UNIVERSITY OF WEST LONDON
The Career University

UWL REPOSITORY

repository.uwl.ac.uk

Randomised controlled trial assessing the efficacy of balance acceptance and commitment therapy (ACT) for post-COVID syndrome: a study protocol

Carvalho, Nicole, Kalfas, Michail, Jolley, Caroline, Rafferty, Gerrad F, Pearson, Oliver, Emsley, Richard, Metcalfe, Alan J, Barrett, Barbara, Brewin, Debbie, Felton, Lily, Khan, Tasbiha, Hart, Nicholas, Duncan, Emma L, Nicholson, Timothy, Witard, Oliver C, Evans, Rachael A, Beckwith, Carole and Chalder, Trudie (2026) Randomised controlled trial assessing the efficacy of balance acceptance and commitment therapy (ACT) for post-COVID syndrome: a study protocol. BMJ Open, 16 (8).

https://doi.org/10.1136/bmjopen-2026-122602

This is the Published Version of the final output.

UWL repository link: https://repository.uwl.ac.uk/id/eprint/15580/

Alternative formats: If you require this document in an alternative format, please contact: open.research@uwl.ac.uk

Copyright: Creative Commons: Attribution-Noncommercial 4.0

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy: If you believe that this document breaches copyright, please contact us at open.research@uwl.ac.uk providing details, and we will remove access to the work immediately and investigate your claim.

Rights Retention Statement:

BMJ Open

Randomised controlled trial assessing the efficacy of balance acceptance and commitment therapy (ACT) for post-COVID syndrome: a study protocol

Nicole Carvalho ,[1] Michail Kalfas ,[1,2] Caroline Jolley ,[3,4] Gerrard F Rafferty ,[5] Oliver Pearson ,[6] Richard Emsley ,[6,7] Alan J Metcalfe ,[3,8] Barbara Barrett ,[9] Debbie Brewin ,[1] Lily Felton ,[1] Tasbiha Khan ,[1] Nicholas Hart ,[3,10,11] Emma L Duncan ,[12,13] Timothy Nicholson ,[14] Oliver C Witard ,[3] Rachael A Evans ,[15] Carole Beckwith,[1] Trudie Chalder [1]

To cite: Carvalho N, Kalfas M, Jolley C, *et al*. Randomised controlled trial assessing the efficacy of balance acceptance and commitment therapy (ACT) for post-COVID syndrome: a study protocol. *BMJ Open* 2026;**16**:e122602. doi:10.1136/bmjopen-2026-122602

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2026-122602).

Received 14 May 2026
Accepted 15 July 2026

Check for updates

© Author(s) (or their employer(s)) 2026. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ Group.

For numbered affiliations see end of article.

Correspondence to
Professor Trudie Chalder;
trudie.chalder@kcl.ac.uk

ABSTRACT

Introduction Post-COVID syndrome (PCS) is an ongoing legacy of the SARS-CoV-2 pandemic. Defined as symptoms persisting beyond 12 weeks following SARS-CoV-2 infection unexplained by an alternative diagnosis, many individuals continue to experience symptoms for months post-infection. Fatigue, breathlessness, cognitive difficulties and sleep disturbances are all commonly reported, frequently impairing daily functioning and quality of life. Acceptance and commitment therapy (ACT), which enhances psychological flexibility and supports values-based behaviour change, has shown effectiveness across long-term health conditions. This protocol describes the evaluation of *Balance-ACT* as a novel, adapted ACT-based intervention to address the complex physical and psychological needs of people with PCS.

Methods and analysis A randomised controlled trial (RCT), co-developed with people with PCS, will evaluate the efficacy and cost-effectiveness of Balance-ACT for PCS. A total of 196 adults with PCS will be recruited from specialist long COVID services within secondary care across NHS organisations in England and randomised 1:1 to Balance-ACT or treatment as usual (TAU). *Balance-ACT* consists of 10 therapist-delivered sessions delivered over 13 weeks. TAU comprises brief educational videos and a self-help leaflet for COVID-19 recovery. Outcomes will be assessed at 7, 14 and 20 weeks post-randomisation. The primary outcome is health-related quality of life, measured using the SF-36 Physical Component Score at 14 weeks post randomisation. Secondary outcomes include physical health-related quality of life at 20 weeks, perceived fatigue, clinical global improvement, sleep disturbance, cognitive functioning, depressive symptoms, anxiety symptoms, post-exertional malaise, breathlessness, muscle strength, muscle fatigue and heart-rate variability. Mediation analyses will examine whether the intervention leads to changes in psychological flexibility, fear-avoidance beliefs, damage beliefs, embarrassment-avoidance, symptom focusing, muscle strength and physical activity and whether these changes are associated with physical health outcomes. We will also conduct a nested qualitative study to explore participants' views of the intervention. Cost-effectiveness will be assessed by comparing health and social care service costs and quality of life outcomes between Balance-ACT and TAU at 20 weeks.

Ethics and dissemination Ethical approval has been granted by the NHS Camberwell St Giles Research Ethics Committee (reference 23/LO/0941). The study results will be disseminated in peer-reviewed journals and presented at international conferences.

Trial registration number NCT06231238.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study uses a robust randomised controlled trial design.
⇒ The intervention is explicitly theory-driven, targeting both behavioural and physiological mechanisms associated with post-COVID syndrome (PCS), which enhances its conceptual and clinical relevance.
⇒ The inclusion of a formal health economic evaluation enables assessment of the potential cost-effectiveness of the intervention within National Health Service, supporting its translational value.
⇒ The study will generate a large and comprehensive dataset incorporating both psychological and physiological outcome measures, enabling a multidimensional assessment of PCS and treatment response.
⇒ Participant engagement and retention may present challenges due to the fluctuating and heterogeneous nature of PCS symptoms, which could affect adherence over time.

INTRODUCTION

Post-COVID syndrome (PCS), also known as 'long COVID', emerged as a public health concern following SARS-CoV-2 infection.[1] The National Institute for Health and Care Excellence (NICE) defines PCS as signs and symptoms that develop during or after an

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

infection consistent with COVID-19, which continue for more than 12 weeks, without an alternative explanation.[2] The latest self-reported (and uncontrolled) estimates from the Office for National Statistics (March 2024) indicated that 2 million people in the UK were experiencing ongoing symptoms of PCS, 75% of whom report that symptoms adversely affected their day-to-day activities.

The most common reported symptoms of PCS are fatigue, breathlessness, cognitive impairment and sleep disturbances, which all substantially impair daily functioning, employment and health-related quality of life.[3–5] These symptoms are associated with increased healthcare visits, including frequent medical appointments and hospital attendance.[6] Although PCS imposes a burden on individuals and healthcare services, there are currently few established treatments for the condition, leaving many patients feeling unsupported and isolated.[7]

Recent research by Fernandez-de-las-Peñas *et al*[8] underscores the complex and multifactorial nature of PCS, highlighting substantial variability in symptom presentation and the influence of pre-existing health conditions on symptom persistence and severity. Identified risk factors for the development of PCS include female sex, greater comorbidity and higher levels of psychological distress.[9–11] Conversely, the severity of COVID-19 infection may not predict the development of PCS, and individuals with initially mild infections also appear susceptible to persistent symptoms.[12] This clinical uncertainty complicates diagnosis and treatment planning, reinforcing the need for flexible interventions that address both the physical and psychological dimensions of the condition.[13]

Guidelines from NICE recommend a multidisciplinary rehabilitation approach to PCS, recognising the need for holistic, person-centred interventions.[2] Emerging evidence is beginning to identify potentially beneficial interventions.[2] A recent systematic review[14] reported moderate certainty that cognitive behavioural therapy (CBT) and combined physical and mental health (MH) rehabilitation programmes are likely to improve symptoms of PCS. Despite these promising findings, the evidence base remains limited, and further rigorous evaluation of accessible interventions is warranted. A therapeutic model that may be particularly relevant in this context is acceptance and commitment therapy (ACT), a behavioural intervention that aims to increase psychological flexibility by helping individuals accept difficult thoughts and feelings while engaging in actions aligned with their personal values. ACT has demonstrated effectiveness in improving functioning and well-being in people with long-term health conditions.[15] Previous work demonstrates that ACT supports individuals to accept ongoing symptoms that may not be controllable while engaging in meaningful, values-based behaviour change.[16]

We co-developed an intervention using ACT integrated with the principles of homeostasis, the self-regulating process by which individuals maintain psychological and physiological stability in response to internal and external changes,[17] called *Balance-ACT*.[18] As disruptions in homeostatic processes may contribute to PCS symptoms,[19–22] the intervention is aligned with the principles of ACT (mindfulness strategies and values-based goal setting) alongside helping individuals to establish balance, regulating behaviours such as sleep and physical activity and reducing stress. Improving sleep and reducing stress may indirectly support homeostasis, given their influence on multiple physiological systems.[23–27] Mindfulness has also been shown to improve sleep, self-reported fatigue and cognitive function, which are frequently impaired in PCS.[28 29]

To ensure acceptability, *Balance-ACT* was co-developed with patients and healthcare professionals through qualitative interviews[18 30] and a patient and public involvement (PPI) advisory group. This paper presents a study protocol for *Balance-ACT* as a novel ACT-based intervention that is specifically tailored to address the complex needs of people with PCS.

