PAIN-AT-WORK TOOLKIT FOR EMPLOYEES WITH CHRONIC PAIN (DEFINITIVE TRIAL)

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Short title: Pain-at-Work Toolkit

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2. SYNOPSIS

Title	Pain-at-Work Toolkit for employees with chronic pain (definitive trial)
Short title	Pain-at-Work Toolkit
Chief Investigator	Professor Holly Blake
Objectives	The aim of this study is to carry out a definitive cluster randomised controlled trial, with a built-in process and implementation evaluation, to assess how effective and cost-effective the Pain-at-Work Toolkit is at helping employees self-manage chronic pain across a range of UK workplaces. The two research questions (RQs) and study objectives are: **RQ1**. What is the effectiveness and cost-effectiveness of the Pain-at-Work Toolkit? This will be addressed through a definitive cluster randomised controlled trial. The primary objective for RQ1 is: • To determine the effectiveness of the Pain-at-Work Toolkit for improving work ability in working-age adults with chronic pain. The secondary objectives for RQ1 are: • To evaluate differences compared to controls in other outcomes including work self-efficacy, sickness absence, presenteeism, work productivity loss, job satisfaction, job stressfulness, turnover intentions, and symptoms of anxiety and depression. • To determine the cost-effectiveness of the Pain-at-Work Toolkit. **RQ2**. How is the Pain-at-Work Toolkit delivered, received, and used, and how this is shaped by contextual factors? Alongside the trial, a process and implementation evaluation will explore experiences of the intervention implementation from the perspective of employees and organisational representatives. This will help us to understand how and why the Pain-at-Work Toolkit was effective or ineffective and to identify contextually relevant strategies for future successful implementation, scale-up, and sustainability. The objectives for RQ2 are: • To determine intervention fidelity. • To explore the relationship between implementation fidelity and outcomes. • To understand the barriers and facilitators to successful implementation and rollout. • To generate strategies for future implementation, maintenance, and scalability.

	If shown to be effective and cost-effective, the Pain-at-Work Toolkit could be rolled out through routes identified in the implementation study (e.g., policymakers, professional bodies, employers, healthcare professionals). Ultimately, it could contribute to reducing social inequalities (work participation/disability 'pay-gap'), and the overall health, societal and economic burden of chronic pain.
Trial Configuration	3 work-packages: effectiveness trial (WP1); health economics evaluation (WP2); process and implementation study (WP3).
Setting	United Kingdom employment settings in different sectors (public, private, third), varying in size (small:10-49 workers; medium: 50-249 workers; large: >250 workers).
Sample size estimate	We aim to recruit a minimum of 30 clusters from across the UK (15 per arm), allowing for 40% attrition, and with an expected cluster size of 20 per cluster. With a 2-tailed hypothesis, 0.05 significance, and 80% power. A total sample size of 685 will be sufficient to identify a 0.6 difference in Work Ability Index (WAI) with an SD of the change in WAI of 2.0 (based on our feasibility trial) and an intra-cluster correlation of 0.02
Number of participants	• >30 Organisations (clusters) across all UK nations. • >685 Participants (employees) • 60 Stakeholders (individuals and groups of working-age adults who experience chronic pain or stakeholders involved in employment of, support for, or policy-development for adults with chronic pain.
Eligibility criteria	• **Organisations:** >10 employees, based in the UK. • **Participants (employees):** Working-age adults (employees), aged 18 and over, with chronic pain, able to comprehend English language and provide informed consent. • **Implementation exploration**: individuals and groups of working-age adults who experience chronic pain or stakeholders involved in employment of, support for, or policy-development for adults with chronic pain.
Description of interventions	Organisations are randomised to either i) an active control group (SAU: support as usual), or ii) SAU plus Pain-at-Work Toolkit and Pain-at-Work Manager Toolkit. **Active Control** - SAU: Depending on the employing organisation, SAU may include (but is not limited to) any combination of the following: occupational health, counselling, line manager support, and signposting to education on factors that may have positive or negative effects on chronic pain. **Intervention** – Pain-at-Work Toolkit: Our digital web-based toolkit [1] is designed to support people with chronic pain in self-managing their condition at work. Pain-at-Work Toolkit offers evidence-based advice about chronic or persistent pain (Section 1), disability rights (Section 2), work capacity (Section 3. e.g., reasonable adjustments), pain self-

	management strategies (Section 4), and signposting to support (Section 5 e.g., Access to Work scheme). It can be accessed on any device, at any time, any location, worked through at any pace and revisited (e.g., dose, duration and intensity are at user preference). The Pain-at-Work Managers Toolkit has been developed to support managers in supporting their staff.
Duration of study	36 months (17.03.2026 to 28.02.2029) or from when all necessary approvals have been received.
Randomisation and blinding	Cluster-randomisation (rather than individual randomisation) is required due to the nature of the intervention and risk of contamination between intervention and control participants working at the same organisation. Employment settings will be randomised to an intervention or a control group, with a 1:1 allocation ratio, by the statistician. Due to the nature of the intervention, the project researcher is not blind to group allocation.
Outcome measures	**Work-related Participant-reported outcome measures (PROMs),** which includes the primary outcome Work Ability Index (WAI), using a between-group comparison over time. Additionally, other measures of work participation. **Employer-reported measures,** which include details about the employment setting and Support-As-Usual (SAU) for staff with chronic pain. **Employee-reported PROMs:** in addition to the work-related measures, employees provide socio-demographic, health, psychological and health-related quality of life, and health resource use, **Technology-adoption PROMs** (3 months, intervention group only) about the employees' use of the Pain-at-Work Toolkit. **Process and implementation evaluation measures,** including interview data with employees, employer representatives, and stakeholders. The resulting reflexive thematic analysis will be accompanied by a mapping of themes onto relevant constructs to interpret the findings through an implementation science lens. Full details of the process and implementation evaluation design, methods, and analysis (WP3) are provided in Section 5.3.
Statistical methods	Quantitative data will be analysed descriptively to examine patterns of engagement, intervention fidelity, and satisfaction, and to explore variation across sites and participant groups. The analysis will be performed on an intention-to-treat basis using all available data. The primary analysis will be a between-group comparison of the WAI score at 3 months, adjusted for the baseline and taking into account any clustering effect. This will be accomplished using a multi-level model to adjust for clustering. A further exploratory secondary analysis will be undertaken on the data at both 3 and 6 months. However, give the exploratory nature of this analysis no adjustment will be made to multiple testing.

	PROMS: we will present total scores (baseline, 3 months, 6 months) and change from baseline to 3 months and 6 months. Differences between arms may be presented with 95% confidence intervals where appropriate. We will calculate two anchor-based responsiveness statistics for each PROM: (i) standardised response mean (SRM), and (ii) effect size (ES). ***Health economic measures:*** The economic evaluation will comprise a cost-utility analysis conducted from a societal perspective. Differences in total costs and Quality-Adjusted Life Years (QALYs) between the intervention and comparator groups will be estimated using generalised linear models, adjusting for relevant baseline covariates. Uncertainty will be assessed using non-parametric bootstrapping, and results will be presented using Cost-Effectiveness Acceptability Curves showing the probability that the intervention is cost-effective across a range of conventional willingness-to-pay thresholds. To assess longer-term value for money, a decision-analytic model will be developed to extrapolate costs and QALYs beyond the trial follow-up period (e.g. 5–10 years), integrating trial data with evidence from published literature. The analysis and reporting will adhere to the CHEERS guidelines. ***Process and Implementation Evaluation:*** process evaluation will include fidelity, engagement and satisfaction measure and will be analysed descriptively.

3. ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator overall
cRCT	cluster-Randomised Controlled Trial
CRF	Case Report Form
DMC	Data Monitoring Committee
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
ES	Effect size
GB	Great Britain (England, Scotland, and Wales)
GCP	Good Clinical Practice
GP	General Practitioner
HWB	Health and Wellbeing
ICF	Informed Consent Form
IRB	Institutional Review Board
MRC	Medical Research Council
NHS	National Health Service
NI	Northern Ireland
PHQ-9	Patient Health Questionnaire-9 items
PIS	Participant Information Sheet
PPIE	Patient and Public Involvement and Engagement
PROM	Participant Reported Outcome Measure
QALYs	Quality-Adjusted Life Years
R&D	Research and Development Department
RCT	Randomised controlled trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SME	Small and medium-sized enterprise
SRM	Standardised response mean .
TAG	Trial Advisory Group
TAM	Technology Acceptance Model
SAU	Support as Usual
TMF	Trial Masterfile
TMG	Trial Management Group
ToR	Terms of Reference
TSG	Trial Steering Group
UoN	University of Nottingham
WAI	Work Ability Index
WP	Work package

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4. TRIAL / STUDY BACKGROUND INFORMATION AND RATIONALE

Chronic pain affects 28 million adults in the UK, significantly impacting their ability to be productive at work, feel fulfilled at work and/or remain in the active workforce. However, most people living with chronic pain cannot access work-related support from healthcare services, and the majority of employers do not routinely provide it. The Pain-at-Work Toolkit is a web-based resource that could help to reduce unfair differences in working lives for people with chronic pain, and positively impact their health and wellbeing, enhancing their productivity in the wider community. Co-created with people who live with pain, healthcare professionals and employers, this toolkit provides education and self-management advice to help people with chronic pain stay in, and thrive, at work.

We tested the Pain-at-Work Toolkit in a preliminary trial in England ('feasibility trial'). This showed that the Pain-at-Work Toolkit can be a very helpful support tool in the workplace for those living with chronic pain. We recruited 18 organisations and 380 employees (50% and 217% more than expected, respectively), demonstrating that this toolkit meets a gap in employer provisions. Employees who received access to the toolkit valued its content and engaged with it without technical issues. Workers told us that their ability to work had improved after 6 months but these results need to be confirmed in a larger trial. Employers told us that they valued being able to offer it to their staff. We are now updating the toolkit content to ensure it is relevant to employees across the UK.

The next step is to carry out a larger UK-wide study ('definitive trial'). The aim is to find out whether The Pain-at-Work Toolkit helps people to feel more able and confident at work, take fewer sick days, and be productive at work, and whether it provides good value for money.

We will recruit at least 30 different organisations from across UK. These organisations will be randomly placed into one of two groups: one will access and use the Pain-at-Work Toolkit (the intervention group), and the other will continue as usual (the control group), so we can compare results fairly. A Pain-at-Work Manager Toolkit will be made available to line managers of organisations in the intervention group.

Over 600 employees will be recruited from these organisations. They will all be invited to complete online questionnaires at three time points: at recruitment, 3 months, and 6 months. We will ask about their health and wellbeing, and factors relating to work, such as work ability, self-efficacy (confidence), sickness absence, work productivity, and intentions to leave.

This larger trial will include an 'implementation study'. This will involve conducting interviews with up to 60 people who have taken part in the trial and other stakeholders (such as employer representatives, line managers, HR or occupational health specialists, policymakers, professional bodies). The findings will shape our plans to make the Pain-at-Work Toolkit available widely to all workers with pain in the future.

5. TRIAL / STUDY OBJECTIVES AND PURPOSE

5.1. PURPOSE

The aim of this study is to conduct a definitive cluster-randomised controlled trial, with a built-in process and implementation evaluation, to assess the effectiveness and cost-effectiveness of the Pain at Work Toolkit for improving work ability in working-age adults with chronic pain across a range of UK workplaces.

The research questions (RQs) and study objectives are:

5.2. PRIMARY OBJECTIVE

RQ1. What is the effectiveness and cost-effectiveness of the Pain-at-Work Toolkit?
This will be addressed through a definitive cluster randomised controlled trial (cRCT).

Primary objective for RQ1 is:

- To determine the effectiveness of the Pain-at-Work Toolkit for improving work ability in working-age adults with chronic pain.

RQ2. How is the Pain-at-Work Toolkit delivered, received, and used, and how contextual factors shape this?
Alongside the trial, a process and implementation evaluation will explore experiences of the intervention implementation from the perspective of employees and organisational representatives. This will help us understand how and why the Pain-at-Work Toolkit was effective or ineffective and to identify contextually relevant strategies for future successful implementation, scale-up, and sustainability.

The objectives for RQ2 are:

- to determine intervention fidelity.
- to explore the relationship between implementation fidelity and outcomes.
- to understand the barriers and facilitators to successful implementation and rollout.
- to generate strategies for future implementation, maintenance, and scalability.

If shown to be effective and cost-effective, the Pain-at-Work Toolkit could be rolled out through routes identified in the implementation study (e.g., policymakers, professional bodies, employers, healthcare professionals). Ultimately, it could contribute to reducing social inequalities (work participation/disability ‘pay-gap’), and the overall health, societal, and economic burden of chronic pain.

5.3. SECONDARY OBJECTIVES

Secondary objectives for RQ1 are:

- To evaluate differences compared to controls in other outcomes, including work self-efficacy, sickness absence, presenteeism, work productivity loss, job satisfaction, job stressfulness, turnover intentions, and symptoms of anxiety and depression.
- To determine the cost-effectiveness of the Pain-at-Work Toolkit.

6. DETAILS OF THE INTERVENTION – Pain-at-Work Toolkit

Description: This web-based toolkit [2, 3] offers evidence-based advice about chronic pain, disability rights, work capacity, pain self-management strategies (e.g., pacing, self-care) and signposting to additional support. Content and presentation were developed to consider known enablers and barriers to engagement in digital interventions for people with chronic pain, through flexibility for access, inclusivity for people with disabilities, and low technological skill requirements. It can be accessed on any device, at any time, in any location, worked through at any pace, and revisited (e.g., dose, duration, and intensity are at the user's preference). Two regions are covered: Great Britain (GB; England, Scotland, and Wales) and Northern Ireland (NI), as these regions have different disability discrimination laws. The Pain-at-Work Toolkit has five sections:

- Section 1 - What is chronic or persistent pain?
- Section 2 - Chronic or persistent pain and disability.
- Section 3 - Work capacity, advice and support.
- Section 4 - Self-management strategies
- Section 5 – Resources

The Pain-at-Work Managers Toolkit has been developed in a similar format to the Pain-at-Work Toolkit and is provided to give managers access to information that may help them support employees with pain. This will be made available by the research team to all organisations in the intervention group. The mechanics of sharing this part of the toolkit will be discussed with the organisation at engagement, but it may be shared with a weblink. This Toolkit was requested by organisations in the feasibility trial. However, this is not part of the testing of the Pain-at-Work Toolkit for employees with chronic pain. Sending this to all managers will not identify individuals with chronic pain. In the past, some employees voluntarily shared their toolkit with their managers. Individual managers may use the Pain-at-Work Managers Toolkit, but this is optional.

Theoretical underpinning: Pain-at-Work Toolkit is aligned with the MRC framework for developing and testing complex interventions [4]. An intervention was co-created, developed, and tested. It is based on a theory of change: “Providing employees with access to Pain-at-Work Toolkit will increase knowledge about employee rights, how to access support for managing a painful chronic condition in the workplace, and lifestyle behaviours that facilitate the management of chronic or persistent pain. This in turn will lead to improved self-management of pain at work”. The ultimate outcome is to improve outcomes for individuals (work ability, job satisfaction, job stress, quality of life), and organisations (presenteeism, sickness absence, staff turnover)”. The toolkit draws on the principles of persuasive systems design [3]. Evaluation of Pain-at-Work draws on the Technology Acceptance Model [5] and behaviour change theory (COM-B:[6]).

Intervention fidelity and engagement have been established [2, 7]. To maximise engagement, text message reminders will be sent (1 message per week throughout the intervention period). Our text messages are designed using behaviour change theory (BCW: Behaviour Change Wheel; COM-B: capability, opportunity, motivation [8]. In our feasibility study, 97% of trial participants opted in to receive the messages, indicating the acceptability of this approach [8].

As suggested by PPI representatives, we will offer a 'frequently asked questions' section on the definitive trial website to address (https://xerte.nottingham.ac.uk/play_48279) any queries raised by the participants, allowing us to respond quickly to any issues that may arise. Further strategies to enhance engagement may be included if required, determined through input from people with lived experience of pain. Emerging findings from the feasibility trial suggest that employees with access to the Pain-at-Work Toolkit would like aligned resources to share with their managers. The Pain-at-Work Manager Toolkit has been developed to align directly with Pain-at-Work Toolkit content and will be provided to intervention organisations in the definitive trial. The organisations can make this available to all line managers within their organisation.

