An Acceptance and Commitment Therapybased workplace intervention for improving wellbeing of NHS staff

Submission date 11/07/2018	Recruitment status No longer recruiting	Prospectively registered		
		[X] Protocol		
Registration date 20/07/2018	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 23/08/2023	Condition category Injury, Occupational Diseases, Poisoning	[X] Individual participant data		

Plain English summary of protocol

Background and study aims

Changes in the organisation and the management of health care provision in the UK, coupled with the nature of medical practice have increased the experience of stress, burnout and poor psychological wellbeing in health professionals. These high levels of distress are likely to have implications for patient care and for the health professionals' health and wellbeing. As a result, workforce surveys in the UK suggest that 25-40% of workers in a variety of occupations meet the criteria for a mental health disorder.

These findings show the importance of implementing and evaluating interventions that have the potential to improve mental health in the workplace, particularly within the NHS. To prevent and reduce distress among employees, researchers have begun developing methods to help better cope with stress, such as Acceptance and Commitment Therapy (ACT). ACT is different from more traditional stress management approaches, as it does not seek to reduce employees' unwanted thoughts and emotions. Indeed, ACT promotes a willingness to experience pleasant and unpleasant psychological events and encourages the acceptance of negative thoughts and emotions.

This study aims to determine the effectiveness of a group-based ACT training programme for improving well-being, reducing burnout and improving patient safety in NHS primary care staff.

Who can participate?

Employees of the NHS West Yorkshire and Humber currently at work.

What does the study involve?

Participants will be allocated to either an intervention group or a control group. The intervention group will receive ACT psychological training, whereas the control group will be on a waiting list and receive ACT training later.

ACT training will involve four two-hour workshops on consecutive weeks, designed to increase awareness of how to manage unwanted thoughts and emotions, improve mindfulness and clarify personal values.

Participants in both groups will complete questionnaires relating to wellbeing, burnout and psychological flexibility four times - before starting the intervention period, 1 week into the

intervention, after 4 weeks (end of the ACT training) and at a 14 week follow-up. Participants in the control group will complete the questionnaires at the same time as those in the intervention group, but begin their ACT training after the follow-up period is complete.

What are the possible benefits and risks of participating?

A benefit of taking part in this study is that participants will receive free four-week ACT training that may improve wellbeing and reduce burnout. In addition, participants will be contributing to important research that may yield benefit to the wider NHS workforce. There are no known risks to participants of taking part

Where is the study run from? NHS Leeds West CCG, Leeds

When is the study starting and how long is it expected to run for? July 2017 to December 2018

Who is funding the study?

- 1. NHS Leeds West CCG (UK)
- 2. University of Leeds (UK)
- 3. Bradford Institute for Health Research (UK)

Who is the main contact? Miss Arianna Prudenzi psap@leeds.ac.uk

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 228214

Study information

Scientific Title

An Acceptance and Commitment Therapy-based workplace intervention for improving well-being and reducing burnout in NHS staff

Study objectives

- 1) Compared to a wait-list control group, those receiving ACT will have significantly better scores on primary and secondary outcome measures at post-intervention time-points.
- 2) Improvements in outcomes will be mediated by improvements in psychological flexibility and mindfulness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Research Ethics Administrator, 21/09/2017, 18/HRA/0200 School of Psychology Research Ethics Committee, 22/07/2017, 17-0212

Study design

Interventional single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Wellbeing and occupational burnout

Interventions

NHS staff participants will be randomised into two groups, an intervention and control group, by independent primary care managers following a randomisation schedule using an online randomisation tool. Details of the allocated groups were then sent to participants by email by independent NHS CCG staff to ensure allocation concealment.

Acceptance and Commitment Therapy (ACT; Hayes, 1987; Hayes, Strosahl, & Wilson, 1999) is a newer type of cognitive behaviour therapy, specifically designed to improve psychological flexibility (PF). The intervention will be based on an existing standardised ACT protocol designed for workplace settings described by Flaxman and Bond (2006; see also Flaxman & Bond, 2010a; Flaxman et al., 2013).

Participants will be invited to attend four two-hour group sessions. The four-week workshop will be delivered to 10 -15 participants and will occur on four consecutive weeks. It will be facilitated by three experienced mindfulness teachers who are either on the national register or who comply with the Good Practice Guidelines.

