RESEARCH PROTOCOL

Empowering workplace self-management for individuals with long-term health conditions and health-related disabilities: a randomised controlled feasibility trial of the 'Co-Manage' intervention compared with usual workplace support.

Short title of study
Co-Manage Feasibility Trial

Protocol version and date	Research Ethics Committee (REC) reference
1.3 (19.02.26)	IRAS ID: 368966 Loughborough University: LEON24912
Sponsor organisation	**Controlled trials registration number**
Loughborough University	ISRCTN17076421

Research team

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Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:
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Name (please print):

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Position:
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Chief Investigator:

Signature: Date:
..../...../.....

Name: (please print):

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1. Synopsis of the study

Short study title	Co-Manage Trial
ISRCTN registration no.	ISRCTN17076421
Study Design	Cluster randomised controlled feasibility trial
Setting	At least eight organisations located in the UK from any sector (public, private, third) and have ≥10 employees (*small*: 10-49; *medium*: 50-249; *large*: ≥250).
Study Participants	The primary target population is individual workers (or employees) who self-identify as having a long-term health condition or disability. All managers and employer stakeholders (e.g., senior managers/leaders, Human Resources staff, Health and Well-being/Occupational Health professionals) within participating organisations will also be invited to take part in the study.
Aim	To undertake a two-arm cluster randomised control feasibility trial of the Co-Manage intervention to inform a future fully powered definitive trial.
Objectives	To assess/conduct: a. Willingness/readiness of organisations and their workers to adopt and implement Co-Manage. b. Willingness of organisations to take part in a 20-month study and be randomised. c. Willingness of participants (workers with LTCs/disabilities, managers) to take part and retention through follow-up (6 months) with intervention uptake and completion as primary endpoints. d. Potential for selection bias in control and intervention organisations as measured using participant characteristics at baseline. e. Implementation of intervention adherence, delivery, and fidelity. f. Changes in the primary and secondary outcomes to inform a larger trial and estimate the inter-cluster (or intraclass) correlations (ICC) for these outcomes. g. Pilot process evaluation to monitor how Co-Manage is perceived by participants from different demographic groups (e.g., age, gender identity, ethnicity, job role/type) and test a full process evaluation methodology in advance of a full trial. h. Feasibility of collecting data on parameters needed for health economic evaluation in a subsequent larger trial.
Primary outcome	The number of sick/disability leave days.
Intervention	Co-Manage is an online, multi-component intervention designed to improve work-health outcomes for people with any long-term condition or health-related disability.
Randomisation and data collection	Participating organisations will be randomised into intervention or control arms and, where possible, will be stratified by area and organisational size/type. Measurements (online surveys) will be collected at baseline, as well as 3- and 6-months.
Planned Sample Size	Minimum sample of 120 participants (60 per arm), recruited from at least 8 clusters (organisations): 4 randomised to intervention and 4 to control groups.
Data analysis method	1. Trial data will be summarised using a CONSORT diagram and analyses will be based on *intention-to-treat* principles. 2. Data on both cluster (organisations) and participants will be summarised using means, standard deviations, medians and ranges for continuous variables and counts and percentages for categorical variables. 3. Exploratory analyses of work-health outcomes will be carried out (i.e., between-group effect sizes and ICC coefficient) to inform the sample size calculation of a future definitive trial.
Study Period	24 months
Funding	NIHR Public Health Research (PHR): NIHR174567
Key Protocol Contributors	Dr David Maidment (details above) Professor Fehmidah Munir. E. f.munir@lboro.ac.uk, T. 01509 228228 Loughborough University, Epinal Way, Loughborough LE11 3TU
Committees	**Project Management Group** Dr David Maidment, Professor Fehmidah Munir, Professor Jo Yarker, Professor Holly Blake, Dr Zahid Asghar, Ms Helen Barrow (PPIE Co-Investigator).

	Trial Steering Group Dr Vaughan Parsons (Chair), Ms Helen Barrow (Public Member), Professor Joanna McParland, Professor Ewan MacDonald, Dr Evangelia Demou, Professor Gwenllian Wynne-Jones. **Data Monitoring Committee** Dr Bart Vorslaars (Chair), Paul Weiss, Dr Will Mueller, Dr Priya Lall, Dr Joseph Akanuwe. **Expert Advisory Group** Dr David Maidment (Co-Chair), Professor Jo Yarker (Co-Chair), Rachel Suff, Dr Richard Heron, Dr John Ballard, Professor Kim Burton, Dr Sally Hemming, Dr Lara Shemtob, Tash Heydon, Ms Susan Cleadby, Ms Dianne Lightfoot. **PPIE Group** Dr David Maidment (Co-Lead), Ms Helen Barrow (Co-Lead), Dr Emma Shiel, Mr Robert Mitchell, Ms Kirandip Gill, Ms Alissa Nehrlich, Ms Erin Gill, Ms Lynne McEwan, Ms Fran Keogh, Ms Jan Short.
Key words	Long-term conditions; Disability; Self-management; Workplace; Feasibility study; Digital intervention.

Role of study sponsor and funder

Loughborough University will act as the Sponsor for this research project, assuming overall responsibility for the initiation and management of the study. The sponsor will work closely with the National Institute of Health and Care Research (NIHR), the funder, in support of the Chief Investigator to report study progress as necessary.

Certain research activities surrounding study conduct, data analysis, and reporting are delegated to the Chief Investigator and these are outlined in an agreement separate to this protocol. Regular meetings will be held between the Sponsor and the Chief Investigator as grant holder to discuss the management of the study finances.

Roles and responsibilities of study management committees/groups & individuals

A Project Management Group (PMG) will oversee the research project, meeting at least monthly (in-person or via videocall) to monitor progress against the project plan. Trial Steering, Expert Advisory and PPIE Groups will provide further oversight.

The PMG is uniquely placed to deliver this research. All members have extensive experience producing and evaluating evidence-based workplace interventions. The PMG will include two postdoctoral research assistants (one based at Loughborough University and another within the University of Lincoln). In addition, the PMG will be supported by a statistician (Asghar), health economist, and trial coordinator/data manager, all based at the University of Lincoln. The PMG has the necessary experience of methodology for knowledge transfer and practical collaboration with all key stakeholders in the work-health space that will benefit the project and future trial.

Maidment. Expertise in the development and evaluation of novel self-management support strategies for adults with chronic diseases and disabilities. Previously led externally funded projects, including NIHR Work and Health Development Award, involving user-centred and participatory design approaches that utilise mixed methods. Also has extensive experience leading PPIE activities.

Munir. Expert knowledge in workplace self-management research, including the prevention of and intervention for chronic conditions impacting quality of life, understanding the influence of biopsychosocial factors related to ill-health, sickness absence, and work outcomes, and designing self-led interventions for recovery, enhancement of wellbeing, and work engagement.

Barrow. PPIE Co-applicant, has lived with hearing loss her whole life. A qualified lipreading tutor and hearing loss management consultant and has set-up Lipreading.me.uk. Works part-time as an administrator with Disability Support Services at the University of Nottingham. Has previously contributed to and received training in PPIE activities.

Yarker. An Occupational Psychologist specialising in work, health, and wellbeing. Is Managing Partner of Affinity Health at Work and Professor at Birkbeck University of London. Will contribute expertise in stakeholder engagement, digital toolkit design and optimisation, workshop facilitation and reporting.

Blake. Professor of Behavioural Medicine at the University of Nottingham. Expertise in the design, delivery, evaluation, and implementation of complex (digital) interventions. This includes a focus on self-management for people with long-term health conditions, with a particular interest in workforce health and wellbeing.

Asghar. Associate Professor in the School of Health & Care Sciences, University of Lincoln. Former Director of the Lincoln CTU, leading a team of Data managers, Trial Coordinators, Health Economists, and other support staff. Is also Senior Statistical consultant for NIHR Research Support Service (RSS) Hub and founding member of the NIHR Methodology Group and ONS Accredited Researcher.

2. Background and rationale

Background

The prevalence of UK workers with long-term health conditions (LTCs) and disabilities is rising. Government statistics in 2023 suggest that there were 5.53 million working-aged people with health-related disabilities (e.g., hearing/vision loss, cerebral palsy, multiple sclerosis) in employment, an increase of 338,000 (6%) from the previous year[1]. The Health Foundation reports that this includes 3.9 million people in employment with work-limiting LTCs[2] (e.g., musculoskeletal disorders, mental ill-health), which restrict the type of work they can do or the amount of work they can perform. In 2019, it was estimated that work loss due to LTCs and disabilities cost the UK around £100 billion per year due to lost productivity, reduced income tax receipts, increased long-term sickness (131 million days lost), increased caregiving, and higher healthcare costs[3]. Such estimates are now likely to be much higher due to COVID-19. Sickness rates, for instance, are continuing to increase year-on-year. In 2023, UK businesses recorded an average of 128 sick leave days, an increase from 81 days (58%) in 2019[4].