7. TRIAL / STUDY DESIGN

7.1. TRIAL / STUDY CONFIGURATION

Design: This study is an open-label, two-arm cluster-randomised controlled trial (cRCT) comparing the Pain-at-Work Toolkit with a Support-as-usual (SAU, i.e., standard support from their employer) control group in working adults with chronic pain. The analysis will be performed on an intention-to-treat basis.

Setting: The study setting is UK employment settings (referred to as 'organisations') in different sectors (public, private, third), varying in size (small:10-49 workers; medium: 50-249 workers; large: >250 workers). At least 30 organisations will be recruited as the unit of randomisation.
Worksites that are incorporated within larger organisations may be included as independent sites if they are separated by ≥1 km (criteria used in prior workplace cRCT, e.g., [9].

The study consists of 3 work packages:

- Effectiveness trial (WP1),
- Health economic evaluation (WP2),
- Process and implementation evaluation (WP3).

Clusters are randomised to either i) a control group (SAU: support as usual), or ii) SAU plus Pain-at-Work Toolkit plus Pain-at-Work Manager Toolkit after the completion of the baseline survey. At the recruitment of employees, both participants and the organisation are blind to the allocation.

***Control - SAU**:* Depending on the employing organisation, SAU may include (but is not limited to) any combination of the following: occupational health, counselling, line manager support, and signposting to education on factors that may have positive or negative effects on chronic pain. Our feasibility trial demonstrates that we can successfully collect this information from employers.

Intervention Pain-at-Work Toolkit – described above in Section 6.

The design draws on the Medical Research Council (MRC) guidelines for evaluating complex interventions. These guidelines highlight the importance of detailed groundwork on the

implementation of experimental design and methods before a definitive evaluation of effectiveness is undertaken. Study reporting will be in accordance with the CONSORT Extension for Cluster Randomised Trials and the Template for Intervention Description and Replication (TIDieR) checklist.

7.1.1. Primary endpoint

The analysis will be a between-group comparison of the Work Ability Index (WAI) score at 3 and 6 months, adjusted for baseline and accounting for clustering. This will be accomplished using a multi-level model to adjust for clustering. A further exploratory secondary analysis will be undertaken on the data at both 3 and 6 months. However, given the exploratory nature of this analysis, no adjustment will be made for multiple testing.

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(a) Work-related PROMS. (WP1, WP2)

Primary outcome:
Work Ability Index (WAI) three item {Ilmarinen, 2007 #1638;Ebener, 2019 #6550}: measures work ability and significantly improved T0-T2 in the feasibility study.

Other outcomes:
Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI: GH) [11]: measures sickness absenteeism, presenteeism, work productivity loss, and activity impairment.
Work Self-Efficacy Scale (WSE-S) and the Occupational Self-efficacy scale and OSS-SF {Hammond, 2022 #1598;Rigotti, 2008 #6551}: measures an individual's confidence in their ability to handle various aspects of their work.
Demand Control Support Questionnaire (DCSQ) sub-scale: measures work demands, autonomy and social support at work [13].
Single-item measures: Job satisfaction [14], job stressfulness [15], turnover intentions [16].

7.1.2. Secondary endpoint

Employer-reported data: At the time of organisation engagement , details about the employment setting will be collected from the organisation representative (“gatekeeper”). This will document the sector, organisation type, and size; number of staff; job role of the “gatekeeper”; and description of SAU in terms of existing provisions to support staff with long-term health conditions. Sickness absence data will be requested from the organisation’s records, with consent from the participants at T0 (baseline), T1 (3 months), and T2 (6 months) to be collected at T2. Sickness absence data will not be collected from NHS Trusts.
Participant-reported outcome measures (PROMS): Participants provide sociodemographic and health data, employment characteristics, and the SAU support available from their employer. PROMs are collected via a web-based survey at T0, T1, and T2 to measure changes over time.

Outcomes include:

(a) Psychological and Health-Related Quality of Life (HRQoL) PROMS. (WP1, WP2)

Measures of anxiety and depression are included to capture work-related psychological impact rather than for diagnostic purposes.
Generalised Anxiety Disorder (GAD-7) [17]: measures symptoms of anxiety.
Patient Health Questionnaire (PHQ-2) [18]: measures symptoms of depression.
EQ-5D-5L [19]: measures HRQoL.

(b) Healthcare resource use for health economics data capture (adapted from [20, 21]). The economic evaluation (WP2) will comprise a cost-utility analysis conducted from a societal perspective. Costs will comprise resource use associated with the delivery and receipt of the intervention and potential cost offsets. The intervention costs relate to activities undertaken to enhance uptake, access, and implementation of the intervention amongst employees within organisations (i.e., staff time and any associated administrative tasks). These will be collected from records kept by trial staff. Costs to participants (e.g., loss of earnings) and potential cost offsets (e.g., fewer visits to workplace occupational health services, occupational therapy, fewer nurse or general practitioners in primary care, fewer follow-up hospital appointments) will be recorded by participants using structured questionnaires. Resource use quantities will be multiplied by unit costs from standard NHS sources (NHS reference costs, PSSRU Unit Costs of Health and Social Care) using a common price year. Health outcomes will be measured using the EQ-5D-5L, and QALYs will be calculated from these responses using existing published value sets. Generalised linear modelling will be used to estimate the difference in costs and difference in QALYs attributable to the intervention, adjusting for baseline covariates. Data will be summarised by construction of Cost-Effectiveness Acceptability Curves, generated from bootstrapped confidence intervals, showing probabilities that the intervention is cost-effective at conventional Willingness to Pay (WTP) thresholds. Where appropriate, the analysis will be extended by a decision analysis model of costs and QALYs, where existing data from previously published studies and the trial estimates will be integrated to estimate cost-effectiveness over a longer time horizon (e.g. 5-10 years, depending on data availability). We will adhere to the updated 2022 Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement [22].

(c) Technology adoption and intervention engagement questions (WP3)(mapped to the Technology Acceptance Model:[5] to measure perceived knowledge, perceived ease of use, perceived understandability, attitudes, and behaviour related to the Pain-at-Work Toolkit**.**

Process and implementation evaluation (WP3) We will conduct a mixed-methods process and implementation evaluation of the cRCT to understand how the PAW Toolkit was delivered, received, and used, and how contextual factors influenced its uptake and impact in UK workplaces. This work package is guided by two complementary implementation science frameworks. Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) [64] will help assess how widely and effectively the Toolkit was used and its potential for long-term adoption. Consolidated Framework for Implementation Research (CFIR) [65] will provide deeper insights into organisational and contextual factors influencing implementation, such as leadership, culture, and resources. Using both frameworks allows us to capture not only what happened, but also why and how implementation varied across settings.

At T2, we will conduct up to 60 semi-structured interviews with employees, and organisational stakeholders from at least six participating intervention organisations.

Stakeholders are approached via the organisational 'gatekeepers' and include those in roles which support employees e.g., welfare officers, Human Resources and line managers. They are reached via email and snowball sampling. All interviews are optional. Sampling and sample size will be guided by analytic sufficiency rather than a priori numerical targets, with recruitment continuing until sufficient depth and diversity of perspectives have been achieved across key stakeholder groups.
Sampling will ensure diversity in organisation type, size, sector, and location (with coverage from each of the four UK nations), as well as employee characteristics such as age, gender, and job role. Qualitative interview questions will be informed by a framework for qualitative research in trials [23] and reviewed by people with lived experience of chronic pain. Questions will explore participants' views about the trial processes and outcome measures, and any perceived changes in individual or organisational outcomes. Participants will be purposively selected to reflect diverse views from across self-identified employee groups (age, gender, job type), sectors, organisation size and type. Employee questions are mapped to the COM-B model [6] to explore influencers of Capability (C), Opportunity (O) and Motivation (M) to self-manage their condition at work (including knowledge, attitudes, and confidence).

7.1.3. Safety endpoints

The methods used in trial are completion of online surveys and interviews. We will capture any exacerbation of pain symptoms and monitor any adverse events spontaneously reported during the trial.

7.1.4. Stopping rules and discontinuation

Employees will be made aware that they can withdraw their consent at any time during the trial, without it affecting their employment. If a participant chooses to leave the study prematurely, the primary reason for discontinuation will be determined and recorded, if possible. Withdrawn participants will not be replaced. Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

In the unlikely event that an organisation withdraws after randomisation, it will not be replaced. The organisation will be made aware that data collected on the organisation AND its employees to date cannot be erased and may still be used in the final analysis. Participants will be advised that their organisation has withdrawn.

