RESEARCH PROTOCOL

Sustainable return to work: A pilot cluster randomised controlled trial of a multicomponent workplace 'IGLOO' intervention compared with usual return-to-work support

Short title of study	
IGLOO Trial	
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1. Synopsis of the study

Short study title	IGLOO Trial
ISRCTN registration no.	TBC
Study Design	Pilot cluster randomised controlled trial
Setting	Large organisations (N≥600 employees) in the South Yorkshire and South Humber region.
Study Participants	Employees on long term sick leave, and their line-managers.
Aim	To undertake a two-arm pilot cluster randomised control trial of the IGLOO sustainable return-to-work intervention to inform a future fully-powered definitive trial.
Objectives	▪ To determine willingness of organisations and their workers on long-term sick leave and their line managers to take part in a 30 month study, and retention through follow up (12 months) with intervention uptake and completion as primary endpoints. ▪ To monitor the potential for selection bias in control and intervention organisations as measured using participant characteristics at baseline. ▪ To assess implementation of intervention delivery, dose (i.e. number of steps used in the toolkit, number of coaching sessions attended) and fidelity whilst the worker is on long-term sick leave, and implementation of intervention delivery and adherence after the worker has returned to work. ▪ To assess the likely changes in the primary outcome (number of days until return to work (RTW) either part- or full-time) and main secondary outcome (number of days in work over a 6-month period after returning with no exit or long-term sick leave re-occurrence (SRTW)) to inform the planning of a larger trial and estimate the inter-cluster correlations for these outcomes. ▪ To conduct a pilot process evaluation to monitor how the intervention is perceived by participants from different demographic groups (to understand what works for whom in which circumstances) and test a full process evaluation methodology in advance of a full trial. ▪ To determine the willingness and readiness of employers and their workers to adopt the proposed intervention in a manualised format (written as an instruction manual) that is flexible enough to meet individual and organisational needs in different settings.
Primary outcome	Number of days until return to work either part-time or full-time
Intervention	The IGLOO intervention consisting of a multicomponent toolkit delivered online
Randomization and data collection	Participating organisations will be randomised into intervention or control arms; and where possible will be stratified by area and organisational size. Measurements (online surveys) will be collected at baseline, then at 3, 6, 9 and 12 months.
Planned Sample Size	Minimum sample of 100 participants, recruited from 8 clusters (organisations)
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 return-to-work outcomes will be carried out (i.e., between-group effect sizes and intra-cluster correlation coefficient) to inform the sample size calculation of a future definitive trial.
Study Period	36 months

2. Background and rationale

Sickness absence costs UK businesses approximately £9 billion/year.[1] Most long-term sickness absences are attributed to common mental health conditions (e.g., stress, depression, anxiety)[1], which are also highly prevalent in people with acute (e.g., cardio-respiratory, stroke) or musculoskeletal health conditions. [1,2] Keeping people in work following long-term sick leave is a societal challenge because long-term sick leave is strongly linked to disability pension, unemployment and job termination. [3] With and aging workforce, the risk of ill-health and life-long disability is also rising, [4] bringing further societal challenges. Moreover, the COVID-19 pandemic brings unprecedented difficulties to people's mental health.

The need for practical measures to enable employer-led *sustainable* return to work has received considerable attention over the last decade.[5] In 2019, NICE[1] highlighted a UK research gap on effective and cost-effective interventions to reduce long-term sickness absence (i.e., those occurring for >7 consecutive days) and supportive return to work particularly for common mental health conditions. Long-term sickness absence costs the UK economy more than £7 billion per year,[6] and has a significantly detrimental effect on workers.[7]

Evidence shows that "good work" supports health and wellbeing; this refers to work characterised by fair pay, job satisfaction and support for well-being and career progression.[8] For people returning to work following long-term sick leave, good work can be therapeutic by minimising the harmful effects of long-term sickness absence, loss in work productivity and the risk of long-term incapacity.[9] However, returning people back to work and enabling them to stay at work is challenging, especially where a common mental health condition is the main reason for long-term sick leave or is present for another reason. [10-12]

An interplay of factors beyond the health condition is known to impact both return-to-work (RTW) outcomes (defined as the number of sick leave days until first day of RTW with adjusted working hours or usual working hours)[13] and sustainable return-to-work (SRTW) outcomes (defined as number of days staying on work over a 6-month period after returning with no exit or long term sick leave re-occurrence). [14] Lower education and socio-economic status, older age, lower self-efficacy, poor line manager and/or co-worker support, inadequate work adjustments or flexibility (i.e., job crafting) and inadequate workplace return-to-work policies can all hamper sustainable return to work. [14-17] This has a detrimental impact on workers, leading to early retirement, job termination, unemployment, [3] and reduced quality of life.[5] It also has a negative impact on employers through sick pay, staff turnover and productivity loss, [5] and, more broadly, society through health-related state benefits.

