

LOCOMOTION: Can we optimise the treatments and services provided across the NHS for long COVID?

Submission date 11/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/04/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Around one million people in the UK are affected by Long Covid (LC). LC severely impacts people's daily life. There are 83 LC clinics in England, but waiting times are long and access is delayed for many people. There is increasing urgency for LC patients to access prompt, appropriate and efficient care in clinics and doctors' surgeries.

The aim of this study is to produce a 'gold standard' for care by analysing what is happening to patients now, creating new systems of care and evaluating them to establish best practice. This research takes place in 10 UK-wide LC clinics treating 5000 patients and involves three parallel workstreams (WS1, WS2 and WS3). Working with health professionals and people with LC, we found that the key priorities are correct clinical assessment; advice and treatment; and help with returning to work and other roles.

Who can participate?

Healthcare professionals and patients aged over 18 years, with experience of long COVID.

What does the study involve?

Workstream (WS) 1 involves the close cooperation between health professionals and researchers from the ten clinics. Using their combined experiences and various research methods, they will codesign with patients the best possible approaches that will inform training and resources to address the care and vocational challenges facing patients.

WS2 involves developing precise methods for measuring symptoms and difficulties with daily living, and identifying triggers for these difficulties. This includes the wearing of digital devices and further development and testing of the first published LC patient-reported outcome measure (C19 YRS Yorkshire Rehabilitation Scale).

WS3 will use existing data from care of LC patients and the best practice guidance developed in WS1 to develop and evaluate new service models.

By comparing findings of these workstreams across our ten LC Clinics, we will establish a 'gold standard' of treatment and real-time education for healthcare staff and patients that can be shared within England and the rest of the UK.

The research will take place in three settings: LC clinics; at home (including self-monitoring on a mobile device using a set of questions on symptoms built into an app); and in doctors' surgeries. We will track where patients are being referred or not referred and learn from the experience of clinics by interviewing patients and recording outcomes. Throughout, specialists in 'Healthcare Inequality' will reach people who are not accessing clinics. We will put in place new processes in clinics and doctors' surgeries, monitored throughout to ensure they are the correct standard, accessible for patients and staff, and cost-effective.

What are the possible benefits and risks of participating?

None

Where is the study run from?

University of Leeds (UK)

When is the study starting and how long is it expected to run for?

August 2021 to June 2024

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

UK Research and Innovation

Who is the main contact?

Dr Manoj Sivan, M.Sivan@leeds.ac.uk

Prof Brendan Delaney, brendan.delaney@imperial.ac.uk

Study website

<https://locomotion.leeds.ac.uk/>

Contact information

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

303623

ClinicalTrials.gov number

NCT05057260

Secondary identifying numbers

CPMS 51044, IRAS 303623

Study information**Scientific Title**

Long Covid Multidisciplinary consortium: Optimising Treatments and services across the NHS (LOCOMOTION)

Acronym

LOCOMOTION

Study objectives

There is an urgent need to develop a UK-wide efficient integrated Long-Covid service. Our research aims to produce a 'gold standard' for care by analysing what is happening to patients now, creating new systems of care and evaluating them to establish best practice. Comparing findings across our partnership of ten LC Clinics, we will learn more about treatment, providing real-time education to other healthcare staff and patients, and establishing a 'gold standard' that can be shared within England and the rest of the UK.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/12/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0276

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Community, GP practice, Home, Hospital, Medical and other records, Workplace

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

Interventions

Current interventions:

The study will comprise three parallel related workstreams and involves the comprehensive collection and examination of qualitative and quantitative data from potentially 5000 patients in ten UK-wide LC rehabilitation clinics.

WORKSTREAM I (WS1: LC CLINICS QUALITY IMPROVEMENT COLLABORATIVE)

There are four objectives (tasks) in WS1: tasks 1.1, 1.2, 1.3 and 1.4.

Task 1.1: Create a Quality Improvement Collaborative (QIC) that includes a diverse range of Long COVID (LC) services from across the UK to share knowledge, best practice and learning for management of LC medical problems, rehabilitation, and appropriate service pathway. By month 3, each clinic will have identified a system within the clinical team for implementing feedback from the meetings into local action and wider organisational learning. They will meet online approximately every six to eight weeks to identify topics, to set goals, to identify data sources, to undertake an improvement cycle of implementing change and collecting data. These meetings will last 90 to 120 minutes. The QIC will be a forum for sharing examples of good practice and also sharing problems and challenges. These findings on best practice on the topics will be written formally and made available for publication and widespread information nationally by 12 months. Other site participants will be drawn from the wider local teams with experience of LC clinics e.g. clinicians and managers from long Covid clinics who will discuss priorities for improving services, set goals, and agree on work to undertake before the next meeting. Patients from the PPI Patient Network will be invited to join the QI collaborative (their family members /partners will be also welcome to join as support.)