Most long-term sickness absences are attributed to common mental health conditions (e.g., stress, depression, anxiety), which are also highly prevalent, or comorbid, in people with LTCs and health-related disabilities[5,6]. Critically, individuals with mental and/or multiple health conditions, as well as those experiencing socioeconomic deprivation, can face disproportionate challenges in managing LTCs and disabilities within the workplace[7,8]. With an ageing workforce, the risk of work disability and worklessness due to LTCs and disabilities is also rising[6]. According to the Department for Work and Pensions (DWP)[6], this brings new challenges to improving the quality of working life among individuals with LTCs and disabilities, as well as to reducing the risks of sickness/disability absence, dismissal, unemployment, and early retirement.

Rationale

Supporting self-management is a priority in the NHS Long-term Plan[9] and DWP policy for employers to create inclusive workplaces[10]. Guidance from professional bodies[11,12] and the National Institute for Health and Care Excellence (NICE)[13] recommend that employers should support workers' health. Self-management refers to actions taken by individuals to recognise, treat, and manage their health[9], such as monitoring and responding to symptoms, accessing peer support, and adapting work tasks. Most people with LTCs and disabilities can maintain a productive working life if they can self-manage their health or

disability at work[14,15]. To self-manage at work effectively, people with LTCs and disabilities require the support of their employer, particularly their line manager. While studies in the USA have found workplace self-management support reduces sick/disability leave, transferability to the UK context is not known.

There is currently no clear framework for UK employers to use in terms of when and how to provide self-management support. This likely stems from a combination of factors, including a voluntary approach, inconsistent guidance, and a lack of clear legislative requirements[16]. Moreover, an estimated 1 in 3 employees with a LTC or disability in the UK do not disclose this to their employer[3], which is a key barrier to support, and workers and managers struggle with these conversations due to stigma, work pressures, and lack of knowledge[17-19]. A better understanding of how to deliver self-management support in UK workplaces is crucial for aligning efforts between healthcare providers and employers.

Our previous research

As part of a previous NIHR Work and Health Development Award (NIHR206282), we conducted a rapid systematic review of self-management interventions for workers with multiple LTCs or disabilities[7]. All six studies included were based in the USA[20-25] and assessed a chronic disease self-management programme, which showed positive effects on work and health outcomes (e.g., attendance, wellbeing). However, interventions were time-consuming to implement and lacked support for managers and employer stakeholders (e.g., senior managers/leaders, Human Resources [HR], Health and Well-being/Occupational Health [OH]). As interventions were trialled outside the UK, we do not know how easily they would translate to the UK employer context given differences in health services and integrated care systems, as well as available social support/welfare systems. Access to healthcare in the UK, for instance, is fundamentally tax-funded and largely free at the point of use. The USA, by comparison, has no universal healthcare coverage but a more complex, mixed system where the cost of healthcare is largely covered by employer-sponsored health insurance, which can result in potential coverage gaps and out-of- pocket expenses[26].

We have therefore co-developed Co-Manage with key stakeholders, a UK-focused workplace intervention based on our rapid review findings[7] and evidence-based self-management support model[19,27] (**Figure 1**). This model incorporates the Psychosocial Flags Framework[28] and Feuerstein et al.'s[29] biopsychosocial Cancer and Work Model. The former identifies psychosocial obstacles to self-management and potential support needs using the concept of three coloured 'flags': features of the person/worker (yellow), their workplace (blue), and how they interact with the world (black). The Cancer and Work Model helps identify needs affecting work-health balance, focusing on work demands, environment, symptoms, policies, and practices, to guide the exploration of potential needs within these areas. It can be used to identify targets/solutions to support and maintain work-health balance in the face of health needs. For example, employers can introduce management policies and practices that offer greater flexibility in work adjustments, as well as placing equal responsibility on workers and managers to solve needs.

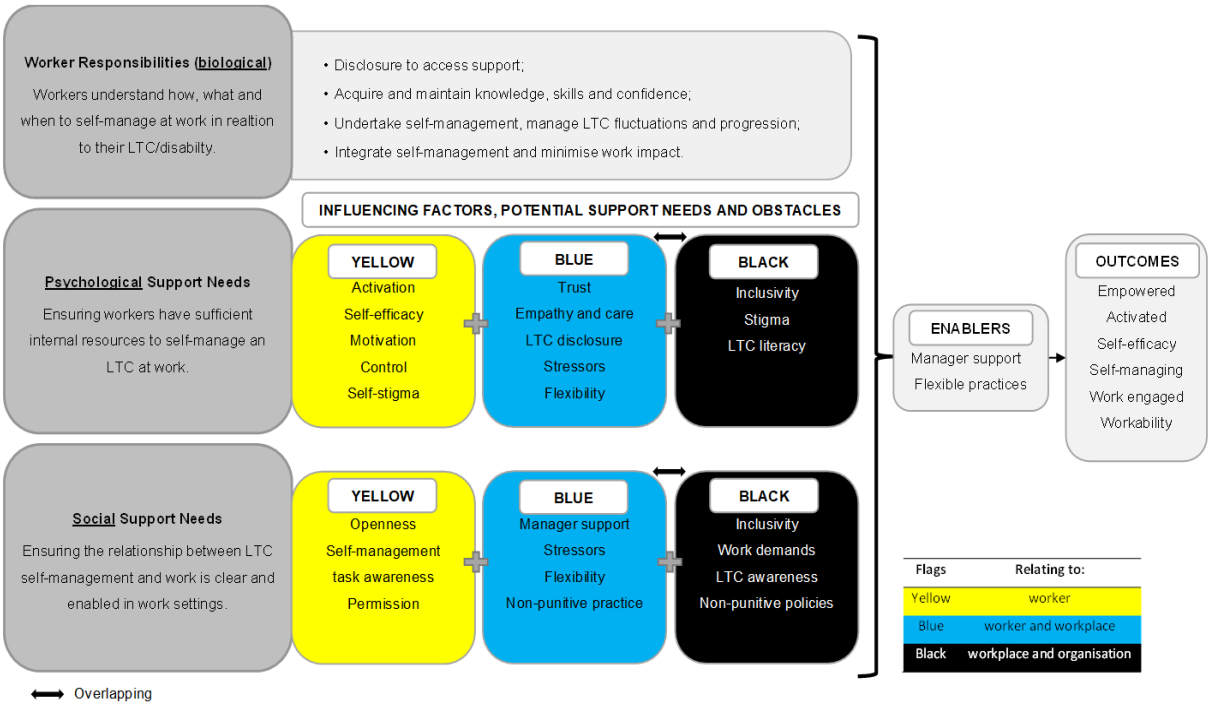
Co-Manage fosters improved understanding between workers, managers, and employer stakeholders about managing LTCs and disabilities at work. It was co-produced with input from 85 stakeholders, including workers (office-based and manual), employers, and professional group members who all agreed that Co-Manage should be suitable for any LTC or health-related disability. A three-round Delphi study guided its design, emphasising the need for practical and directed guidance for all stakeholders. A digital format with downloadable resources for use in paper form was also preferred by all stakeholders for its scalability, so that it could be more readily accessible for a wide range of workers, managers and organisations.

Co-Manage further builds on the learnings from our IGLOo digital intervention[30], which offers resources for individuals, groups, managers, and organisations to facilitate a shared approach to supporting

workers' return to work following long-term sick leave. The IGLOo intervention is designed to be implemented by employers by targeting key resources or 'levels' within the workplace, including:

- **Individual level** – e.g., providing tools to improve resources inherent within the individual, such as self-efficacy and job crafting strategies to help them stay at work.
- **Group level** – e.g., enabling the worker to access relevant support, such as through family, friends and colleagues.
- **Leader level** – e.g., providing access to manager support and information on accessing appropriate services from primary health care.
- **Organisation level** – e.g., making changes to policies and processes, offering wellbeing programmes to support self-management of LTCs and disabilities in and outside the organisation.
- **Overarching level/social environment** – e.g., employing NICE guidelines for managing sickness/disability absence and executing evidence-based practice in changing cultural attitudes towards workers with LTCs and disabilities.

Figure 1. *Biopsychosocial model of workplace self-management support for LTCs/disabilities*[19,27].



IGLOo is underpinned by several psychosocial theories, including the Cognitive Theory[31], Communication Accommodation Theory[32], Conservation of Resources Theory[33], Job-Demand Resource Theory[34], and Socio-Cognitive Theory[35]. Research suggests that IGLOo is effective across all five levels in relation to supporting workers to return to work, as well as stay in and thrive at work following a period of long-term sick leave[36].

Based on our IGLOo intervention, Co-Manage similarly adopts a multi-component approach to address the needs of all key stakeholders, without relying solely on worker-initiated support requests. Specifically, online resources are offered to:

- **Employer stakeholders** (**organisation/overarching level**). Educational resources downloadable by employer stakeholders outlining the scientific evidence on what works best to support self-management of LTCs/disabilities at work.
- **Managers** (**leader/group level**). Toolkits outline when and how they can offer support.