Systematic reviews on mental health and long-term sick leave suggest that multi-component return-to-work interventions targeting the symptoms of poor mental health in the individual worker (e.g. work-focused cognitive behaviour therapy or solution-focused skills training) and elements of their workplace (e.g. regular line manager contact during sick leave) show improvement in RTW outcomes. [13,14,17] Specifically, a Cochrane review, [17] found moderate evidence that a combination of work-directed and clinical interventions (such as psychological treatment), reduce sickness absence days within the first year of follow-up (SMD -0.25, 95% CI -0.38 to -0.12: 9 studies). Whilst this translates "to 0.5 fewer (95% CI -0.7 to -0.2) sick leave days in the past two weeks or 25 fewer days during one year (95% CI -37.5 to 11.8)",[17] the authors of the review propose that integration of clinical and work-directed elements of an intervention is key to improving work outcomes.

In summary, these reviews highlight two important issues: [1] where workers with poor mental health receive a multi-component intervention targeting both work (line manager support) and the self

(cognitive and affective well-being) they are more likely to return quicker than those who do not receive such and intervention, [13,17,18] and [2] The type of intervention received by the worker whilst on sick leave as well as the work-related support received after they return to work impacts how long they stay in work without a relapse or long-term sick leave re-occurrence. [14.15] However, sustainable return-to-work interventions are in their infancy and more workplace return-to-work research is needed on combined multi-component and multi-levelled interventions, their effectiveness, and the mechanism by which the intervention works.[17] A review by Philpot et al. [19] found that multi-level interventions are more effective as they build resources at multiple levels and create a synergistic effect for sustainable return-to-work.

Midlands Engine return-to-work pilot study

Co-investigators Munir and Yarker are currently conducting a return-to-work pilot study in the Midlands region, funded by the Midlands Engine and involving eight organisations randomised into intervention or control groups (ends June 2022). The pilot study delivers an online intervention aimed at workers on long-term sick leave due to a common mental health problem as a primary reason or where it is known as an associated comorbidity.[10-12] It also delivers an online intervention for the worker's line manager. The return to work intervention is a multi-component intervention promoting early communication and support for the worker to reduce the number of days on long term sick leave and to enable a successful return to work. The intervention comprises of two RTW toolkits – an employer toolkit manual and a worker toolkit. Both toolkits are self-led interventions used by the line manager and the worker themselves. The guidance and resources in the toolkits for the worker and the employer mirror each other to ensure both receive the same messages and to encourage transparency. The intervention is grounded in several psycho-social theories including the Conservation of Resources (CoR) Theory,[20] Cognitive Theory (CT), [21] Communication Accommodation Theory (CAT)[22] and the Socio-Cognitive Theory (SCT),[23] with an emphasis on accessing and using 'resources' within the workplace and outside of work.
Our ongoing process evaluation and process outcome data shows that employers are engaged in the study and recruitment of line managers and workers on sick leave is better in larger organisations. However, the pilot study is not a multi-level intervention study and does not include an intervention component for employers or an intervention component to address sustainable return-to-work as outlined in this proposed study. Our process evaluation shows that line managers and workers are keen to have an intervention that helps workers to stay in work after returning. We have therefore proposed and intervention study that addresses the gaps in our current pilot study and the existing evidence review, and also addresses some of our key learnings around recruitment, intervention content and addresses systematic barriers to change, therefore strengthening the design and implementation of the proposed study.

3. Aim, Objectives and Hypotheses

3.1. Aim

To pilot the IGLOO sustainable return-to-work intervention in public and private sector organisations.

3.2. Objectives

- To determine willingness of organisations, their employees on long term sick leave, and the line managers of those on sick leave to take part in a 30-month study, and retention through follow up (12 months) with intervention uptake and completion as primary endpoints.
- To monitor the potential for selection bias in control and intervention organisations as measured using participant characteristics at baseline.
- To assess implementation of intervention delivery, dose (i.e. number of steps used in the toolkit, number of coaching sessions attended) and fidelity whilst the worker is on long-term sick leave, and implementation of intervention delivery and adherence after the worker has returned to work.