Task 1.2: Co-design by LC patients and healthcare professionals of fair, even services and the

development of training packages and resources for both. Patients will be interviewed online about their experiences in Long Covid services. This will last 30 to 60 minutes using Zoom or Teams. Training will be provided for patients not familiar with these platforms, and relatives, friends or carers can help. The interview can be split into shorter interviews over several days if necessary. The interviewer will ask each patient to tell their story and pay particular attention to experiences that made them either angry and frustrated or (if their experience was positive) happy and relieved. The interviewer will ask patients to imagine ways in which these negative experiences could be improved – or how their own positive experience might inform better services for other patients. Then patients will be asked to join an online group of other patients to share experiences and think how the service overall might be improved. During this meeting, a researcher will help guide the discussion and make notes on key themes raised. The researcher, along with patients if they wish, will then attend an online meeting of staff to feed back the patient experience and discuss how to improve services.

Task 1.3 Understand and address inequalities for people of different gender, ethnic background and socioeconomic status in LC and in LC service utilisation. Using data from Task 3.1 we will examine inequalities among the caseload of LC clinics in terms of access and treatment outcomes for different population groups in relation to age, sex, ethnicity, pre-existing conditions, disability, deprivation, socioeconomic circumstances and environmental exposures. We will conduct interviews involving 15 Key Informants [individuals with relevant expertise relating to Long Covid and health inequalities (from clinical, academic or advocacy backgrounds)] and 30 LC individuals from a range of disadvantaged and intersecting social groups (e.g. women, minority ethnic, socioeconomically deprived, disabled, homeless and Traveller communities) who have not been seen in LC clinics, including those with pre-existing conditions and high exposure to COVID-19 risk. Individuals not seen in LC clinics will be identified through snowballing techniques (asking 1.1 and 1.2 interviewees whether they know anyone who has ongoing symptoms but not attending a LC Clinic) and Key Informants, as well as recruitment via GP practices and relevant community organisations (see poster and leaflet in uploaded documents section) and social media (Twitter). Interviews will take place at a place chosen by the interviewee and can be online or face-to-face. Interviews will explore symptom recognition (including by clinicians), health-seeking behaviour, care pathways, motivations/disincentives to accessing healthcare support, attitudes towards LC and stigma (e.g. relating to psychological symptoms). We will also explore emotional touch points, patient support networks and trajectories of care to support incorporation of findings from these interviews into the service co-design (see above). Evidence from interviews will be analysed by NVivo software package and used to inform outcomes from other project tasks LC service improvement (Tasks 1.1 and 1.2), features of LC (Task 2.1 and 3.1) and PROM validation (Task 2.2).

We will aim to conduct qualitative interviews and analysis between by month 10 and draw on this work between months 6 -24 to further support diverse representation on PPIE, inclusive outcomes from other work packages and final project outputs. Task 1.4: Understand the vocational rehabilitation needs of a representative cohort of individuals and develop return to work programmes.

Qualitative interviews will be conducted with people with LC who have returned to work and people whose health has prevented them from doing so to understand the impact of LC on people's ability to return to work and their ability to fulfil their work role (if they have returned). Interviews will be conducted remotely using videotelephony. The interviewer will explore the impact of LC on return-to-work and job retention, including access to and from work and within work, adaptations required at work and flexibility of employment. With the consent of the participants, we will interview a sample of employer representatives (line managers, human resources professionals) who have been involved in return-to-work and work-retention discussions with participants. We will also interview professionals involved in LC clinics to identify the goals agreed with participants and the treatment plans put in place around employment and whether these have been successful or not.

Phase 1.

Qualitative interviews will be conducted to understand the impact of LC on people's ability to return to work and their ability to fulfil their work role if they have returned. Interviews will be conducted remotely using videotelephony. The interviewer will explore the impact of LC on return-to-work and job retention, including access to and from work and within work, adaptations required at work and flexibility of employment. There will be two interactions; one for taking consent and one for the qualitative interview. Interviews are expected to take up to 60 minutes and participation will be for one day. With the consent of the participants, we will also interview a sample of employer representatives (line managers, human resources professionals) who have been involved in return-to-work and work-retention discussions with participants. We will also interview professionals involved in LC clinics to identify the goals agreed with participants and the treatment plans put in place around employment and whether these have been successful or not.