- **Workers** (**individual level**). Toolkits provide step-by-step actions that they can take to support self-management, such as when and how to request support.

The next step is to rigorously evaluate the effectiveness of Co-Manage in improving work-health outcomes for individuals with LTCs and disabilities across diverse workplace settings in the UK.

3. Aim, Objectives and Hypotheses

3.1. Aim

To assess whether a cluster randomised controlled trial of Co-Manage, a digital toolkit designed to support workplace self-management for individuals with any LTC or disability, can be done.

3.2. Objectives

Specific objectives are to assess/conduct:

a. Willingness/readiness of organisations and their workers to adopt and implement Co-Manage.
b. Willingness of organisations to take part in a 20-month study and be randomised.
c. Willingness of participants (workers with LTCs/disabilities, managers) to take part and retention through follow-up (6 months) with intervention uptake and completion as primary endpoints.
d. Potential for selection bias in control and intervention organisations as measured using participant characteristics at baseline.
e. Implementation of intervention adherence, delivery, and fidelity.
f. Changes in the primary outcome (number of sick/disability leave days) and secondary outcomes (e.g., work-based attendance, wellbeing, self-management) to inform a larger trial and estimate the inter-cluster (or intraclass) correlations (ICC) for these outcomes.
g. Pilot process evaluation to monitor how Co-Manage is perceived by participants from different demographic groups (e.g., age, gender, ethnicity, job role/type) and test a full process evaluation methodology in advance of a full trial.
h. Feasibility of collecting data on parameters needed for health economic evaluation in a subsequent larger trial.

3.3. Hypotheses

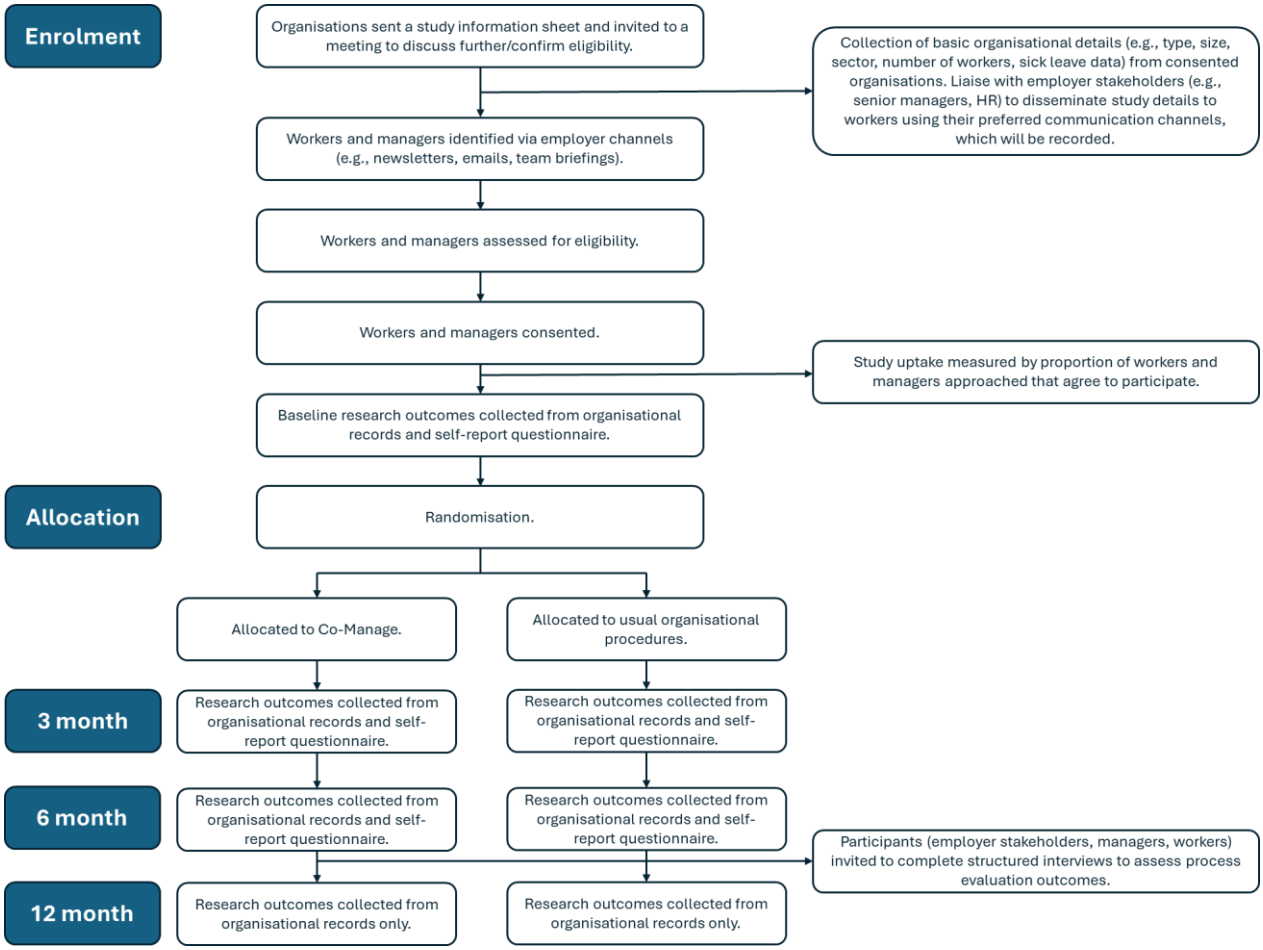
As this trial is primarily concerned with feasibility, acceptability and preliminary data collection, it is not designed or statistically powered to test a specific hypothesis.

4. Study design

The study design follows the Medical Research Council (MRC) guidance for complex interventions[37,38] and will be conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) extension to randomised pilot and feasibility trials[39].

A two-arm cluster randomised controlled feasibility trial of the Co-Manage intervention, which will inform a fully powered definitive trial to evaluate workplace co-management for individuals with LTCs and disabilities. The study will last 24 months. Key feasibility and process evaluation outcome measures will be collected monthly, and research outcome measures will be collected at baseline, 3, and 6 months (see **Figure 2** for study flow chart).

Figure 2. *Study flow chart.*



4.1. Setting and participants

Organisations located in the UK with high ethnic diversity and/or social deprivation (e.g., Greater London, Midlands, Northeast), from any sector (public, private, third), and have ≥10 employees (small: 10-49; medium: 50-249; large: ≥250)[40].

At least eight organisations will be recruited to take part as the unit of randomisation. We will collect basic organisational details (e.g., type, size, number of workers, sick leave data) from employer stakeholders and liaise with them to disseminate study details to workers using their preferred communication channels, which will be recorded.

Based on our learnings from the IGLOo intervention pilot evaluation[30], we will work with each participating organisation to ensure optimal recruitment opportunities by first addressing any systemic barriers to recruitment. We will engage with employee champions who will promote the study within their teams, as well as seek their views on how best to recruit workers with LTCs/disabilities and managers.

Inclusion criteria

- For employers, organisations from any sector with ≥10 employees with no existing processes or policies that conflict with Co-Manage (e.g., an alternative self-management support programme).

- Any individual worker aged ≥18 years with any LTC or disability requiring ongoing management for ≥12 months[41]. To enable assessment of the primary outcome, participants must have been employed for at least 12 months prior to the start of the intervention.
- Managers supporting workers with any LTC or disability.
- All participants must be able access to the internet and be able to understand English sufficiently to provide informed consent, complete online questionnaires, and use Co-Manage.

Exclusion criteria

- Organisations with <2% of workers that have taken sick/disability leave (primary outcome) in the past 12 months, making it difficult to demonstrate potential impact of Co-Manage.
- Worker participants who are <18 years of age, do not have a LTC/disability requiring ongoing management for ≥12 months, have been in their current employment for <12 months prior to the start of the intervention, and/or are unable to provide informed consent or participate in study procedures (e.g., due to cognitive or language barriers that cannot be reasonably accommodated).

4.2. Intervention

Co-Manage intervention

Co-Manage is a multi-component intervention designed to promote positive changes in work-health outcomes (e.g., self-management, wellbeing, job crafting) to help individuals to stay in work (i.e., to reduce long-term sickness/disability leave). Co-Manage is suitable for any LTC or health-related disability and offers digital resources for employer stakeholders, managers and workers, which can also be downloaded for use in paper form. Therefore, Co-Manage is designed to be flexible and scalable, allowing workers, managers and employers to tailor actions based on the specific challenges they experience, whether related to a single condition or the interaction of multiple conditions.

- *Employers.* At the organisational/overarching level, Co-Manage provides educational e-resources for employer stakeholders to help them support individuals in self-managing a LTC or disability at work. The e-resources consist of presentations, case studies and videos. They cover an overview of common LTCs and health-related disabilities (e.g., musculoskeletal disorders, mental ill-health) and associated comorbidities, recognition of how LTCs and disabilities can affect absenteeism and work-health outcomes, the importance of reviewing existing policies and processes, alignment of internal policies and processes to evidence-based best practices, identification of 'gaps' in resources that could support self-management, strategies for meaningful engagement and action, and ongoing monitoring and evaluation. Active learning strategies and feedback are embedded throughout the e-resources to maximise engagement and ensure that employer stakeholders gain the knowledge and confidence needed to foster a supportive work environment for employees with any LTC or health-related disability.

