ISRCTN12040087 https://doi.org/10.1186/ISRCTN12040087

Can the Prevail programme for employees and managers improve workplace productivity, decrease sickness absence and reduce stigma due to common mental disorder?

Submission date
29/04/2020

Recruitment status
No longer recruiting

Registration date
04/05/2020

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
Common mental illnesses such as anxiety and depression contribute around a sixth of the burden of adult disease in the UK. Common mental illnesses are also major factors in sickness absence from work. This has significant negative effects for the employee, the employer, and the economy due to lost productivity. The effects of common mental disorders in the workplace may be more common than is realised. Sick days taken due to mental health problems are often recorded as due to other (physical health) problems. Standard treatments for common mental disorders, such as talking therapies and medication can reduce symptoms, but so far have only a limited impact on return to work and only modest effects on sick leave. Perhaps workplace-based interventions might be more effective at reducing sickness absence due to mental health problems if these involved both the person and their employer/manager working together for the benefit of both (termed co-production).
Prevail is a multi-faceted programme aimed at reducing sickness absence and presenteeism due to common mental health problems. It involves two interventions. The first intervention (Prevail-staff) is aimed at all employees. Its aims are to improve attitudes about mental health and to increase help-seeking behaviour. It also aims to reduce stigma related to mental health issues, and in particular self-stigma (the internalisation of negative stereotypes about mental health problems), and thus promote help-seeking behaviours both within and outside the workplace. The second intervention (Prevail-manager) is aimed at the managerial level of employment and is designed to teach managers how to assess and help improve situations involving mental ill-health. The focus here is on listening, understanding and valuing the person, and problem-solving. The aim is to co-produce an action plan (where both the employer and the employee share input to the action plan and deliver an intervention that both the employer and the employee feel able to sign up to) with the aim of preventing/reducing sick leave and enhancing productivity.

Who can participate?
80 managers across 4 divisions of the DVLA will be selected by the DVLA for participation in the

RCT. 40 of these managers, and their teams (approximately 480 people), will be randomly allocated to be in the active arm of the study and will receive the Prevail intervention programme, while the other 40 will be in the control arm of the study and will not receive the Prevail intervention programme.

What does the study involve?
In a single large workplace, 40 managers and their teams (around 480 people) will receive training on Prevail. There will also be a control group of 40 managers and their teams in the workplace who do not receive the training. Before the start of the training, 1-4 weeks after the end of the training and 12 months after the end of the training, both groups will fill out questionnaires anonymously to assess their attitudes and beliefs about mental health issues and their health and well-being. Sickness absence at a group level will assessed using the organisation's records over the 12 months before the Prevail programme and the 12 months afterwards.

What are the possible benefits and risks of participating?
Those receiving Prevail will gain knowledge about good mental health practices and information about dealing with stress, distress, and other problems (e.g., bereavement). There are not expected to be any risks involved in participating in the programme.

Where is the study run from?
Swansea University (UK)

When is the study starting and how long is it expected to run for?
??? to April 2021

Who is funding the study?
The Driver and Vehicle Licensing Agency (DVLA) (UK), which is the workplace where the study will be carried out

Who is the main contact?
Professor Nicola Gray, Nicola.S.Gray@Swansea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Nicola Gray

ORCID ID
http://orcid.org/0000-0003-3849-8118

Contact details
Department of Psychology
Singleton Campus
Swansea University
Swansea
United Kingdom
SA2 8PP

-
nicola.s.gray@swansea.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PRCT-001

Study information

Scientific Title
Reducing stigma, decreasing sickness absence, and increasing workplace productivity due to mental health difficulties in a large government organization in the UK: A protocol for a randomised controlled trial (RCT) of a low-intensity psychological intervention and stigma reduction programme for common mental disorder (Prevail)

Study objectives
Employees that received the 'Prevail' intervention programme, in comparison to a control cohort, will show: 1. Less mental health related stigma
2. Increased positive mental health behaviours (including less avoidant coping and more help-seeking)
3. Fewer sickness absences from work
4. Less presenteeism at work

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/09/2019, Swansea University Department of Psychology Ethics Committee (Singleton Park,
Swansea, SA2 8PP; +44 (0)1792 295111; g.jiga@swansea.ac.uk), ref: 1521

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)

Other

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Mental health and well-being

Interventions
A sample of 80 managers and their teams (approximate total of 960 employees) will be selected by the UK Driver and Vehicle Licensing Agency (DVLA) to be eligible to take part in the Prevail intervention programme across four of their divisions (Information Technology Services [ITS], Contact Centre [CC], Case work and Enforcement [CAEG], and Input Services Group [ISG]) in order to ensure that there is a broad cross section of teams and individuals. These managers will then be randomly assigned to the Prevail intervention (N = 40) or control group (N = 40) using a random number generator and stratified by division and gender (to ensure equal numbers of managers in each of the four divisions and an equal gender split of manager in each arm of the study).