The Trial Management Group (TMG) and the Trial Steering Committee (TSC) will review recruitment targets, data collection, and delivery of the Pain-at-Work Toolkit intervention. Strategies to increase recruitment and adherence will be implemented if required.

Following six months of recruitment, the TSC will formally review recruitment and provide recommendations. The funder reserves the right to discontinue this study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The Funder

shall take advice from the TSC as appropriate in making this decision. Should the trial be terminated, the research data will not be destroyed.

7.2. RANDOMIZATION AND BLINDING

Organisations will be randomised by the study statistician to either (1) the control group or (2) the intervention. Cluster-randomisation (rather than individual randomisation) is required due to the nature of the intervention and risk of contamination between intervention and control participants working at the same organisation. Organisations are randomised into intervention or control groups after baseline measures are collected using an allocation ratio of 1:1.

The Trial Statistician will generate the randomisation sequence, and write the code, also send to study team. Participating organisations will be randomised (in size-matched pairs) to intervention or control groups.

7.2.1. Maintenance of randomisation codes and procedures for breaking code

Due to the nature of the intervention, the researchers and participants are not blind to cluster allocation.

7.3. TRIAL/STUDY MANAGEMENT

The Trial will be managed by the University of Nottingham (UoN), supported by the Trial Management Group.

A Trial Management Group composed of all co-applicants (including consultants, statistical and health economic representatives) will meet monthly to oversee day-to-day management of the study and to address any emergent issues.

The appointed trial researcher will contact the Chief Investigator weekly to discuss project oversight and operational matters.

A Trial Steering Group, including 3 independent members, will meet every 6-months to review recruitment, data collection, and safety data. The Trial Management Group will submit updates on recruitment, data collection, and safety to the Study Steering Group every 6 months. The first meeting of the Trial Steering Group will be prior to starting employment setting recruitment.

A Trial Advisory Group will provide recommendations, and will respond to situations as they arise (e.g., in the instance of low recruitment) and provide guidance on alignment with the broader context in work and health that may influence the interpretation of the study findings (e.g., policy or practice advances).

University of Nottingham template terms of reference will be used for the Trial Management Group and Trial Steering Group, which will be agreed by the University of Nottingham.

The Chief Investigator has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator.

7.4. DURATION OF THE TRIAL / STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: 36 months commencing 17th March 2026 or from when all necessary approvals have been received.
Ethical approval will be sought prior to the start of the study.
Enrolment of organisations will commence in March 2026 and continue until August 2027 (18 months) on a rolling recruitment basis.

Organisation Duration: up to 12 months
Participant Duration: up to 8 months
Stakeholders Duration: is one single interview, approximately 1 hour (this may be split into 2 sessions - if required due to technical failure or stakeholder request).
Data collection will be completed within 24 months.

7.4.1. End of the Trial

The end of the study will be the last interview of the last participant.

7.5. SELECTION AND WITHDRAWAL OF PARTICIPANTS

7.5.1. Recruitment

Employee recruitment to trial

Organisations will be identified via employer professional networks and professional bodies, and our Trial Advisory Group will be consulted to ensure social inclusion and underserved populations are considered during recruitment. The engagement of organisations (cluster sites) and recruitment of employees (participants) will be undertaken by the research team on a rolling basis. We will engage at least 30 organisations (at a rate of 2-3 per month) and 685 employees from the United Kingdom over 18 months. Given the variability in organisation size and the number of employees with chronic pain within each organisation, we may engage additional organisations to reach our target of 685 employees. We are confident this is achievable as our feasibility trial [3, 7] exceeded recruitment targets (18/12 organisations - over by 50%, 380/120 employees - over by 217%).

Eligible organisations will be contacted by email/video call to introduce the study, and a formal invitation to participate will be sent to a relevant employer representative by email and letter. Due to variations in organisation type and size, the employer representative providing organisation-level consent may be the CEO, Human Resources Manager, Line Manager, Occupational Health lead, or another role. Roles of employer representatives will be recorded. For organisations that volunteer to participate, a review of each organisation against the eligibility criteria will be conducted to confirm that they meet the entry criteria. NHS organisations will complete the mNC_PIC_Agreement.

Participating organisations will be randomised (in size-matched pairs) to intervention or control groups.

Employee (participant) recruitment to trial

.The employer will provide information about the study to all employees using the schedule of Communication Routes v1.0 17.04.2026 document, to record the method. Small- and medium-sized organisations will select at least one method of communication from section A, and larger organisations with ≥250 employees, including NHS Trusts, will additionally select at least one method from section B. Section B requires processing of staff data to screen and match eligibility criteria and send targeted emails to groups of employees. Employees will determine for themselves whether they meet the eligibility criteria (since the presence of a chronic pain condition may only be known to individuals). Interested employees will be asked to read the participant information sheet (PIS) and provide individual-level informed consent online, and complete online baseline measures. Employees who wish to take part but do not routinely use email or are less comfortable completing online surveys will be able to contact the study team directly, and an appointment will be made to complete these processes remotely (e.g., by telephone).

It will be explained to the potential participant that entry into the trial is entirely voluntary and that their legal rights will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased, and we will seek consent to use the data in the final analyses where appropriate.

Selection of participants for interview study (WP3)

Employees in organisations participating in the study will be asked to consent to being contacted and invited to take part in an interview, as part of their consent to participate in the trial. From the organisations taking part in the study, up to 60 stakeholders will be identified using purposive selection criteria and invited to participate in an interview. All interviews are optional. Additional verbal consent will be obtained and audio-recorded before the interview begins. The qualitative researcher(s) conducting the interviews will provide information to participants, explain the study, and obtain consent. It will be explained to the potential participant that entry into the study is entirely voluntary and that their employment will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

7.5.2. Eligibility criteria

Organisation eligibility criteria: Employment settings in the United Kingdom, with more than 10 employees.

Organisation exclusion criteria:

- Organisations outside of the United Kingdom.
- Organisations with less than 10 employees.

Employee inclusion criteria:

- Working-age adults (employees), aged 18 and over,
- Working in a participating organisation in the UK.
- With chronic pain interfering with their ability to undertake or enjoy productive work,
- Able to comprehend the English language and provide informed consent.

We will include employees of any age, sex, gender, nationality, ethnicity, income level, occupation (e.g., manual/office-based, low/high skilled, low/high income), or employment status (full or part-time, permanent, contracted or subcontracted, gig workers). We use the term 'employee' in this protocol to cover any type of paid worker.

Employee exclusion criteria

- Under 18 years of age,
- No chronic or persistent pain,
- Working in an employment setting outside of the UK
- Inability to comprehend written English (which is required to provide informed consent and understand the Pain-at-Work Toolkit materials).
- Volunteers

Employees with an inability to comprehend written English are excluded because they require this both to provide informed consent and understand the current toolkit materials. ONS data shows 98% of UK workers speak English (91.1% as first language, 7.1% proficient). We received no requests for translation in the feasibility study, but we will record any requests for other languages and incorporate translation into plans for future rollout. We will exclude volunteers as they operate under different terms, expectations, and legal rights, which could introduce sample bias. We also have an interest in exploring the dynamics of employee/employer relationships and organisational culture, which may be different for volunteers than paid workers.

Eligibility criteria for interview study (WP3)

- Be aged 18 years or older (no maximum age).
- Be able to provide informed consent.
- Working for, or sub-contracted to, an intervention organisation participating in the trial and selected for participation in the interview study (Employees).
- Employed in a role providing management or support for employee(s) in a participating organisation (Stakeholders)
- Individuals and groups of working-age adults who experience chronic pain or stakeholders involved in employment of, support for, or policy-development for adults with chronic pain (Stakeholders).

7.5.3. Expected duration of participant participation

Organisations will participate for up to 12 months. Study participants will participate for up to 8 months. Interview participants will participate in a single interview.

7.5.4. Removal of participants from assessments/Participant Withdrawal

Organisations may withdraw from the trial at their own request or at the discretion of the investigator.

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator(s). Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

Participants should not be accepted as lost to follow-up unless phone calls (2 maximum per survey) and emails (3 maximum per survey) to the participant have been fruitless. All attempts to contact the participant will be logged to allow time for a response and to avoid bombardment.