- *Managers.* At the leader/group level, Co-Manage provides managers with e-resources outlining how they can support individuals to self-manage a LTC or health-related disability in the workplace. The e-resources consist of presentations, interactive case studies and videos, as well as additional self-led activities (e.g., practical tools and checklists to record actions taken) to encourage managers to apply their learning to their worker's with LTCs and disabilities. This includes, for instance, how to address health-related concerns with a worker (e.g., what to say, how to demonstrate compassion but remain professional etc.), how best to support the worker with a LTC or health-related disability, including strategies to address barriers to self-management, how to suggest resources and/or provide appropriate work adjustments, and how to raise awareness among colleagues of LTCs and disabilities.

- *Workers.* Co-Manage targets the individual level through self-led activities (e.g., 'how-to' guides and action checklists) designed to increase worker's self-control and self-management skills to improve, for example, their relationship with their manager and work self-efficacy. The content was informed by our self-management support model[19,27] and extensive PPIE and stakeholder input completed during our NIHR Work and Health Development Award. Co-Manage includes self-led activities on problem-solving (e.g., identifying and formulating practical ways to deal with barriers in self-managing a LTC/disability in the workplace), building a support network, communicating work adjustments and support needs, and goal setting (e.g., managing health symptoms through identifying and accessing support). The toolkit also includes practical tools (e.g., conversation starter guides/checklists) to help workers address health-related concerns with their manager/employer.

Intervention delivery and dose

Co-Manage will be hosted on its own dedicated website, https://www.co-manage.co.uk/. User engagement (workers, managers, employer stakeholders) will be monitored via Google Analytics and other analytics built into the website, alongside qualitative interviews. Analytics will distinguish between different user types (workers with LTCs/disabilities, managers, employer stakeholders), as each will access Co-Manage through a unique login linked to their role and organisation.

Dose will be assessed as a composite measure, combining the duration of time spent engaging with materials and the breadth of resources accessed (e.g., number and type of activities or toolkits completed). This approach will allow us to capture both depth and variety of engagement across user groups. Metrics will include, for example, time spent on key pages, number of e-resources and activities accessed/downloaded, and submission of completed activities to the research team through the website, frequency of return visits, and overall duration of engagement during the intervention period. These data will be used to establish thresholds for what constitutes sufficient exposure to Co-Manage (i.e., a minimum dose) across different user types. These analyses will clarify how intervention dose should be defined, measured, and interpreted during the main trial. Nevertheless, all user types (workers with LTCs/disabilities, managers, and employer stakeholders) must complete the introductory pages before accessing the other resources and activities, thereby ensuring a minimum dose for the feasibility study. On this basis, completion of the intervention during the feasibility study will be defined as completion of this minimum dose, ensuring a consistent measure of intervention completion across all user types.

Control arm

Organisations assigned to the usual practice control arm will be asked to continue with their usual policies and processes for supporting workers with LTCs/disabilities. As there is currently no standard practice for UK workplaces to support self-management of LTCs/disabilities, standard/usual practice for each organisation recruited will be recorded using a standardised audit form completed by employer stakeholders at onboarding. Examples may include access to HR policies of OH referrals, the provision of reasonable adjustments under the Equality Act 2010[41], use of existing internal resources (e.g., employee assistance programmes), and/or employer-mandated sickness absence management systems. Organisations that record conflicting processes or policies related to Co-Manage will be excluded from participation (see also, 'inclusion/exclusion criteria').

While usual practice will be documented at organisational onboarding using a standardised audit form, we will also assess the extent of utilisation of these practices. This will be achieved through self-report surveys completed at baseline, 3 and 6 months (e.g., reporting use of workplace adjustments or support services), as well as semi-structured interviews with workers, managers, and employer stakeholders. This will enable us to test the feasibility of capturing both the availability and actual uptake of usual practice, informing whether refinements are needed for the definitive trial.

Participants in the control organisations will be asked to complete the same study measurements and relevant process outcomes/evaluation measures as those in the intervention arm at the same time-points. Upon completion of the study, control participants will be freely provided with Co-Manage.

4.3. Measures

Outcome measures have been guided by the Integrative Process Evaluation Framework (IPEF)[42] in conjunction with our rapid review findings[43], PPIE and expert advisory group input, and a core outcome set[44]. The IPEF (**Figure 3**) is a five-phased framework that has been designed to understand what works and for whom in 'real-world' multi-level workplace-based interventions. It combines the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework[45,46], which evaluates the translation of an intervention from research to practice, and Realist Evaluation Theory[47] to understand mechanisms of action and the contextual factors influencing implementation. Measures will be collected from organisational records (from baseline to 12 months) or self-report surveys (baseline, 3 and 6 months). As this is a feasibility study, any variability in follow-up durations will be recorded and explored.

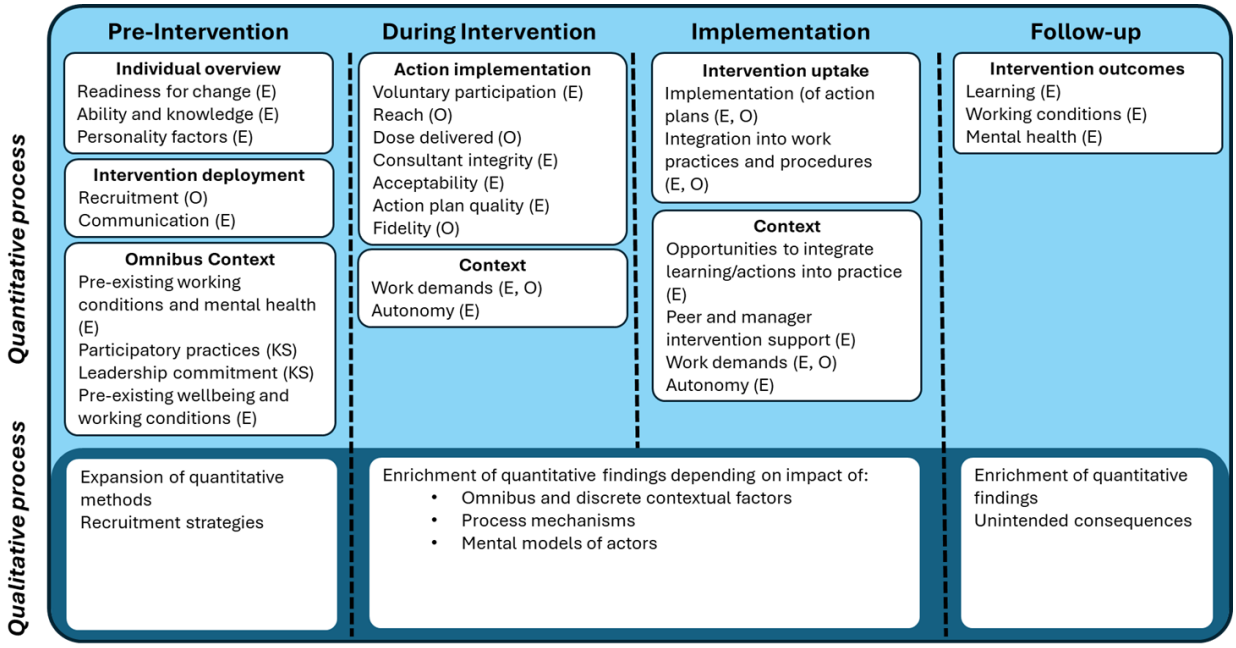
Feasibility-related outcomes

Study uptake measured by proportion of organisations that are willing to be randomised, and the proportion of participants (workers and managers) that agree to participate against the recruitment target. We will also record any missing data from organisational records, and how many participants complete the data collection at all time-points. We will record information on individual participants who may drop-out of the study and, where possible, reasons for withdrawals. As staff turnover rates may vary between, for example, organisation sector/type and size and levels of seniority, these variables will also be collected to contextualise the data.

Sample Characteristics

Participants (workers and managers) will be asked to complete some demographic information, including age, gender, ethnicity and highest level of education. The average wage for each worker will be identified using UK Standard Occupational Classification coding and annual earnings data for each job type. Workers will also be asked if they are the main wage earner.

Figure 2. *The Integrative Process Evaluation Framework (IPEF)[42]. E, employee rated through surveys; O, objective measure, KS, key stakeholder rated through surveys.*



Primary research outcome measure

The primary outcome will be the number of sick/disability leave days (total days and discrete absence spells). Data will be collected at baseline from organisational records in a 12-month period prior to intervention start and up to 12-months from study consent. All participants will be asked during the consent process whether the research team can request their employer records. If they do not consent, or if they report that they have not disclosed their LTC/disability to their employer, we will instead collect self-report absence data via online surveys. As part of the feasibility study, we will also assess consent rates for use of organisational records. If consent is low, we will consider switching to self-report absence data as the primary outcome measure for the definitive trial, while retaining employer records where available for triangulation. As part of the feasibility study, we will also assess the level of granularity available in organisational absence records, including whether reasons for absence can be separated (e.g., sickness- or disability-related absence). This will determine whether data are sufficiently detailed to inform the main trial.