Phase 2

Within phase 2, analysis of the interview transcripts, field notebooks and other artefacts will form the basis for the development of a LC-specific vocational rehabilitation programme. Based on our experience of designing vocational rehabilitation programmes for other acute-onset, long-term conditions, the overall package will be an individually tailored, co-ordinated programme of support, education and advice to people with LC, their family and others involved in the person's vocational role, such as employers and disability employment advisors. We will test the proposed programme with a further stratified sample from our linked centres, interviewing participants and Clinician Research Fellows to assess acceptability of the programme and feasibility of its implementation. The primary outcome will be a manualised vocational rehabilitation programme suitable for deployment in LC clinics.

Task 1.5: Long COVID was first characterised in online peer support groups and several participating sites have local peer support groups, but it is not known how best to structure and support such groups. We will undertake a hermeneutic literature review of peer support models in comparable conditions (eg, chronic pain) and conduct interviews with stakeholders involved in delivering or supporting peer support for long COVID. We will share findings with task 1.1. Through discussion, we will identify which features of successful peer support are relevant to long COVID and consider how to improve existing models (if present) or establish new peer support services. Using the quality improvement cycle, we will collect data to evaluate and improve as the peer support groups evolve.

WORK STREAM II (WS2: HOME MONITORING AND SELF-MANAGEMENT)

There are two objectives (tasks) in WS2:

Task 2.1: Wearables for home monitoring of fluctuation of symptoms and patient feedback This is a two-part study involving the use of wearable technology and daily tasks to gather information about symptoms, daily patterns of symptoms and to identify triggers for worsening of symptoms. This study will take place over 12 weeks, with patients involved for seven days at the start (time 0), seven days at six weeks (time 1) and then seven days at 12 weeks (time 2). At referral to study site prior to rehabilitation (time 0), entry to rehabilitation (time 1), and at 6 weeks (time 2) and 12 weeks (time 3) participants will be asked to complete an online form collecting data on physical activity, fatigue, quality of life, self-efficacy (people's knowledge, skills and confidence in managing their own wellbeing), Covid symptoms, social roles, COVID-related stress, worry and rumination. This will be captured using REDCap, a secure online (web-based) application for building and managing surveys, and for collecting data for research studies and operations. Demographic and clinical data will be collected from patients and linked to participants. During the seven day periods at time 0, time 1 and time 2, participants will wear small unobtrusive sensing devices (called accelerometers) on their wrist. These accelerometers measure movements and can detect the level of activities, like walking. There are accelerometers in smart phones and in devices like Fitbits. They are widely used in health research to measure physical activity. Participants will be encouraged to always wear the sensor

except when bathing. The sensor will be sent to, and returned by, participants by post with appropriate cleaning before and after use. Data collection will happen for seven days. During this 7-day period of using personal mobile devices and wearable sensors, participants will be asked to carry out up to six daily mental and physical tests (these are called Ecological Momentary Assessments (EMA)). They will take place at two fixed (on arising and before bed) and up to four random time points, take three minutes each and will help us to identify causes of symptom fluctuation and to identify triggers. Pilot work has demonstrated that this approach is feasible and acceptable to LC patients. The participants will have access to the clinical researchers at NHS sites if they have any problems using the equipment or if they have any concerns about any of the readings. The data gathered from this part of the study will be combined with the health assessment data obtained from the patients' clinical assessments at Long Covid clinics. The daily EMA includes continuous data collection of the following using activity sensors (Axivity) and, in the sub-study, heart rate using the Fitbit Sense and polar H10 Heart rate monitor: physical activity levels (step count, intensity of physical activity, timings and duration of physical activity), sleep (timing and duration). Participants also answer a series of questions throughout the day about their sleep health, daily activities, symptoms and symptom impact, post exertional malaise, stress and anxiety. EMA schedule and questions are presented in attachments to the IRAS submission. EMA will be conducted using AthenaCX, a mobile application accessible on both Android and iOS platforms. Participants will be asked to download it on their mobile devices from Google Play Store or App store, depending on their devices. Then, they'll be asked to access the EMA using an anonymised participant ID assigned to them for the study. There are two sub studies within task 2.1, for which participants will be recruited separately: Sub study 1. Fifty patients in Oxford will be invited to voluntarily participate in the following, and will be able to opt in or out of the following components at each testing time point: Home digital physiological measures via a wrist worn sensor to measure heart rate and heart rate variability to explore the potential for using measure heart rate and heart rate variability as feedback. Individuals will be invited to participate in further data collection for an additional 7 days for the recording of data after a moderate physical and mental activity. Sub study 2 will be a co-design study between 20 patients and 10 clinicians and using a clinician survey to establish utility of using prospective symptom fluctuation and triggers diaries at clinic appointments. We will conduct a short debrief interview with up to 30 participants during either week 3 or week 4 of their study. This will be conducted by phone / videocall and recorded. The interviewer will take notes during the interview. The interview will be structured around the usability dimensions of efficiency, effectiveness and satisfaction. In particular, the interview will ask about both the apps and using them in daily life, any 'bugs' identified and any suggestions for improvement to the app or the study design. The interview will include a "would you recommend to someone you know?" question and explore reasons for this. The interview will also include a think-aloud component in which the interviewer asks the participant to go through a data entry cycle and describe what they are thinking or doing as they go along. Towards the end of the interview the interviewee will be asked to complete the 10 item System Usability Scale.