Trial objectives

The *Balance-ACT* trial will assess the efficacy and cost-effectiveness of *Balance-ACT* (see 'Main research question').

Main research question

What is the efficacy and cost-effectiveness of *Balance-ACT* as a novel psychological intervention versus treatment as usual (TAU, ie, videos and self-help leaflet for COVID-19) in people with PCS.

Research objectives

Primary objective

To investigate the impact of *Balance-ACT* on self-reported physical health-related quality of life, assessed using the Physical Component Summary (PCS) of the 36-item Short Form Health Survey (SF-36) compared with TAU in people with PCS, at 14 weeks post randomisation.

Secondary objectives

To investigate the impact of *Balance-ACT* self-reported outcomes (physical health-related quality of life (measured at week 20), perceived fatigue, clinical global improvement, sleep disturbance, cognitive functioning, anxiety symptoms, depressive symptoms, post-exertional malaise and breathlessness) and physical measurements (muscle strength, muscle fatiguability and heart-rate variability) and cost-effectiveness, compared with TAU in people with PCS at 14 weeks post randomisation.

Mechanistic (mediator) objectives

To examine potential mechanisms through which Balance-ACT may influence physical health outcomes by examining whether changes in mediators at week 7 (adjusted for baseline) mediate the association between treatment allocation and physical health (SF-36 PCS) at 14 weeks post randomisation. Please note that these will be reported in a secondary trial paper.

Mediators include:

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

- Psychological flexibility measured using the Comprehensive Assessment of Acceptance and Commitment Therapy Processes (CompACT).
- Cognitive and behavioural responses to symptoms, including fear avoidance, damage beliefs, embarrassment avoidance and symptom focusing, measured using the Cognitive and Behavioural Responses Questionnaire—Short Form (CBRQ-SF).
- Muscle strength assessed using handgrip strength.
- Physical activity measured using the International Physical Activity Questionnaire—Short Form (IPAQ-SF).

It is hypothesised that *Balance-ACT* will improve psychological flexibility, reduce maladaptive cognitive and behavioural responses to symptoms, increase muscle strength and increase physical activity, which will subsequently be associated with improved physical health related quality of life.

Exploratory moderator objective

To examine whether baseline post-traumatic stress disorder symptoms, measured using the PTSD Checklist for DSM-5 (PLC-5), moderate the effect of Balance-ACT on physical health (SF-36 PCS) at 14 weeks post randomisation.

Exploratory measurement objective

To explore the associations between objective and subjective measures of sleep, fatigue, breathlessness and muscle strength.

Process evaluation objectives

To evaluate the implementation of the Balance-ACT intervention by:

- Assessing treatment fidelity.
- Exploring the acceptability of Balance-ACT through semi-structured qualitative interviews with participants.

Health economic objective

To estimate the cost-effectiveness of *Balance-ACT* vs TAU interventions.

METHODS

Study status

Recruitment for this trial began on 04 June 2024. The estimated date for primary completion is 30 May 2026, and the final study completion is expected by 01 August 2026.

Trial design

A single-blind randomised controlled trial (RCT).

Method

196 participants with a diagnosis of PCS will be recruited from specialist long COVID services within secondary care across seven London National Health Service (NHS) Trusts. Participants will be individually randomised with a 1:1 allocation ratio to *Balance-ACT* or TAU. Follow-up assessments will be conducted at 7, 14 and 20 weeks post randomisation.

Setting

This is a single-centre trial conducted at King's College London (KCL). Participants are given the option of receiving the intervention either face-to-face at KCL or via Teams, according to their preference, and this will be recorded.

Target population

Inclusion criteria

- Age 18 years or older.
- PCS diagnosis as defined by NHS/NICE (ie, symptoms that develop during or after an infection consistent with COVID-19, which continue for more than 12 weeks and are not explained by an alternative diagnosis). A checklist will be used by the research assistants to ensure participants fulfil the diagnostic criteria as per the NICE guidelines.
- Ability to travel to the research site for the study assessments.
- Having registered with a general practitioner (GP) in the UK and consent to provide their details for the study team to contact.
- Ability to provide informed consent.
- Ability to read and write English.

Exclusion criteria

- Current diagnosis of an active major MH disorder likely to interfere with participation.
- Unstable alcohol/drug dependency.
- Unstable complications associated with long COVID.*
- Past hospitalisation for COVID-19.
- Current or recent participation in other treatment intervention studies (<4 weeks after completion).
- Currently receiving psychological support or psychotherapy.
- Pregnancy.

*Unstable complications associated with PCS were predefined by the study's respiratory physician as conditions that would make participation unsafe or interfere with trial procedures. This checklist was applied by the Research Assistants during screening, and any unclear presentations were discussed with the respiratory physician to ensure appropriate eligibility decisions.

Participants who meet exclusion criteria for electrical stimulation (eg, pacemaker/defibrillator or implanted neurostimulator/infusion device; artificial hip/knee replacement) will be excluded from the physical tests requiring electrical stimulation but will be able to take part in the remaining study interventions and assessments. These participants will be discussed with a senior member of the study team prior to inclusion and the outcome documented in the participant's case report form (CRF).

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Withdrawal criteria

Participants will be withdrawn from the trial if there are any concerns regarding their continued willingness or ability to provide informed consent. Participants may withdraw from the study at any point of the trial without stating a reason. Participants wishing to withdraw can inform either a member of the research team, comprising the research assistants and trial coordinator, or their Balance-ACT therapist. This information will be communicated to the trial coordinator, who will discuss the available withdrawal options with the participant and complete the relevant withdrawal documentation. Participants may choose to (1) withdraw from all aspects of the study and treatment; (2) discontinue treatment but continue participating in research follow-up assessments; (3) continue treatment while withdrawing from the research follow-up assessments or (4) where appropriate, continue contributing data to the primary outcome measure only. The trial coordinator will ensure that the relevant members of the research team are informed of the participant's decision. Participant withdrawal forms will be used to document withdrawals and, where possible, the reason for withdrawal.

Planned intervention: Balance-ACT

Balance-ACT is a structured psychological therapy, with flexible/individualised elements, based on ACT, specifically designed to support individuals experiencing PCS. Rooted in ACT principles, *Balance-ACT* supports individuals in accepting what they cannot change while committing themselves to the things they value and can change (ie, meeting their goals in life and doing these alongside symptoms and distress within reason).

Structure and delivery

Balance-ACT consists of 10 sessions, delivered over a 13-week period. Sessions will be of 60 min duration and conducted weekly. The intervention will be delivered face-to-face or remotely (ie, via Microsoft Teams or telephone), allowing accessibility for participants experiencing fatigue and mobility challenges associated with PCS. Participants in the TAU group will receive a self-help leaflet for COVID-19 recovery, along with a document containing links to 10 brief educational videos supporting recovery after COVID-19.

Patient and public involvement

The intervention has been co-developed with individuals with lived experience of PCS through qualitative interviews[18 30] and a PPI advisory group. These insights have shaped the session structure, language and delivery format to ensure feasibility and relevance. In addition, a PPI member with lived experience of PCS is involved throughout the study and attends regular study meetings, including the Trial Steering Committee and Trial Management Group. Their contributions have informed the development of participant-facing materials, recruitment approaches, choice of outcome measures and dissemination planning, and they continue to provide input throughout the study to ensure that the research remains sensitive to the needs and experiences of people living with PCS.

Therapy training

Training was delivered via interactive workshops over 5 days to three therapists (one occupational therapist and two physiotherapists), all with experience of working with people with physical persistent symptoms or PCS. Therapists were informed of the trial protocol which included information on how to deal with any protocol violations and confidential storage of audio/video recordings. Throughout the trial, all records of the therapy sessions will be kept in accordance with the clinical service in which participants are recruited from and in accordance with professional guidelines.

Therapy supervision

All therapists will receive monthly group supervision and ad hoc 1:1 supervision to ensure adherence to the intervention. During supervision, therapists will have the opportunity to discuss clinical issues that are problematic or challenging. In addition, the supervision will check that the manual is largely being followed and ensure that the quality of therapy is sustained.