Secondary outcome measures

Main secondary outcomes for worker participants will include other aspects of work-based attendance (turnover, work exit, intention to leave, ill-health/disability retirement), collected from organisational records and/or self-report where appropriate in a 12-month period prior to intervention start and up to 12-months from study consent. Other secondary outcomes (i.e., work-health balance, work productivity/impairment, work engagement, communication, self-efficacy, job crafting, work adjustments, autonomy, wellbeing, self-management, disclosure) for workers will be taken at all time points (baseline, 3, and 6 months) via online questionnaires (see also **Table 1**). Short-form measures will be employed and have been selected on the basis that they are suitable for any LTC or disability (i.e., can assess communalities across different groups), and reflect the mechanisms (or processes) through which Co-Manage is expected to lead to changes in the primary and secondary outcomes. The feasibility study will help guide which secondary measures are most appropriate and should be taken forward to the main trial.

Economic evaluation measures

Worker participants will be asked to complete the EuroQoL-5DL (EQ-5DL)[48] quality of life measure for the quality-adjusted life years (QALYs). Information on medical diagnosis of health conditions, prescribed medication use and other current therapeutic treatments will be collected using the modular resource-use measure (ModRUM)[49]. The number of lost working days, presenteeism costs, wages and intervention delivery costs (delivering the interventions components, website build and delivery, training delivery including line managers time) will also be collected.

Process evaluation

Information concerning the delivery and fidelity (implementation) of Co-Manage will be collected using analytics built into the website hosting Co-Manage. Data will be collected on the number of individual and repeated logins and number of downloads of resources.

Monthly interviews between the research team and employer stakeholders will be undertaken to monitor study progress and address recruitment challenges. We will invite all participants (workers with LTCs/disabilities, managers, employer stakeholders) enrolled in the quantitative element of study to take part in interviews 6 months post-recruitment to explore their perceptions of the study including data collection methods and time commitments. Interviews will also be used to understand the contextual factors that influenced the extent to which mechanisms were activated (e.g., time to practice having a conversation about managing work-relevant symptoms, issues/challenges regarding non-disclosure). To evaluate maintenance, we will explore interest in on-going usage of Co-Manage, and whether it could form part of any policies and processes.

Table 1. *List of outcome measures for worker (W), manager (M) and lead stakeholder (e.g., HR, OH, senior manager) (S) participants collected via online survey unless otherwise specified.*

Outcome measure	Description	Form (estimated time to complete)	Time point administered
Sample characteristics (W, M, S)	Demographic and occupation questions	16-items, 10 minutes	Baseline only
Primary outcome			
Number of sick/ disability leave days (W)	Total days and discrete absence spells	Depending on consent, collected from organisational records or via self-report, online surveys 2 items, 2 minutes	Baseline, 3, 6 and 12 months (online surveys only) Baseline, 12 months (organisational records only)
Secondary Outcomes			
Work-based attendance (W)	Turnover/work exit, intention to leave, ill-health/disability retirement	Depending on consent, collected from organisational records or via self-report, online surveys 3 items, 3 minutes	Baseline, 3, 6 and 12 months (online surveys only) Baseline, 12 months (organisational records only)
Work-health balance (W)	Work Ability Index[50]	7 items, 5 minutes	Baseline, 3, and 6 months
Work productivity/ impairment (W)	Work Productivity and Activity Impairment Questionnaire[51]	6 items, 5 minutes	
	Job satisfaction	1 item, 1 minute	
Work engagement (W)	Utrecht Work Engagement Scale-3 Item[52]	3 items, 3 minutes	
Communication (W)	Workplace Health Communication Scale	3-items, 6 minutes	
	Communication satisfaction	2-items, 2 minutes	
	Manager satisfaction	1 item, 1 minute	
Self-efficacy (W)	Work Self-efficacy Scale[53]	10 items, 10 minutes	
Job crafting (W)	Short Broad Job Crafting Scale[54]	4 items, 3 minutes	
Work adjustments (W)	Adjustments implemented in the workplace	5 items, 7 minutes	
Autonomy (W)	Basic Psychological Needs Satisfaction at Work - Autonomy Sub-scale[55]	4-items, 5 minutes	
Wellbeing (W)	Utrecht Burnout Scale[56], Exhaustion sub-scale only	3 items, 3 minutes	
	World Health Organization-Five Well-Being Index[57]	5 items, 4 minutes	
Self-management (W)	Self-Efficacy to Manage Chronic Disease scale[58]	6 items, 4 minutes	
Disclosure (W)	Disclosure of health/disability status to organisation	2 items, 3 minutes	
Policies and practices (M, S)	Intervention Preparedness Tool[59]	8 items, 10 minutes	Baseline only (intervention group only)
	Intervention readiness	5 items, 5 minutes	Baseline only
Experiences (M)	Supporting worker self-management	3 items, 3 minutes	Baseline, 3, and 6 months
Economic evaluation measures			
Health-related quality of life (W)	EuroQoL-5DL (EQ-5DL)[48]	6 items, 7 minutes	Baseline, 3, and 6 months
Health resource use (W)	Modular resource-use measure (ModRUM)[49]	12 items, 15 minutes	

4.4. Recruitment, study procedures and data collection

Participant recruitment process

- Organisations will be contacted by the research team, via email, to promote participation.
- After receiving the relevant ethical and organisational approvals, the key organisational contact (local collaborator) at participating organisations will have discussions with the research team about the study setup procedures. They will also have monthly video-calls or in-person contact with a project researcher to discuss number of workers on sick/disability leave in the past month and how many met the inclusion criteria. At the end of the study, the key organisational contact will take part in in a one x 1 hour telephone or MS Teams interview to explore their experience of taking part in the study.
- Participating organisations will be provided with study promotional materials for dissemination across their workforce. These materials will outline the purpose of the study, what participation involves, and how staff can provide informed consent. Participation will be entirely voluntary. Reminder communications will be issued at appropriate intervals to maximise awareness and encourage uptake.
- From the organisations consenting to take part, we will collect the following information prior to randomisation: summary of absence data for the past 12 months (only total numbers and % by reasons); size and sector; copies of sickness absence policy and frameworks; copies of return-to-work policy and frameworks; and details on workplace-based health training and support.
- We will also collect questionnaire data from manager participants, as well as lead stakeholders (e.g., director of human resources) on their experiences of supporting self-management, as well as readiness and expectations for the intervention to help us understand in which context Co-Manage works. This information will be gathered through the completion of electronic surveys. Findings will help us identify potential contextual barriers and facilitators to implementing the intervention. Additionally, contextual barriers and facilitators will be explored through semi-structured interviews in more detail.
- We will work with each participating organisation to ensure optimal recruitment opportunities by first addressing any systemic barriers to recruitment. This includes gaining leadership commitment to the study, implementing a strong communication strategy about the intervention and its purpose, and aligning Co-Manage with current self-management policies and practices so that HR personnel, managers and individual workers understand the purpose of the intervention and are therefore more comfortable in taking part. This will be further supported by employee champions who will promote the study within their teams.
- We will implement an 8-month-long recruitment period (with employers participating for a total period of 20 months), to maximise the recruitment of workers. **Figure 2** illustrates this process.
- Using a ratio of 1:1, organisations will be randomised into intervention or control group and where possible, will be stratified by organisational (cluster) type/size. Randomisation into the study will be done by an independent statistician (Asghar).

Data collection and safeguarding procedures

- The measures will be collected by the research team using a secure, web-based, industry standard data collection system (i.e., Qualtrics). Participants will be contacted at least monthly via email, telephone and/or SMS message on the use of Co-Manage and to prompt the completion of outcome measure where appropriate.
- Participants will be asked to complete the primary and secondary measures at three assessment points (baseline, 3 and 6 months).
- Sample characteristics (described above) will only be completed once, at the time when participants provide informed consent.
- A hard copy of the consent form will be available on request.
- HR departments will be asked to send documentation out to all staff for them to read about the study and consent to participate.

- The dataset will be stored in a secure, password protected network drive, only accessible to members of the research team. As the delivery team (in charge of recruitment and data collection) is based within Loughborough University, data will be stored in a secure and restricted-access network drive managed by Loughborough University IT systems (i.e., OneDrive). This will ensure the security and adequate storage of research data, consistent with NHS and academic codes of information governance and data protection. Data transfer between the organisations and the academic team at Loughborough will be carried out strictly using password encrypted data files (using 7zip software). For NHS organisations, we will use secure file transfer facilities (e.g., Secure Electronic File Transfer: SEFT) to comply with data protection and information governance policies.

