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Development of a return-to-work intervention for COVID-19 patients

Submission date
31/08/2023

Recruitment status
No longer recruiting

Registration date
06/09/2023

Overall study status
Completed

Last Edited
04/09/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background ad study aims
COVID-19, caused by SARS-CoV-2, primarily affects the respiratory system, showing symptoms such as breathlessness, fever, and loss of smell and taste, although many do not present any symptoms. A large portion of patients experience symptoms sometimes months after recovery resulting in difficulties in returning to pre-covid life, particularly work. Clinical guidelines have been put in place, but are based on general principles that may not be applicable to long covid (e.g., standard 4 weeks phased return). Vocational rehabilitation is a process supporting those with health problems to maintain or return to employment or vocational activities. Long COVID is a diverse condition and whilst some vocational rehabilitation programmes have been developed for it, none are specific to returning to work. There is a need to understand the factors affecting a successful return to work and how these could be implemented in vocational rehabilitation. This study aims to use findings from a previous study identifying facilitators and barriers to returning to work for those with long COVID to adapt previously developed and tested return-to-work vocational rehabilitation interventions, using a person-based approach, and explore the potential acceptability of delivering this remotely.

Who can participate?
Adults aged between 18 and 65 years old with long COVID who are struggling to return to or maintain pre-COVID work

What does the study involve?
An up-to-twelve weeks long intervention with an occupational therapist to understand the limitations induced by their long COVID symptoms, and use techniques to reduce their impact. The intervention also focuses on the broader impact of reduced work (for example, financial). Given the emphasis on work, it often involved the patient's employer to educate them on the condition, how it may affect the patient's work, and how the work may be adapted.

Participants receive four telephone assessments with a researcher to assess their symptoms (before, at six weeks, at twelve weeks, and four weeks after the intervention) and a recorded post-intervention telephone interview with the researcher to discuss their thoughts on the intervention.

What are the possible benefits and risks of participating?
The participants receive a £15 voucher upon completion of the final interview. The participants receive support from the occupational therapist to support them with work-related difficulties resulting from long COVID. However, we cannot guarantee that it will be helpful.

The risks and disadvantages involve:
Some of the questions asked are about symptoms including emotions such as feeling anxious or low. Whilst most people do not mind answering these questions, some may feel upset. It is important that these questions are asked to understand the challenges that the participants face and find out if an intervention can improve these symptoms. Many people find that talking or sharing concerns can be helpful. Only what is necessary for the study will be asked.
The intervention will require an hour of the patient's time every week for up-to-12 weeks (or as frequently as agreed between the participant and their therapist) and the patients attend telephone questionnaires 4 times – each one lasting an hour. Participants are also required to attend a 30-minute telephone acceptability interview.

Where is the study run from?
The study is run remotely and the intervention will be delivered via telephone or videoconference. The two sites involved in the study are Nottingham University Hospital NHS Trust and Royal Free London NHS Trust (UK).

When is the study starting and how long is it expected to run for?
September 2020 to July 2022.

Who is funding the study?
University of Nottingham (UK)

Who is the main contact?
Clement Boutry (Research Associate), clem.boutry@nottingham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
292227

Protocol serial number
Protocol number 20076, IRAS 292227

Study information

Scientific Title
Developing a job retention vocational rehabilitation intervention for people with long Covid: A person-based approach

Acronym

COVID VR

Study objectives
The study hypothesises that a digitally delivered vocational rehabilitation program, delivered remotely by occupational therapists, will effectively address the multifaceted challenges faced by those with long COVID. This program is expected to improve physical, mental, and vocational factors, leading to increased functional capacity and successful reintegration into the workforce. The intervention's adaptability to individual needs and its remote delivery will prove valuable in overcoming barriers posed by COVID-19's lasting effects on physical, cognitive, and emotional well-being.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/04/2021, REC Nottingham 1 - Nottingham Research Ethics Committee 1 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8089; nottingham1.rec@hra.nhs.uk), ref: 21/EM/0039

Study design
Multicenter non-randomized single-arm intervention development study

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Individuals with long COVID experiencing challenges in resuming or sustaining employment.

Interventions
This study is a multicenter, non-randomised, single-arm intervention development study using the person-based approach, comprising interviews and clinical contact, informed by workshops and findings from a separate study exploring the barriers and facilitators related to returning to work for those with long COVID; and followed by participant qualitative assessment /acceptability interviews.

Participants consenting to take part will receive vocational rehabilitation delivered by an Occupational Therapist (OT) experienced in neurological and vocational rehabilitation. The OT will also have experience in telerehabilitation delivery. On being informed that a participant has consented to participate in the study and a baseline assessment has been agreed upon, the OT will attempt to make contact with the participant by telephone.