Treatment fidelity

All therapy sessions will be audio/video recorded for treatment fidelity during the trial. A proportion of recordings will be analysed by two independent clinicians, trained in ACT, once the trial has been completed. As there is no universally applicable ACT fidelity measurement, and the most widely used measurement[31] has not been comprehensively validated, fidelity to the therapy will be assessed using the adapted ACT fidelity measure (ACT-FM)[32] in conjunction with a bespoke *Balance-ACT*-specific rating scale. The bespoke Balance-ACT-specific rating scale includes three intervention-specific items: (1) *therapist-delivered therapy consistent with the Balance-ACT intervention logic model (addressing the regulation of sleep, activity, stress and emotions)*; (2) *therapist-supported routines, long-term habit formation and behaviour change in line with Balance-ACT targets*; and (3) *the intervention delivered aimed to restore balance physiologically and psychologically*. Each item will be rated on a 5-point scale (0–4), where 0 indicates the behaviour did not occur despite being relevant or necessary for the session; 1 indicates the therapist rarely enacted the behaviour; 2 indicates the therapist sometimes enacted the behaviour; 3 indicates the therapist consistently enacted the behaviour and 4 indicates the therapist consistently enacted the behaviour with a high degree of skill. The bespoke rating scale was developed by the chief investigator (CI), who is an ACT therapist, as well as the therapist supervisor and trainer.

Intervention adherence

The therapists will record how many *Balance-ACT* sessions out of 10 the participant attended, session modality

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

(face-to-face, video link or telephone) and whether any adverse events occurred. At the end of therapy, the therapist will also score how well the participant adhered to therapy on a 4-point Likert rating scale: participant change, participant adherence to in-between sessions work and the degree to which the participant accepted the model of therapy.

If participants do not attend a session, the therapist will contact the participant by telephone to ascertain the problem regarding attendance and will discuss options regarding how to proceed. This process will be followed up by an email should the participant not respond.

Recruitment

Participants will primarily be recruited from specialist long COVID services within secondary care across NHS organisations in England, including King's College Hospital NHS Foundation Trust, South London and Maudsley NHS Foundation Trust, Guy's and St Thomas' NHS Foundation Trust, Bromley Healthcare, Central and North West London NHS Foundation Trust, University College London Hospitals NHS Foundation Trust and Whittington Health NHS Trust.

Study procedure

Interested participants will be asked to sign an agreement to be contacted by the research team. The research assistants will then be responsible for screening patients to check trial eligibility. Eligible patients will be provided with verbal and written information on the trial. To formally enrol, patients will be required to complete a signed informed consent form. The participant informed consent form is available in online supplemental file 1. Informed consent will be obtained by appropriately trained members of the research team. Once consent is obtained, they will be asked to complete the baseline assessment, which consists of psychological and physical components. Participants will then be randomised to one of two arms: *Balance-ACT* or TAU (an information leaflet for COVID-19 and a link to 10 videos available online, developed by the South East London Long COVID Programme, Guy's and St Thomas' NHS Foundation Trust).

Outcomes will be assessed at 7, 14 and 20 weeks after randomisation. Figure 1 provides a Consolidated Standards of Reporting Trials (CONSORT) diagram, outlining the journey of all participants through the trial.

Randomisation

Following verbal and written consent, participants will be randomised in a 1:1 ratio to one of the two trial arms (Balance-ACT or control group (TAU)) within 48 hours of completing the baseline assessment. The randomisation will be conducted by the unblinded study coordinator using the King's Clinical Trial Unit (KCTU) randomisation system. The randomisation system will be managed by the KCTU and will be hosted on a server within KCL. The system will employ block randomisation with randomly varying block sizes. The details needed for randomisation (month and year of birth, initials and unique participant identity number) will be held in a dedicated database. Following randomisation, the unblinded study coordinator will inform participants of their allocation group by telephone and within one working day. Following allocation to the treatment group, the study coordinator will inform the therapists who will contact the participant to arrange the first session.

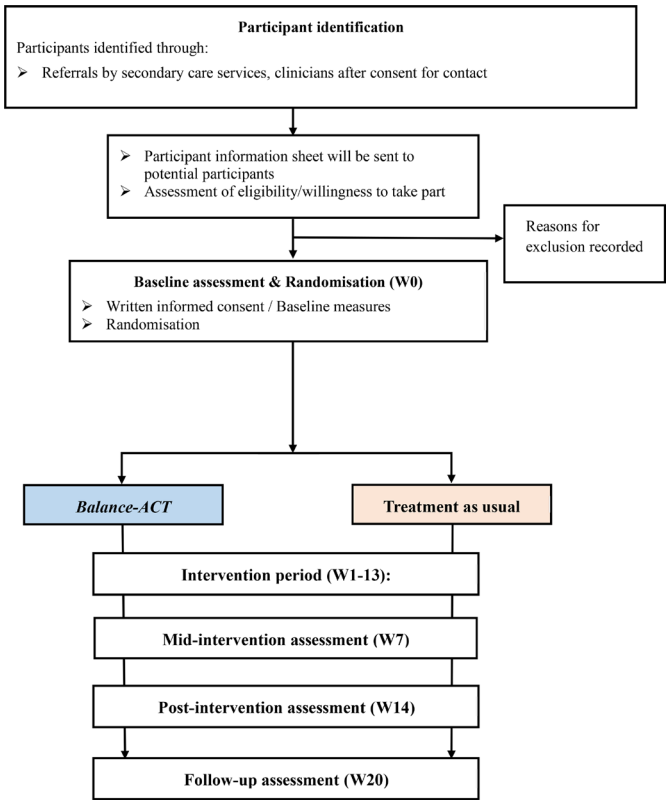


Figure 1 Planned Consolidated Standards of Reporting Trials (CONSORT) flow diagram illustrating participant flow through the Balance-acceptance and commitment therapy (Balance-ACT) trial from screening and eligibility assessment to randomisation, allocation and follow-up.

Proposed sample size

A total sample size of 196 participants (98 per arm) will be recruited to allow for 15% attrition. This sample provides 80% power to detect a minimally clinically important effect size (Cohen's d) of 0.4 at a two-sided 5% significance level. The target effect size is informed by existing literature, including a trial of CBT for long COVID reporting an effect size of 0.34 on the SF-36 physical functioning (PF) subscale.[33] The anticipated attrition rate was informed by clinical experience within participating specialist PCS services, where patients were actively seeking treatment for persistent symptoms. They were considered likely to remain engaged with both the intervention and study follow-up procedures. To minimise the impact of missing data, all reasonable efforts will be made to retain participants and to ensure

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

completion of at least the primary outcome measure in instances where participants discontinue further involvement in the study.

Data management

Patient data will be pseudo-anonymised, and participants will be given a unique participant number that will be used for identification purposes. Identifiable information (eg, name, contact details) will be filed securely in a separate password-protected document on the KCL OneDrive. Data will be stored in line with the General Data Protection Regulation (UK GDPR) and the Data Protection Act and archived according to Sponsor requirements. A web-based electronic data capture (EDC) system will be designed (MACRO). The EDC will be created in collaboration with the trial statistician and the CI and will be maintained by the KCTU for the duration of the project. The EDC will be hosted on a dedicated server within KCL. Data entry and management will be undertaken by the research assistants, and random checks will be undertaken by the study coordinator. The CI will be the custodian for the trial dataset.

Blinding

All research assistants assigned to collect outcome data will be blinded to participants' allocated arm. The CI (TC) will also be blinded to allocation. The senior statistician will be blinded until review of the statistical report; the trial statistician was initially blinded, then became unblinded from preparing Data Monitoring and Ethics Committee and Trial Steering Committee (DMEC/TSC) reports from May 2025. The study coordinator and the *Balance-ACT* therapists are the only other members of the study team who will be unblinded, to ensure the participants randomised to the intervention receive the intervention in a timely fashion.

Data collection and follow-ups

Outcome measurements will be collected at baseline (pre-randomisation) and at 7, 14 and 20 weeks post randomisation. A ±21 day window around each scheduled follow-up assessment will be permitted for data collection. Participants will be asked to complete self-report measures in writing, electronically via Qualtrics, or in special circumstances, over the telephone. If participants decline to complete the full follow-up assessment but have not revoked their consent to be followed up, they will be asked to fill in only the primary outcome questionnaires. Participants who do not return their questionnaires will be contacted by the Research Assistants via telephone/email to remind them to complete and return their questionnaires.

Measures

All measurements are summarised in table 1; subscales and detailed descriptions are reported in the 'Secondary outcome measures' section.

Baseline

1. Demographic variables: A number of baseline demographic variables will be collected to describe the sample. These variables include gender, age, ethnicity, weight, height, occupational status, educational attainment, marital status, living arrangements and details of healthcare professional.
2. Medical history: Date of PCS diagnosis made by clinician, comorbid MH or physical health conditions, current pharmacological (name, type, dose, frequency, date started) and non-pharmacological treatments (type, frequency, date started). NHS number, service use, details about past hospital admissions for MH and physical health reasons.
3. *Psychiatric disorders:* The Mini International Neuropsychiatric interview (7)[34] will be used to assess the presence of: major depressive episode, panic disorder, agoraphobia, social anxiety disorder, obsessive compulsive disorder, post-traumatic stress disorder, generalised anxiety disorder (modules A, D, E, F, G, H, N).