- To gather and quantify preliminary outcomes data in the primary and secondary measures to inform the planning of a larger trial and estimate the inter-cluster correlations for these outcomes.
- To conduct a process evaluation to monitor how the intervention is perceived by participants from different demographic groups (to understand what works for whom in which circumstances) and test a full process evaluation methodology in advance of a full trial.
- To determine the willingness and readiness of employers and their workers to adopt the proposed intervention in a manualised format (written as an instruction manual) that is flexible enough to meet individual and organisational needs in different settings.

3.3. Hypotheses

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

4. Study design

The study design follows the UK Medical Research Council guidance for complex interventions.[30] This will be a pilot cluster randomised controlled trial (RCT) of the IGLOO intervention. The aim is to inform a fully-powered definitive trial to evaluate sustainable return to work in people with primary or secondary mental ill-health who go on long-term sick leave. The study will last 36 months with organisations participating for 30 months. Recruitment of workers on long-term sick leave will take place over 12 months. Workers will be recruited between >14 to <42 days for their long-term sick leave. Key process outcome measures will be collected monthly, research outcome measures will be collected from each worker and line manager participant at baseline, 3,6,9 and 12 months. As a cluster RCT, the unit of randomisation will be the organisation, such that some organisations will receive the experimental intervention and others will not, although collection of the outcome measures will take place in all participating organisations.

4.1. Setting and participants

Employer organisations in South Yorkshire and South Humber with 600 or more employees (to minimise the risk of missing recruitment targets) will be recruited into the study. This regional setting has been chosen because of its socioeconomic diversity. For example, 9.4% of its population are from Black, Asian and other minority ethnic backgrounds[31] with 4.7% in Doncaster and 6% in Sheffield describing themselves as 'non-white' in the 2011 census.[32] The region also has some of the most socioeconomically deprived areas[31] and with around 75% of 16-64 year olds in active employment,[33] the area has one of the highest rates of sickness absence, at 2.3%, in England.[34] The primary target population are workers on long-term sick leave due to mental ill-health or for a condition known to be associated with mental-ill health, [1, 10-12] and who will be recruited into the study between >14 days and <42 days of their long-term sick leave. The line manager of the individual worker on long-term sick leave will also be recruited into the study. Participation of the line manager is entirely voluntary, whether or not their employee is taking part.

Inclusion criteria

- Large organisations with 600 employees and above. This will include NHS trusts, public and private sector employers in the South Yorkshire and South Humber region.
- Public and private sector organisations.
- Line managers of participants on long-term sick leave.
- Individuals on long-term sick leave (defined as >14 days) due to occupational burnout and/or a common mental health problem as a primary reason or where is it known as an associated comorbidity. [1, 10-12]
- Consistent with national clinical guidelines, common mental health problems meeting eligibility criteria for this study include: adjustment disorders (including reactive stress), major depressive disorder, generalised anxiety disorder, mixed anxiety and depressive disorder, post-traumatic

stress disorder, obsessive-compulsive disorder, phobias, social anxiety disorder, panic disorder with/without agoraphobia, health anxiety, functional disorders and anxiety-related somatic symptoms.

- The study will also include participants whose sickness absence is related to other chronic illnesses which are known to be highly comorbid with common mental disorders listed above; such as coronary heart disease, diabetes, musculoskeletal problems, chronic obstructive pulmonary disease, and other long-term conditions (LTC). This inclusion criterion is necessary to properly identify participants who are affected by common mental disorders, but whose primary reason for sickness absence may be a LTC recorded in their occupational records. We acknowledge that some employees may prefer to report a LTC as a primary reason for sickness, rather than a mental health problem, considering that the latter may be perceived as stigmatising.

Exclusion criteria

- Organisations that outsource their return-to-work management.
- Organisations that have <2% of workers taking long term sick in the past 12 months.[34]
- Individuals on long-term sick leave due to a severe mental disorder (psychotic disorder; bipolar disorder); substance use disorder; a neurological condition such as dementia; or under investigation for misconduct or formal disciplinary action.
- Workers under 18 years of age.