The COVID VR intervention is an early, individually tailored intervention that seeks to lessen the impact of COVID-19 by assessing the patient’s role as a worker and finding acceptable strategies to overcome problems e.g. assessing and addressing COVID-19-related restrictions on function and activity limitations which might have a direct impact on work activities in relation to work demands – these may be physical, cognitive, psychological or task/environment-based interventions.

The intervention will last for as long as is needed up to 12 weeks. The intervention will predominantly be delivered online on a one-to-one basis. Interventions may be delivered remotely in the participant's home or workplace via Microsoft Teams or phone. The number of intervention sessions will be determined by participant needs. Liaison with or about the participant may also take place by email, letter or over the telephone with calls or texts and may involve online face-to-face meetings with others such as workplace representatives (e.g., occupational health or line managers) and other health or social care professionals with the participant's consent. Meetings would typically involve planning the return to work, negotiating phased return, workplace accommodations such as changes in hours or responsibilities or supernumerary support as needed, to enable the participant to return to and remain in work.

The intervention will be individually tailored in content, dose, intensity and duration according to participants' needs and preferences e.g. whether the participant consents to employer liaison and remote workplace visits or whether the participant accepts advice only about employer liaison and employment context e.g. where there is no employer to liaise with or, participants return to work early and are unable to meet the therapist in person at the intended frequency, resulting in online or telephone intervention.

The primary outcome of the study is participants' goals that will be assessed using the Goal Attainment Scale (GAS) whereby SMART goals will be established with patients whilst evaluating their difficulty and importance at the start with the OT and used throughout the intervention. Following the intervention, based on patients' attainment of their goals, a score will be produced and a reliable change index will be calculated using the Leeds Reliable Change Index calculator.

Intervention Type
Behavioural

Primary outcome(s)
1. The extent to which the participant's individual goals are achieved measured using the Goal Attainment Scale (GAS) following the intervention
2. Whether or not reliable change occurred measured using the Leeds Reliable Change index calculator at one timepoint

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline, 6, 12 and 16 weeks unless otherwise stated:

1. Acceptability if the intervention will be measured using qualitative interviews after completion of the intervention
2. Depression will be measured using the Patient Health Questionnaire (PHQ-9)
3. Anxiety will be measured using Generalised Anxiety Disorder Assessment (GAD-7)
4. Trauma will be measured using the Trauma Screening Questionnaire (TSQ)
5. Fear of COVID-19 will be measured using the Fear of COVID-19 scale
6. Exposure to stigma regarding COVID-19 infection will be measured using the COVID-19 Stigma Scale
7. Cognitive and emotional presentation of illness will be measured using the Brief Illness Perception Questionnaire (BIPQ)
8. Disability and function impairment will be measured using the World Health Organisation Disability Assessment Schedule (WHODAS-ii)
9. Breathlessness levels will be measured using the MRC Breathlessness Scale

10. Fatigues will be measured using the Chalder fatigue Scale
11. Impairment in functioning will be measured using the Work and Social Adjustment Scale (WSAS)
12. The participants' self-efficacy to return to work will be measured using the Return to Work Efficacy Scale
13. The financial impact of work difficulties will be measured by asking about access to benefits, loss in earnings since COVID, sick days taken (and whether they were paid) and concerns about financial implications in general
14. Impairment at work will be measured using the Work Productivity and Activity Impairment Questionnaire: General Health V2.0

Completion date
12/07/2022

Eligibility

Key inclusion criteria
1. Working age (18-65)
2. Tested positive for COVID-19
3. Employed, self-employed, in full-time education or voluntary work
4. Able to give informed consent
5. Assessed as Level 1-6 (requires modifications) on the Work Ability Support Scale (WSS) and/or or self-identified need for support with returning to or remaining in work or self-reported ‘work issues’ (contextual/workplace factors affecting job stability). This will be completed by a trained occupational therapist providing rehabilitation in the vocational rehabilitation outpatient service. For participants from the Royal Free, the WSS will be conducted post-consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
6

Key exclusion criteria

1. Active mental or physical condition causing physical deconditioning
2. Current diagnosis of other respiratory illness

Date of first enrolment
26/05/2021

Date of final enrolment
21/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)
The University of Nottingham

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository within the University of Nottingham.
The datasets generated during and/or analysed during the current study are not expected to be made available due to consent for research data sharing not being obtained from participants.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	14/04/2021	04/09/2023	No	Yes
Participant information sheet	version 1.2	14/04/2021	04/09/2023	No	Yes
Participant information sheet	version 1.2	23/03/2021	04/09/2023	No	Yes
Participant information sheet	version 1.2	23/03/2021	04/09/2023	No	Yes