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A study of a goal-setting intervention for staff in workplaces enrolled in health and wellbeing programmes

Submission date
08/04/2022

Recruitment status
No longer recruiting

Registration date
07/06/2022

Overall study status
Completed

Last Edited
08/05/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is important that employees of any organisation are well, both physically and mentally. Preventing problems with health and wellbeing at work can mean that employees take fewer days off sick from work, are more productive at work, and are less likely to quit their jobs because they are too sick to go to work. This project conducts research to understand how to prevent problems with ill health at work.
One part of the research will involve a trial in the West Midlands. The trial will test the effectiveness of an established behavioural intervention called mental contrasting. Key aspects of mental contrasting include articulating goals and how to address barriers to achieving them, which our public contributors identified as important drivers of health behaviours.

Who can participate?
Organisations who are taking part in a local government workplace health and wellbeing initiative will be able to participate. Individual staff members who are aged 16 years and older and willing to consent to take part can participate.

What does the study involve?
The study involves attending group meetings with other colleagues and a researcher. During the meetings, participants will be asked to answer some questions about health and wellbeing at work. Some groups will receive extra help for their health and wellbeing at work by proving support achieving health and wellbeing goals.

What are the possible benefits and risks of participating?
Sometimes people benefit from taking part in research like this because they pay more attention to their own health and wellbeing as a result, which can improve it. It is an opportunity to contribute to improving our understanding of health and wellbeing, which may benefit people if this knowledge is successfully applied later on to improve health and wellbeing. There are minimal risks involved with participation in this research, although the researchers will ask for some of the participants' time that they could spend doing other things.

When is the study starting and how long is it expected to run for?
July 2021 to October 2023

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

Who is the main contact?
Dr Laura Kudrna
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Contact information

Type(s)
Principal Investigator

Contact name
Dr Laura Kudrna

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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
A cluster randomised waitlist-controlled trial of a goal-setting behaviour change intervention for employees in workplaces enrolled in workplace health and wellbeing initiatives

Study objectives
1. Does the intervention result in participants perceiving they have made progress towards achieving their health and wellbeing goals?
2. Does the intervention change employees' perceptions of their health, health behaviour, and wellbeing?
3. What barriers, enablers, and mechanisms do employees perceive as related to the effectiveness of the intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2022, the University of Birmingham Technology, Engineering and Mathematics Ethical Review Committee (Finance Office, University of Birmingham, c\o Room 106 Aston Webb, B Block, Edgbaston, Birmingham, B15 2TT, UK; Tel: not applicable; aer-ethics@contacts.bham.ac.uk), ref: ERN_21-0744A

Study design
Mixed methods cluster randomized waitlist-controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Workplace

Study type(s)
Prevention

Participant information sheet
Please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Self-reported progress towards goal attainment, health and wellbeing

Interventions
Group 1 (intervention arm) at baseline receives the intervention, which is mental contrasting plus implementation intentions, and has a general discussion about health and wellbeing at work. The intervention is delivered once in a group setting lasting around one hour. The endline follow up period is a minimum of 4 weeks.

Group 2 (waitlist control warm) at baseline only has a general discussion about health and wellbeing at work and does not receive the intervention. The endline follow up period is a minimum of 4 weeks. The intervention (mental contrasting plus implementation intentions) is delivered after endline follow up in a group setting lasting around 1 hour.

Randomisation: All workplaces will be assigned an anonymous ID. An independent statistician will generate an allocation sequence using the random number generator in Stata v16.1 with

assignments to the intervention or control group stratified by company size. Random block sizes of two and four will be used to maintain both balance within stratum and prevent lack of allocation concealment. A company will be considered small if there are less than 50 employees, medium is 51 to 250 employees and large is more than 250 employees. The independent statistician will retain this list and it will be kept concealed from the study team. After baseline data collection has occurred in each workplace, its assignment will be revealed based on the next assignment in the sequence for its particular stratum.