5. Data analysis

5.1. Sample size calculation

There is no formal requirement to conduct sample size calculations for feasibility studies. Based on prior studies with a similar design[60], for the quantitative element of the study, our aim is to recruit at least 120 participants workers with LTCs/disabilities (60 per arm) and 120 managers (60 per arm) from at least 8 organisations (4 randomised in each arm) to calculate the targeted sample size for a definitive trial. This will allow us to estimate an ICC to assist with the targeted sample size calculation for a definitive trial.

For the pilot process evaluation, we will invite participants (workers with LTCs/disabilities, managers, employer stakeholders) enrolled in the quantitative element of study to take part in interviews. Based on our previous research[30], we expect to recruit approximately 2-4 employer stakeholders from each organisation, resulting in an overall total of around 8-16 employer stakeholders. In addition, we aim to recruit approximately 6-8 workers with LTCs/disabilities and managers combined from each organisation, giving an estimated total of 24-32 worker and manager participants. Throughout data collection, we will iteratively assess whether sufficient information power has been achieved by considering the study aim (narrow or broad), sample specificity (dense or sparse), theoretical background (applied or none), quality of dialogue (strong or weak), and strategy for analysis (case or cross-case). To ensure representativeness, a purposive, maximum variation sampling strategy will be used to capture diversity across a range of departments, job roles and seniority levels, as well as ages, genders, ethnicities, and LTCs/disabilities. This approach will ensure that the qualitative data collected will provide sufficient depth and breadth to meaningfully inform the design of the main trial.

5.2. Descriptive statistics and summary of quantitative data

Data will be analysed and reported according to the CONSORT statement. We will examine the primary and secondary outcomes to mimic practice for a full trial in addition to finalising sample size. Results will be treated as preliminary and interpreted with caution.

Quantitative data for both process and research outcomes will be summarised using means, standard deviations, medians and ranges for continuous variables and counts and percentages for categorical variables. The number of organisations agreeing to participate in the trial will be summarised in terms of their size, sector, sick/disability leave policies, and number of workers who were on sick leave/disability in the past 12 months prior to the start of the study. The number of worker participants recruited into the study will be reported, along with the number of participants followed up at each time-point. Withdrawals (and where possible, reasons for withdrawals) will be reported. A priori, we have defined a success criterion of 50% of the total number of participants invited to be recruited to the research evaluation to make a main trial feasible. We will consider a rate of 70% of those staying in the trial at 6 months follow-up as satisfactory. We will provide the point estimate of the proportion and its 95% confidence interval (CI). Difference in recruitment uptake rate and follow-up rates at each time point will be compared between the intervention and control arms.

As organisations of different sizes are taking part, it is likely there will be some imbalance between participants in each treatment arm on one of more baseline characteristics. Baseline comparisons will be carried out to detect any substantial differences between participants recruited from the control and intervention arms. This will be done by scrutinising the baseline table for any serious imbalances in observable baseline variables and the trends of the imbalance if any. The recruitment rates will also be estimated and compared between the control and intervention arms. We will examine the size of any imbalances and decide if there is evidence of systematic selection bias in the types of patients being recruited in control versus intervention arms. Key baseline characteristics will be compared between those participants followed up and those lost to follow-up at each timepoint. Intervention fidelity will be assessed by analytics built into the Co-Manage intervention.

5.3. Analysis of adherence, usability and completion

For the main trial to take place, the following traffic light system will be employed:

- Recruitment of organisations into the study (green: >50% proceed to main trial; amber: 30-50% proceed with adjustments; red: <30% no main trial).
- Recruitment of eligible workers with LTCs/disabilities (green: ≥50% of our recruitment target; amber: 30-49%; red: <30%). Eligibility will be based on the number of workers who self-identify during study recruitment, recognising that disclosure rates vary and records alone underestimate prevalence. Recruitment materials will be disseminated to all workers to ensure inclusivity and avoid singling out individuals.
- Recruitment of invited managers (green: ≥50% of recruitment target; amber: 30-49%; red: <30%). All managers within participating organisations will be invited, regardless of whether they directly manage a participating worker. Management roles will be identified through HR records using standard job classifications (e.g., line manager, team leader). Managers with a LTC/disability may participate both as a worker participant (with LTC/disability) and as a manager participant, if applicable.
- Retention of participants at 6-month follow-up (green: ≥70%; amber: 40-69%; red: <40%).
- Complete sick/disability leave (primary outcome) data at baseline, 3, and 6 months (green: ≥70% of completion; amber: 40-69%; red <40%).
- Intervention completion (green: ≥50%; amber: 25-49%; red: <25%) assessed using website analytics and interviews.
- Intervention acceptability (green: ≥80% of respondents; amber: 50-69%; red: <50%) and usability of intervention materials (green: ≥75% achieving score of ≥70; amber: 50-74%; red: <50%) assessed using standardised self-report items via the online surveys at 3 and 6 months. Acceptability will be assessed by items such as: 'Overall, I found the toolkit acceptable for people in my situation' (5-point Likert) and calculated as the proportion of participants rating ≥4 ('agree' or 'strongly agree'). Usability will be assessed using the 10-item System Usability Scale (SUS) with a score ≥70 indicating good usability. Semi-structured interviews will also be used to provide further in-depth information to aid interpretation of these ratings.

5.3. Qualitative data analysis

Qualitative interviews will be transcribed verbatim and analysed using inductive reflexive thematic analysis[61]. The sample size will be reviewed during data collection to determine whether sufficient information power has been obtained[62]. Quantitative and qualitative data will be triangulated and systematically coded using core underpinning theoretical frameworks[31-35] to identify the change mechanisms of how worker and manager participants translate Co-Manage into behaviour changes and the barriers and facilitators to doing this. This will provide us with invaluable information on what works and under what context (e.g., readiness for change, stigma culture) and how these lead to our intended outcomes (e.g., reduced sick/disability leave).

5.4. Exploratory analyses of outcomes data

Analysis will be conducted for outcomes data, but this will be treated as exploratory and will mainly be descriptive. A baseline table (descriptive statistics and frequencies) will compart the demographic and clinical characteristics (gender, age, education, number of days on sick leave, health status, work support, communication, work productivity) between the two arms. We will summarise both cluster (worksites) and participant-level baseline characteristics using means, standard deviations, medians and ranges for continuous variables and counts and percentages for categorical variables.

As this is a feasibility trial, no emphasis will be put on the *p*-values for any inferential statistical tests conducted. Statistical analysis will be carried out on an intention-to-treat basis with missing outcome data being imputed using multiple imputation. Exploratory cluster analysis methods (e.g., hierarchical clustering, k-means, latent class analysis) will be used to identify clusters of LTCs (e.g., musculoskeletal, mental health, cardiovascular). To ensure these clusters are clinically meaningful, we will consult our PPIE and expert advisory group members, which include OH Physicians and GPs, to review and validate the LTC clusters. We will then assess whether cluster membership influences recruitment, retention, intervention use, and outcomes. In addition, we will compare outcomes and engagement with Co-Manage between worker participants who have and have not disclosed their LTC/disability to their employer. This will also allow us to contextualise any discrepancies between self-reported and employer-reported data, and identify whether disclosure influences intervention use, recruitment, or retention.

Findings will inform the design of the definitive trial, such as whether to stratify randomisation, adjust analyses, or adopt targeted sampling approaches based on specific LTC clusters or multimorbidity profiles. In a future main trial, we will conduct a mixed effect model, which allows all available data at all time points to be used and account for missing data/clustering effects. We will estimate a two-sided 95% CI to show a reliable range for the true difference in the primary outcome between intervention and control arms.

5.5. Health economic evaluation

The economic analysis will be exploratory, focusing on the feasibility of collecting data on outcomes needed in a larger trial of Co-Manage. We will examine the outcomes to mimic practice for a full trial. Results will be treated as preliminary and interpreted with caution (i.e., they will not be used to generate formal cost effectiveness estimates).

Specifically, we will pilot data collection tools, including resource use data collected via a bespoke questionnaire and valued using national unit costs, accounting for both set-up and delivery costs of the intervention across the trial period. Participants (i.e., workers with LTCs/disabilities) will complete the EQ-5DL[48] measure at baseline, 3, and 6 months. This measure is widely used and recommended by NICE for estimating quality-adjusted life years (QALYs). Additional information will be gathered using the ModRUM[49] capturing medical diagnoses, prescribed medications, and healthcare utilisation, including GP and practice nurse appointments, hospital inpatient stays, outpatient visits, and accident and emergency attendances. These data will be valued using national unit prices. The analysis will also capture resource use relevant to the Personal Social Services (PSS) perspective, including the number of days lost to sick or disability leave, presenteeism-related costs, wages, use of healthcare services, out-of- pocket expenses, and informal care.