Task 2.2: There is currently no consensus on core set of measures to be used in Long Covid. LOCOMOTION task 1.1 will determine a core set of outcome measures by consensus and QIC methods. Task 2.2 aims at collection of data from C19-YRS (Yorkshire Rehabilitation Scale) and a core set of outcome measures (maximum five measures/questionnaires) at three monthly intervals from the participating sites using a digital system that comprises a phone application and web portal. Some sites (Leeds and Salford) are already using this system incorporated in their clinical service with patients completing the C19-YRS measure using a phone application and clinicians accessing the results on the web portal of the system. Other centres are completing outcome measures in paper format and uploading to their clinical records but not collected via a phone application. The data collected captures the burden of the condition on body function, activity, participation, contextual factors, health-related quality of life, and

economic impacts such as work and productivity losses. The data will permit full development of the C19-YRS through psychometric testing using the Rasch model and also allow estimating construct validity against established measures (EuroQol EQ-5D 5L). The Coronavirus-19 Yorkshire Rehabilitation Scale (YRS) was developed as a screening tool and symptom collection questionnaire but was found to have promising psychometric properties in preliminary testing. The measure is recommended for routine use in LC clinics by NHS England in their latest clinical guidance for all LC clinics in England. A private digital health company called ELAROS has jointly developed the YRS, previously just a paper-based questionnaire, into a digital app; using this digital platform, patients complete the YRS on a phone app and clinicians operate and access the application through a web-based portal. The app will include five outcome measures and will gather pseudonymised data from these outcome measures in an automated process. For those who are unable or unwilling to use the digital phone application platform, the agreed core outcome measures will be made available in different formats they can choose from: a) weblink or b) paper form or c) on the phone with clinician completing the measures on the webportal. All participants attending LC clinics or primary care settings will be potentially eligible. Task 2.3: Some LC patients have autonomic dysfunction that can be assessed using a home based test called aAP (adapted Autonomic Profile). The test involves measuring Blood Pressure BP and Heart Rate HR at different times of the day in relation to position, food intake and activity. The recordings provide information on neuro cardiovascular autonomic responses to key activities in daily life such as postural change, and before and after food and exertion. The test provides adequate data to exclude autonomic dysfunction and initial autonomic diagnosis and guidance on treatment. The advantage with the aAP is that it can be repeated on a typical or an atypical day and objectively can assess the response to intervention, be it non pharmacological or pharmacological. There is however lack of normative data for this test to define the thresholds for deciding which values are to be regarded as abnormal, so we will be collecting aAP test results from 500 'healthy' volunteers to establish normative values for the test.

WORK STREAM III (WS3: EVALUATING AND DEVELOPING LC INTEGRATED CARE PATHWAYS)

This workstream involves the use by academics of existing patient data and patient data collected in other workstreams. There is no involvement or participation of LC patients. There are two objectives (tasks) in WS3: task 3.1 and 3.2. Task 3.1: Develop and evaluate new integrated care pathways for managing LC. We will harness data across the health system including from patients in primary care who have not accessed LC clinics. Some of the databases explored will be: Pillar 1: iCARE/NW London WSIC (HDRUK Alliance) and Salford - unique pan-local health economy data containing detailed complete patient-level data across all providers from a population of 2.5M in NW London and the Salford Integrated Record (including the participating ICHT and Salford LC clinics). Pillar 2: The Oxford-RCGP Research and Surveillance Centre consists of a network of more than 1800 practices' data (N > 15million) being made available in ORCHID, an HDRUK listed trusted research environment supporting national COVID-19 surveillance and four national core studies (Lusignan 2020). Pillar 3: National GP Data for Research and Planning (GPDfRP) via the National Core Studies Portal.