Within the workshop, participants will be introduced to different techniques that are designed to: (1) increase their awareness of how they manage unwanted thoughts and emotions; (2) equip them with mindfulness skills (3); help them to clarify their own personal values and to enact behaviours that are consistent with these values. To do this the intervention will also include two of ACT's well-known metaphors (passengers on the bus and the polygraph metaphor (Hayes, Strosahl, & Wilson, 1999)). Participants will be invited to follow-up homework activities. Trainers will be supervised by an expert Clinical Psychologist (CG).

Those allocated to the waiting list control will receive an ACT training later. These participants will complete the questionnaire at four time measurements in parallel to the experimental group but start their training after the follow-up measures are being completed and returned.

Intervention Type

Behavioural

Primary outcome measure

General well-being and mental health measured using the GHQ-12 (Goldberg & Williams, 1988) at the baseline, one-week after beginning the intervention, after 4 weeks and at the 14 week follow up.

Secondary outcome measures

- 1. Burnout measured using the Shirom-Melamed Burnout Measure (SMBM; Shirom, 2003; Shirom & Melamed, 2006).
- 2. Work-related worry and rumination during non-work time using the Affective Rumination Subscale of the Work-related Rumination Questionnaire (WRRQ; Cropley, Michalianou, Pravettoni, & Millward, 2012).
- 3. Patient safety measured using items from Louch et al. (in press; 2016).

Process of change measures:

- 4. Psychological flexibility measured using the Multidimensional Experiential Avoidance Questionnaire (MEAQ) Distress Endurance subscale (Gamez et al., 2011).
- 5. Mindfulness measured using the 15-item Five Facet Mindfulness Questionnaire (Gu et al., 2016; Baer et al., 2006, 2008).
- 6. Values measured using the Valuing Questionnaire (VQ; Smout et al. 2014).
- 7. Self-Compassion measured using the Self-Compassion Scale short-form (SCS-SF; Raes et al., 2011).

Overall study start date

01/07/2017

Completion date

30/06/2019

Eligibility

Key inclusion criteria

- 1. NHS staff
- 2. Working in Leeds, West Yorkshire and the Humber
- 3. Aged 18 years or older

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Based on sample sizes from other ACT studies in similar settings (e.g., Waters et al., 2018; Flaxman & Bond, 2010; Flaxman et al., 2016).

Total final enrolment

98

Key exclusion criteria

There will also be one exclusion criterion: not presently at work.

Date of first enrolment

01/09/2017

Date of final enrolment

01/08/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

NHS CCG Leeds

NHS Leeds Clinical Commissioning Group Suites 2 – 4, Wira House Wira Business Park Leeds LS16 6EB Leeds United Kingdom LS16 6EB

Sponsor information

Organisation

University of Leeds

Sponsor details

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Sponsor type

University/education

Website

https://www.leeds.ac.uk/

ROR

https://ror.org/024mrxd33

Funder(s)

Funder type

Not defined

Funder Name

University of Leeds

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

NHS Leeds Clinical Commissioning Group

Funder Name

Bradford Institute for Health Research

Results and Publications

Publication and dissemination plan

Aligning with research best practice, the plan to report or disseminate results include publication in peer-reviewed journals. In line with open science initiatives we will, after an embargo period of three years, store the anonymised data within the University of Leeds research data repository (https://library.leeds.ac.uk/news/article/210/research_data_leeds_repository).

Intention to publish date

31/10/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository (https://archive.researchdata.leeds.ac.uk) as anonymised data after an embargo period of three years. Aligning with research best practice, we will store anonymised data on the Leeds University of Leeds research data repository for a longer period of time (5 years). This data will not be shared for an embargo period of three years. Only the research team (O'Conner, Graham, and Arianna Prudenzi) will have access to person identifiable data safely stored on a University-issued password protected computer. The data will be collected from the questionnaire answers given on Bristol Online Surveys and will kept completely anonymous. Participants will be only identified using their unique ID number.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	13/09/2018	02/04/2019	No	Yes
<u>Dataset</u>		21/01/2022	22/04/2022	No	No
Results article		20/04/2022	22/04/2022	Yes	No
Protocol (other)			23/08/2023	No	No