PROWORK: promoting a sustainable and healthy return to work toolkit for employers and their employees

	Submission date 14/12/2020	Recruitment status No longer recruiting	[X] Prospectively registered		
			[X] Protocol		
	Registration date	Overall study status	[] Statistical analysis plan		
	15/12/2020	Completed	[_] Results		
	Last Edited 25/04/2025	Condition category Mental and Behavioural Disorders	[_] Individual participant data		
			[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

The purpose of the return to work pilot study is to provide employees on long-term sick leave with early and positive workplace communication that supports the employee's wellbeing whilst on sick leave and when returning to work.

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 wellbeing even if that is not the reason for their sick leave. Research shows that poor mental wellbeing 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, are more likely to feel ready to return to work and to also return to work earlier than they expected. They are also further likely to have a more positive work experience once they are back at work.

Our return to work pilot study, called PROWORK, provides employees who are on sick leave with an online toolkit they can access from 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. 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 in how to support the employee whilst on sick leave and when returning to work.

Our research wants to see how practical it is for employees on long term sick leave and the person responsible for managing their return to work to use the online toolkits and to follow the steps. We also want to see whether the toolkits are effective in reducing the number of days an employee is on long-term sick leave.

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?

Participant organisations will be randomly allocated to the control group or the intervention group using the PROWORK intervention toolkit.

The PROWORK intervention is a multicomponent intervention promoting recovery and return to work in employees. The employee intervention toolkit has three distinct steps where each step outlines self-led actions the employee can take to support them whilst on sick leave and when returning to work step 1: managing sick leave, step 2: preparing to return to work, and step 3: Being back at work. Each step has self-led actions that are underpinned by behaviour change methods (commitment, social support, communication, action planning, goal-setting, self-monitoring, framing/reframing, reducing negative emotions, problem-solving and graded tasks). The use of the toolkit is supported by three 1-hour health coaching sessions.

What are the possible benefits and risk of participating?

1. Organisations in the intervention group will receive a report on the study outcomes and may continue using the intervention resources.

2. Organisations in the control group will receive a personalised report on their return to work processes

3. 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 information the organisation on 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? Loughborough University (UK)

When is the study starting and how long is it expected to run for? September 2020 to October 2023

Who is funding the study? Midlands Engine (UK)

Who is the main contact? Dr Fehmidah Munir, f.munir@lboro.ac.uk

Contact information

Type(s) Scientific

Contact name Dr Fehmidah Munir

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers Nil known

Study information

Scientific Title

PROWORK - PROmoting a sustainable return to Work: Randomised controlled pilot study assessing a Return to Work toolkit and support for line managers and their employees on long-term sick leave

Acronym

PROWORK

Study objectives

The PROWORK intervention reduces the number of days on long-term sick leave compared to usual care

Ethics approval required Old ethics approval format

Ethics approval(s)

Approved 27/11/2020, Loughborough Ethics Committee (Loughborough University, Loughborough, Leicestershire LE11 3TU, UK; +44 (0)1509 222423; regulatory@lboro.ac.uk), ref: 2020-1889-2041

Study design Two-arm randomized controlled pilot trial

Primary study design Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request participant information sheet.

Health condition(s) or problem(s) studied

Reducing long-term sick leave in employees with a common mental health condition as a main condition or alongside another condition

Interventions

A cluster randomised controlled trial with large, medium and small employer organisations with the unit of randomisation being at the level of each organisation

- The intervention arm will receive a multicomponent online intervention toolkit and health coaching (employee participants) and an online training and multicomponent intervention toolkit (line managers)

- The control will receive usual practice

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The line manager online toolkit has three distinct steps which outline the actions and behaviours the line managers need to undertake to support the employee whilst on sick and when they have returned to work step 1: managing sick leave, step 2: preparing to return to work, and step 3: Being back at work. Each step is underpinned by behaviour change methods (commitment, instructions on how to perform a behaviour, demonstration of the behaviour, behavioural practice, action planning and problem-solving). The manager toolkit is supported by an online training module.

Intervention Type

Behavioural

Primary outcome measure

1. 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. This data will be captured at baseline, and then each month up to month 6 2. Number of days taken until first day of return to work (partial or full return) using organisational records and self-report. Data collected monthly (organisational records) and at 3 months and 6 months (self-report)

Secondary outcome measures

1. Depression measured using the PHQ-9 at baseline, 3 months and six months

2. Anxiety measured using GAD-7 at baseline, 3 months and six months

3. Return to work measured by intentions to return to work scale, return-to-work self-efficacy scale and the readiness to return to work measured at baseline, 3 months and six months 4. workplace support and communication and support measured by six items developed by the research team at baseline, 3 months and six months

5. Work outcomes measured by the work productivity and activity impairment questionnaire at baseline, 3 months and six months

6. Quality of life measured by EQ5D-5L measured at baseline, 3 months and six months

7. demographic questions will be asked at baseline,

8. Use of health resources will be asked at baseline, 3 months and six months

9. Process evaluation interviews (experiences of participants, engagement with the intervention, barriers and facilitators) will take place at one time point (at 6 months for employees and line managers and at 9-12 months for employers)

Overall study start date

01/09/2020

Completion date 31/10/2023

Eligibility

Key inclusion criteria

Employee:

1. To have been on sick leave for at least eight days and less than six weeks (42 days)

Participant type(s) Other

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 60

Key exclusion criteria

Employee:

1. Under 18 years of age

2. On sick leave with a psychotic episode such as schizophrenia, or with substance abuse 3. On sick leave whilst under formal investigation for misconduct or in the formal process of disciplinary action

4. On sick leave being diagnosed with cancer and signed off work for at least 6 months 5. On sick leave due to a neurological condition (e.g. multiple sclerosis, Parkinson's disease, dementia)

Date of first enrolment

11/01/2021

Date of final enrolment

31/10/2023

Locations

Countries of recruitment England

United Kingdom

Study participating centre Loughborough University School of Sport, Exercise and Health Sciences Epinal Way Loughborough United Kingdom LE11 3TU

Sponsor information

Organisation Loughborough University

Sponsor details

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Sponsor type

University/education

Website https://www.midlandsengine.org/

ROR https://ror.org/04vg4w365

Funder(s)

Funder type Government

Funder Name Midlands Engine

Results and Publications

Publication and dissemination plan

The pilot protocol will be published in 2021 in an open access journal. The main results will be published within 1 year of completing the pilot study.

Intention to publish date

31/03/2024

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 the sensitive and contentious nature of the data being collected directly from business organisations. Consent to share data beyond the study has not been included in the participant consent forms.

IPD sharing plan summary

Not expected to be made available

Study outputs							
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?		
<u>Protocol file</u>	version V1	01/11/2020	04/01/2021	No	No		
Protocol article	Toolkit development	19/08/2022	22/08/2022	Yes	No		
Other publications		02/09/2023	25/04/2025	Yes	No		