Where possible, the reason for discontinuation/withdrawal will be sought and noted. Enrolled participants who are not yet randomised can be replaced (though keeping their trial ID), but participants who withdraw after randomisation will not be replaced.

7.5.5. Informed consent

Two levels of consent are required: organisation consent and individual employee consent.

Organisation consent
Consent of an employer representative is required to ensure compliance with the trial process. Due to variations in organisational type and size, the employer representative may be the CEO, Human Resources Manager, Line Manager, Occupational Health, or another role. The roles of employer representatives will be recorded as part of the feasibility trial, along with their views on the organisation's culture.

Individual employee consent
All participants will provide online informed consent. The Informed Consent Form is completed before the participant before they enter the trial. The Investigator will explain the details of the trial and provide an online Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation. Informed consent will be collected from each participant before they undergo any interventions (including physical examination and history taking) related to the study.
Online consent will be obtained using the SmartSurvey platform. Participants read a series of statements and confirm they understand the trial procedures, have read the PIS, and are willing to participate. They then provide their full name, year of birth, organisation, email address, and mobile number (optional). The participant is then sent a Participation Identification Number to permit the participant to complete questionnaire. This will act as a verification of the participant, and that they are eligible for the study. If any details are unclear, direct contact will be made to ascertain the participant's eligibility. An online pdf of the consent form will be retained by the UoN at this time and date-stamped.

The study researcher(s) will obtain informed consent online. A copy of the pdf will be sent with the Participant Identification Number to the participant via email. The Chief Investigator retains overall responsibility for the informed consent of participants in the study overall and will ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained, and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

The right of a participant to refuse participation without giving reasons will be respected. The participant will remain free to withdraw from the trial at any time without giving reasons and without prejudicing his/her employment, and will be provided with a contact point for further information or questions about the trial.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended consent form, which will be signed by the participant.

Consent for interview study

Employees and stakeholders will provide informed consent online before entering the trial. Verbal consent will be audio-recorded prior to the interview. The Investigator will explain the details of the trial and provide a Participant Information Sheet, ensuring the participant has sufficient time to consider participating. The Investigator will answer any questions that the participant has concerning study participation.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended consent form, which will be signed by the participant.

An online pdf of the consent form will be retained by the UoN, this time and date stamped.

8. TRIAL / STUDY TREATMENT AND REGIMEN

A schematic diagram of the trial design and an assessment timeline is provided.

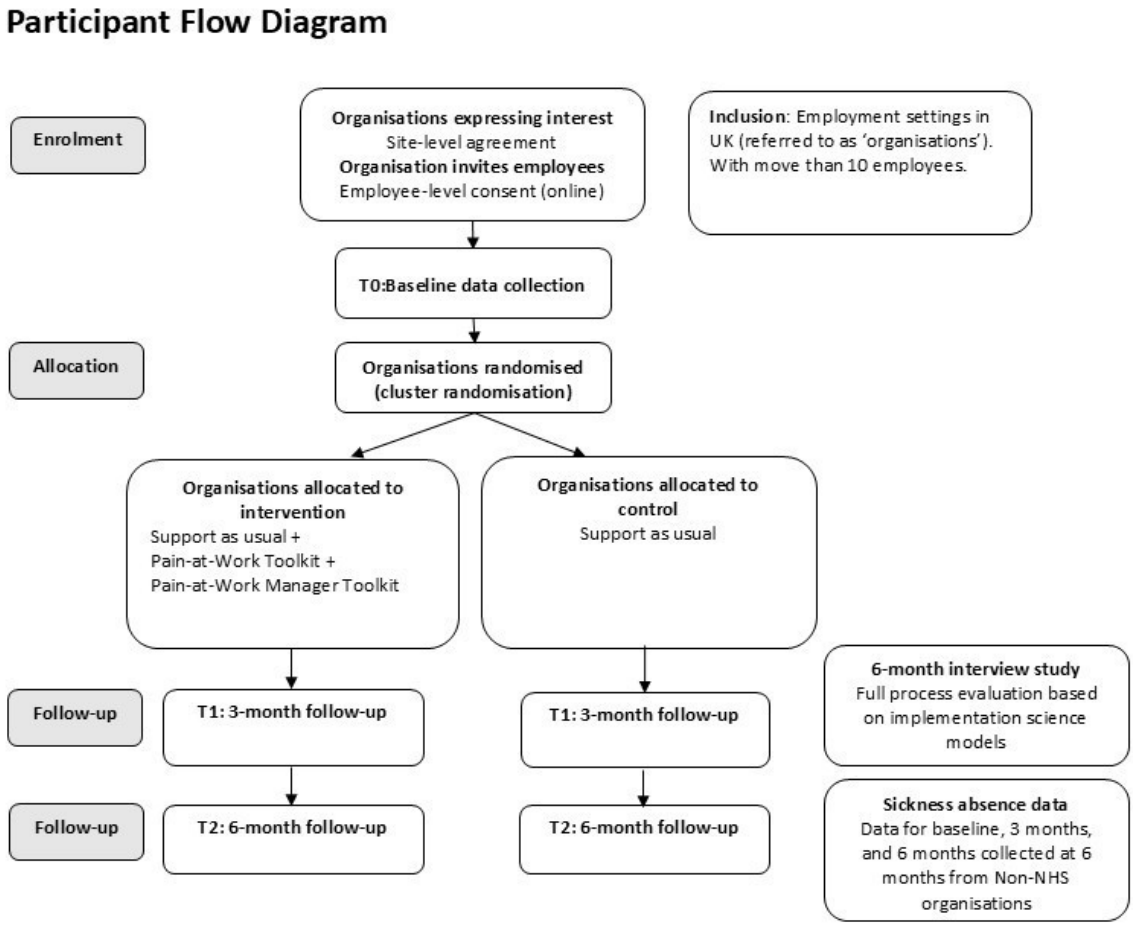

Figure 1 Pain-at-Work Participant Flow

Regimen for organisations and stakeholders

Organisation eligibility criteria will be requested when organisations express an interest to participate in the study. Once organisation eligibility is confirmed, organisation representatives will provide site-level agreement to participate.

Characteristics of organisations will be collected on:

- Sector, type, and size
- Number of staff, number of sites
- Support as Usual (SAU) – existing provisions to support staff with long-term health conditions (e.g., policies, services, facilities, education, wellbeing initiatives).
- Name and contact details of organisation representative.

Organisations randomised to the intervention or SAU may receive study information about the number of employees recruited. During the intervention period, organisations will be sent a newsletter in either paper or digital format to provide an update on study progress These can be shared within organisations using the channels used to recruit participants e.g., newsletters or staff intranet.

After the final 6 months follow-up, participants in the control group will be sent the Pain-at-Work Toolkit directly.
A sub-sample of stakeholders (employers: e.g., CEOs, human resources, trade union, occupational health, line managers) will be purposively selected to take part in an individual interview to explore their views towards the study processes, and the Pain-at-Work Toolkit.

At 6 months, with participant permission, their sickness absence data for the trial period will be collected from their employer (if they are non-NHS employees). The employer will be asked to identify a named contact for providing this information, e.g., a member of the Human Resources department. The research team will liaise with this member of staff. The data is treated as highly confidential; the organisation requires sight of the consent document confirming that the participant has agreed to the release of this information. All data transfer is by secure means, and where possible, the organisation will use the Participant Identification Number. Some organisations have previously conducted their own checks with employees who have consented to the release of this information.

Employees and other stakeholders will provide informed consent online for interviews. Verbal consent will be audio-recorded prior to the interview. The qualitative researcher(s) conducting the interviews will provide participants with information about the study, explain the study, and obtain consent. It will be explained to the potential participant that entry into the study is entirely voluntary and that their employment will not be affected by their decision. Details of the qualitative analysis and framework mapping approach are described in the Qualitative Data section (page 29).

Regimen for employee participants
Consenting employees will register online for the trial and provide their contact details (email address - required, telephone number - optional). They will be issued with a Participation Identification Number and invited to the baseline online survey (WP1, WP2). All surveys are conducted using the Smartsurvey platform. Surveys take between 15 and 45 minutes, progress can be saved and the survey is divided into sections to encourage participants to take break. Employees may contact the study researcher for support in completing the online surveys.
The baseline data collected includes work-related measures, employees provide socio-demographic, health, psychological and health-related quality of life, and health resource use. Subsequent surveys will include only items that may change. For example, ethnicity will only be asked at baseline. At 3 months, intervention participants will also be asked to complete the technology acceptance questionnaire this is attached to the 3-month questionnaire, the questions relate directly to use of the Pain-at-Work Toolkit.