Task 3.2: Evaluating cost-effectiveness of current and alternative care pathways. We will use real world data from task 3.1 and from our knowledge about the structural organisation of clinics and integrated care systems (referral criteria, location, staffing, resources available) including options for investigations in primary care. We will incorporate emerging evidence on LC diagnosis, prognosis and therapies. Discrete Event Simulation models will be built using the statistical software R and populated with the following data: 1. Structural alternatives from the QI Collaborative (Task 1.1) 2. Phenotypes, sub-phenotypes and characteristics from task 3.1 supplemented with evidence from targeted literature reviews.

3. Relationships between patient groups, resource use, economic costs and outcome measures from task 2.2 and 3.1, PROMS (including the EQ-5D-5L) from task 2.2, supplemented with evidence from targeted literature reviews.

Previous interventions:

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written formally and made available for publication and widespread information nationally by 12 months. Other site participants will be drawn from the wider local teams with experience of long covid clinics e.g. clinicians and managers from long Covid clinics who will discuss priorities for improving services, set goals, and agree on work to undertake before the next meeting. Patients from the PPI Patient Network will be invited to join the QI collaborative (their family members /partners will be also welcome to join as support.)

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We will conduct interviews involving 15 Key Informants [individuals with relevant expertise relating to Long Covid and health inequalities (from clinical, academic or advocacy backgrounds)] and 30 LC individuals from a range of disadvantaged and intersecting social groups (e.g. women, minority ethnic, socioeconomically deprived, disabled, homeless and Traveller communities) who have not been seen in LC clinics, including those with pre-existing conditions and high exposure

to COVID-19 risk. Individuals not seen in LC clinics will be identified through snowballing techniques (asking 1.1 and 1.2 interviewees whether they know anyone who has ongoing symptoms but not attending a LC Clinic) and Key Informants, as well as recruitment via GP practices and relevant community organisations (see poster and leaflet in uploaded documents section) and social media (Twitter). Interviews will take place at a place chosen by the interviewee and can be online or face-to-face. Interviews will explore symptom recognition (including by clinicians), health-seeking behaviour, care pathways, motivations/disincentives to accessing healthcare support, attitudes towards LC and stigma (e.g. relating to psychological symptoms). We will also explore emotional touch points, patient support networks and trajectories of care to support incorporation of findings from these interviews into the service co-design (see above). Evidence from interviews will be analysed by NVivo software package and used to inform outcomes from other project tasks LC service improvement (Tasks 1.1 and 1.2), features of LC (Task 2.1 and 3.1) and PROM validation (Task 2.2). We will aim to conduct qualitative interviews and analysis between by month 10 and draw on this work between months 6 -24 to further support diverse representation on PPIE, inclusive outcomes from other work packages and final project outputs.

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With the consent of the participants, we will interview a sample of employer representatives (line managers, human resources professionals) who have been involved in return-to-work and work-retention discussions with participants. We will also interview professionals involved in LC clinics to identify the goals agreed with participants and the treatment plans put in place around employment and whether these have been successful or not.

Phase 1.

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Phase 2

Within phase 2, analysis of the interview transcripts, field notebooks and other artefacts will form the basis for the development of a LC-specific vocational rehabilitation programme. Based on our experience of designing vocational rehabilitation programmes for other acute-onset, long-term conditions, the overall package will be an individually tailored, co-ordinated programme of support, education and advice to people with LC, their family and others involved in the person's vocational role, such as employers and disability employment advisors. We will

test the proposed programme with a further stratified sample from our linked centres, interviewing participants and Clinician Research Fellows to assess acceptability of the programme and feasibility of its implementation. The primary outcome will be a manualised vocational rehabilitation programme suitable for deployment in LC clinics.

WORK STREAM II (WS2: HOME MONITORING AND SELF-MANAGEMENT)

There are two objectives (tasks) in WS2:

Task 2.1: Wearables for home monitoring of fluctuation of symptoms and patient feedback This is a two-part study involving the use of wearable technology and daily tasks to gather information about symptoms, daily patterns of symptoms and to identify triggers for worsening of symptoms.

