and patients will be able to join the face to face component at a later point. All group-based sessions will be offered at two timepoints across the course of the day, with an AM and PM option. All one to one activity such as the weekly phone calls will be booked according to participant preference on a weekly basis.

Phase 2
Following successful completion of phase 1, patients will progress to the phase 2 face to face programme. This phase will be conducted in strictly controlled gym environments conforming to all necessary Government and Public Health England (PHE) guidance. As per phase 1, phase 2 will consist of 3 exercise sessions per week. The first session of the week will be a rehabilitation specialist lead group exercise programme. In appropriately prepared and ventilated spaces, groups of up to 5-10 patients will engage in a 45-minute exercise class followed by 15 minutes for questions and answers. Exercises will consist of aerobic and strength-based exercises as well as stability and mobility. In order to promote continued self-management, the second exercise session of the week will be a remote pre-recorded session that the patient will carry out at home independently, as per phase 1. Similarly, the third session of the week, 'build your own' will remain; however, the patient will be encouraged to complete this session within a supervised gym environment. The rehabilitation specialist will be on hand within pre-defined time slots to provide advice and guidance. The patient will again receive a weekly consultation with the rehabilitation specialist following the aforementioned themes. This will culminate between weeks 12-13 with a final assessment, summary report and signposting to additional services where required.

What are the possible benefits and risks of participating?
By participating in this rehabilitation programme individuals stand to improve their overall quality of life and see a reduction in symptoms relating to COVID-19. The programme also affords an opportunity to receive education on health and wellbeing as well as form new social connections. As with all rehabilitation programmes, whilst low and unlikely, there are potential risks. The involvement of exercise carries a risk of discomfort through overeating, sweating and musculoskeletal soreness. There is an inherent risk of symptom exacerbation which will be mitigated throughout via close participant monitoring and appropriately judged intensity exercise interventions.

Where is the study run from?
Nuffield Health (UK)

When is the study starting and how long is it expected to run for?
The evaluation will begin on 14/09/2020 and is expected to run for at least 3 years.

Who is funding the study?
Nuffield Health (UK)

Who is the main contact?
Dr Ben Kelly
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NHCRP001

Study information

Scientific Title
Scalable models of community rehabilitation for individuals recovering from COVID-19 related illness: a longitudinal service evaluation

Acronym

SeaCole

Study objectives
It is hypothesised that:
1. The 12-week rehabilitation programme will be effective in improving quality of life and reducing symptoms related to COVID-19 at 6 and 12 weeks and those benefits will be retained at 6 and 12 months
2. The blended model will be cost-effective when compared to previously described rehabilitation methodologies, specifically outpatient multidisciplinary pulmonary rehabilitation; c) we expect the programme to be acceptable to both patients and specialists

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/08/2020, Manchester Metropolitan University Ethics Committee (Birley Building, Bonsall St, Hulme, Manchester M15 6GR, UK; +44 (0)161 247 5915; research.governance@mmu.ac.uk), ref: 25307

Study design
Single-center observational longitudinal service evaluation

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The evaluation will review the effectiveness of a 12-week community rehabilitation programme on improvements in quality of life and reductions in symptoms of COVID-19, in individuals recovering from the disease. The programme will utilise exercise and education as core interventions. This evaluation will be conducted in concert with the National Health Service, UK. The NHS sites will be serviced by surrounding Nuffield Health Fitness and Wellbeing Centres, located within a 20-mile radius of a participating NHS site.

Following referral, patients will complete an online pre-assessment health questionnaire. Once completed the questionnaire is made available digitally to a specialist trained physiotherapist who will contact the patient to conduct a telephone triage assessment. Following successful

triage, the patient is handed on to a rehabilitation specialist who will then take up responsibility of the patients care. All patients will receive the identical 12-week programme structure consisting of two 6-week phases, described in detail below.

Rehabilitation Programme

1. NHS healthcare professionals will utilise inclusion/exclusion criteria at the point of discharge to refer a patient to the programme. Alongside the provision of a patient information document, the patient will be fully informed verbally about the programme, being given the opportunity to join the programme should they so wish. The patient will be made aware that their data will be utilised anonymously for research purposes. The patient may also request that their data is not utilised and will still be able to participate in the programme. Should they choose not to progress they will be sign-posted to alternative community / NHS services where available. If the patient accepts to progress on to the programme the NHS healthcare professional will complete an online referral, sent directly to Nuffield Health using a secure online form. Data sharing agreements have been completed between NHS and Nuffield Health and all processes conform to GDPR and NHS digital requirements.
2. When an online referral is completed, an automated booking process will be triggered. Via email or telephone (based on patient preference) the patient will choose an appointment time for an initial triage screening. The patient will also be asked to complete pre-screening questions, designed to support the triage process.
3. The patient next joins a telephone or online video triage consultation utilising this feature. The triage will be conducted by specialist physiotherapists trained in remote consultation. The 45-min triage will also act to collect additional relevant patient information that may be pertinent when tailoring their exercise programme. Information such as details on additional co-morbidities, emotional wellbeing and medication will be discussed. Should any contraindications to exercise be identified during the triage the patient will be informed that they are unable to progress on the programme at that time. The patient will be sign-posted back to their General Practitioner, who will also be notified in writing. The original referring clinician will also be notified. At the end of triage, if deemed appropriate, the specialist physiotherapist will refer the patient to the rehabilitation specialist with recommendations for the intensity of entry-level exercise and specific needs and goals.
4. Following successful triage, the patient will be automatically sent a welcome pack via post as well as email. This will provide full guidance on how to download, access and register on the digital platforms and will provide links to learning materials. The patients GP will also be made aware that their patient has initiated the programme. The digital application platform utilises the functionality of a platform already used extensively across Nuffield Health (MyTherapy, Nuffield Health, London, UK). All other virtual audio-visual communication will be delivered by a separate digital system (Microsoft Teams, Microsoft, Redmond, USA).
5. Within 72 hours of referral, the patient will be contacted by their assigned rehabilitation practitioner based at a Nuffield Health site within a 20-mile proximity to the referring hospital. The practitioner will provide a welcome to the programme, offer the opportunity to ask any questions and to inform them of the start date of the programme.
6. The patient begins the 12-week programme. This programme phases are as follows:

Phase 1

Weeks 1-6 will consist of 3 exercise sessions per week. Session 1 will be an online live-streamed activity conducted by 2 Nuffield Health trained rehabilitation specialists. One practitioner will run the exercise session and the second will answer questions via the online chat function. The stream will be a 1-way stream, meaning that whilst multiple patients will access the stream at any given time, they will not be recorded/filmed nor will their personal details be visible to the group. A maximum of 10 patients will join a stream at any time. The live stream will last up to 45-minutes followed by a 15-minute period for questions via the secure online chat function or

alternatively spoken questions can be provided should the patient have microphone functionality.

The second session of the week during phase 1 will be self-directed. The patient will be directed to a pre-recorded guided exercise session located on a dedicated online platform (Vimeo, New York, USA). This will be a 45-minute activity which the patient completes at their leisure. All exercises are designed such that they can be carried out with ease at home.

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Each week the patient will be provided a phone call that will last up to 45-minutes with the rehabilitation specialist. The aim of the phone call is to listen to any patient queries but to also offer support on themes such as exercise selection, symptom management and emotional wellbeing. Nuffield Health specialists have comprehensive training in each of these areas. Prior to progressing to Phase 2 patients will receive a remote mid-point review by the rehabilitation practitioner. Progress will be discussed in detail and the patient will be asked if they feel ready and willing to progress to phase 2. If their progress is deemed insufficient, the patient will be recommended to complete another 6-week digital programme in full, before moving into a gym-based setting. Progress will be reviewed weekly and patients will be able to join the face to face component at a later point. All group-based sessions will be offered at two timepoints across the course of the day, with an AM and PM option. All one to one activity such as the weekly phone calls will be booked according to participant preference on a weekly basis.

Phase 2
Following successful completion of phase 1, patients will progress to the phase 2 face to face programme. This phase will be conducted in strictly controlled gym environments conforming to all necessary Government and Public Health England (PHE) guidance. As per phase 1, phase 2 will consist of 3 exercise sessions per week. The first session of the week will be a rehabilitation practitioner lead group exercise programme. In appropriately prepared and ventilated spaces, groups of up to 5-10 patients will engage in a 45-minute exercise class followed by 15 minutes for questions and answers. Exercises will consist of aerobic and strength-based exercises as well as stability and mobility. In order to promote continued self-management, the second exercise session of the week will be a remote pre-recorded session that the patient will carry out at home independently, as per phase 1. Similarly, the third session of the week, 'build your own' will remain; however, the patient will be encouraged to complete this session within a supervised gym environment. The rehabilitation practitioner will be on hand within pre-defined time slots to provide advice and guidance. The patient will again receive a weekly consultation with the rehabilitation practitioner following the aforementioned themes. This will culminate between weeks 12-13 with a final assessment, summary report and signposting to additional services where required.

Intervention Type
Behavioural

Primary outcome measure
Quality of life measured using EuroQoL Five Dimension Five Level Version (EQ-5D-5 L) at baseline, 6 and 12 weeks and 6 and 12 months

Secondary outcome measures

1. Symptoms relating to COVID-19 measured using Dyspnea-12 at baseline, 6 and 12 weeks and 6 and 12 months
2. Functional capacity measured by The Duke Activity Status Index (DASI) at baseline, 6 and 12 weeks and 6 and 12 months
3. Patient strength and endurance measured using the 30-second sit to stand test at baseline, 6 and 12 weeks and 6 and 12 months
4. General anxiety measured using General Anxiety Disorder-7 at baseline, 12 weeks and 6 and 12 months

Overall study start date
06/04/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Previous confirmed diagnosis of COVID-19
2. Able to walk independently for a minimum of 20 meters
3. Must have access to the internet and smartphone/tablet/personal computer (with adequate technological literacy)
4. Over 18 years of age
5. Access to transport to attend rehabilitation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Have active COVID-19 symptoms
2. Are already receiving community rehabilitation
3. Have un-managed medical conditions that contraindicate unsupervised exercise
4. Have a formal diagnosis of post-traumatic stress syndrome, clinically significant anxiety or depression where low-intensity mental health intervention will not assist
5. Have been diagnosed with Chronic Fatigue Syndrome

Date of first enrolment
09/10/2020

Date of final enrolment
09/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Health
2 Ashley Avenue
Epsom
United Kingdom
KT18 5AL

Sponsor information

Organisation
Nuffield Health

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Sponsor type
Charity

Website
http://www.nuffieldhealth.com

Funder(s)

Funder type
Charity

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication of methodology within a relevant healthcare journal. It is intended that cohort outcomes will be submitted annually for publication in high-impact peer-reviewed journals. The protocol and statistical analysis will be made available.

Intention to publish date
10/10/2020

Individual participant data (IPD) sharing plan
Participant data that underlie the results reported in publications, after de-identification will be made available upon reasonable request to the corresponding author Dr Ben Kelly (Benjamin.Kelly@nuffieldhealth.com). Data will be made available beginning 9 months and ending 36 months following article publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/05/2021	01/06/2021	Yes	No
Results article		24/05/2023	09/06/2023	Yes	No