The primary economic analysis will consider the PSS perspective, with a secondary analysis conducted from a combined NHS and PSS perspective, in line with NICE guidance. This multi-perspective approach will help evaluate the utility, completeness, and acceptability of cost data. To inform the design of a robust evaluation in the full trial, the economic analysis will assess data completeness and variability, identify key cost drivers, and explore challenges in collecting employer and societal cost data, as well as the acceptability of economic measures. Key outcomes will include the number of sick/disability leave days and QALYs derived from EQ-5DL data using the UK tariff. We will present incremental cost per an

additional sick/disability leave day and QALYs gained, and cost- effectiveness acceptability curves based on QALYs.

6. Ethical and regulatory considerations

Prior to the commencement of the research, including the recruitment of potential participants, the protocol and all supporting documentation (Patient Information Sheet, Consent Form, etc.) will be reviewed and approved by the Sponsor, an NHS Research Ethics Committee (REC), the Health Research Authority (HRA), and R&D in participating NHS Trusts. Review is in line with the UK Framework for Health and Social Care Research, the Declaration of Helsinki, and guidelines for Good Clinical Practice.

6.1. Ethical considerations

Informed consent

To obtain informed consent in line with good practice guidelines, we will take the following steps:

- Potential participants will be invited to contact a member of the research team if they have any thoughts or questions. Contact details will be provided as part of promotional materials.
- Participants will consent to being contacted on personal email addresses and mobile phone numbers with reminders as well as with links.
- Potential participants will be advised of their right to withdraw from the study at any stage and the right to request their data to be deleted from the study dataset up until 1 week after the last data has been collected from them. After this point it will not be possible for participants to withdraw their individual data. This will be explicit in the electronic participant information sheet and in the consent form.

Potential risks to participants

The Co-Manage intervention is low risk and we have received ethical approval for previous work of this nature, so we do not anticipate ethical concerns. We do however acknowledge that we are dealing self-management of LTCs and disabilities, so participants will receive contact information for the Chief Investigator in the participant information sheet, if they should wish to make a complaint or to raise any concerns about the intervention or conduct of the study. In the rare event that a participant should become distressed, they will be provided information by the research team about available support services. To mitigate any potential for distress, a comprehensive range of resources and contact points will be provided as part of the intervention, enabling participants to access both self-guided and professional help where required.

Risks to research team

The study is considered to present minimal risk to members of the research team. All data collection will be conducted remotely via online questionnaires and optional interviews (telephone or MS Teams), meaning there is no physical risk associated with face-to-face contact or travel. Researchers may be exposed to potentially sensitive or emotionally challenging information, as participants may discuss long-term health conditions, workplace difficulties, stress, or sickness absence. To mitigate this, interviews will be conducted by trained members of the research team with experience in handling sensitive topics. Researchers will have access to supervision and peer support, and any concerns arising during data collection will be discussed with the Chief Investigator.

Participant Confidentiality

All information collected during the study will be treated as strictly confidential and handled in accordance with the General Data Protection Regulation (GDPR), the Data Protection Act, and Sponsor (Loughborough University) data protection policies.

Participants will be assigned a unique study ID, and all research data (e.g., questionnaire responses, interview transcripts) will be pseudonymised using this identifier. Identifiable information (e.g. names and contact details) will be stored separately from research data and will be accessible only to authorised members of the research team for the purposes of study administration (e.g. obtaining consent, sending questionnaire links, arranging interviews). Electronic data will be stored on secure, password-protected servers with access restricted to the research team. Any audio recordings will be transcribed verbatim and anonymised during transcription, with identifiable details removed. Audio files will be deleted once transcription and accuracy checks are complete. Hard-copy materials, if generated, will be stored in locked filing cabinets within secure university offices. Importantly, employers will not have access to individual-level questionnaire responses, interview data, or identifiable information. Any data shared with organisations or reported in outputs will be fully anonymised and presented in aggregate form only, ensuring that no individual participant or organisation can be identified.

In line with funder and institutional requirements, to comply with principles of Open Science anonymised datasets that support published findings may be archived for a maximum of 10 years in Loughborough University's Research Repository for future research and teaching purposes. Archived data will contain no identifiable information and will be deposited either as open-access or confidential datasets, as appropriate. Identifiable data will not be archived and will be securely deleted once it is no longer required, and no later than the end of the data collection and verification period. Participants will be informed of these arrangements in the Participant Information Sheet and may withdraw their data up to the point of anonymisation without providing a reason.

6.2. Regulatory considerations

Protocol compliance

An independent Trial Steering Group will be established to ensure the safe and effective conduct of the study and to recommend conclusion of the trial if/when significant benefits or risks have developed, of the trial it unlikely to be concluded successfully. The committee will meet on a 6 monthly basis. Any issues raised will be addressed with the Chief Investigator and reports and recommendations will be provided.

Researchers are expected to conduct the study in accordance with the protocol. All protocol non-compliances are expected to be reported to the sponsor, who will assess the non-compliance and report to REC is deemed appropriate. Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Amendments

For any amendments to the study, the Chief Investigator will submit information to the Sponsor and NHS Ethics Committee. Only once an amendment has been given a favourable opinion will the Chief Investigator and study team put these processes in place. If an amendment is required, the Chief Investigator will consult with the wider study team to decide if it is a substantial or non-substantial amendment. A document tracking any amendments will be stored on a secure university server and will be updated by the Chief Investigator as required to ensure the protocol is kept up to date.

Patient and Publish Involvement and Engagement (PPIE)

Co-Manage was initially developed through an NIHR Work and Health Development Award (completed July 2024), which incorporated extensive stakeholder co-production to shape the content and format. This included a newly established PPIE group and expert advisory group. Building on the model of PPIE involvement, a dedicated PPIE group, co-led by Dr David Maidment (Chief Investigator/PPIE Lead) and Helen Barrow (PPIE Co-I), will be established.

PPIE members will play active roles across the proposed project, including co-designing study materials, contributing to data analysis and interpretation, advising on recruitment strategies, and helping shape the design and delivery of the full-scale trial. Their insights will help ensure that our outputs are accessible, acceptable, and relevant to both workers and employers.

We will provide comprehensive
induction and ongoing support, including tailored training through the NIHR Learning for Involvement platform, and bespoke development opportunities facilitated by the Regional Research Delivery Network East Midlands. Support needs will be identified early and reviewed regularly. All members will receive appropriate honoraria in line with NIHR guidance, and monthly meetings will be held through flexible, accessible formats (e.g., online platforms or community-based venues) to support participation.

7. Dissemination

After the conclusion of data analysis, we plan to disseminate findings about this study using a variety of forms of communication, including:

- Scientific presentations.
- Peer reviewed publications in scientific journals.
- Participation in local, national and international meetings and conferences.
- Articles for trade publications (e.g., HR Zone and Occupational Health Today).
- Presenting findings at employer and professional practice conferences (e.g., Health and Well-being at Work Summit).
- We will produce practitioner guidelines for occupational health, vocational rehabilitation and human resource practitioners that bring together findings in an accessible way.
- Engage with professional bodies through the "Work, Health and Wellbeing" Research Consortium.
- Cross-care and industry networks.
- Specific healthcare networks such as the UK Faculty of Public Health (UKFPH) and Royal College of General Practitioners (RCGP).

8. References

1. UK Parliament. Disabled people in employment. House of Commons Library. https://commonslibrary.parliament.uk/research-briefings/cbp-7540/#:~:text=There%20were%205.53%20million%20working,are%20not%20disabled%20was%2082.0%25. Published 2024. Accessed July 2025.
2. The Health Foundation. *Commission for Healthier Working Lives. Towards a healthier workforce. .* 2024.
3. Public Health England. Health matters: health and work. Department of Health and Social Care,. https://www.gov.uk/government/publications/health-matters-health-and-work/health-matters-health-and-work. Published 2019. Accessed July 2025.
4. Access PeopleHR. Sick Leave Report 2024: How are different industries faring? https://www.peoplehr.com/en-gb/resources/blog/sick-leave-report-how-are-different-industries-faring/. Published 2024. Accessed July 2025.
5. National Institute for Health and Care Excellence. *Workplace health: long term sickness absence and capability to work.* United Kingdom2019.