This study will take place over 12 weeks, with patients involved for seven days at the start (time 0), seven days at six weeks (time 1) and then seven days at 12 weeks (time 2). At referral to study site prior to rehabilitation (time 0), entry to rehabilitation (time 1), and at 6 weeks (time 2) and 12 weeks (time 3) participants will be asked to complete an online form collecting data on physical activity, fatigue, quality of life, self-efficacy (people's knowledge, skills and confidence in managing their own wellbeing), Covid symptoms, social roles, COVID-related stress, worry and rumination. This will be captured using REDCap, a secure online (web-based) application for building and managing surveys, and for collecting data for research studies and operations. Demographic and clinical data will be collected from patients and linked to participants. During the seven day periods at time 0, time 1 and time 2, participants will wear small unobtrusive sensing devices (called accelerometers) on their wrist. These accelerometers measure movements and can detect the level of activities, like walking. There are accelerometers in smart phones and in devices like Fitbits. They are widely used in health research to measure physical activity. Participants will be encouraged to always wear the sensor except when bathing. The sensor will be sent to, and returned by, participants by post with appropriate cleaning before and after use. Data collection will happen for seven days. During this 7-day period of using personal mobile devices and wearable sensors, participants will be asked to carry out up to six daily mental and physical tests (these are called Ecological Momentary Assessments (EMA)). They will take place at two fixed (on arising and before bed) and up to four random time points, take three minutes each and will help us to identify causes of symptom fluctuation and to identify triggers. Pilot work has demonstrated that this approach is feasible and acceptable to LC patients. The participants will have access to the clinical researchers at NHS sites if they have any problems using the equipment or if they have any concerns about any of the readings. The data gathered from this part of the study will be combined with the health

assessment data obtained from the patients' clinical assessments at Long Covid clinics. The daily EMA includes continuous data collection of the following using activity sensors (Axivity) and, in the substudy, heart rate using the Fitbit Sense and polar H10 Heart rate monitor: physical activity levels (step count, intensity of physical activity, timings and duration of physical activity), sleep (timing and duration). Participants also answer a series of questions throughout the day about their sleep health, daily activities, symptoms and symptom impact, post exertional malaise, stress and anxiety. EMA schedule and questions are presented in attachments to the IRAS submission. EMA will be conducted using AthenaCX, a mobile application accessible on both Android and iOS platforms. Participants will be asked to download it on their mobile devices from Google Play Store or App store, depending on their devices. Then, they'll be asked to access the EMA using an anonymised participant ID assigned to them for the study.

There are two sub studies within task 2.1, for which participants will be recruited separately: Sub study 1. Fifty patients in Oxford will be invited to voluntarily participate in the following, and will be able to opt in or out of the following components at each testing time point:

Home digital physiological measures via a wrist worn sensor to measure heart rate and heart

rate variability to explore the potential for using measure heart rate and heart rate variability as feedback.

Individuals will be invited to participate in further data collection for an additional 7 days for the recording of data after a moderate physical and mental activity.

Sub study 2 will be a co-design study between 20 patients and 10 clinicians and using a clinician survey to establish utility of using prospective symptom fluctuation and triggers diaries at clinic appointments. We will conduct a short debrief interview with up to 30 participants during either week 3 or week 4 of their study. This will be conducted by phone / videocall and recorded. The interviewer will take notes during the interview. The interview will be structured around the usability dimensions of efficiency, effectiveness and satisfaction. In particular, the interview will ask about both the apps and using them in daily life, any 'bugs' identified and any suggestions for improvement to the app or the study design. The interview will include a "would you recommend to someone you know?" question and explore reasons for this. The interview will also include a think-aloud component in which the interviewer asks the participant to go through a data entry cycle and describe what they are thinking or doing as they go along. Towards the end of the interview the interviewee will be asked to complete the 10 item System Usability Scale.

Task 2.2: There is currently no consensus on core set of measures to be used in Long Covid. LOCOMOTION task 1.1 will determine a core set of outcome measures by consensus and QIC methods. Task 2.2 aims at collection of data from C19-YRS (Yorkshire Rehabilitation Scale) and a core set of outcome measures (maximum five measures/questionnaires) at three monthly intervals from the participating sites using a digital system that comprises a phone application and web portal. Some sites (Leeds and Salford) are already using this system incorporated in their clinical service with patients completing the C19-YRS measure using a phone application and clinicians accessing the results on the web portal of the system. Other centres are completing outcome measures in paper format and uploading to their clinical records but not collected via a phone application.

The data collected captures the burden of the condition on body function, activity, participation, contextual factors, health-related quality of life, and economic impacts such as work and productivity losses. The data will permit full development of the C19-YRS through psychometric testing using the Rasch model and also allow estimating construct validity against established measures (EuroQol EQ-5D 5L).