4.2. Intervention

The proposed IGLOO intervention is a multi-component intervention promoting positive changes in return-to-work outcomes and in the sustainability of staying in work. The IGLOO intervention was informed by a seminal conceptual framework published by three of the applicants,[15] and the most consistent evidence on SRTW (i.e., keeping people at work *after* they return from long term sick leave) for workers and organisations. The intervention is designed to be implemented by employers to optimise workers' return to work, and capability to stay in work, by targeting five key 'resources' or 'levels' within the workplace and outside of work. [1] The *individual level* is addressed by providing tools to improve resources inherent within the individual such as self-efficacy to return to work, and training in job crafting strategies to help individuals stay at work. [2] The *group level* is addressed by enabling the worker to access relevant support through family, friends and colleagues. [3] The *leader level* involves providing access to line manager support and information on accessing appropriate support from primary health care. [4] The *organisation level* involves making changes to return-to-work policies and processes, offering wellbeing programmes to support mental health in and outside the organisation. [5] The *overarching/social environment level* involves employing NICE guidelines for managing sickness absence and executing evidence based practice in changing cultural attitudes towards workers with mental health issues.

The intervention is underpinned by key psychosocial theories that informed our earlier project – the Midlands Engine Pilot.[20-23] It includes a new component called job crafting (underpinned by the Job-Demand Resource Theory (JDR)[24]), designed to improve sustainable return-to-work outcomes. [14] The benefits of job crafting in terms of work engagement and productivity have been shown in a meta-analysis of 14 intervention studies,[25] through likely mechanisms of cognitive crafting (cognitive re-framing, job identity), task crafting (structuring and focusing work efforts), and relational job crafting (managing expectations and interactions).[25,26] Preliminary research by Professor Nielsen and Dr Jo Yarker on the intervention framework with workers taking long-term sick leave, shows promising results for all five levels in relation to supporting workers to return to work after long-term sick leave; and to stay in and thrive at work,[27] after long-term sick leave.

The first part of the intervention is already developed and being trialled in the Midlands Engine return-to-work pilot intervention study. It has been developed over six months with input from workers, human resources professionals, line managers and small employers. The pilot is due to be completed June 2022 but the learnings from its ongoing process evaluations, particularly around recruitment and intervention implementation have been applied to the planned study intervention. As a result, IGLOO has been refined and extended to include post-return to work intervention components to address sustainability of returning to work. Intervention preparatory work aligned with INVOLVE guidance has been completed over the past 12 months with input from seven workers with a history of long-term sick leave (with mental ill-health or associated co-morbidity), six employers from different sectors and the Health and Safety Executive (HSE), Department or Work and Pensions (DWP), Society of Occupational Medicine (SOM) and Mind charity, alongside primary data collection from workers and employers. [26] This pilot study has been presented to HSE, DWP, ACAS, SOM, British Association for Counselling and Psychotherapy (BACP), the British Psychological Society and Mind. Stakeholders welcomed such a study to address a key UK research priority and indicated their commitment to support and engage collaboratively.

The intervention targets the five IGLOO levels in three phases:

Phase 1: The *organisation level* and *overarching level* are first targeted by providing the employer (e.g., Management Committee, Human Resources, Health and Well-being/Occupational Health) with an education e-resource information pack on what works best in [a] supporting people back to work, and [b] enabling them to stay at work. It is recognised that changing organisational behaviours can be a challenge. Phase 1 is therefore grounded in several behaviour change theories – COR,[20] SCT,[23] and JDR[24] – targeting leaders as key agents of change,[35,36] as leaders are in a good position to implement organisational policies , review well-being programmes and human resources options.[37] For example, drawing upon conservation or resources theory,[20] the e-resource training will give examples of how leaders can help reduce the barriers to return-to-work use by presenting different scenarios of when workers need resources, what sort of resources they need, and how workers can access these resources whilst on sick leave (e.g. keeping in touch with colleagues). Previous studies evaluating the mental health training for workplace leaders suggest that e-resources can significantly improve leaders' knowledge, self-efficacy, and promotion intentions with regard to worker mental health and reduce leaders' stigmatising attitudes surrounding common mental health problems,[38.39] and lead to organisational and behavioural changes.[40,41]

The e-resource will consist of materials which will take a maximum or three hours to complete. The resources will consist of three 10-30 minute presentations, interactive case studies and videos on [a] understanding common mental health problems (i.e., depression, anxiety, stress, burnout) and their behavioural warning signs; and their associated comorbidity with physical conditions; [b] recognising impact of mental health problems on long-term sick leave and outcomes [c] reviewing existing long-term sick leave and return-to-work policies and processes, [d] aligning internal policies and processes to evidence-based best practice [e] identifying 'gaps' in resources to support return-to-work, [f] taking appropriate engagement or action, and [g] ongoing monitoring or evaluation. The e-resources will incorporate active learning strategies and feedback.

