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# A training and service intervention to optimise pharmacist-based treatment for smoking cessation

**Submission date**
26/03/2018

**Recruitment status**
No longer recruiting

**Registration date**
03/04/2018

**Overall study status**
Completed

**Last Edited**
14/11/2024

**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
Community pharmacists and smoking cessation advisors are currently experiencing a rapid expansion of their role providing front line services for the NHS. This is a direct result of policy which identifies pharmacies as being an easily accessible and cost effective platform for delivering health care. Smoking cessation is one of the earlier tasks given to pharmacists /smoking cessation advisers. While a large number of people who smoke passing through the NHS Stop Smoking Programme (NHS SSP) quit, a significant number of people do not. To date there has been very little research to find out the best ways of helping people to stop smoking in community pharmacies. This study tests whether a service improvement and training programme (called the STOP intervention) for pharmacy staff will improve the uptake and reduce dropouts in the NHS Stop Smoking Programme and improve quit rates.

Who can participate?
Current smokers aged 18 and over

What does the study involve?
The participating community pharmacies are randomly allocated to either the STOP intervention or to usual practice. STOP involves training for pharmacy staff and associated study materials (e. g. badges, posters). Usual practice involves only NCSCT training (Level 1 or Level 2 depending on staff experience). Smoker recruitment into the NHS stop smoking programme and quit rates are assessed at 4 weeks and continuous abstinence is assessed at 6 months.

What are the possible benefits and risks of participating?
Participating may improve smoker quit rates. There is no risk for those taking part in the study.

Where is the study run from?
1. 29 pharmacies recruited from the following five boroughs in London: Tower Hamlets, Newham, City & Hackney, Islington, Barking & Dagenham (UK)
2. 19 pharmacies recruited from Coventry (UK)
3. 12 pharmacies recruited from Wales (UK)

When is the study starting and how long is it expected to run for?
May 2017 to August 2019

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

Who is the main contact?
Wai Yee James

# Contact information

### Type(s)
Scientific

### Contact name
Ms Wai Yee James

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
33564

# Study information

### Scientific Title
A training and service intervention to optimise pharmacist-based treatment for smoking cessation: a cluster randomised controlled trial

### Acronym
STOP

### Study objectives

Community pharmacists or smoking cessation advisors are currently experiencing a rapid expansion of their role providing front line services for the NHS. This is a direct result of policy which identifies pharmacies as being an easily accessible and cost effective platform for delivering health care. Smoking cessation is one of the earlier tasks given to pharmacists /smoking cessation advisers. While a large number of people who smoke passing through the NHS Stop Smoking Programme (NHS SSP) quit, a significant number of people do not. To date there has been very little research to find out the best ways of helping people to Stop Smoking in community pharmacies.

This study (called the STOP study) will test whether a service improvement and training programme (called the STOP intervention) for pharmacy staff (pharmacists who are smoking cessation advisers and other pharmacy support staff e.g. counter assistants who might not be trained in smoking cessation) in community pharmacies will improve the uptake and reduce dropouts in the NHS Stop Smoking Programme and improve quit rates. The STOP intervention has been developed through a systematic review of community pharmacy based interventions, a detailed qualitative study (REC ref 13/SC/0189), and refined following a pilot study (REC ref 14 /LO/2162). The trialists will now test the STOP intervention in 60 community pharmacies in North East London, South London (Southwark and Lambeth), Warwick and South East Wales to see whether the intervention is effective and cost-effective in improving the uptake and reducing dropout in the NHS SSP and thereby improving quit rates.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South Central - Hampshire A Research Ethics Committee, 03/04/2017, ref: 17/SC/0067

## Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Complex Intervention

## Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
See additional files

## Health condition(s) or problem(s) studied
Specialty: Primary care, Primary sub-specialty: Public Health; UKCRC code/ Disease: Other/ General symptoms and signs

## Interventions

The STOP trial is a pragmatic, cluster randomised controlled trial to assess the effect of the intervention on smoker recruitment into the NHS stop smoking programme and quit rates at four weeks and continuous abstinence at six months.

The community pharmacies (the cluster level) will be randomised to STOP training and service optimization intervention arm or usual care using stratified randomisation. The randomisation will be at the pharmacy level with 1:1 allocation ratio.

Intervention
STOP is a complex intervention based on behavioural theory involving training for pharmacy staff and associated study materials (e.g. badges, posters). The intervention training focuses on team approach in delivering the NHS STOP smoking service.

Usual practice
The National Centre for Smoking Cessation and Training (NCSCT) offers a range of training, assessment and certification programmes for both clinical and non-clinical health and social care workers to become more skilled in smoking cessation. Control pharmacies will only receive NCSCT training (Level 1 or Level 2 depending on staff experience).

