ISRCTN11788559 https://doi.org/10.1186/ISRCTN11788559

IGLOo: Sickness absence and sustainable return to work pilot study

Submission date	Recruitment status	[X] Prospectively registered
09/09/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/10/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol
Background and study aims:
The purpose of this return-to-work pilot study is to provide employees on long-term sick leave with an employee education pack of materials aimed at helping improve wellbeing whilst on long-term sick leave and improve their likelihood of remaining in work when they return.
Many people go on long-term sick leave for lots of different reasons including back pain, poor mental health and conditions that might need treatment or recovery time. Sometimes, those on long-term sick leave might experience poor mental well-being even if that is not the reason for their sick leave. Research shows that poor mental well-being is linked to longer lengths of sickness absence. However, a number of studies show that employees who experience good quality communication and contact with their workplace can feel positive about their work, and are more likely to feel ready to return to work and also return to work earlier than they expected. They are also more likely to have a more positive work experience once they are back at work.
Our return-to-work pilot study, called IGLOo (Individual, Group, Leaders, Organisation), provides employees who are on sick leave with an online toolkit they can access through a website. The online toolkit provides new guidance and step-by-step support from initial sick leave through to returning to work for the employee and remaining in work into the future. The employee's manager, workplace return-to-work contact or employer will be asked to use a similar online toolkit that provides them with step-by-step guidance on how to support the employee whilst on sick leave and when returning to work. The leaders of the organisation will also have access to online webinars while colleagues will have the option of receiving information on how they can help so the means of support is complete.
Who can participate?
1. Organisations interested in supporting their employees during sick leave and upon their return to work
2. Employees who are on long-term sick leave in the participating organisations
3. Line managers who are managing an employee on long-term sick leave in the participating organisations

What does the study involve?
Taking part will provide employees on long-term sickness absence and line managers with mirrored toolkits designed to promote compassion and empathy towards the employee during

their absence, to encourage early and positive workplace communication that supports an employee's wellbeing whilst on sick leave and when returning to work and to offer checklists of actions to perform during their absence to ensure nothing is missed and a smooth return to work is set up. Additional emphasis is placed on making work adjustments to meet the employee' s needs once they return to work. Additional toolkits and webinars are designed for leaders within the organisations and colleagues of the employees on long-term sick with a view to shifting the organisation's culture around long-term sickness absence from one of the negative assumptions and pressure to return to work as quickly as possible, to one of support, care and accommodation. Eight large organisations will be recruited where four will receive our programme and four will act as a comparison group, carrying on as normal. We will measure how many days employees stay at work without taking long-term sick leave again or leaving work within six months of returning. We will also ask participants to complete questions about their mental health and work, these will be asked before the programme and at 3, 6, 9 and 12 months. Organisations in the intervention group will receive a report on the study outcomes and may continue using the intervention resources. Organisations in the control group will receive a personalised report on their return-to-work processes

What are the possible benefits and risks of participating in the study?
Employee participants receiving the intervention may experience health benefits and feel better supported by their line manager. A potential risk is that the employee may feel coerced into participating by their employer (who will send the employee the study information after the employer has identified them as being on long-term sick leave). However, every effort will be made to reduce this risk by informing the organisation of the study protocol, promoting the study before the trial starts and by the research team checking with each employee that their participation is entirely voluntary before consenting them.

Where is the study run from?
University of Loughborough (UK)

When is the study run from and how long is it expected to run for?
March 2022 to February 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main study contact?
Professor Fehmidah Munir
f.munir@lboro.ac.uk

Study website
https://www.returntowork.co.uk/

Contact information

Type(s)
Scientific

Contact name
Miss Jeannie McKie

Contact details

Rotherham, Doncaster and South Humber NHS Foundation Trust
Bungalow 2
St Catherine's Close
Tickhill Road
Doncaster
United Kingdom
DN4 8QN
+44 (0)7970049942
j.mckie@nhs.net

Type(s)
Principal Investigator

Contact name
Prof Fehmidah Munir

ORCID ID
http://orcid.org/0000-0002-5585-0243

Contact details
School of Sport
Exercise and Health Sciences
University of Loughborough
Clyde Williams Building
Epinal Way
Loughborough
United Kingdom
LE11 3TU
+44 (0)1509 228228
f.munir@lboro.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313499

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53316, IRAS 313499

Study information

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

Acronym
IGLOo

Study objectives
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. The IGLOo intervention reduces the number of days of long-term sickness when compared with business-as-usual control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/08/2022, East Midlands – Leicester Central Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8066, +44 (0)207 104 8199; leicestercentral.rec@hra.nhs.uk), ref: 22/EM/0143

Study design
Pilot cluster randomized case-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Mental health

Interventions
Feasibility outcome: quantitative data describing recruitment (types of organisations participating, number of employees on long-term sick leave eligible to take part, number of employees who consent to take part, number of line managers who consent to take part), intervention (e.g. number of participants completing the steps in the online toolkits, number of times each section of the toolkit is used and attrition, number of health coaching sessions received, online training viewed and completed) gathered using study logs and predesigned forms. The forms to capture the specific data will be unique to this study and developed for its purpose.