Prevail is a mental health intervention training programme consisting of two programmes. In Prevail-staff, employees (staff and managers) receive a one-day intervention programme that aims to reduce stigma related to mental health difficulties, increase positive mental health practices (including problem-solving behaviours and help-seeking behaviours), and inform staff about evidence-based low-intensity psychological interventions for common mental disorders. The common mental disorders that are specifically targeted by the Prevail programme are depression, anxiety, stress, and distress (including loss and bereavement). This part of the intervention programme is delivered by a group of train-the-trainers working at the DVLA over a time period of around 10 weeks. The train-the-trainers have all been trained to deliver Prevail-staff by the research team and the authors of the intervention programme.
In Prevail-manager the organisation's managers receive a one-day intervention programme that covers basic psychological skills such as active listening, validation, formulation, and co-production of action plans in order to inform managers of evidence-based techniques that will enhance their ability to support any of their staff who present with mental health difficulties. Prevail-manager is delivered by our research team during this same 10-week time period, with the proviso that the manager receives the manager intervention programme soon after both themselves and their staff-team receiving the Prevail-staff intervention programme.

The evaluation of Prevail has three components.
1. A questionnaire examining employees' qualitative evaluation of the Prevail-staff intervention programme. This evaluation will be delivered at the end of the Prevail-staff intervention programme to those in the active arm of the study. This questionnaire asks for no personal details and so responses will be anonymous. Completed questionnaires will be placed in a large post-box within the training room so that there is no way of identifying any individual.
2. Questionnaires relating to attitudes to mental health issues, and an employee's own mental health. The Stigma and Self-Stigma (SASS) questionnaire was a measure specially designed for this study (Docksey, Gray, Davies, and Snowden, submitted) and has been developed within the DVLA to include measures of personal stigma (cognitive and affective), self-stigma, avoidant coping, and help-seeking. It consists of 42 items that are answered on a 5-point Likert scale

(Strongly agree, agree, don't know, disagree, strongly disagree). Responses are used to construct six scales relating to mental health: stigma to others, anticipated stigma, self-stigma, help-seeking/disclosure, social distance, and avoidant coping style. In addition, it also contains a scale of social desirability not related to mental health attitudes in order to capture biased response style and those people with high levels of positive impression management. The researchers predict that rates of stigma to others, anticipated stigma, self-stigma, social distance, and avoidant coping style will be reduced, while rates of help-seeking behaviour will be increased, at both immediate follow up and at the 12-month follow-up for those in the Prevail active arm of the study. Measures of mental health are the Work and Social Adjustment Scale (WSAS; Mundt et al, 2002), which consists of five questions (e.g., "Because of my mental health, my ability to work is impaired") that are answered on an 8-point scale (0 indicates no impairment at all and 8 indicates very severe impairment); Generalised Anxiety Disorder assessment – 7 (GAD-7; Spitzer et al, 2006), in which participants rate how often they have been bothered by the seven symptoms of anxiety (e.g. trouble relaxing) over the past 2 weeks on a 4-point scale (not at all, several days, more than half the days, nearly every day); Patient Health Questionnaire-9 (PHQ-9; Kroenke et al, 2001), which is a 9-item depression scale based on the diagnostic criteria for major depressive disorder in which participants rate how often they have been bothered by the nine symptoms of depression (e.g. "Little interest or pleasure in doing things?") over the past 2 weeks on a 4-point scale (not at all, several days, more than half the days, nearly every day); and K6 screening for serious mental health in the general population (Kessler et al, 2003). The K6 non-specific distress scale screens for severe mental distress. The K6 was developed with the aim of being sensitive to the upper 90-99th percentile of the population distribution of mental distress (irrespective of diagnosis), measuring mental distress over a period of 4 weeks prior to administration. Participants self-report 6 symptoms: felt nervous, hopeless, restless and fidgety, worthless, depressed, and that everything was an effort. Each question is rated on a scale of 'none of the time, a little of the time, some of the time, most of the time, all of the time' (with scores of 0-4 being awarded to each respectively). Responses to the 6 items are summed to yield a K6 score of 0-24. Severe mental distress is defined as a K6 score of >= 13. Prochaska et al (2012) have also used the K6 for identifying mental distress as a moderate level that still impacts functioning and necessitates treatment. A K6 cut score of >=5 was found to be the optimal score for identifying respondents with mental health treatment needs based upon a moderate level of distress, with little variance in ethnic group. The K6 has been found to be a useful screening tool in primary care settings (Kessler et al, 2002) and as a screening for serious and moderate levels of mental disorder in the general population. It has been found that levels of greater mental distress are reported by the younger members of the population and by women (Prochaska et al, 2012). The EQ-5D-5L (Herdman et al. 2011) is a generic measure of quality of life. It can be used to measure an individual's quality of life and changes in this due to intervention programmes targeting physical or mental health. It is based on a descriptive system that defines health in terms of 5 dimensions: Mobility, Self-Care, Usual Activities, Pain /Discomfort, and Anxiety/ Depression. Each dimension has 3 response categories corresponding to no problems, some problems, and extreme problems. Respondents also rate their overall health on the day of completion on a scale of 0–100 vertical visual analogue scale (EQ-VAS). The research team will also assess self-reported presenteeism and absenteeism based on the World Health Organization (WHO) Health and Work Performance Questionnaire (HPQ; Kessler et al, 2003). This measures a person's typical work performance and how this compares to an average person doing the same job.