Phase 2: grounded in CT, [21] CAT, [22] SCT,[23] and COR[20] the online toolkit targets the *individual level* through self-led activities designed to increase worker's self-control,[42] and self-management skills,[43] to improve for example, their cognitive and affective wellbeing, their relationship with their line manager and work self-efficacy. The toolkit also promotes early communication with the line manager/workplace,[22] and supporting strategies for the worker to reduce the number of days on long term sick and enable a successful return to work. The content of the toolkit is based on the evidence of what works, [13,17,44] particularly for online interventions,[45] with input from members of the public who have been on long-term sick leave. The toolkit is split into three sections that are completed at the different stages of the

workers' sick leave and return to work process: step 1 managing initial sick leave, step 2 preparing to return to work, and step 3 managing back at work. Based on cognitive-behavioural principles, each step includes self-led activities on problem-solving (e.g., identifying and formulating practical ways to deal with barriers in returning to work, building a support network, communicating work adjustments and work support needs), and goal-setting (e.g., managing mental health symptoms through identifying and accessing support, improving physical activity, sleep and diet). The toolkit also includes practical tools (e.g., conversations checklists).

The *leader* and *group* levels are targeted by providing the worker's line manager with online training in how to support the worker's work self-efficacy and well-being and an online return to work toolkit that mirrors some of the self-led activities in the workers' toolkit to ensure the worker is supported. The online training is evidence-based,[38] and consists of three 10-30 minute presentations, interactive case studies and videos including additional learning activities to encourage managers to apply their learning to their worker's long-term sick leave management and return-to-work process including [a] how to address mental health concerns with a worker (e.g., what to say; how to demonstrate compassion but remain professional), [b] how to support the worker whilst on long-term sick leave, [c] how to support the worker on their return-to-work strategies including addressing barriers to their return-to-work, and [d] how to suggest resources and/or provide appropriate work adjustments, and [e] raise awareness among colleagues of mental health, its links to long-term sick leave and how colleagues can support the worker on long-term sick leave when they return to work. The line manager toolkit includes the same three sections as the workers' toolkit, with each section outlining best practice (e.g., recording sickness absence, keeping in regular touch, holding a return-to-work conversation), as well as practical tools and checklists to record actions taken (e.g., redistribution of work, communication with the worker's colleagues, return-to-work and work adjustment discussions, well-being check-ins). For phase two, the primary return-to-work outcome, days until return to work (RTW)[13] will be calculated until first day of return.

Phase 3: Within 1-month of returning to work, online training is offered to the worker designed to increase their self-control and work self-efficacy in initiating changes to their job or how work is done (i.e., job crafting). Grounded in COR,[20] SCT,[23] and JDR[24] and using evidence from the few studies that show the importance of job crafting for sustainable return to work by improving work engagement.[14,15,29] This *individual level* training includes three presentations lasting 10-30 minutes, interactive case studies and videos and practical tools on how to [a] modify job tasks in a personally meaningful way to suit the worker's needs, skills and values, [b] develop a self-set personalised crafting plan (i.e. goal setting and action planning) to undertake for a period of four weeks, [c] keep "crafting logbooks" that details their crafting activities of each week to discuss successes, problems, and solutions with their line manager in weekly meetings.

Online training (three 10-30 minute presentations, interactive case studies and videos and practical tools) is also provided to the line manager (*leader level*) on how to support their worker and their colleagues (*group level*) in job crafting by [a] understanding what job crafting is, its benefits for the worker returning from long-term sick leave, [b] identifying resources to enable job crafting to occur, [c] supporting the worker and their colleagues in their job crafting plans. The training will incorporate active learning strategies and feedback. Sustainable return-to-work outcomes will be assessed from day 1 until month 6 (assessed at 12 months).

Some of the intervention components for Phase 1 and 2 are already developed with their feasibility assessed with workers and employers (data not yet published). For phase 3 acceptability and feasibility will be assessed focusing on the effectiveness of the online training; and the outcome measure for assessing sustainability of return to work.

Intervention delivery

The intervention will be delivered over the internet using a secure web-based platform requiring individual logins within each intervention cluster. Over the 12-month study period, participating workers on long-term sick leave will be consented into the study and supported to use the online toolkit through three online health coaching sessions during phase 1 which will be delivered by a trained researcher. The aim of the health coaching sessions are to support the worker on long-term sick leave using the resource, whilst on sick leave, when preparing to return to work, and when they have initially returned to work. All participants will also be able to contact the researchers for one-to-one support via telephone or online video and will also receive a hard copy of the toolkit. Participating workers and line managers will also receive regular text messages to reinforce training behaviours and toolkit use,[46] as well as reminders to complete online data collection.