The organisations will then be randomised. Participants working at the intervention organisations will then be emailed a web link to the Pain-at-Work Toolkit. Control group participants will be emailed to inform them they are in the control group, and remind them they will receive the Toolkit at the end of the study.

During the intervention period, all employees will receive a quarterly digital newsletter providing an update on study progress, which will also be available on the study website. The researcher will send a weekly reminder to all participants about their participation in the study (surveys and support contact details), and, for intervention participants, also include reminders about the toolkit. Reminders will be sent by text message. Text messages are sent from the SmartSurvey platform, the only data stored is the first name and the mobile number. Texts will be in the following format:
Hi #FirstName#, the Pain-at-Work survey is now open. Your responses are important to us. Option to enter prize draw. Need help? HS-PAW-Trial@nottingham.ac.uk

All employees recruited into the study will be contacted at 3 and 6 months and invited to complete the follow-up surveys (WP1, WP2). A sub-sample will be purposively selected to be invited to take part in a follow-up interview. Those participants who have not completed the follow-up surveys may be texted or called (twice) to increase the response rate. This is a digital remote trial, and sometimes emails may not be received or disappear; previously a text reminder was sufficient to prompt a response. If the online follow-up survey has not been completed, text messages requesting primary PROMs (e.g., pain level and WAI up to a maximum of 6 responses) may be sent; the participant can opt out at any time. These measures will avoid loss to follow-up where possible.

It will be explained to employees that entry into the study is entirely voluntary, comments they make will not be individually attributed in any written report, and no aspect of their work will be affected by their decision. It will also be explained that they can withdraw from the study at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Regimen for interview study (WP3)
Up to 60 participants (employees and stakeholders) will be invited to take part in the interview study. In the case of intervention employees, this will be after the 6-month survey has been completed. Stakeholders may be interviewed at any time during the study duration, but if they are from the intervention organisation, it is likely this will be after the employees have completed their 6-month survey. Selection will be purposive to include:

1. Younger/older workers; diversity in gender/ethnic group identification; employed/contracted.
2. Small-to-medium sized organisations; large organisations.
3. Public sector; private sector; third sector.
4. Different geographical locations.

It is anticipated that there will be an even distribution in each category, but this may change if study data indicates interest/value in focusing upon a particular characteristic(s). We will invite participants from both the intervention and control groups to participate, alongside stakeholders involved in policy implementation.

We will conduct semi-structured interviews at 6-months post-randomisation (within 2 months of study end) to explore the views of employees and key stakeholders that employees identify as being involved in their support (e.g., line managers, company owners, HR / occupational health, trade union).

Interviews will ascertain participants' views about the Pain-at-Work Toolkit, trial processes and outcome measures, and any perceived changes in individual or organisational outcomes.

Employee questions were developed with PPI input and mapped to the COM-B model to explore influences of Capability (C), Opportunity (O) and Motivation (M) to self-manage pain at work (including knowledge, attitudes, and confidence). We will explore any barriers or facilitators of engagement with or use of the intervention and recommendations for future implementation.

We expect the interviews to last approximately 45-60 minutes, though they may be shorter or longer depending on the discussion generated. Interviews may be split into two sessions at the participant's request to accommodate their health condition or work requirements. Discussion will be informed by a semi-structured topic guide - questions were developed using a framework for qualitative research in feasibility RCTs [23, 24] and reviewed by PPIE partner / contributors.

Interviews will be facilitated by a member of the project team. The interviews will be held by telephone or videoconferencing (e.g., Microsoft Teams) at a mutually convenient time, and will be audio-recorded with consent. Recordings will be transcribed in full and anonymised. Transcription will either be using the automated Teams transcription process and immediately checked by the researcher for accuracy and anonymised; or interviews may be transcribed by a University of Nottingham approved transcription service. Audio files will be securely transferred to this service via the University of Nottingham approved method, which uses encryption and security measures, including a secure 128-bit SSL connection, and passwords. All transcripts will be anonymised with identifiable information extracted. Once the transcribed the audio or video files will be destroyed.
Due to the nature of the package content (chronic or persistent pain) there is some potential that there will be some emotionally challenging issues raised. The interviewers will be trained in good clinical practice (GCP) and will be sensitive to the types of issues that may be raised during interviews and the signposting required. Facilitators will manage the discussion accordingly and will raise any concerns with the chief investigator in the first instance (who is a chartered psychologist), who can discuss with the study management team where appropriate (which includes medical and psychosocial expertise). If there are issues which cannot be resolved within the study team, the individual will be signposted to appropriate services (such as their general practitioner), and publicly available sources of information.

We will ensure that participants are aware that they may take a break from the interview should they wish. We will support participants in terminating the interview should they feel unable to continue.

Data stored on SmartSurvey is pseudonymised it will contain the Participation Identification Number (PIN), organisation, age, and initials once the data is downloaded as a .csv file and verified that the PIN is correct (not transposed), then the initials field is removed. The PIN is kept in a separate file with participant contact details. This is registered on the SoHS asset register and stored securely. At the end of the trial, when contact is no longer required with participants, this will be destroyed, and the data will be fully anonymised.

8.1.1. Compliance

For WP1/2 – participants will be considered to have complied with the research protocol if they complete the baseline measures.
For WP3 - participants will be considered to have complied with the research protocol should they attend the interview which they have agreed to attend.
Compliance with the intervention will be evaluated as part of the process evaluation.

8.1.2. Criteria for terminating trial

Recruitment will be conducted over an 18-month period, and progress will be reviewed at 6 months. The Trial Management Group (TMG) and the Trial Steering Group (TSG) will review recruitment targets, and delivery of the Pain-at-Work Toolkit intervention. Strategies to increase recruitment and adherence will be implemented if required. After 6 months, the TSG will formally review recruitment and provide recommendations. The funder reserves the right to discontinue this study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The Funder can take advice from the TSG as appropriate in making this decision. Should the trial be terminated, the research data will not be destroyed.

In the unlikely event an organisation withdraws participation after randomisation, the organisation will not be replaced. The organisation will be made aware that data collected on the organisation AND employees at that organisation to date cannot be erased and may still be used in the final analysis. Participants will be advised that their organisation has withdrawn participation.

9. ANALYSIS

9.1.1. Methods

Quantitative data will be analysed descriptively to examine patterns of engagement, intervention fidelity, and satisfaction, and to explore variation across sites and participant groups. Data will be analysed by research staff under the guidance of the trial statistician. Analysis will be conducted using Stata [25] or similar software on UoN computers and backed up to the UoN servers, in accordance with the Statistical Analysis Plan.

The primary analysis will be a between group comparison of the WAI score at 3 and 6 months, adjusted for the baseline and taking into account any clustering effect. This will be accomplished using a multi-level model to adjust for clustering. A further exploratory

secondary analysis will be undertaken on the data at both 3 and 6 months. However, give the exploratory nature of this analysis no adjustment will be made to multiple testing.

PROMS: we will present total scores (baseline, 3 months, 6 months) and change from baseline to 3 months and 6 months. Differences between arms may be presented with 95% confidence intervals where appropriate. We will calculate two anchor-based responsiveness statistics for each PROM: (i) standardised response mean (SRM), and (ii) effect size (ES).

Health economic measures: The economic evaluation will comprise a cost-utility analysis conducted from a societal perspective. Differences in total costs and Quality-Adjusted Life Years (QALYs) between the intervention and comparator groups will be estimated using generalised linear models, adjusting for relevant baseline covariates. Uncertainty will be assessed using non-parametric bootstrapping, and results will be presented using Cost-Effectiveness Acceptability Curves showing the probability that the intervention is cost-effective across a range of conventional willingness-to-pay thresholds.
Where appropriate, and depending on data availability, to assess longer-term value for money, a decision-analytic model will be developed to extrapolate costs and QALYs beyond the trial follow-up period (e.g. 5–10 years), integrating trial data with evidence from published literature. The analysis and reporting will adhere to the CHEERS guidelines.