## Intervention Type
Other

## Primary outcome measure
Throughput, defined as number of smokers who join the NHS SSP, attend a treatment session and set a firm quit date i.e. a 'treated smoker' (TS)

## Secondary outcome measures
Secondary outcomes:
1. 4 week retention rate, defined as proportion of treated smokers retained at 4 weeks i.e. a treated smoker is counted as 'lost to follow up at 4-weeks' (LFU4W) if, on attempting to determine the 4-week quitter status s/he cannot be contacted
2. 4 week quit rate, defined as proportion of smokers who quit smoking at 4 weeks from set quit date i.e. a 'CO-verified 4-week quitter'
3. Continuous abstinence rate, defined as proportion of smokers who quit at 4 weeks (CO-verified) and remained so at 6 months
4. Effect of the training intervention on additional (routine) data provided by the consented service users

Process outcomes:
5. Satisfaction about the NHS SSP via questionnaire
6. Self-efficacy in smoking cessation delivery via questionnaire
7. Study recruitment and retention rates of pharmacies and pharmacy staff, reasons for non-participation and dropout, service user consent/recruitment rates for additional data collection and retention rates
8. Intervention training attendance and completion rates, reasons for non-attendance and dropout
9. Acceptability of intervention training and delivery in practice via questionnaire
10. Delivery of skills in practice at the pharmacy counter around engagement of service users into the NHS SSP via simulated client using checklist
11. Skills around retention of service users in pharmacy consultation room via audio-recording of consultations

12. Views and experiences about the STOP training and its delivery in practice
13. Views and experiences about the NHS SSP with a focus on engagement and retention, reasons for completion and non-completion of the NHS SSP

Health economic outcomes:
1. Cost data from advisers: time spent (in minutes) by advisers on smoker service user delivering the NHS SSP and taking individual consent for STOP study additional data collection procedures and carrying out the data collection e.g. saliva samples
2. Cost data from study researchers: cost of delivery of training to pharmacy staff and costs associated with delivery of training such as travel expenses, refreshments, room hire, use of printed materials, use of assistive technology; provision of financial incentive; attending feedback meeting with trainer

### Overall study start date
15/05/2017

### Completion date
01/08/2019

## Eligibility

### Key inclusion criteria
NHS SSP eligibility criteria:
1. Current smokers aged 18 and above
2. All types of smoking (cigarettes, cigar, pipe)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 1320; UK Sample Size: 1320

### Total final enrolment
1272

### Key exclusion criteria
Exclusion criteria for community pharmacies and pharmacy staff:
1. Sites that lack the facilities for secure storage and transfer of the study data
2. Advisors who refuse GCP training

Exclusion criteria for service users who will be part of the study exploring individual participant level outcomes:
1. Non-smokers
2. Unable to understand the STOP study service user information sheet and consent form
3. Unable/unwilling to give written informed consent for STOP study additional data collection procedures for detailed analysis

Note: The risks and benefits of nicotine replacement need to be explained to pregnant or breastfeeding women and to people who have unstable cardiovascular disorders according to usual practice in the NHS Stop Smoking Service. Neither varenicline nor bupropion should be offered to pregnant or breastfeeding women. Varenicline or bupropion may be offered to people with unstable cardiovascular disorders, subject to clinical judgement https://www.nice.org.uk/guidance/PH10/chapter/1-Key-priorities

### Date of first enrolment
30/05/2017

### Date of final enrolment
03/01/2019

## Locations

### Countries of recruitment
United Kingdom

### Study participating centre
**29 pharmacies recruited from the following five boroughs in London: Tower Hamlets, Newham, City & Hackney, Islington, Barking & Dagenham**
United Kingdom
-

### Study participating centre
**19 pharmacies recruited from Coventry**
United Kingdom
-

### Study participating centre
**12 pharmacies recruited from Wales**
United Kingdom
-

## Sponsor information

### Organisation
Queen Mary University of London

### Sponsor details
c/o Dr Sally Burtles
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### Sponsor type
University/education

### ROR
https://ror.org/026zzn846

## Funder(s)

### Funder type
Government

### Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0609-10181

## Results and Publications

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

### Intention to publish date
01/08/2020

### 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.

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Participant information sheet | version V1.3 | 21/03/2017 | 03/04/2018 | No | Yes |
| Participant information sheet | version V1.3 | 21/03/2017 | 03/04/2018 | No | Yes |
| Results article | results | 19/05/2019 | | Yes | No |
| Results article | | 28/06/2022 | 28/06/2022 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Protocol article | | 10/06/2019 | 10/05/2024 | Yes | No |
| Other publications | Pilot study results | 10/01/2017 | 14/11/2024 | Yes | No |