Intervention Type
Behavioural

Primary outcome measure
Self-reported progress towards goal attainment is measured with the item, “So far, how much progress would you say that you have made towards what you wished to do for your health and wellbeing?” (1-7) at endline (minimum of 4 weeks)

Secondary outcome measures
1. Self-reported progress in changing behaviour related to goal attainment is measured with the item, “And how much progress in changing your behaviour would you say you have made towards what you wished to do for your health and wellbeing?” (1-7) at endline (minimum of 4 weeks)
2. Self-rated general health is measured with the item, “Overall, how would you rate your health? (poor, fair, good, very good, excellent) at baseline and endline
3. Self-rated empowerment to change health and wellbeing is measured at baseline and endline with the items:
3.1. I am confident in my ability to look after my health and wellbeing, 1-5
3.2. I know what to do to improve my health and wellbeing, 1-5
3.3. When problems arise with my health and wellbeing, I handle them well, 1-5
3.4. I am confident that I can make the best choices to look after my health and wellbeing, 1-5
4. Psychological wellbeing measured at baseline and endlineL life and job satisfaction, hedonic wellbeing, eudemonic experiences are measured with the items (all 0-10 scale):
4.1. Overall, how satisfied are you with your life nowadays?
4.2. Overall, how satisfied are you with your job nowadays?
4.3. Overall, to what extent do you feel the things you do in your life are worthwhile?
4.4. Overall, how happy did you feel yesterday?
4.5. Overall, how anxious did you feel yesterday?
4.6. How meaningful do the activities that you do at work feel to you?
4.7. How enjoyable do the activities that you do at work feel to you?
4. Mental wellbeing is measured using the short form of the Warwick Edinburgh mental wellbeing scale at baseline and endline

Overall study start date
28/07/2021

Completion date
16/10/2023

Eligibility

Key inclusion criteria

Current inclusion criteria as of 14/12/2022:
Workplace eligibility criteria (cluster-level):
1. Signed up to participate in the WHI in any geographic region
2. Willing and able to allow at least three employees to participate in data collection activities

Employee eligibility criteria (individual-level):
1. Aged 16 years of age or older
2. Willing to provide written consent

Previous inclusion criteria as of 10/10/2022 to 14/12/2022:
Workplace eligibility criteria (cluster-level):
1. Signed up to participate in the WHI in any geographic region
2. Willing and able to allow at least ten employees to participate in data collection activities

Employee eligibility criteria (individual-level):
1. Aged 16 years of age or older
2. Willing to provide written consent

Previous inclusion criteria:
Workplace eligibility criteria (cluster-level):
1. Signed up to participate in the Coventry WHI
2. Willing and able to allow at least ten employees to participate in data collection activities

Employee eligibility criteria (individual-level):
1. Aged 16years of age or older
2. Willing to provide written consent

Participant type(s)
Employee

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
60 workplaces including at least 3 and no more than 30 employees per organisation

Total final enrolment
225

Key exclusion criteria
Current exclusion criteria as of 14/12/2022:
Workplace exclusion criteria (cluster-level):
1. Not signed up to participate in the Coventry WHI
2. Not willing and able to allow at least three employees to participate in data collection activities

Employee exclusion criteria (individual-level):
1. Aged less than 16years of age
2. Not willing to provide written consent

Previous exclusion criteria:
Workplace exclusion criteria (cluster-level):
1. Not signed up to participate in the Coventry WHI
2. Not willing and able to allow at least ten employees to participate in data collection activities

Employee exclusion criteria (individual-level):
1. Aged less than 16years of age
2. Not willing to provide written consent

Date of first enrolment
13/06/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Coventry City Council
Council House
Earl Street
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CV1 5RR

Sponsor information

Organisation
University of Birmingham

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
Planned publication in a peer-reviewed academic journal

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Laura Kudrna (l.kudrna@bham.ac.uk) for anonymous participant-level

quantitative datasets after publication in a peer-reviewed journal. Access criteria will be based on evaluating if the reason for access is ethical. Data may be shared via email. Participants are informed that their anonymised data will be stored for 10 years according to the University of Birmingham's guidelines.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/09/2023	29/09/2023	Yes	No
Results article		08/03/2025	08/05/2025	Yes	No