Primary outcome measure

The primary outcome will be assessed using the PCS of the 36-item Short Form Health Survey (SF-36) at week 14. The study will administer the RAND 36-Item Health Survey,[35] which contains the same items as the SF-36.[36] Scoring will follow the SF-36 manual to compute the PCS. The SF-36 is a widely used questionnaire designed to assess health-related quality of life.[37] It consists of 36 items that measure eight different domains of health: PF, role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and MH. These eight domains can be further summarised into two distinct concepts: a physical dimension, represented by the PCS, and a mental dimension, represented by the Mental Component Summary (MCS).

Secondary outcome measures

Secondary outcomes to be analysed using formal statistical comparisons

The following secondary outcomes will be analysed using formal statistical comparisons at weeks 14 and 20, unless not collected at week 20 (please see table 1).

1. PCS of SF-36 at week 20.
2. *Fatigue:* The Functional Assessment of Chronic Illness Therapy Fatigue Scale is a short, 13-item tool that measures an individual's level of fatigue during their usual daily activities over the past week. The level of fatigue is measured on a four-point Likert scale (4=not at all fatigued to 0=very much fatigued).[38]
3. *Global improvement:* The clinical global improvement (Modified Clinical Global Impressions Scale—Improvement; CGI-I) is a clinician-rated measure used to assess how much a patient's condition has improved or worsened compared with a baseline assessment. It is a variation of the standard CGI-I scale, commonly used in clinical trials to evaluate treatment

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Table 1 Screening and data collection across the trial

Procedures/measures	Screening (preW0)	Baseline (W0)	Mid-therapy (W7)	Post (W14)	Follow-up (W20)
Eligibility criteria	x				
Sociodemographic/medical and illness history		x			
Mini international neuropsychiatric interview 7 (modules A, D, E, F, G, H, N)		x			
Height		x			
Weight/body mass index/resting heart rate/blood pressure/SpO_2		x		x	
Post-COVID syndrome recovery (single item)			x	x	x
Adult service use schedule		x			x
Short-Form 36 Health Survey		x	x	x	x
EuroQoL 5D		x		x	x
Modified Clinical Global Impressions Scale—Improvement				x	x
Functional Assessment of Chronic Illness Therapy		x	x	x	x
Pittsburgh Sleep Quality Index		x	x	x	x
Cognitive and Behavioural Responses Questionnaire—Short Form		x	x	x	x
Comprehensive assessment of Acceptance and Commitment Therapy processes		x	x	x	x
Modified Patient Health Questionnaire 15		x	x	x	x
Work and Social Adjustment Scale		x	x	x	x
International Physical Activity Questionnaire—Short Form		x	x	x	x
Modified DePaul post exertional malaise questionnaire		x	x	x	x
Perceived Deficits Questionnaire		x	x	x	x
Montreal cognitive assessment- telephone version		x		x	x
Patient Health Questionnaire 8		x	x	x	x
Generalised Anxiety Disorder—7		x	x	x	x
Post Traumatic Stress Disorder Checklist for DSM 5		x		x	x
Borg Rating of Perceived Exertion		x		x	
Nijmegen Questionnaire		x		x	x
Modified Medical Research Council Dyspnea Scale/ Dyspnoea-12		x		x	x
Volitional handgrip strength		x	x	x	x
Volitional quadriceps strength		x		x	
Quadriceps activation using twitch interpolation		x		x	
Volitional handgrip muscle fatigue		x		x	
Non-volitional quadriceps muscle fatigue		x		x	
Spirometry and oxygen levels (SpO_2)		x		x	
Short Physical Performance Battery: 4 m gait speed/ balance		x		x	
1 min sit-to-stand test		x		x	
Heart-rate variability via ECG/average heart rate via ECG		x		x	
Treatment satisfaction				x	
Adverse events		x	x	x	x

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

effectiveness.[39] This is rated on a 7-point Likert scale where 1 is very much better and 7 is very much worse.

4. *Sleep disturbance*: The Pittsburgh Sleep Quality Index is a widely used self-report questionnaire designed to assess sleep quality and disturbances over a 1-month period. It is commonly used in research and clinical settings to evaluate various aspects of sleep.[40] Each of the questionnaire's 19 self-reported items belongs to one of seven subcategories: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication and daytime dysfunction. Five additional questions rated by the respondent's roommate or bed partner are included for clinical purposes and are not scored.[40]
5. *Cognitive deficits:* The Perceived Deficits Questionnaire,[41] which assesses self-reported difficulties in attention, retrospective memory, prospective memory, planning and organisation, and overall cognitive functioning will be used. Each of the 20 items are rated on a 5-point Likert scale (0=never, 4=almost always).
6. *Depression*: The Patient Health Questionnaire 8 (PHQ-8) will be used to monitor and measure the severity of depression in participants.[42] Each item is rated on a 4-point Likert scale (0=not at all; 1=several days; 2=more than half the days; 3=nearly every day) and the total score can range from 0 to 24 where a higher score indicates greater depressive severity. The PHQ-8 is a reliable and well-validated measure of depression severity.[42]
7. *Anxiety:* The Generalised Anxiety Disorder—7 (GAD–7) questionnaire will be used to measure the severity of GAD in participants.[43] Each item is rated on a 4-point Likert scale (0=not at all; 1=several days; 2=more than half the days; 3=nearly every day), and the total score can range from 0 to 21 where a higher score indicates greater anxiety. The GAD-7 has demonstrated reliable psychometric properties in the measurement of anxiety in the general population.[44]
8. *Post-exertional malaise:* The modified DePaul Post exertional malaise questionnaire[45] is a validated self-report measure designed to assess post-exertional malaise, a hallmark symptom of long COVID. It assesses symptom worsening, time to onset, duration, triggers and recovery time. Items are rated on a 5-point Likert scale (0=never, 4=very often).
9. *Breathlessness:* Breathlessness was measured using the Dyspnoea-12,[46] which captures both physical and affective components of breathlessness.
10. *Muscle strength*: Volitional handgrip strength will be assessed using a handheld dynamometer in the dominant hand. Participants will be seated, shoulder adducted, elbow flexed at 90° with the forearm and wrist in a neutral position. With the dynamometer in hand, the participant will be instructed to squeeze as hard as possible. The participant will perform at least five sustained (3–5 s) maximal efforts with 60 s of rest between repetitions.[47]
11. *Muscle fatigue:* Handgrip volitional fatigue: A digital grip force transducer will be used to assess volitional handgrip fatigue in the dominant hand. Using the same approach adopted when measuring handgrip force, participants will be asked to maintain a grip force equal to 50% of their MVC for as long as possible. Handgrip fatigue will be quantified as the time taken for grip force to fall below 40% of their MVC. This testing methodology has good reliability and fair variability.[48]
12. *Heart-rate variability:* Heart-rate variability will be assessed using root mean square of successive differences from analysing 5 min of a 10 min resting three-lead ECG. These short-term recordings provide a non-invasive measure of autonomic nervous system function.[49]
13. *Average heart rate:* Average heart rate will be assessed from 5 min of a 10 min resting three-lead ECG. These short-term recordings provide a non-invasive measure of autonomic nervous system function.

Secondary outcomes to be analysed as part of the health economics analysis

1. *Economic evaluation*: The Adult Service Use Schedule (AD-SUS)[50] is a structured tool designed to collect information on participants' use of health and social care services, including primary care, MH services, hospital contacts, medications and community support. Data from the AD-SUS will be used to inform the economic evaluation of the intervention.
2. *Health-related quality of life*: The 5-Level EuroQoL 5D (EQ-5D-5L) is a reliable and valid tool to measure health related quality of life.[51] Each dimension (mobility, self-care, usual activity, pain/discomfort and anxiety/depression) is rated on five levels (1=no problems; 2=slight problems; 3=moderate problems; 4=severe problems; 5=extreme problems). The participant will also rate their own perception of their current health on a visual analogue scale ranging from 0 to 100, where 0=the worst health you can imagine and 100=the best health you can imagine.[51]

Secondary outcomes to be reported using descriptive summaries

The following secondary outcomes will be reported using descriptive summaries at weeks 14 and 20, unless not collected at week 20 (please see table 1).

1. *Mental health-related quality of life*: The MCS of SF-36.[35]
2. *Somatic symptoms*: The modified Patient Health Questionnaire-15 (PHQ-15) will be used to measure somatic symptoms.[52] Each item is rated on a 3-point Likert scale (0=not bothered at all; 1=bothered a little; 2=bothered a lot), and the total score can range from 0 to 30 where a higher score indicates higher symptom severity. The modified PHQ15 is a brief well-validated tool for detecting somatisation.[52]
3. *Cognitive function:* The Montreal cognitive assessment-telephone version (MoCA-T)[53] is a validated screening tool used to assess cognitive function remotely

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

over the phone. It is based on the standard Montreal Cognitive Assessment (MoCA) but adapted for telephone administration. It has a maximum score of 22 points where higher scores indicate better cognitive functioning.