The Coronavirus-19 Yorkshire Rehabilitation Scale (YRS) was developed as a screening tool and symptom collection questionnaire but was found to have promising psychometric properties in preliminary testing. The measure is recommended for routine use in LC clinics by NHS England in their latest clinical guidance for all LC clinics in England. A private digital health company called ELAROS has jointly developed the YRS, previously just a paper-based questionnaire, into a digital app; using this digital platform, patients complete the YRS on a phone app and clinicians operate and access the application

through a web-based portal. The app will include five outcome measures and will gather pseudonymised data from these outcome measures in an automated process. For those who are unable or unwilling to use the digital phone application platform, the agreed core outcome measures will be made available in different formats they can choose from: a) weblink or b) paper form or c) on the phone with clinician completing the measures on the webportal. All participants attending LC clinics or primary care settings will be potentially eligible.

WORK STREAM III (WS3: EVALUATING AND DEVELOPING LC INTEGRATED CARE PATHWAYS)

This workstream involves the use by academics of existing patient data and patient data collected in other workstreams. There is no involvement or participation of LC patients.

There are two objectives (tasks) in WS3: task 3.1 and 3.2

Task 3.1: Develop and evaluate new integrated care pathways for managing LC

We will harness data across the health system including from patients in primary care who have not accessed LC clinics. Some of the databases explored will be:

Pillar 1: iCARE/NW London WSIC (HDRUK Alliance) and Salford - unique pan-local health economy data containing detailed complete patient-level data across all providers from a population of 2.5M in NW London and the Salford Integrated Record (including the participating ICHT and Salford LC clinics).

Pillar 2: The Oxford-RCGP Research and Surveillance Centre consists of a network of more than 1800 practices' data (N > 15million) being made available in ORCHID, an HDRUK listed trusted research environment supporting national COVID-19 surveillance and four national core studies (Lusignan 2020).

Pillar 3: National GP Data for Research and Planning (GPDfRP) via the National Core Studies Portal.

Task 3.2: Evaluating cost-effectiveness of current and alternative care pathways

We will use real world data from task 3.1 and from our knowledge about the structural organisation of clinics and integrated care systems (referral criteria, location, staffing, resources available) including options for investigations in primary care. We will incorporate emerging evidence on LC diagnosis, prognosis and therapies. Discrete Event Simulation models will be built using the statistical software R and populated with the following data:

1. Structural alternatives from the QI Collaborative (Task 1.1)
2. Phenotypes, sub-phenotypes and characteristics from task 3.1 supplemented with evidence from targeted literature reviews.
3. Relationships between patient groups, resource use, economic costs and outcome measures from task 2.2 and 3.1, PROMS (including the EQ-5D-5L) from task 2.2, supplemented with evidence from targeted literature reviews.

Intervention Type

Other

Primary outcome measure

Long COVID management measured using the C19-YRS (Yorkshire Rehabilitation Scale) at 3-monthly intervals

Secondary outcome measures

1. Quality of life measured using EQ5D (Euroqol Quality of Life 5 Dimensions) at 3-monthly intervals
2. Qualitative data will also be collected to understand the patient experience of the condition and views on the care received using interviews at 12 months

Overall study start date

01/08/2021

Completion date

30/06/2024

Eligibility

Key inclusion criteria

Current participant inclusion criteria:

Task 1.1. There are no demographic restrictions on eligibility, other than all professional members of the QI collaborative must by definition be of working age. Patient members of the

QI collaborative will need to be at least 18 years of age.

Task 1.2. The LOCOMOTION study is not evaluating healthcare services for children. All participants recruited to Task 1.2 must be at least 18 years of age.

Task 1.3. All participants must be at least 18 years of age, and be able consent and participate in an interview (in person or virtually). Key Informants must have experience of working within health inequalities and Long Covid.

Task 1.4. All patient and HCP participants must be 18 years or older and willing to participate. For employers to participate, consent must have been granted by the employee. For phase 2 of the study, participants must have experience with delivering (Clinical Research Fellow) or completing (as a patient) the vocational rehabilitation programme.

Task 1.5. People who are involved in peer-support activity or key stakeholders in LC care.

Task 2.1.

1. Patients will be included who are 18 years and over whom are willing and able to participate in the study, i.e. able to complete the ecological momentary assessment and use the wearable technology.

2. Participants must have capability to provide informed consent and have English language use to the level of conducting health consultations.

3. Participants will not be included or excluded based on past or current illness or medication at the time of the presumed covid infection, however they will be asked to describe these at the start of this study.

Task 2.2. Patients aged 18 and over and who are receiving care for Long Covid symptoms at one of the participating LC sites.