6. Department for Work and Pensions. Employment of disabled people 2022. https://www.gov.uk/government/statistics/the-employment-of-disabled-people-2022/employment-of-disabled-people-2022. Published 2023. Accessed July 2025.
7. Maidment DW, Clarkson K, Shiel EV, Nielsen K, Yarker J, Munir F. A rapid systematic review assessing the effectiveness of interventions to promote self-management in workers with long-term health conditions and disabilities. *IJERPH.* 2024;21(12):1714.
8. Woodward A, Davies N, Walters K, et al. Self-management of multiple long-term conditions: a systematic review of the barriers and facilitators amongst people experiencing socioeconomic deprivation. *PloS One.* 2023;18(2):e0282036.
9. NHS England. The NHS Long Term Plan. https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/. Published 2019. Accessed.
10. Department for Work and Pensions & Department of Health. *Improving lives: the future of work, health and disability.* 2017.
11. Chartered Institute of Personnel and Development. *Long-term health conditions: how people professionals can support employees.* 2024.
12. Nicholson PJ. Occupational Health: The Value Proposition. https://www.som.org.uk/sites/som.org.uk/files/Occupational_Health_The_Value_Proposition_March_2022.pdf. Published 2022. Accessed1-44.
13. National Institute for Health and Care Excellence. Workplace health: long-term sickness absence and capability to work. https://www.nice.org.uk/guidance/ng146. Published 2019. Accessed July 2025.
14. Nazarov S, Manuwald U, Leonardi M, et al. Chronic diseases and employment: which interventions support the maintenance of work and return to work among workers with chronic illnesses? A systematic review. *International Journal of Environmental Research and Public Health.* 2019;16(10):1864.
15. Meunier S, Roberge C, Coulombe S, Houle J. Feeling better at work! Mental health self-management strategies for workers with depressive and anxiety symptoms. *Journal of Affective Disorders.* 2019;254:7-14.
16. Department for Work and Pensions & Department of Health and Social Care. *Health is everyone's business: proposals to reduce ill health-related job loss.* UK;2019.
17. Hemming S, Munir F. Using the patient activation measure to examine the self-management support needs of a population of UK workers with long-term health conditions. *Chronic Illness.* 2022;18(3):702-707.
18. Hemming S, McDermott H, Munir F, Burton K. Employer perspectives concerning the self-management support needs of workers with long-term health conditions. *International Journal of Workplace Health Management.* 2021;14(4):440-458.
19. Hemming S. *Do workers with long-term health conditions need self-management support at work?* , Loughborough University; 2020.
20. Adepoju OE, Bolin JN, Ohsfeldt RL, et al. Can chronic disease management programs for patients with type 2 diabetes reduce productivity-related indirect costs of the disease? Evidence from a randomized controlled trial. *Population Health Management.* 2014;17(2):112-120.
21. Haynes NJ, Vandenberg RJ, Wilson MG, DeJoy DM, Padilla HM, Smith ML. Evaluating the impact of the live healthy, work healthy program on organizational outcomes: A randomized field experiment. *Journal of Applied Psychology.* 2022;107(10):1758-1780.

22. Schopp LH, Bike DH, Clark MJ, Minor MA. Act Healthy: promoting health behaviors and self-efficacy in the workplace. *Health Education Research.* 2015;30(4):542-553.

23. Smith ML, Wilson MG, Robertson MM, et al. Impact of a translated disease self-management program on employee health and productivity: Six-month findings from a randomized controlled trial. *International journal of environmental research and public health.* 2018;15(5):851.

24. Wilson MG, DeJoy DM, Vandenberg RJ, et al. Translating CDSMP to the workplace: results of the live healthy work healthy program. *American Journal of Health Promotion.* 2021;35(4):491-502.

25. Shaw WS, McLellan RK, Besen E, et al. A worksite self-management program for workers with chronic health conditions improves worker engagement and retention, but not workplace function. *Journal of Occupational Rehabilitation.* 2022;32(1):77-86.

26. The King's Fund. *How does the NHS compare to the health care systems of other countries?* UK;2023.

27. Hemming S, McDermott H, Munir F, Burton K. A workplace support model for workers with long-term conditions. *Occupational Medicine.* under review.

28. Kendall NA, Burton AK, Main CJ, Watson P. *Tackling musculoskeletal problems: a guide for clinic and workplace-identifying obstacles using the psychosocial flags framework.* London UK: The Stationery Office; 2009.

29. Feuerstein M, Todd BL, Moskowitz MC, et al. Work in cancer survivors: a model for practice and research. *Journal of Cancer Survivorship.* 2010;4:415-437.

30. Davis O, Dawson J, Degerdon L, et al. Protocol for a pilot cluster randomised controlled trial of a multicomponent sustainable return to work IGLOo intervention. *Pilot and Feasibility Studies.* 2024;10(1):23.

31. Beck AT, Dozois DJ. Cognitive theory and therapy: past, present, and future. *Journal of Consulting and Clinical Psychology.* 1993;61:194-198.

32. Giles H, Coupland N, Coupland J. Accommodation theory: communication, context, and consequence. In: Giles H, Coupland J, Coupland N, eds. *Contexts of accommodation: developments in applied sociolinguistics.* Cambridge University Press; 1991:1-68.

33. Hobfoll SE. Conservation of resources: a new attempt at conceptualizing stress. *American Psychologist.* 1989;44(3):513-524.

34. Bakker AB, Demerouti E. Job demands–resources theory. In: Chen P, Cooper C, eds. *Work and Wellbeing: a complete reference guide* Chichester, UK: Wiley-Blackwell; 2014:37-64.

35. Bandura A. *Self Efficacy.* New York: WH Freeman & Co; 1997.

36. Nielsen K, Yarker J, Evans H. *Thriving at Work: The resources required to support employees returning to work following mental ill-health absence.* Productivity Insights Network;2019.

37. Skivington K, Matthews L, Craig P, Simpson S, Moore L. Developing and evaluating complex interventions: updating Medical Research Council guidance to take account of new methodological and theoretical approaches. *The Lancet.* 2018;392.

38. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.

39. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ.* 2016;355(i5239).

40. Blake H, Chaplin WJ, Wainwright E, et al. The web-based pain-at-work toolkit with telephone support for employees with chronic or persistent pain: protocol for a cluster randomized feasibility trial. *JMIR Research Protocols.* 2023;12(1):e51474.

41. UK Government. Equality Act 2010. In:2010.

42. Nielsen K, De Angelis M, Innstrand ST, Mazzetti G. Quantitative process measures in interventions to improve employees' mental health: A systematic literature review and the IPEF framework. *Work & Stress.* 2023;37(1):1-26.

43. Maidment D, Clarkson K, Shiel E, Nielsen K, Yarker J, Munir F. A rapid systematic review assessing the effectiveness of interventions to support self-management in workers with long-term health conditions and disabilities. *International journal of environmental research and public health.* 2024;21(12):1714.

44. Ravinskaya M, Verbeek JH, Langendam M, et al. Which outcomes should always be measured in intervention studies for improving work participation for people with a health problem? An international multistakeholder Delphi study to develop a core outcome set for Work participation (COS for Work). *BMJ Ppen.* 2023;13(2):e069174.

45. Glasgow RE, Harden SM, Gaglio B, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Frontiers in public health.* 2019;7:64.

46. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *American Journal of Public Health.* 2013;103(6):e38-e46.

47. Pawson R, Tilley N. *Realistic Evaluation.* Sage; 1997.

48. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research.* 2011;20:1727-1736.

49. Garfield K, Thorn JC, Noble S, Husbands S, Hollingworth W. Development of a brief, generic, modular resource-use measure (ModRUM): piloting with patients. *BMC Health Services Research.* 2023;23(1):994.

50. Ilmarinen J. The work ability index (WAI). *Occupational Medicine.* 2007;57(2):160-160.

51. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics.* 1993;4(5):353-365.

52. Schaufeli WB, Bakker AB, Salanova M. The measurement of work engagement with a short questionnaire: a cross-national study. *Educational and Psychological Measurement.* 2006;66(4):701-716.

53. Pepe SJ, Farnese ML, Avalone F, Vecchione M. Work Self-efficacy Scale and Search for Work Self-efficacy Scale: a validation study in Spanish and Italian cultural contexts. *Revista de Psicología del Trabajo y de las Organizaciones.* 2010;26(3):201-210.

54. Vanbelle E, Griep Y, Van den Broeck A, De Witte H. Development and validation of a short broad job crafting scale. *Group & Organization Management.* 2023:1-35.

55. Deci EL, Ryan RM, Gagné M, Leone DR, Usunov J, Kornazheva BP. Basic Psychological Need Satisfaction at Work Scale. *Personality and Social Psychology Bulletin.* 2019.

56. Schaufeli WB, Van Dierendonck D. *Utrechtse burnout schaal (UBOS): Testhandleiding [Utrecht Burnout Scale: Test Manual].* Lisse, The Netherlands: Swets Test Publishers; 2000.

57. Sischka PE, Costa AP, Steffgen G, Schmidt AF. The WHO-5 well-being index–validation based on item response theory and the analysis of measurement invariance across 35 countries. *Journal of Affective Disorders Reports.* 2020;1:100020.

58. Ritter PL, Lorig K. The English and Spanish self-efficacy to manage chronic disease scale measures were validated using multiple studies. *Journal of clinical epidemiology.* 2014;67(11):1265-1273.

59. Nielsen K, Marzocchi I, Di Tecco C, et al. Validation of the Intervention Preparedness Tool: a short measure to assess important precursors for successful implementation of organisational interventions. *Work & Stress.* 2024;38(4):380-398.

60. Blake H, Chaplin WJ, Gupta A. The effectiveness of digital interventions for self-management of chronic pain in employment settings: a systematic review. *British Medical Bulletin.* 2024;151(1):36-48.

61. Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qualitative research in sport, exercise and health.* 2019;11(4):589-597.

62. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. *Qualitative Health Research.* 2016;26(13):1753-1760.