4. *Functional impairment:* The Work and Social Adjustment Scale is a 5-item scale used to measure the extent to which people's problems interfere with their ability to carry out normal activities, go to work, partake in private and social activities and impact on relationships.[54]
5. *Post-traumatic stress disorder*: The Post-Traumatic Stress Disorder Checklist for DSM 5 (PCL-5)[55] is used to assess the presence and severity of post-traumatic stress disorder symptoms.
6. *Hyperventilation*: The Nijmegen Questionnaire[56 57] is a self-report measure used to assess symptoms associated with dysfunctional breathing or hyperventilation. It captures common symptoms such as breathlessness, chest tightness, dizziness and anxiety-related sensations, and helps identify individuals who may be experiencing hyperventilation syndrome or breathing pattern disorders.
7. *Breathlessness:* Breathlessness was additionally measured using the Modified Medical Research Council Dyspnoea Scale,[58] a brief measure of functional breathlessness.
8. *Physical activity:* The IPAQ-SF is a widely used self-report measure for assessing physical activity levels in adults. It provides an estimate of total physical activity across different domains and is commonly used in research to evaluate physical activity patterns over the past 7 days.[59] Consists of seven questions about walking, moderate activity, vigorous activity and sedentary time.
9. *Long COVID recovery*: A self-reported single item questionnaire "Do you consider yourself recovered from long COVID?"
10. *Treatment satisfaction:* At week 14, participants will complete a brief single-item treatment satisfaction question: "How satisfied are you with the treatment you received?" Response options range from 1 (very satisfied) to 7 (very dissatisfied). This item provides a simple global index of participant-perceived treatment acceptability.

Secondary outcomes to be reported in secondary papers

The following outcomes will be reported in secondary papers, separate to the primary trial paper.

1. *Muscle strength*: Volitional quadriceps strength will be assessed by performing at least five sustained maximal voluntary isometric contractions (QMVICs) using a dedicated testing chair with the back upright at 90° and the knee flexed at 90°. Quadriceps strength will be measured in both the dominant and non-dominant limbs.[60] To assess the degree of voluntary activation (VA) during QMVIC, twitch interpolation will be performed during five additional maximal contractions in the dominant limb using carbon rubber stimulating electrodes placed over the quadriceps femoris.[61] An interpolated twitch (Tw) will be delivered during the QMVIC followed by a potentiated twitch delivered approximately 2 s after the QMVIC manoeuvre. VA was determined as (1 - interpolated Tw/potentiated Tw) × 100.
2. *Muscle fatigue*: Quadriceps non-volitional fatigue: Quadriceps muscle endurance will be assessed non-volitionally in the dominant leg using transcutaneous electrical stimulation applied using the two electrodes placed over the quadriceps femoris muscle to assess VA. A constant current stimulator will be set to deliver 300 µs square wave pulses at 30 Hz with a duty cycle of 250 ms on and 750 ms off for 180 s. The stimulus intensity is adjusted for each participant to elicit an initial force equivalent to 30% of QMVIC. Force production is measured continuously and the time for quadriceps force to fall to 70% of baseline is used as a marker of fatiguability.[48]
3. *Functional capacity:* This will be measured using the 1 min sit-to-stand test, a validated assessment of lower-limb function and exercise tolerance.[62] Participants will be shown the Borg Rating of Perceived Exertion Scale[63] and asked to rate their perceived breathlessness and leg fatigue prior to the start of the test, immediately after completion of the test, and following 1 min of recovery.
4. *Frailty:* Frailty will be assessed using the Short Physical Performance Battery, which includes the 4 m gait speed test, standing balance tests and repeated chair stand test.[64]
5. *Spirometry and oxygen levels (SpO_2):* Pulmonary function will be assessed using spirometry conducted according to standardised procedures.[65] Peripheral oxygen saturation (SpO_2) will be measured at rest using a pulse oximeter.
6. *Cognitive and behavioural responses:* A shortened 18-item version of CBRQ is a valid and reliable tool used to assess participants' cognitive and behavioural responses to their symptoms.[66] Each item is measured on a five-point Likert scale, scored from 0 (strongly disagree) to 4 (strongly agree) where a higher subscale score indicates more unhelpful cognitions and behaviours. The measure comprises six subscales; four are cognitive subscales that assess fear avoidance, damage beliefs, embarrassment avoidance and symptom focusing. The remaining two subscales pertain to behavioural patterns capturing resting behaviour and all-or-nothing behaviour.[66]
7. *Psychological flexibility:* CompACT is a self-report questionnaire designed to measure psychological flexibility. It comprises 23 items each rated on a 7-point Likert scale, where 0=strongly disagree and 6=strongly agree.[66] The measure includes three subscales: Openness to Experience, Behavioural Awareness and Valued Action.

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Statistical analysis

A statistical analysis plan will be developed by the statisticians and agreed with the CI, senior statistician and DMEC/TSC before database lock. The analysis will be reported in line with the CONSORT guidelines with the 2018 extension for reporting social and psychological intervention trials.[66] Descriptive statistics will be used to summarise assessments of recruitment, drop-out and completeness of therapy.

The analysis will follow intention-to-treat principles whereby participants are included in the treatment group to which they were randomised. Hypothesis tests will be two-sided and estimated treatment effect will be accompanied by a 95% CI. For all analyses, a significance level of 5% will be used. Methods for handling missing data will be prespecified in the 'Statistical analysis plan.

The primary analysis will be a mixed effects linear regression of the PCS of the SF-36. Fixed effects will be recruitment source, baseline assessment for the outcome under investigation, random allocation, time and time*random allocation interactions. Participants will be included as random intercepts. For continuous secondary outcomes the same approach will be followed, and for binary secondary outcomes logistic mixed models will be used. The minimum number of therapy sessions for the per protocol analysis will be 5.

Mediation analysis

Causal mediation analysis will use parametric regression models.[67] This will be reported in a secondary paper, separate from the primary trial paper.

Mediators include

- Psychological flexibility measured using CompACT.
- Cognitive and behavioural responses to symptoms, including fear avoidance, damage beliefs, embarrassment avoidance and symptom focusing, measured using the CBRQ-SF.
- Muscle strength assessed using handgrip strength.
- Physical activity measured using the IPAQ-SF.

For each mediator, we will estimate a linear model with random allocation, baseline outcome, baseline mediator, and recruitment source as covariates. A separate linear model will be estimated for each outcome, including the mediator and the same covariates. The indirect effect will be calculated by multiplying the effect of random allocation on the mediator by the effect of the mediator on the outcome, while the direct effect will be the effect of random allocation on the outcome, adjusted for the mediator.

Moderation analysis

Moderation analyses will involve adding interaction terms between random allocation, time and the respective moderators. The treatment effect difference between levels of the moderator will be interpreted as the difference in estimated treatment effects between participants with baseline moderator values of a+1 and a. This will be reported in a secondary paper, separate from the primary trial paper. Additional exploratory analyses may also be conducted to investigate other potential moderators of treatment response where clinically or theoretically justified.

Participants are offered the option of receiving the intervention either face-to-face or via Microsoft Teams. Although this factor was not included in the original analysis plan, an exploratory moderator analysis will be conducted, in a secondary paper, to assess whether treatment effects vary according to mode of intervention delivery.

Thematic analysis

The qualitative interviews will be transcribed verbatim and analysed inductively using reflexive thematic analysis as outlined by Braun and Clarke[68 69] following their six-phase approach. Consistent with Braun and Clark's later work,[69] data analysis will be an active and reflexive process, with themes developed through interpretative engagement with the dataset rather than emerging passively.

Economic evaluation

A health economics analysis plan will be developed by the economists and agreed with the grant holders (CJ, ELD, NH, GFR, TN, OCW) before database lock. The analysis aims to compare service use and costs between *Balance-ACT* versus TAU and assess the cost-effectiveness of *Balance-ACT* in relation to TAU. Service use data will be collected using the AD-SUS and combined with unit costs to calculate total health and social care costs. The cost of the *Balance-ACT* intervention will be estimated using standard costing procedures. Quality-adjusted life-years (QALYs) will be derived from EQ-5D-5L data using the NICE recommended approach. Cost-effectiveness will be evaluated by combining costs and outcomes, with results presented as incremental cost-effectiveness ratios and cost-effectiveness acceptability curves.

Internal pilot

The study incorporated an internal pilot phase which followed the progression criteria in RCTs.[70] The internal pilot lasted 5 months and included a two-tiered system, as described in table 2, which presents the progression criteria. If 30% of participants (60/196) were recruited within the first 5 months and at least 85% completed the 7-week follow-up questionnaire, the trial proceeded as planned. If these recruitment and retention targets were not met, predefined modifications to study procedures would have been considered prior to continuation into the main trial.

