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STOP: The staff smoking project

Submission date
10/02/2020

Recruitment status
No longer recruiting

Registration date
21/02/2020

Overall study status
Completed

Last Edited
31/08/2022

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The proportion of smokers in and around Portsmouth is significantly higher than the national average. It is estimated that 20% of the staff working at Portsmouth Hospitals currently smoke. The Royal College of Physicians have reported that a smoking member of staff costs the NHS £2,800 a year due to illness absence, smoking breaks and seeking NHS care for smoking related diseases. It is also well known that staff smokers are less likely to approach patients about smoking cessation, and patients are less likely to respond to a member of staff who currently smokes.

Therefore by helping to support NHS staff to stop smoking, the researchers can also impact the care of patients.

To achieve this we have designed a new smoking cessation programme. It is a mixture of one to one and group sessions and underpinned by pharmacotherapy, all of which will be accessible on the hospital site in line with NICE guidance. The researchers now need a feasibility study to test whether this is effective compared to standard care, which is self-referral to a smoking cessation service. The researchers will also be assessing the health economic aspect of the study, to ensure that the investment is providing positive financial results.

Who can participate?
Staff at Queen Alexandra Hospital, Portsmouth, aged 18 years or above, who are current smokers.

What does the study involve?
The study aims to compare the ‘new programme’ to the smoking cessation support that we are currently offering (‘standard care’). Participants will be randomly allocated to the ‘standard care’ group or the ‘new programme’ group.
Information such as age, other medical problems and information about smoking history will be collected. All participants will be asked to complete questionnaires at baseline 4, 12 and 24 weeks. After 12 weeks, participants will be asked to attend a small focus group or a one-to-one interview so that participants can give their views and opinions about how effective different parts of the study were and what made the most difference. Standard care refers to the smoking cessation services that we currently offer to Staff at QAH. This will involve speaking to a trained member of the study team and being advised of local stop smoking services that are available.

After 6 months, if participants of this group and have been unsuccessful in stopping smoking, they will be offered the opportunity to take part in the new programme. The new programme is made up of several parts. After the first appointment, participant consent and demographics will be taken. The research team will arrange for an appointment with Occupational Health, to introduce the programme. They will discuss different types of Nicotine Replacement Therapy (NRT) including patches and mist or Champix. There will then be an invitation to attend a meeting each week for 3 weeks, followed by another one-to-one, and this cycle will continue for 3 rounds (over 12 weeks). The meetings will be run by the occupational health team with support from local smoking cessation services. They will be informal, and discussion is encouraged, and they will loosely focus on topics which are important to think about during a quit attempt.

What are the possible benefits and risks of participating?
The aim of the project is to support as many staff members as possible to stop smoking. If this is successful, the programme will help many more members of staff to quit smoking, as well as possibly staff in other hospitals and in the community.
We do not anticipate any risks from the programme. Nicotine Replacement Therapy and Champix have side effects but participants will be counselled about these before they are dispensed.

Where is the study run from?
Queen Alexandra Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2019 to June 2020

Who is funding the study?
RESPIACTION CIC (UK)

Who is the main contact?
Prof Anoop Chauhan
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Contact information

Type(s)
Scientific

Contact name
Prof Anoop Chauhan

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42146

Study information

Scientific Title
A randomised feasibility study comparing a novel intervention for smoking cessation in NHS staff to standard care

Acronym
STOP

Study objectives
The staff smoking project intervention will be feasible to deliver in a population of NHS staff.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2019, Health Research Authority (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 19/HRA/2778

Study design
Interventional randomized controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Smoking cessation to prevent respiratory disease in hospital staff