These questionnaires will be given to employees in the active arm of the study on three occasions:

2.1. Prior to the commencement of the Prevail intervention programme

2.2. 1-4 weeks post-delivery of Prevail

2.3. 12 months follow-up after the delivery of Prevail

Employees in the control arm of the study will be yoked to the active group and will also

complete these questionnaires at the same three intervals (although they will not receive the Prevail intervention programme). Prevail train-the-trainers administer and collect the questionnaire measures with groups of staff who are invited to a testing session, but are blind to which arm of the intervention each group of staff belong. The questionnaires are colour-coded (red and blue) to identify which staff are in the active group and which are in the control group, but the staff administering the questionnaires are blind to which is which. Completion of the questionnaires is voluntary and we will obtain written informed consent from all participants in the study. All responses will be anonymous. Completed questionnaires will be placed in a large post-box so that there is no way of identifying any individual. However, in order to track individuals from one stage of the study to the next we will ask participants to produce a 'code' that will be written on all completed questionnaires. This code is produced by the name of their first pet, the name of their primary school, and the day-date of their birthday (e.g. 21 for someone born 21st January 1964). Thus, a person's code may be Wobble Glenbrooke 21. This code allows us to track participants across the 3 waves of the study while preserving anonymity.
3. Data related to sickness absence over the 12 months prior to Prevail and 12 months post-Prevail will be extracted from the organisation's sickness absence records for those in both arms of the RCT. Data extraction will be performed by Human Resources staff at the DVLA for both the active and the control group. All personal identifiers will be removed before this data is transferred to the research team at Swansea University. Only group data will be provided with group sizes always being of at least N = 10 (e.g. females working in the contact centre over the age of 50). Data will not be extracted from people who move from an active to a control work-based team (or vice versa) during the 12-month follow-up period. The researchers predict that rates of sickness absence overall will be reduced for those in the Prevail arm of the study during this follow-up period in comparison to the control arm. Types of absence will be classified according to physical or mental health reasons. We predict that mental health problems may not be reduced by the Prevail intervention due to greater disclosure of mental health reasons of absence (related to reduced stigma and self-stigma, and enhanced help-seeking). However, we predict that physical health problems will decrease due to people now correctly reporting the real reason for their absence (i.e., mental rather than physical health) and a possible reduction in actual mental health problems.

Intervention Type
Behavioural

Primary outcome measure
1. Attitudes to mental health assessed using the Stigma and Self-Stigma scale (SASS) at baseline (before delivery of the Prevail programme), 1-4 weeks after Prevail delivery and 12 months after Prevail delivery
2. Rates of absenteeism during the 12 months prior to Prevail and 12 months post-Prevail will be extracted from the organisation's sickness absence records

Secondary outcome measures
1. Work performance assessed using the Health and Work Performance Questionnaire (HPQ).
2. Impairment in functioning due to a common mental disorder assessed using the Work and Social Adjustment Scale (WSAS)
3. Symptoms of general anxiety assessed using the General Anxiety Disorder Assessment (GAD-7) measures
4. Depression severity assessed using the Patient Health Questionnaire (PHQ-9)
5. Mental distress assessed using the Kessler Psychological Distress Scale (K6)
6. Quality of life assessed using the EQ-5D-5L questionnaire

All secondary outcome measaures will be assesed at at baseline (before delivery of the Prevail programme), 1-4 weeks after Prevail delivery and 12 months after Prevail delivery.

Overall study start date
01/02/2018

Completion date
30/04/2021

Eligibility

Key inclusion criteria
Employees of DVLA in divisions of Information Technology Services (ITS), Contact Centre (CC), Case work and Enforcement (CAEG), and Input Services Group (ISG).

Participant type(s)
Employee

Age group
Adult

Sex
Both

Target number of participants
We will initially approach 80 managers and approximately 960 employees to take part in the study. We anticipate around 30% non-completion of the study (due to absences, moving teams, leaving DVLA, refusal to consent to participate, etc.) which will leave us with a sample of approximately 672 participants (336 per arm of the study).

Total final enrolment
1051

Key exclusion criteria
Not selected to take part in the Prevail intervention programme

Date of first enrolment
01/10/2019

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Driver and Vehicle Licensing Agency
Long View Road
Morriston
Swansea
United Kingdom
SA6 7JL

Sponsor information

Organisation
Swansea University

Sponsor details
Singleton Campus
Swansea
Wales
United Kingdom
SA2 8PP
+44 (0)1792 513100
researchintegrity@swansea.ac.uk

Sponsor type
University/education

Website
http://www.swansea.ac.uk/

Funder(s)

Funder type
Government

Funder Name
Driver and Vehicle Licensing Agency

Results and Publications

Publication and dissemination plan
Data from the RCT will be disseminated via publication in scientific journals. The protocol for the study will also be published prior to completion of data collection.

Intention to publish date
21/10/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		01/05/2020	15/05/2020	No	Yes
Protocol article		09/06/2020	14/06/2023	Yes	No
Results article		10/07/2023	11/07/2023	Yes	No