Process and Implementation Evaluation: process evaluation will include fidelity, engagement and satisfaction measure and will be analysed descriptively. Intervention fidelity will be examined in relation to reach, exposure, and engagement with core Toolkit components, rather than adherence to a prescribed 'dose', reflecting the flexible, self-directed nature of the intervention. Process data will be triangulated with quantitative outcomes to explore whether differences in engagement and fidelity are associated with variation in work ability and other work-related outcomes.

The health economic evaluation (WP2) will be at the University of Aberdeen using anonymised data, overseen by Professor P McNamee. Standard statistical software (STATA) will be used to perform the cost-utility analysis. All data sharing agreements will be in place before any data is shared.
Evaluation and Implementation Processes (WP3) data be collected by the University of Nottingham and overseen by Professor Yeliz Prior. Descriptive quantitative process data (including fidelity, engagement, and satisfaction measures) will be analysed using standard statistical software (e.g. STATA). Qualitative interview data will be managed and analysed using qualitative data analysis software (e.g. NVivo), to support systematic coding, data management, and framework mapping.

Qualitative data
We will use a two-stage qualitative analysis approach. First, we will conduct inductive reflexive thematic analysis (RTA) to identify patterns of meaning in participants' accounts, allowing themes to be identified directly from the data without being constrained by predefined categories. This approach supports a rich understanding of how individuals and organisations experienced the Pain-at-Work Toolkit and trial processes. Reflexive thematic analysis will be conducted iteratively, with reflexive discussion within the research team to consider how

researcher perspectives may shape interpretation. In the second stage, we will map the themes onto relevant constructs from CFIR (e.g., inner setting, leadership, individual characteristics) and RE-AIM (e.g., reach, adoption, fidelity, maintenance) to interpret findings through an implementation science lens. This will enable us to identify barriers and facilitators to implementation, explore how fidelity relates to outcomes, and inform future scale-up and sustainability. We have used both RE-AIM and CFIR previously for workplace-delivered interventions [26-28].

9.1.2. Sample size and justification

We aim to recruit a minimum of 30 clusters from across the UK (15 per arm), allowing for 40% attrition and with an expected cluster size of 20 per cluster) a 2-tailed 0.05 significance and 80% power.
A total sample size of 685 will be sufficient to identify a 0.6 difference in WAI with an SD of the change in WAI of 2.0 (based on our feasibility trial) and an intra-cluster correlation of 0.02.
Data will be analysed using STATA (v18.5) [25]

9.1.3. Assessment of efficacy

The analysis will be a between-group comparison of the Work Ability Index (WAI) score at 3 and 6 months, adjusted for baseline and accounting for clustering. This will be accomplished using a multi-level model to adjust for clustering. A further exploratory secondary analysis will be undertaken on the data at both 3 and 6 months. However, given the exploratory nature of this analysis, no adjustment will be made for multiple testing.

9.1.4. Assessment of safety

The methods used in trial are completion of online surveys and interviews. We will capture any exacerbation of pain symptoms and monitor any spontaneously reported adverse events during the trial.

9.1.5. Procedures for missing, unused and spurious data

The amount and distribution of missing data will be examined to determine the type of missing data and appropriate methods to impute will be assessed according to the Statistical Analysis Plan that will be agreed with the Trial Steering Group and Trial Management Group.

9.1.6. Definition of populations analysed

Populations to be analysed will be the organisations (and corresponding employees) in the group to which they were allocated regardless of their compliance with the intervention.

10. ADVERSE EVENTS

Adverse events are not expected from this trial and will not be collected.

10.1.1. Reporting of adverse events

Participants will be asked to contact the study site immediately in the event of any serious adverse event. All adverse events will be recorded and closely monitored until resolution, stabilisation, or until it has been shown that the study treatment / intervention is not the cause. The Chief Investigator shall be informed immediately of any serious adverse events and shall determine seriousness and causality in conjunction with any treating medical practitioners.

10.1.2. Participant removal from the study due to adverse events

In the unlikely event that a participant shows evidence of distress, this will be documented, and the participants will be appropriately signposted to relevant services within (e.g., employer services) or outside of their organisation (e.g., general practitioner). Any participant who experiences an adverse event may be withdrawn from the study at the discretion of the Chief Investigator.

11. ETHICAL AND REGULATORY ASPECTS

11.1. ETHICS COMMITTEE AND REGULATORY APPROVALS

The trial will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

11.2. INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Informed Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Trial Master File. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the trial.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn

at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

11.3. RECORDS

11.3.1. Case Report Forms

Each participant will be assigned a trial identity code number, allocated at randomisation if appropriate, for use on CRFs other trial documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and year of birth (yyyy).

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, year of birth, and Participant Identity Code (the Trial Recruitment Log), to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required
CRFs shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Trial Delegation Log.'

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief or local Principal Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

11.3.2. Participant Identification Number

The electronic database and CRF will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and year of birth (yyyy).
A study recruitment log will be maintained in a separate password-protected file, containing the participant's trial identity and identifiers, along with their name and contact details, and will be accessible by the CI and the Project Researcher.

11.3.3. Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, and records. Online documentation will be stored in a secure password protected format on UON systems. Any paper records will be stored securely. A CRF may also completely serve as its own source data, these are completed online using the SmartSurvey

platform. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below.

11.3.4. Direct access to source data/documents

The CRF and all source documents, including progress notes, are available at all times for review by the Chief Investigator, Sponsor's designee, and inspection by relevant regulatory authorities.

11.4. DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the trial. CRFs will be held securely, on a password-protected computer. Access to the information will be limited to the trial staff, investigators, and relevant regulatory authorities (see above). Computer-held data, including the trial database, will be held securely and password-protected. All data will be stored on a secure, dedicated web server. Access will be restricted by user identifiers and encrypted passwords (using a one-way encryption method). Electronic data will be backed up every 24 hours to both local and remote media in encrypted format. Online survey data collection is ISO 27001- and GDPR-compliant, and data are stored in the UK.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

Each participant will be assigned a trial identity code number, allocated after consent, for use on Case Report Forms (CRFs), questionnaires, and other trial documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and year birth (yyyy). The participant identity code will be a 7- alpha-numeric comprising of their organisation code (3 letters) and participant identification number (4 digits). CRFs will be treated as confidential documents and held securely in accordance with regulations.

The investigator will maintain a separate confidential record of each participant's name, year of birth, contact details, and participant identity code (the Trial Recruitment Log) to permit the identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required. CRFs shall be restricted to those personnel approved by the Chief Investigator and recorded on the 'Trial Delegation Log.' CRFs are used to record consent and clinical trial data and are an integral part of the study and subsequent reports. The CRFs, therefore, must be legible and complete.
The Chief Investigator shall sign a declaration ensuring the accuracy of data recorded in the CRF.

No participant survey or interview data will be provided to employers by the research team, and employees may take part in this trial without disclosing their chronic pain condition (or any other health information) to their employer.

12. QUALITY ASSURANCE & AUDIT

12.1. INSURANCE AND INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in the event of claims made by research subjects.

12.2. TRIAL CONDUCT

Trial conduct may be subject to systems audit of the Trial Master File for inclusion of essential documents; permissions to conduct the trial; Trial Delegation Log; CVs of trial staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); adverse event recording and reporting; accountability of trial materials and equipment calibration logs.

The Trial Coordinator, or where required, a nominated designee of the Sponsor, shall carry out a site file audit at least yearly and an audit report shall be made to the Trial Steering Committee.

12.3. TRIAL DATA

Monitoring of trial data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Trial Coordinator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of trial data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the trial database will be checked. Where corrections are required these will carry a full audit trail and justification.

Trial data and evidence of monitoring and systems audits will be made available for inspection by REC as required.

12.4. RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Trial Master File and trial documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all trial databases and associated meta-data encryption codes.

Costs for preparing data for archiving have been included in the budget (post-award administrative costs).
We plan to share anonymised data via depositing it into the repository at the University of Nottingham https://rdmc.nottingham.ac.uk/, which allows for open access. Data will be fully anonymised at both the individual participant level and the employer level.
Participants will be informed of the plans for data archiving via the Participant Information Sheet (PIS).

12.5. DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Trial Steering Committee and Data Monitoring Committee as appropriate in making this decision.

12.6. STATEMENT OF CONFIDENTIALITY

Individual participant self-reported medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.
Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this trial will be available for inspection on request by University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

13. PUBLICATION AND DISSEMINATION POLICY

Communications plan: A communications plan will be developed in collaboration between the Trial Management Group and Trial Steering Group, drawing on the knowledge, expertise, and professional networks of the project's expert Trial Advisory Group and Patient Public Involvement (PPI) partners.