Task 2.3. 18 years or older, no pre-existing chronic condition with autonomic dysfunction, and able to complete the aAP test with their own BP machine.

Task 3.1 Uses routine data and all available data will be used unless a patient has opted out of data sharing.

Previous participant inclusion criteria:

Task 1.1. There are no demographic restrictions on eligibility, other than all professional members of the QI collaborative must by definition be of working age. Patient members of the QI collaborative will need to be at least 18 years of age.

Task 1.2. The LOCOMOTION study is not evaluating healthcare services for children. All participants recruited to Task 1.2 must be at least 18 years of age.

Task 1.3. All participants must be at least 18 years of age, and be able consent and participate in an interview (in person or virtually). Key Informants must have experience of working within health inequalities and Long Covid.

Task 1.4. All patient and HCP participants must be 18 years or older and willing to participate. For employers to participate, consent must have been granted by the employee. For phase 2 of the study, participants must have experience with delivering (Clinical Research Fellow) or completing (as a patient) the vocational rehabilitation programme.

Task 2.1.

1. Patients will be included who are 18 years and over whom are willing and able to participate in the study, i.e. able to complete the ecological momentary assessment and use the wearable technology.

2. Participants must have capability to provide informed consent and have English language use to the level of conducting health consultations.

3. Participants will not be included or excluded based on past or current illness or medication at the time of the presumed covid infection, however they will be asked to describe these at the start of this study.

Task 2.2. Patients aged 18 and over and who are receiving care for Long Covid symptoms at one

of the participating LC sites.

Task 3.1 Uses routine data and all available data will be used unless a patient has opted out of data sharing.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 5000; UK Sample Size: 5000

Key exclusion criteria

Task 1.1. Potential participants with no experiences of long covid healthcare provision will be excluded and will not be eligible to take part in this phase of the LOCOMOTION study.

Task 1.2

1. Potential participants with no experiences of long covid healthcare provision will be excluded and will not be eligible to take part in this phase of the LOCOMOTION study.

2. Patients without capacity to consent for themselves will not be eligible for this phase of the LOCOMOTION study.

3. Patients under the age of 18 will not be eligible to take part in this phase of the LOCOMOTION study.

Task 1.3. Patients who are unable to consent and those under the age of 18 will not be eligible to participate in qualitative interviews. Patients currently receiving care and rehabilitation from a Long Covid clinic will also be excluded.

Task 1.4. Patients who are unable to consent and under the age of 18. Patients will be excluded from Phase 2 of the study if they have not completed the LOCOMOTION Vocational Rehabilitation program.

Task 2.1. Participants will be excluded who are under 18 years old, unable to attend the rehabilitation Centre, unable to use the ecological momentary assessment App technology or use the wearable technology, are pregnant, have a known previous diagnosis of dementia or cognitive impairment preventing participation in the use of the EMA or wearable technologies, or are unable to understand the language used in the EMA.

Task 2.2. Inability to independently complete electronic or paper-based outcome measures, questionnaires or other research-based paperwork, and those patients who are unable to give Informed Consent.

Date of first enrolment

05/01/2022

Date of final enrolment

30/06/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Salford Royal

Stott Lane

Salford

United Kingdom

M6 8HD

Study participating centre

Glenfield Hospital

Groby Road

Leicester

United Kingdom

LE3 9QP

Study participating centre

Birmingham Community Healthcare NHS Foundation Trust

3 Priestley Wharf

Holt Street

Birmingham Science Park, Aston

Birmingham

United Kingdom

B7 4BN

Study participating centre

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

Study participating centre

Leeds Community Healthcare NHS Trust

Stockdale House

8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Second Floor, Ouh Cowley
Unipart House Business Centre
Garsington Road
Oxford
United Kingdom
OX4 2PG

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Warneford Hospital
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre

Hertfordshire Community NHS Trust

Unit 1a Howard Court
14 Tewin Road
Welwyn Garden City
United Kingdom
AL7 1BW

Study participating centre**Leicester Royal Infirmary**

Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre**NHS Highland**

Reay House
17 Old Edinburgh Road
Inverness
United Kingdom
IV2 3HG

Study participating centre**Northern Care Alliance NHS Foundation Trust**

Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information**Organisation**

University of Leeds

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Sponsor type
University/education

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<http://www.leeds.ac.uk/>

ROR
<https://ror.org/024mrxd33>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/05/2022	18/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol article		08/08/2023	09/08/2023	Yes	No
Results article		15/04/2024	15/04/2024	Yes	No