Control arm
Organisations assigned to the usual practice control arm will be asked to continue with their usual long-term sick leave and RTW policies and processes. 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 provided with all of the online resources provided to the intervention participants but as hardcopies.

4.3. Measures
All measures described below are available in a separate spreadsheet that explains exactly which measure will be completed at each of the study phases.
Sample Characteristics
Participants 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.

Primary outcome measure
The primary outcome will be the number of long-term sick leave days until first day of return to work (RTW).[13]

Secondary outcome measures
We will also record whether the participant has returned to usual working hours or adjusted working hours. Data will be collected from organisational records. The reason for long-term sick leave will also be taken from organisational records which record the information from the participant's fit note. To assess sustainable return to work outcomes, we will record the number of days a participant has stayed in work from their first day of return to six months (data collected at 12 months follow-up) with no exit or long-term sick leave re-occurrence (SRTW). [14] We will record the data from organisational records as well as from self-report in the final follow-up questionnaire.

Other secondary outcomes for workers taken at all time points via online questionnaires (baseline in phase 2 and at 3, 6, 9 and 12 months)

Return to work measures

- Pre-sick leave work hours is a one-item questionnaire to establish the employees' standard working hours pre-sick leave.
- Return to work hours is a three-item questionnaire to establish the employees working hours on returning to work.
- Further sick leave since RTW is a three-item questionnaire to establish how much, if any, sick leave has been taken since returning to work.
- Intention to Quit Questions[48] is a two-item questionnaire to establish whether an employee is considering leaving their role

- Employee's line manager competency questionnaire[49] is a 39-item questionnaire to establish how their manager has managed their long-term sickness absence. We used 16 items from this.
- Autonomy from the Basic Psychological Needs Satisfaction at Work Scale[50-53] is a four-item scale to establish feelings about current role
- Quality of life questionnaire[54] is a questionnaire to establish current quality of life

Self-report mental health

- The Patient Health Questionnaire (PHQ-9)[55] is a nine-item questionnaire used to measure depression. This measure is used by GPs and practitioners involved in the Improving Access to Psychological Therapies (IAPT) initiative and reliably reflects improvement and worsening symptoms of depression.
- The General Anxiety Disorder Questionnaire (GAD-7)[56] is a seven-item questionnaire used to measure anxiety. This measure is used by GPs and practitioners involved in the Improving Access to Psychological Therapies (IAPT) initiative and reliably reflects improvement and worsening symptoms of anxiety.
- The Exhaustion scale taken from Utecht Burnout Scale[57] is a three-item questionnaire used to measure burnout

Readiness to return to work

- Expectations about length of sick leave will be asked using one question,[58] "for how long to you believe you will be on sick leave from today?"
- The Return to work Self-Efficacy Scale[59] is an eleven item scale used to assess confidence to return to work

Workplace support and communication

- The Workplace Health Communication Scale[60] is a six-item scale that will be used to assess the quality of communication between the worker, employer and organisation.
- The Manager Communication Questions[61] are three items taken from a six item inventory looking at Participant's confidence in communicating health matters with their managers Communication satisfaction questions [63] is a two item scale asking participants to rate their satisfaction of communication with their organisation
- Communication satisfaction sick leave is a two-item questionnaire [63] is a two item scale asking participants to rate their satisfaction of communication with their manager whilst on sick leave

Economic questions

- Use of health and wellbeing services[65] is a questionnaire to establish use of NHS and social care services

Additional measures once a worker has returned to work

- The Readiness to Stay at Work Scale[60] is a nine-item scale used to assess a participant's readiness to stay in their role at work
- The Job Crafting Questionnaire[66] is a 15-item scale that measures the changes workers make to their job tasks
- Work Productivity
  - A 1 item job satisfaction scale will be used to assess satisfaction[68]

Outcome measures for participating line managers and employers

- Employee sick leave questions (ESLQ) is assessed using a four-item questionnaire gathering information around dates and reasons for an employees period of sickness.
- Employee back at work questions (BRT) is assessed using a two-item questionnaire where employers give information about the date an employee returns to work.