Our main objective is to enable employees to change their self-management in ways that improve their ability to work and be productive at work. We wish to raise awareness among employees about the prevalence of chronic pain in the workforce, and how employees can manage their condition with support from their employer.

The primary audiences are employees with chronic pain, and employers from any organisation type, size, or sector. Other audiences will be identified as the communications

plan develops, but may include local government, charitable organisations, NGOs, think-tanks, health and social care practitioners, researchers, journalists, and the public.

Key messages will be tailored to each group, to do this we will consult with members of relevant stakeholder groups from our target audiences to help with message framing.

The channels we use to communicate will vary according to the target group. Dissemination of findings will be prioritised to study participants (organisations/employees) who will receive quarterly newsletter updates. At the end of active involvement, participants will receive thank you letters. In month 33 (and beyond), we will communicate findings through meetings, seminars/workshops, conferences, select committee inquiries or government consultations, responses to evidence reviews, articles, email, press release, slide decks, visualisations, blog or vlog, podcasts, or social media (e.g., X, LinkedIn). We will liaise with our University Press Offices to reach business partners (and employees) nationally through media coverage (newspapers, radio). We will write for The Conversation, where the CI has appeared in the Top 3 Most Read Authors and authored in the Top 3 Most Read Articles. Business-facing articles will be written for wide-reaching online magazines. We have previously published on workforce issues for: Employee Benefits, Startups Magazine, Finance Digest, Construction UK, The Construction Index.

Planned outputs include pre-registration of the protocol on clinicaltrials.gov. The Main Public Output (final report) will be produced prior to the project's end and hosted on the University of Nottingham Repository. The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Research findings will be submitted to conferences (e.g., IASP, Arthritis UK Pain Research Conference, UKSBM, SOM) and journals (e.g., BMJ, BMC Musculoskeletal Disorders, Trials, Occupational Medicine) spanning work and health, digital education, pain, rheumatology, rehabilitation, and trial methodology.

Communications Timescale: Final report will be completed by the project end date, journal article(s)/conference(s) within 6 months of project end. Further communications will be undertaken after the project end, on publication of our research findings.

Routes to influencing policy, practice, and social well-being:
To establish routes to implementation and change, we will establish networks with entrepreneurs, SMEs, and local partners via business network events organised by the University of Nottingham Business Engagement and Partnerships team. We will collaborate with academic groups working with industry (e.g., Enterprise Research Centre), charities (e.g., Arthritis UK, NRAS, MIND, Burning Nights), healthcare networks (NIHR Applied Research Collaboration East Midlands), business and employment networks and bodies (Employers, Health and Inclusive Employment (EHIE) at DWP, Chambers of Commerce, Institute for Small Business and Entrepreneurship, Federation of Small Businesses, Midlands Engine), and other professional associations and groups (Healthy Working Lives, Health and Safety Executive, NHS Employers, Career Development Centres, Nottingham Community and Voluntary Services, CEOs: www.ceoemail.com). This will allow us to identify employees with chronic pain, employers and potential business leaders, policy makers, commissioners,

healthcare professionals and researchers. We have prior experience of success here – Blake was recently a keynote speaker at several business-facing events and delivered workforce support sessions to industry partners through the pandemic. Walker-Bone has delivered seminars to EHIE. We have established business partnerships through our involvement in major consortia (e.g., Midlands Engine Mental Health and Productivity Pilot) and our prior 'work and health' studies, as have our Trial Advisory Group members. These networks provide access to organisations of different sizes, types, and sectors, including those with specific types of workers (e.g., gig and migrant workers).

14. USER AND PUBLIC INVOLVEMENT

People with lived experience of chronic or persistent pain are involved at every stage of the research through 'participant and public involvement and engagement' (PPIE). We use a model of co-production in our interactions with PPIE members.

Intervention development:

The idea was conceived by Blake through discussion with members of the University of Nottingham Disability Network (with MSK pain) about workplace support needs for people with chronic conditions. The Pain-at-Work Toolkit was developed alongside people with lived experience of chronic pain and in collaboration with Burning Nights, a UK pain charity [2]. In a collaborative-participatory design, Agile methodology was used to co-create the toolkit in interactions with and between healthcare professionals, employers, and people with chronic pain (N=452). This embedded lived experience into the Pain-at-Work Toolkit from the outset. The process included: (i) a stakeholder consultation event (n = 27) to develop and establish toolkit content and format, and online survey with 274 employees who have chronic pain (from the public, private and third sector), who identified their experiences at work and support needs, (ii) an online survey with 107 employers across sectors and organisation types and sizes, showing that organisations rarely provide workers with self-management materials or education around managing pain at work, and (iii) expert peer review panel (n=40) to finalise the content and technical presentation which included 15 people with lived experience of chronic pain.

People with lived experience of pain changed the Pain-at-Work Toolkit design by highlighting the importance of including materials on mental wellbeing, and healthy lifestyles as a key part of self-management. They also suggested changes to language and terminology and improved content accessibility.

Feasibility Study:

To prepare for the feasibility trial, a group concept mapping study (n=20) was undertaken together with people who have chronic pain to update and refine the Pain-at-Work Toolkit content and presentation ready for feasibility testing [29]. During the feasibility study, we sought guidance from the Aberdeen Epidemiology PPI group, comprising 10 people with MSK conditions. Our Trial Management Group (TMG) included our patient-partner (VAF) who is Chair of the Expert Patient and Carer Committee at the British Pain Society. We sought advice from our Trial Advisory Group (TAG) which included diverse stakeholders including people with chronic pain. Overall, they shared views about the research and advised on the most appropriate and acceptable approaches to recruitment of organisations,

and employees with pain. They suggested strategies for engaging employees with use of the toolkit and retaining people in the study, as well as informing our communications plan.

Definitive Trial:
Our TMG benefits from the continued involvement of our patient-partner (VAF) who will attend study meetings, input across all 3 work-packages and facilitate access to further PPI input through pain charities. We will recruit further lay members from local groups, including the Patient and Public Advisory Group (MSK PPAG) of the Arthritis UK Pain Centre at the University of Nottingham. More than one person will be involved so there will always be lay representation. This will ensure active involvement of lay representatives at all decision-making stages and that their voice is heard in resolving any arising implementation issues. Our Trial Steering Committee (TSG) and TAG includes working people with chronic pain. Our PPIE groups will review our study materials to ensure they are acceptable to members of the public. They will be consulted about how to approach and recruit different types of employers for the definitive trial which has been very successful in our feasibility study [3, 7] and our other studies on work and health (e.g., Test@Work [26, 30]; ManagingMinds [27, 31]; QUICK study [32].

Lay members helped to select and finalise our outcome measures. Further, WP3 is all about exploring the views of people with chronic pain, employers, healthcare professionals, policymakers, charity representatives and other stakeholders.

Communications/dissemination:
Our Pain-at-Work feasibility trial publications to date include our patient-partner as co-author [3, 7, 8, 29, 33]. In the definitive trial, lay members will be given the opportunity (depending upon their individual preferences) to co-author manuscripts, present to PPIE, contribute to writing study materials, and dissemination materials. Training for PPIE is provided by East Midlands Sharebank, and further support can be gained from study team members experienced at working with PPIE members. Reimbursement of expenses will follow INVOLVE guidance.

15. STUDY FINANCES

15.1.1. Funding source

This study is funded by funding from the Nuffield Foundation and Arthritis UK via the Oliver Bird Fund (Ref: OBF 000025871) to support the research costs for the project duration to cover trial set up, trial conduct, analysis, report writing, and data-archiving.

15.1.2. Organisations' stipends and payments

Organisations will not receive any stipend or payment for participating in the trial.

15.1.3. Participant stipends and payments

Participants will not be paid to participate in the study, nor receive reimbursement for their time. Data will be collected remotely, and therefore participants will not incur any costs for

taking part. Since retention can be challenging in remotely delivered workplace studies using digital interventions, to help encourage participation in the study, the study information sheet will inform participants that those who take part in the study and complete all follow-ups (0m, 3m, 6m) will be invited to opt into a prize draw. The winner of the draw will be notified at the end of the trial and will receive a £250 shopping voucher. Interviewees may be invited to opt into a prize draw to receive vouchers.

16. SIGNATURE PAGES

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