For the internal pilot phase, the progression criterion for recruitment was to enrol 30% of the target sample (60 participants). A total of 51 participants were recruited during this period, falling slightly short of the recruitment target. However, several additional participants had already been referred and were in the process of being enrolled. Participant retention exceeded the progression criterion, with more than 85% of participants completing

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Table 2 Internal pilot two-tiered system

Primary outcomes	Green: proceed to main trial	Amber: some adjustments may be required before proceeding to main trial
Proportion of eligible participants randomised into the study within 5 months (12–13 per month)	n=60 (30%)	n=37
Participants randomised to Balance-ACT and receiving at least one session*	50%	30–49%
Proportion of trial participants completing the 7-week questionnaire†	85%	75–84%

*% of those due to have had at least one session.
†% of those where the 7-week questionnaire is due.
ACT, acceptance and commitment therapy.

the 7-week assessment. Recruitment and retention data were reviewed by the combined DMEC/TSC, who recommended progression to the main trial. The mean time required to complete the questionnaire assessments was approximately 1.5–2 hours, while the physical assessment took an average of 2 hours. To reduce participant burden, particularly among those experiencing fatigue and cognitive difficulties associated with PCS, participants were offered the option of completing part of the questionnaire battery online. Any questionnaires not completed during the assessment visit were required to be completed within 24 hours to ensure consistency in outcome measurement.

Trial oversight

A combined DMEC/TSC were established to provide oversight for this study. The DMEC/TSC is comprised of members independent of the study team. Members of the DMEC/TSC include independent clinicians, an independent statistician and one PPI member with lived experience of PCS. The DMEC/TSC meets every 6 months for the trial duration. The role of the DMEC/TSC is to provide oversight for the trial, safeguard the rights of the participants and ensure the trial is conducted to rigorous standards in line with Good Clinical Practice guidelines. The DMEC/TSC also provides advice to the TMG and the Sponsor of the trial. The DMEC/TSC has access to study data and is responsible for monitoring participant safety and trial data. Data extracts are requested by the Trial Statistician prior to each DMEC/TSC meeting, who prepares reports for the DMEC/TSC.

Procedures for recording and reporting serious adverse events

Adverse events (AEs) will be assessed at 7, 14 and 20 weeks after randomisation. All serious adverse events (SAEs) and serious adverse reactions (SARs) will be reported immediately to the CI, sponsor and DMEC/TSC. The reporting of SAEs will be based on the following criteria: (1) death of a participant, (2) life-threatening event, (3) hospitalisation or prolonged hospitalisation, (4) persistent or significant disability or incapacity, (5) significant psychological distress, (6) the disclosure of illegal activity, (7) breaches of security and/or data breaches and (8) safeguarding concerns. Given the psychological nature of the intervention, anticipated harms are considered low risk; however, potential adverse effects may include temporary emotional distress or worsening of symptoms during participation. Harms may be identified through participant self-report, therapist observation or communication with the research team during study procedures and intervention sessions.

The study researchers will discuss any concerns about participants' well-being with the CI (TC) who will decide on the appropriate course of action. If there are any safety concerns, TC or the respiratory physicians (NH, CJ) will be consulted, and the participant's healthcare professional (GP) will be contacted. If a participant states that they are actively suicidal and have plans to harm themselves, they will be assessed by a member of the team. A plan will be agreed to ensure the safety of the participant. All procedures relating to risk management will be conducted in line with the policies and procedures of the relevant participating NHS Trust from which the participant is recruited. Any distress experienced by participants will be formally assessed during the in-person study assessments, at baseline (W0), mid-treatment (W7), post-intervention (W14) and follow-up (W20). Spontaneous AEs reported during therapy sessions will also be recorded.

Stopping rules

If deemed necessary, based on either new safety information or lack of recruitment, the trial may be prematurely stopped by the sponsor, CI, DMEC/TSC or Research Ethics Committee (REC). If the study is discontinued, participants enrolled onto the study will be informed and subsequently data collection will stop.

Auditing

The study will be monitored and audited by the study sponsors KCL.

Plans for communicating important protocol amendments to relevant parties

Amendments will be submitted to the sponsor for assessment, categorisation and approval, prior to

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

submission to the Health Research Authority and REC where necessary. The amendment history will be tracked via version and date control of the protocol and associated documents.

ETHICS AND DISSEMINATION

Research ethics approval

KCL has agreed sponsorship. Ethical approval has been granted by the NHS Camberwell St Giles Research Ethics Committee (reference 23/LO/0941).

Insurance and indemnity

Standard procedures for insurance of University and NHS employees and sites, and NHS patients will apply.

Dissemination policy

The results will be presented to healthcare professionals nationally and internationally and published in peer-reviewed journals. If the intervention is more effective than the control, we plan to offer training workshops to clinical services within the NHS. We will provide lay summaries to charities and the public via websites that already disseminate information on PCS.

Availability of data and materials

The final trial dataset will be anonymised and available upon reasonable request to the corresponding authors once all analysis is complete.

DISCUSSION

PCS presents an ongoing public health challenge, with many affected individuals experiencing persistent symptoms that impair daily functioning, employment and healthcare utilisation. Despite this substantial burden, effective treatments remain limited, highlighting the urgent need for evidence-based interventions and rigorous studies assessing the effectiveness of available care.

This paper outlines the study protocol for a RCT evaluating the efficacy and cost-effectiveness of a novel psychological intervention for PCS. By targeting the behavioural and physiological mechanisms underlying PCS symptoms, Balance-ACT aims to enhance quality of life and overall functioning. Importantly, the intervention is not designed to address all underlying causes of PCS; rather, it seeks to support individuals in developing adaptive coping strategies and engaging in meaningful activities to facilitate recovery. If effective, this intervention could not only improve patient outcomes but also yield long-term economic benefits for the NHS.

Strengths and limitations of the study

The study has several strengths, including its randomised controlled design and the use of a theory-driven intervention targeting both behavioural and physiological processes associated with PCS. The inclusion of a health economic evaluation will also enable assessment of the potential cost-effectiveness of the intervention within NHS services.

Several limitations should also be considered. Participant retention and intervention adherence may be challenging given the fluctuating and heterogenous nature of PCS symptoms. Follow-up completion and intervention adherence will be recorded and summarised, and sensitivity analyses (including a per protocol analysis) will be conducted to explore the impact of intervention adherence. In addition, the study relies primarily on self-reported outcome measures, which may introduce reporting bias. Variability in symptom severity and presentation across participants may also influence treatment response and interpretation of findings. Strategies such as flexible participation (e.g. remote follow-up options and scheduling flexibility) and tailored intervention delivery have been incorporated to mitigate these challenges; however, these factors should be considered when interpreting the study outcomes.

As participants and therapists cannot be blinded to treatment allocation, there is a potential for expectancy bias, particularly for self-reported outcomes such as the SF-36 Physical Component Score, which is a self-reported measure of health-related quality of life. Importantly, participant expectations may influence outcomes in either direction, as individuals may hold positive, neutral, or negative beliefs regarding the likely effectiveness of the intervention. Similarly, participants allocated to TAU may have either positive or negative expectations regarding their recovery. To minimise the risk of bias, outcome assessors and the CI remain blinded to treatment allocation. The research team will also maintain a position of equipoise throughout recruitment, informing participants that there is genuine uncertainty regarding the relative effectiveness of the study intervention. To facilitate interpretation of the results, both subjective and objective outcome measures will be reported, and associations between these measures will be explored. Examining the extent to which self-reported improvements correspond with objective indicators of functioning will provide additional insight into the robustness of the observed treatment effects.

A further limitation relates to the inability to distinguish the specific effects of the Balance-ACT intervention from the non-specific effects associated with regular therapist contact. Participants allocated to the intervention receive up to ten therapist-delivered sessions over 13 weeks, whereas those in the TAU group receive substantially less contact with healthcare professionals. Consequently, any observed benefits may reflect, in part, the effects of therapeutic attention, support, validation and ongoing engagement rather than the specific therapeutic components of Balance-ACT itself. This is an inherent limitation of pragmatic trials comparing a complex intervention with usual care. Findings will therefore be interpreted with caution, and any observed treatment effect will be considered as representing the combined impact of the intervention and the additional therapist contact. Further research

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

may benefit from the inclusion of an attention-matched comparator to better isolate the specific effects of the intervention.

If effective, the findings could inform future clinical guidelines and support the development of tailored interventions for PCS. Further research will be needed to explore the long-term sustainability of intervention effects and explore potential integration with other treatment approaches, including pharmacological options.