- Mental health and RTW experience: Those with responsibility for RTW will be asked about their line manager experience (3 item question) and a 3 item question on return to work training long-term sickness absence and a 6 item questionnaire on return to work climate.
- HSE job demands questionnaire[64] is an eight-item scale assessing the employer's perceived demands of their job role.
- Autonomy from the Basic Psychological Needs Satisfaction at Work Scale[50-53] is a four-item scale to establish feelings about current role
- Confidence in managing mental health issues and promoting a mentally healthy workplace questionnaire[69] is a six-item questionnaire using a scale to measure an employer's confidence in managing mental health issues in their workers.
- Line manager competency Scale[70] is a 39-item questionnaire assessing actions and behaviours conducted by an employer when working with an employee who has been off work with long term sickness.
- Work adjustments questionnaire is a four-item scale gathering information about the adjustments made to their employee's working conditions given their long term sickness.
- Demographic information on age, gender, ethnicity, job role and tenure.

Economic evaluation measures

Participants will be asked to complete the EuroQoL-5DL (EQ-5DL)[71] 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 for mental health will be collected using the health resource questionnaire.[72] 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.

4.4. Recruitment, study procedures and data collection

Participant recruitment process

- Large organisations (with 600 or more employees) 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 1 hour video-calls or in-person contact with a project researcher to discuss number of workers on long-term sick leave in the past month and how many met the inclusion criteria (maximum 30 x 1 hour conversations). At the end of the study (at 30 months), the key organisational contact will take part in in a one x1 hour telephone or MS Teams interview to explore their experience of taking part in the study.
- Participating organisations will receive study promotional materials to disseminate across their workforce. The promotional materials will advertise an organisational survey that all employees are invited to complete on Qualtrics (an online survey platform). Staff participation is voluntary. The survey will ask questions about general wellbeing and questions on what mental health and wellbeing resources and support participants are aware of in their place of work. The survey will be open for 2 months and promotional reminders will be sent to encourage completion.
- To evaluate the reach of the intervention, we will record data on the number of organisations willing to take part in the study. Where possible, we will also record the number of organisations approached.
- From the organisations consenting to take part, we will collect the following information prior to randomisation: summary of long-term sickness 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 mental health training and support.

- We will also collect questionnaire data from lead stakeholders and staff in the wider organisation (e.g., director of human resources) on their 'readiness' and expectations for the interventions and the wider workforce to help us understand in which context the intervention works but also help us to understand why recruitment worked/didn't work, this information will be gathered through the completion of electronic surveys, including the Intervention Readiness Questionnaire (a five item scale designed to assess an organisations receptivity to make changes to their current processes through the intervention) Tailored questions and the Integrated Workplace Safety and Health Assessment Questionnaire on organisation policies will be asked through the OSQ. This data will help us identify potential contextual barriers and facilitators to implementing the intervention. Contextual barriers and facilitators will also be explored through semi structured interviews in more detail, particularly those looking at stigma, communication, overall work support and performance through the Reported and Intended Behaviour Scale (RIBS)[76], the Reported and Intended Behaviour Stigma Scale (RIBSS)[77], the ESS [78] and the Communication About Resources questionnaire (CAR)[79] .
- Participating organisations randomised to the experimental group will then take part in phase 1 of the intervention to address the attitudes and behaviours of stakeholders and leaders toward mental health, sick leave and return-to-work; and aligning the intervention with current long-term sick leave management policies and practices so that human resources personnel, line 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 and seek their views on how best to recruit workers on long-term sick leave and their line managers (co-production).
- Employees who are on long-term sick leave and consenting to take part in the study will also consent to be contacted by the team on their personal mobile phone numbers and email addresses as we know that employees on long-term sick leave may not be checking work devices.
- We will implement a 12-month-long recruitment period (with employers participating for a total period of 30 months), to maximise the recruitment of workers taking long-term sick leave. A flow chart is available to illustrate this process.
- Using a ratio of 1:1, organisations will be randomised into intervention or control group and where possible, will be stratified by area (i.e. Sheffield or Doncaster), and organisational (cluster) size. Randomisation into the study will be done by an independent statistician at Loughborough University.

Data collection and safeguarding procedures

- The measures will be collected by the research team using a secure, web-based, industry-standard data collection system (Qualtrics).
- Participants will be asked to complete the primary and secondary measures at five assessment points, (Baseline in phase 2, 3, 6, 9 and 12 months).
- Sample characteristics (described above) will only be completed once, at the time when participants provided informed consent.
- A hard copy of the consent form will be available on request
- Sites will be required to identify their eligible leaders, managers and staff.
- HR departments will be asked to send documentation out to eligible staff who are on long-term sick leave, for them to read about the study and consent to participate.
- The dataset will be stored in a secure network drive, only accessible to members of the research team. As the delivery team (in charge of recruitment and data collection) is based within the NHS, data will be stored in a secure and restricted-access network drive managed by RDaSH NHS Trust. Backup copies of data will be stored by The University of Loughborough, also using a secure and restricted-access network drive. 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 NHS research team and the academic team at Loughborough will be carried

out strictly using password encrypted data files (using 7zip software) and the NHS secure file transfer facility, in order to comply with data protection and information governance policies.