Intervention Type
Other

Primary outcome measure
The number of days taken until the first day of return to work (partial or full return) using organisational records and self-report. Data collected monthly (organisational records) and at 3 6, 9 and 12 months (self-reported)

Secondary outcome measures
1. Work demands, measured by the HSE Job Demands Questionnaire, completed at baseline and 12 months
2. Return to work self-efficacy, measured by the RSE, at baseline, 3, 6, 9 and 12 months
3. Readiness to stay at work measured by the RRS, completed at 3, 6, 9 and 12 months if the employee has returned to work
4. Depression measured by the PHQ-9 collected at baseline, 3, 6, 9 and 12 months
5. Anxiety measured by the GAD-7, collected at baseline, 3, 6, 9 and 12 months
6. Burnout measured by the Utecht Burnout Scale (items 1, 2 and 3) completed at 3, 6, 9 and 12 months if the employee has returned to work
7. Intention to quit measured by ITQ (2 items) completed at baseline, 3, 6, 9 and 12 months
8. Productivity measured by the PRQ (1 item productivity questionnaire) completed at baseline, 3, 6, 9, and 12 months
9. Communication with the manager, measured by MCQ (3 items from manager communication questionnaire) completed at baseline, 3, 6, 9 and 12 months
10. Communication satisfaction whilst on sick leave will be measured by the CSSQ (communication satisfaction sick leave questionnaire) collected at baseline, 3, 6, 9 and 12 months
11. Return to work competency measured by the employee's line manager competency questionnaire, 16 items collected at 3, 6, 9 and 12 months (if remains on long-term sick leave, do not ask when returned)
12. Manager support measured by the HSE manager's support questionnaire - collected at 3, 6, 9 and 12 months if the employee has returned to work
13. Job crafting measured by the 15-item JCRQ collected at 3,6,9 and 12 months if the employee has returned to work
14. Colleague support measured by 1 item from the workplace acceptance scale collected at 3, 6, 9 and 12 months if the employee has returned to work
15. Autonomy measured by Autonomy from the Basic Psychological Needs Satisfaction at Work Scale collected at 3, 6, 9 and 12 months if the employee has returned to work
16. Quality of life measured by Euro-Qol quality of life questionnaire collected at baseline 3, 6, 9 and 12 months.
17. Economic questions (use of services) measured by the Use of Health Services questionnaire asked at 3, 6, 9 and 12 months
18. Demographic information such as age, gender, ethnicity, household information, and time spent working in the role and for the organisation will be completed at baseline
19. Occupational level gathered by completing the Standard Occupational Classification (SOC) at baseline

Overall study start date
01/03/2022

Completion date
28/02/2025

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 09/05/2023:
1. Individuals aged 18 years and over, 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 associated comorbidity.
2. Line managers of participants on long-term sick leave.
3. 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
4. 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.

Previous participant inclusion criteria:
Large organisations with 600 employees and above. This will include NHS trusts, public and private sector employers in Yorkshire and in particular, the South Yorkshire and South Humber region.
1. Public and private sector organisations
2. Line managers of participants on long-term sick leave
3. Individuals aged 18 years and over 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 associated comorbidity
4. 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
5. 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.

Participant type(s)

Patient, Health professional

Age group

Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 7063; UK Sample Size: 7063

Total final enrolment
7068

Key exclusion criteria
1. Organisations that outsource their return-to-work management.
2. Organisations that have <2% of workers taking long-term sick in the past 12 months.
3. 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
4. Workers aged 17 years of age and under

Date of first enrolment
15/11/2022

Date of final enrolment
15/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
Woodfield House
Tickhill Road
Doncaster
United Kingdom
DN4 8QN

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road

Sheffield
United Kingdom
S5 7AU

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Yorkshire Ambulance Service NHS Trust
Springhill
2 Brindley Way
Wakefield 41 Industrial Estate
Wakefield
United Kingdom
WF2 0XQ

Sponsor information

Organisation
Rotherham Doncaster and South Humber NHS Foundation Trust

Sponsor details
St. Catherine's Hospital
Woodfield House
Tickhill Road
Doncaster
England
United Kingdom
DN4 8QN
+44 (0)3000 212 456
rdash.groundedresearch@nhs.net

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Central Commissioning Facility (CCF); Grant Codes: NIHR202986

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
After the conclusion of data analysis, we plan to disseminate findings about this study using a variety of forms of communication, including:
1. Scientific presentations
2. Peer-reviewed publications in scientific journals
3. Participation in local, national and international meetings and conferences
4. Articles for trade publications (e.g., HR Zone and Occupational Health Today)
5. Presenting findings at employer and professional practice conferences (e.g., Health and Well-being at Work Summit)
6. We will produce practitioner guidelines for occupational health, vocational rehabilitation and human resource practitioners that bring together findings in an accessible way.
7. Engage with professional bodies through the “Work, Health and Wellbeing” Research Consortium
8. Cross-care and industry networks
9. Specific healthcare networks such as the UK Faculty of Public Health (UKFPH) and Royal College of General Practitioners (RCGP)

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to this being a feasibility study. If the data collected are sufficient to share the researchers will reconsider.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 6.1	20/09/2022	28/09/2022	No	Yes
Participant information sheet	version 6.1	20/09/2022	28/09/2022	No	Yes
Participant information sheet	version 6.1	20/09/2022	28/09/2022	No	Yes
Participant information sheet	version 6.1	20/09/2022	28/09/2022	No	Yes
Participant information sheet	version 5.1	20/09/2022	28/09/2022	No	Yes
Protocol file	version 5.2	11/07/2022	28/09/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol article		03/02/2024	05/02/2024	Yes	No