Author affiliations
[1]Department of Psychological Medicine, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK
[2]Division of Psychiatry, Faculty of Brain Sciences, Imperial College London, London, UK
[3]Centre for Human and Applied Physiological Sciences, Faculty of Life Sciences & Medicine, King's College London, London, UK
[4]Department of Respiratory Medicine, King's College Hospital NHS Foundation Trust, London, UK
[5]Faculty of Life Sciences & Medicine, King's College London Centre for Human & Applied Physiological Sciences, London, UK
[6]King's Clinical Trials Unit, King's College London, London, UK
[7]Institute of Psychiatry, Psychology and Neuroscience, King's College London Department of Biostatistics & Health Informatics, London, UK
[8]School of Human and Social Sciences, University of West London, London, UK
[9]Department of Health Service and Population Research, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[10]Lane Fox Clinical Respiratory Physiology Research Centre, St Thomas' Hospital, London, UK
[11]Lane Fox Respiratory Service, St Thomas' Hospital, London, UK
[12]School of Life Course & Population Sciences, King's College London, London, UK
[13]Department of Endocrinology, Guy's and St Thomas' NHS Foundation Trust, London, UK
[14]Institute of Psychiatry, Psychology & Neuroscience, Department of Psychosis Studies, King's College London, London, UK
[15]NIHR Biomedical Research Centre – Respiratory Theme, Division of Respiratory Sciences, University of Leicester, Leicester, UK

Acknowledgements This research has been made possible by the Guy's and St Thomas' Charity, with lead support from Wol and Kerry Kolade, and additional support from donors who wish to remain anonymous.

Contributors NC: writing—original draft preparation. MK, AJM, DB, LF, TK: writing—review and editing. CJ, GFR, OP, RE, BB, NH, ELD, TN, OCW, RAE: investigator, writing—review and editing. CB: patient and public involvement, core member of team. TC: chief investigator, supervision, writing—review and editing. All authors read and approved the final manuscript. TC is the guarantor of the manuscript and accepts full responsibility for the finished work and the conduct of the study.

Funding The study is funded by Guy's and St. Thomas' Charity.

Disclaimer This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data or decision to submit results.

Competing interests TC is part-funded by the National Institute for Health Research (NIHR) Biomedical Research Centre at a UK NHS Foundation Trust. She has authored several self-help books on chronic fatigue; received ad hoc payments for workshops on long-term conditions and long COVID; served on the Expert Advisory Panel for COVID-19 Rapid Guidelines; received travel expenses and accommodation for attending conferences and is in receipt of additional COVID-related grants from UKRI. ELD has received funding for research into Long COVID from the Chronic Disease Research Foundation, specifically for the genetics of PCS/ongoing symptomatic COVID-19. She has also received funding from the BMA Foundation and Guy's and St Thomas' Charity for long COVID-related research. CJ has received funding from the BMA Foundation for research into long COVID. MK reported personal fees from Neurocentrx Pharma outside the submitted work. RAE reported institutional research funding from UKRI, MRC, NIHR, EPSRC, the Wolfson Foundation, Asthma and Lung UK, and Genentech-Roche. She also received a one-time speaker honorarium for a conference (non-promotional). The other authors declare no conflicts of interest.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: https://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs
Nicole Carvalho https://orcid.org/0009-0005-4659-0573
Michail Kalfas https://orcid.org/0000-0003-3029-9149
Caroline Jolley https://orcid.org/0000-0003-3538-2451
Gerrard F Rafferty https://orcid.org/0000-0001-9520-6500
Oliver Pearson https://orcid.org/0000-0003-1149-9284
Richard Emsley https://orcid.org/0000-0002-1218-675X
Alan J Metcalfe https://orcid.org/0000-0001-6293-1706
Barbara Barrett https://orcid.org/0000-0002-0270-6256
Debbie Brewin https://orcid.org/0009-0004-2182-6079
Lily Felton https://orcid.org/0009-0001-8492-0685
Tasbiha Khan https://orcid.org/0009-0000-7419-7895
Nicholas Hart https://orcid.org/0000-0002-6863-585X
Emma L Duncan https://orcid.org/0000-0002-8143-4403
Timothy Nicholson https://orcid.org/0000-0002-2350-2332
Oliver C Witard https://orcid.org/0000-0002-5875-8397
Rachael A Evans https://orcid.org/0000-0002-1667-868X
Trudie Chalder https://orcid.org/0000-0003-0775-1045

REFERENCES

1 Chen C, Haupert SR, Zimmermann L, *et al*. Global Prevalence of Post-Coronavirus Disease 2019 (COVID-19) Condition or Long COVID: A Meta-Analysis and Systematic Review. *J Infect Dis* 2022;226:1593–607.
2 National Institute for Health and Care Excellence. COVID-19 rapid guideline: managing the long-term effects of COVID-19. London; 2024.
3 Davis HE, Assaf GS, McCorkell L, *et al*. Characterizing long COVID in an international cohort: 7 months of symptoms and their impact. *EClinicalMedicine* 2021;38:101019.
4 Sudre CH, Murray B, Varsavsky T, *et al*. Attributes and predictors of long COVID. *Nat Med* 2021;27:626–31.
5 Evans RA, McAuley H, Harrison EM, *et al*. Physical, cognitive, and mental health impacts of COVID-19 after hospitalisation (PHOSP-COVID): a UK multicentre, prospective cohort study. *Lancet Respir Med* 2021;9:1275–87.
6 Menges D, Ballouz T, Anagnostopoulos A, *et al*. Burden of post-COVID-19 syndrome and implications for healthcare service planning: A population-based cohort study. *PLoS One* 2021;16:e0254523.
7 Razai MS, Al-Bedaery R, Anand L, *et al*. Patients' Experiences of "Long COVID" in the Community and Recommendations for Improving Services: A Quality Improvement Survey. *J Prim Care Community Health* 2021;12:21501327211041846.
8 Fernandez-de-Las-Peñas C, Notarte KI, Macasaet R, *et al*. Persistence of post-COVID symptoms in the general population two years after SARS-CoV-2 infection: A systematic review and meta-analysis. *J Infect* 2024;88:77–88.