- The final and fully anonymised study dataset will be held at the University of Loughborough for up to ten years after the conclusion of the study, in order to comply with principles of Open Science, enabling the future inclusion of data in systematic reviews and meta-analyses as data in this area of research accumulates slowly over time.

5. Data analysis

5.1. Sample size calculation

There is no formal requirement to conduct sample size calculations for pilot trials,[73] but a sample of at least 100 participants (50 per arm) is desirable.[74] We will recruit 8 clusters,[75] (randomised in each arm) to calculate the targeted sample size for a definitive RCT. This will allow us to estimate an intracluster correlation to assist with sample size calculation for the full trial, although a recent Cochrane review,[17] indicates that the ICC calculated from four previous studies was negligible. Variation in the primary outcome will be estimated from the pilot as well, but DELTA[2] guidance will be used to determine the effect size chosen for the main trial.

5.2. Descriptive statistics and summary of quantitative data

The study will be analysed and reported according to the Consolidation Standards of Reporting (CONSORT) statement for cluster RCTs. As this is a pilot study we will examine the primary and secondary outcomes to mimic practice for a full trial in addition to finalising the sample size for a definitive main trial. Results from this analysis 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 leave and RTW policies and number of workers who were on long term sick leave in the past 12 months prior to the start of the study. The number of worker participants identified on long term sick leave and the number 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 the log-in and downloads of the resources/toolkits.

5.3. Analysis of adherence, usability and completion

1. We will evaluate adherence using a red-amber-green classification scheme where download of materials by at least 80% of all participants will be classed as green, at least 50% but less than 80% will be classed as amber, or less than 50% will be classed as red.
2. Usability of intervention materials will be evaluated according to at least 75% (green) of participants, at least 50% but less than 75% (amber) or less than 50% (red) in each of the intervention phases (Phase 1: self-guided exercises, Phase 2: Sick leave management and return to work actions, and Phase 3: Action planning and implementation).
3. Completion of all intervention components will be evaluated according to at least 50% (green) of participants, at least 25% but less than 50% (amber) or less than 25% (red) in each of the intervention phases.
4. Changes in behaviour by employees and managers by the end of phase 3 intervention will be evaluated based on at least 25% (green); at least 10% but less than 25% (amber), or less than 10%(red).

An RCT to study the effectiveness of the intervention will be considered feasible when all of the green criteria are met. If not, adjustments for the study protocol will be formulated for amber criteria. If red criteria are met in all four points above, a full RCT will not proceed.

5.3. Qualitative data analysis

Qualitative interview data will be transcribed verbatim and analysed using inductive thematic analysis procedures. Quantitative and qualitative data will be triangulated and systematically coded using the core theoretical frameworks,[20-24,47] to identify the change mechanisms of how workers and line managers translate training 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 (SRTW).

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, mental health status, readiness and self-efficacy to return to work, 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 pilot 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 by chained equations (MICE). In a future main trial, we will conduct a mixed effects Cox regression, which allows all data available at all time points to be used and account for missing data and clustering effect, will be used to estimate a two-sided 95% CI to show a reliable range for the true difference in the primary outcome (i.e., number of days taken to return to work [partial or full] between the intervention and control arms. In order to inform the sample size calculation for a future trial, the present study analysis will carry out a preliminary examination of [1] between-group effect sizes on the outcomes of interest and [2] the magnitude of the intra-cluster correlation coefficient (ICC) using a mixed effects model as outlined above.

6. Ethical considerations

6.1. Considerations about informed consent

Ethical approval will be obtained from a National Health Service research ethics committee prior to commencement and will comply with the UK Framework for Health and Social Care Research. We will also seek Health Research Authority (HRA) approval and R&D permission for NHS staff participants in RDaSH and other participating NHS Trusts.

An independent Trial Steering Committee (TSC) 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 principal investigator and reports and recommendations will be provided.

In order 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, as we know they may not be checking work devices whilst on long-term sick leave.
- 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 for distress
The IGLOO 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 with mental health and so participants will receive contact information for the chief investigator in the 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 psychological 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 psychological help where required.

Risks to participants
See above section.

Risks to research team
See above section.

Potential for disclosure
See above section.

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)

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Study flow diagram