Interventions
The researchers will initially recruit 50 people to the study. Participants will be randomised to either standard care, or to receive our help to quit program. The researchers will advertise the study through our internal communications via email, on the intranet and on the hospital social media. The study will only be available to any Portsmouth Hospital Trust staff member working at the Queen Alexandra site. All participants will have a chance to consider participation in the trial and will be asked to consent to their involvement. Information sheets will be given to the participants with time to ask questions and to decide whether they want to participate in the study. Participants are under no obligation to take part in the study and it will not affect their usual care. Those who are randomised to standard care will be offered the opportunity to receive the intervention at 6 months, if it has been shown to be successful. Both groups will be consented by the research team and independently randomised to either the intervention group or the standard care group. All participants will be asked to complete a set of standard questionnaires before the start of the trial, midway through the trial(4 weeks) and at 12 and 24 weeks. The Intervention Following informed consent, the participant will have a 1:1 meeting with a smoking cessation counsellor to discuss their individual requirements for smoking cessation and be offered their choice of pharmacological intervention. They will be provided with their choice of pharmacotherapy immediately. They will then be invited to attend a group session, where they will have some brief lung function tests and check carbon monoxide levels. Participants will be offered refreshments and receive a bespoke group session to address various aspects of smoking cessation. Group sessions will then take place every week, with every 4th session being an individual meeting. There will be multiple options for times each week to make sure that all participants can attend. There will be a total of 9 group sessions and 4 individual meetings (including the start and close meetings). At 4 weeks, participants will repeat the questionnaires that they answered initially. After 12 weeks, participants will be invited to take part in interviews or focus groups to establish whether they have maintained a successful quit, and to gather information about which aspects of the intervention they found most useful, in order to inform future studies. Participants will also repeat the questionnaires at 12 and 24 weeks. Standard Care Participants who are randomised to the standard care arm will receive very brief advice (VBA) and signposting to local organisations to support a quit. They will also answer questionnaires at 4, 12 and 24 weeks, and be asked to take part in interviews or focus groups after 12 weeks. After 6 months they will be offered the opportunity to receive the intervention, should they wish.

Intervention Type
Behavioural

Primary outcome measure
1. Study process indicators measured by:
1.1. The recruitment and retention rate
1.2. Process indicators measured by completion rates of outcome questionnaires and assessments
2. Qualitative outcomes measured by participants' perceptions of the study, the intervention, including ease of attendance to group meetings and acceptability of the intervention
3. Clinical and behavioural outcomes measured by:

3.1. Number of smokers who achieved a successful quit measured at 4 weeks, 12 weeks and 6 months – smoking status Fagerstrom Test for Nicotine Dependence (FTND)
3.2. Spirometry at weekly intervals
3.3. Intention to stop smoking at baseline, 4, 12 and 24 weeks – intention to quit smoking questionnaire
3.4. Smoking behaviours at baseline, 4, 12 and 24 weeks – smoking specific compensatory health beliefs questionnaire
3.5. Smoking self efficacy at baseline, 4, 12 and 24 weeks – self efficacy to quit smoking questionnaire
3.6. Smoking self quality of life at baseline, 4, 12 and 24 weeks – quality of life questionnaire
3.7. Change in exercise behaviour at baseline, 4, 12 and 24 weeks – international physical activity questionnaire (short form)
3.8. Change in alcohol behaviour at baseline, 4, 12 and 24 weeks measured in units per week
3.9. Change in weight and BMI at baseline, 4, 12 and 24 weeks
4. Cost effectiveness outcomes measured by:
4.1. Number of sick days in the 6 months prior to intervention
4.2. Number of sick days during the intervention
4.3. Time spent away from the work place in the 6 months prior to the intervention (hours)
4.4. Time spent away from the work place during the intervention (hours)
4.5. Number of attendances at other NHS services seeking medical help for smoking related conditions

Secondary outcome measures
n/a

Overall study start date
16/12/2018

Completion date
10/06/2020

Eligibility

Key inclusion criteria
1. Male or Female, aged 18 years or over
2. Willing and able to give informed consent for participation in the study.
3. Must work for PHT at QAH and be able to attend weekly meetings for the duration of the study period
4. Must be a current smoker

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
Unable to comprehend the study and provide informed consent e.g. insufficient command of English in the absence of someone to adequately interpret.

Date of first enrolment
29/05/2019

Date of final enrolment
30/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Alexandra Hospital
Cosham
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

Sponsor details
De La Court House
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Southwick Hill Road
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+44 (0)2392286236
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Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Charity

Funder Name
RESPIACTION CIC

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The de-identified ‘raw data’ will be held on Portsmouth Hospitals NHS trust servers. The type of data that will be available after de-identification will be text, tables, figures. The data will be available at the beginning and ending 12 months after the article publication. Data will be available to researchers who provide a sound proposal – these should be directed to Anoop.chauhan@porthosp.nhs.uk for access and requestors will be to sign a data sharing agreement.

IPD sharing plan summary
Stored in repository