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

9 Notarte KI, de Oliveira MHS, Peligro PJ, *et al*. Age, Sex and Previous Comorbidities as Risk Factors Not Associated with SARS-CoV-2 Infection for Long COVID-19: A Systematic Review and Meta-Analysis. *J Clin Med* 2022;11:7314.
10 Wang S, Quan L, Chavarro JE, *et al*. Associations of Depression, Anxiety, Worry, Perceived Stress, and Loneliness Prior to Infection With Risk of Post-COVID-19 Conditions. *JAMA Psychiatry* 2022;79:1081–91.
11 Maglietta G, Diodati F, Puntoni M, *et al*. Prognostic Factors for Post-COVID-19 Syndrome: A Systematic Review and Meta-Analysis. *J Clin Med* 2022;11:1541.
12 Matta J, Wiernik E, Robineau O, *et al*. Association of Self-reported COVID-19 Infection and SARS-CoV-2 Serology Test Results With Persistent Physical Symptoms Among French Adults During the COVID-19 Pandemic. *JAMA Intern Med* 2022;182:19–25.
13 Sudre CH, Antonelli M, Cheetham NJ, *et al*. Symptoms before and after COVID-19: a population and case-control study using prospective data. *Eur Respir J* 2024;64:2301853.
14 Zeraatkar D, Ling M, Kirsh S, *et al*. Interventions for the management of long COVID (post-COVID condition): living systematic review. *BMJ* 2024;387:e081318.
15 Graham CD, Gouick J, Krahé C, *et al*. A systematic review of the use of Acceptance and Commitment Therapy (ACT) in chronic disease and long-term conditions. *Clin Psychol Rev* 2016;46:46–58.
16 Hayes SC, Luoma JB, Bond FW, *et al*. Acceptance and commitment therapy: model, processes and outcomes. *Behav Res Ther* 2006;44:1–25.
17 von Weissenberg J. Homeostasis and self-regulation. *The Scandinavian Psychoanalytic Review* 2024;47:30–40.
18 Felton L, Kalfas M, Brewin D, *et al*. Codeveloping a Novel Intervention for People With Post-COVID Condition: The Balance-ACT Study. *Health Expect* 2025;28:e70320.
19 Castanares-Zapatero D, Chalon P, Kohn L, *et al*. Pathophysiology and mechanism of long COVID: a comprehensive review. *Ann Med* 2022;54:1473–87.
20 Krapić M, Kavazović I, Wensveen FM. Immunological Mechanisms of Sickness Behavior in Viral Infection. *Viruses* 2021;13:2245.
21 Tate W, Walker M, Sweetman E, *et al*. Molecular Mechanisms of Neuroinflammation in ME/CFS and Long COVID to Sustain Disease and Promote Relapses. *Front Neurol* 2022.
22 Tornero-Aguilera JF, Jimenez-Morcillo J, Rubio-Zarapuz A, *et al*. Central and Peripheral Fatigue in Physical Exercise Explained: A Narrative Review. *Int J Environ Res Public Health* 2022;19:3909.
23 Aggarwal B, Makarem N, Shah R, *et al*. Effects of Inadequate Sleep on Blood Pressure and Endothelial Inflammation in Women: Findings From the American Heart Association Go Red for Women Strategically Focused Research Network. *J Am Heart Assoc* 2018;7:e008590.
24 Dzierzewski JM, Donovan EK, Kay DB, *et al*. Sleep Inconsistency and Markers of Inflammation. *Front Neurol* 2020;11:1042.
25 Scott H, Lechat B, Reynolds A, *et al*. 0204 Sleep Irregularity Is Associated with Increased Risk of Hypertension: Data From Over Two Million Nights. *Sleep* 2022;45:A93–4.
26 Tsereteli N, Vallat R, Fernandez-Tajes J, *et al*. Impact of insufficient sleep on dysregulated blood glucose control under standardised meal conditions. *Diabetologia* 2022;65:356–65.
27 Yaribeygi H, Panahi Y, Sahraei H, *et al*. The impact of stress on body function: A review. *EXCLI J* 2017;16:1057–72.
28 Whitfield T, Barnhofer T, Acabchuk R, *et al*. The Effect of Mindfulness-based Programs on Cognitive Function in Adults: A Systematic Review and Meta-analysis. *Neuropsychol Rev* 2022;32:677–702.
29 Johns SA, Tarver WL, Secinti E, *et al*. Effects of mindfulness-based interventions on fatigue in cancer survivors: A systematic review and meta-analysis of randomized controlled trials. *Crit Rev Oncol Hematol* 2021;160:103290.
30 Kalfas M, Jolley C, Hart N, *et al*. Exploring the Experiences of Living With the Post-COVID Syndrome: A Qualitative Study. *Health Expect* 2024;27:e14108.
31 Plumb JC, Vilardaga R. Assessing treatment integrity in acceptance and commitment therapy: Strategies and suggestions. *International Journal of Behavioral Consultation and Therapy* 2010;6:263–95.
32 O'Neill L, Latchford G, McCracken LM, *et al*. The development of the Acceptance and Commitment Therapy Fidelity Measure (ACT-FM): A delphi study and field test. *J Contextual Behav Sci* 2019;14:111–8.
33 Kuut TA, Müller F, Csorba I, *et al*. Efficacy of Cognitive-Behavioral Therapy Targeting Severe Fatigue Following Coronavirus Disease 2019: Results of a Randomized Controlled Trial. *Clin Infect Dis* 2023;77:687–95.
34 Sheehan DV, Lecrubier Y, Sheehan KH, *et al*. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry* 1998;22–33. Available: https://pubmed.ncbi.nlm.nih.gov/9881538/
35 Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item Health Survey 1.0. *Health Econ* 1993;2:217–27.
36 Ware JE, Sherbourne CD. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36): I. conceptual framework and item selection. *Med Care* 1992;30:473–83.
37 Brazier JE, Harper R, Jones NM, *et al*. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992;305:160–4.
38 Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation. *Health Qual Life Outcomes* 2003;1:79.
39 Busner J, Targum SD. The clinical global impressions scale: applying a research tool in clinical practice. *Psychiatry (Edgmont)* 2007;4:28–37. Available: https://pubmed.ncbi.nlm.nih.gov/20526405/
40 Buysse DJ, Reynolds CF 3rd, Monk TH, *et al*. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989;28:193–213.
41 Sullivan M, Edgley K, Dehoux E. A survey of multiple sclerosis: I. Perceived cognitive problems and compensatory strategy use. *Canadian Journal of Rehabilitation* 1990.
42 Kroenke K, Strine TW, Spitzer RL, *et al*. The PHQ-8 as a measure of current depression in the general population. *J Affect Disord* 2009;114:163–73.
43 Spitzer RL, Kroenke K, Williams JBW, *et al*. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.
44 Löwe B, Decker O, Müller S, *et al*. Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. *Med Care* 2008;46:266–74.
45 Cotler J, Holtzman C, Dudun C, *et al*. A Brief Questionnaire to Assess Post-Exertional Malaise. *Diagnostics (Basel)* 2018;8:66.
46 Yorke J, Moosavi SH, Shuldham C, *et al*. Quantification of dyspnoea using descriptors: development and initial testing of the Dyspnoea-12. *Thorax* 2010;65:21–6.
47 Andrews AW, Thomas MW, Bohannon RW. Normative values for isometric muscle force measurements obtained with hand-held dynamometers. *Phys Ther* 1996;76:248–59.
48 Metcalfe AJ, Mills E, Chalder T, *et al*. Test-Retest Variability and Reliability of Volitional and Nonvolitional Assessments of Muscle Endurance in Healthy Humans. *Med Sci Sports Exerc* 2026;58:619–27.
49 Shaffer F, Ginsberg JP. An Overview of Heart Rate Variability Metrics and Norms. *Front Public Health* 2017;5:258.
50 Kuyken W, Hayes R, Barrett B, *et al*. Effectiveness and cost-effectiveness of mindfulness-based cognitive therapy compared with maintenance antidepressant treatment in the prevention of depressive relapse or recurrence (PREVENT): a randomised controlled trial. *The Lancet* 2015;386:63–73.
51 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
52 Kroenke K, Spitzer RL, Williams JBW. The PHQ-15: Validity of a New Measure for Evaluating the Severity of Somatic Symptoms. *Psychosom Med* 2002;64:258–66.
53 Nasreddine ZS, Phillips NA, Bédirian V, *et al*. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc* 2005;53:695–9.
54 Mundt JC, Marks IM, Shear MK, *et al*. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *Br J Psychiatry* 2002;180:461–4.
55 Weathers FW, Litz BT. PTSD checklist for DSM 5 (PCL-5). National Center for Posttraumatic Stress Disorder-Ptsd; 2024.
56 van Doorn P, Folgering H, Colla P. Control of the end-tidal P(CO2) in the hyperventilation syndrome: Effects of biofeedback and breathing instructions compared. *Bull Eur Physiopathol Respir* 1982;18:829–36. Available: https://pubmed.ncbi.nlm.nih.gov/6821472/
57 van Dixhoorn J, Duivenvoorden HJ. Efficacy of Nijmegen Questionnaire in recognition of the hyperventilation syndrome. *J Psychosom Res* 1985;29:199–206.
58 Mahler DA, Wells CK. Evaluation of clinical methods for rating dyspnea. *Chest* 1988;93:580–6.
59 Craig CL, Marshall AL, Sjöström M, *et al*. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003;35:1381–95.
60 Machado Rodrigues F, Demeyer H, Hornikx M, *et al*. Validity and reliability of strain gauge measurement of volitional quadriceps force in patients with COPD. *Chron Respir Dis* 2017;14:289–97.

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

61 Maffiuletti NA, Barbero M, Cescon C, *et al*. Validity of the twitch interpolation technique for the assessment of quadriceps neuromuscular asymmetries. *J Electromyogr Kinesiol* 2016;28:31–6.
62 Strassmann A, Steurer-Stey C, Lana KD, *et al*. Population-based reference values for the 1-min sit-to-stand test. *Int J Public Health* 2013;58:949–53.
63 Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982;14:377–81. Available: https://pubmed.ncbi.nlm.nih.gov/7154893/
64 Guralnik JM, Simonsick EM, Ferrucci L, *et al*. A Short Physical Performance Battery Assessing Lower Extremity Function: Association With Self-Reported Disability and Prediction of Mortality and Nursing Home Admission. *J Gerontol* 1994;49:M85–94.
65 Graham BL, Steenbruggen I, Miller MR, *et al*. Standardization of Spirometry 2019 Update. *Am J Respir Crit Care Med* 2019;200:e70–88.
66 Ryan EG, Vitoratou S, Goldsmith KA, *et al*. Psychometric Properties and Factor Structure of a Long and Shortened Version of the Cognitive and Behavioural Responses Questionnaire. *Psychosom Med* 2018;80:230–7.
67 Landau S, Emsley R, Dunn G. Beyond total treatment effects in randomised controlled trials: Baseline measurement of intermediate outcomes needed to reduce confounding in mediation investigations. *Clin Trials* 2018;15:247–56.
68 Braun V, Clarke V. Qualitative Research in Psychology Using thematic analysis in psychology Using thematic analysis in psychology. *Qual Res Psychol* 2006.
69 Clarke V, Braun V. Thematic analysis. *J Posit Psychol* 2017;12:297–8.
70 Herbert E, Julious SA, Goodacre S. Progression criteria in trials with an internal pilot: an audit of publicly funded randomised controlled trials. *Trials* 2019;20:493.

BMJ Open: first published as 10.1136/bmjopen-2026-122602 on 3 August 2026. Downloaded from http://bmjopen.bmj.com/ on October 26, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.