Targeted case finding for chronic obstructive pulmonary disease versus routine practice in primary care (TargetCOPD)

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WEB EXTRA MATERIAL

Targeted case finding for COPD *versus* routine practice in primary care (TargetCOPD): a cluster randomised controlled trial

Table S1 Baseline characteristics of patients allocated to opportunistic and active arms†

	Active	Opportunistic
	All (n=15,378)	**All (n=15,387)**
Sex (male) n (%)	8,360 (54.4)	8,428 (54.8)
Age (Years) median (Q1, Q3)	55.0 (47.3, 65.2)	55.1 (47.4, 65.0)
Ethnicity n (%)		
White	8,637 (56.2)	8,535 (55.5)
Mixed	105 (0.7)	107 (0.7)
Asian	813 (5.3)	713 (4.6)
African Caribbean	448 (2.9)	482 (3.1)
Other	274 (1.8)	288 (1.9)
Missing	5,101 (33.2)	5,262 (34.2)
Smoking status n (%)		
Never smoker	3,015 (19.6)	2,974 (19.3)
Ex-smoker	6,594 (42.9)	6,592 (42.8)
Current smoker	5,568 (36.2)	5,609 (36.51)
Missing	201 (1.3)	212 (1.4)
Household link n (%)		
1	10,460 (68.0)	10,494 (68.2)
2	4,628 (30.1)	4,542 (29.5)
3 or more	290 (1.9)	351 (2.3)

†results exclude 22 randomised patients who withdrew their data

Table S2 Response rates by arm †

	Response n/N (%)	Total response: Practice level summaries		
		Mean (%)	Median (%)	Range (%)
All targeted	7781/30765 (25.3)	25.4	23.7	13.1-40.9
Response within arm				
Opportunistic	1973/15387 (12.8)	13.7	10.4	0.0-30.8
Active	5808/15378 (37.8)	37.2	37.4	22.3-53.5
Response by method within the active arm				
Postal	5042/15378 (32.8)	31.2	32.0	18.0-42.8
Non-postal	748/15378 (4.9)	5.9	5.0	0.0-20.8
Unknown	18/15378 (0.1)	0.2	0.0	0.0-2.7
Response by invite within the active arm				
Initial invite	2312/15378	13.7	12.6	6.8-25.7
First Reminder	1624/15378	10.6	10.7	5.6-16.0
Second Reminder	1086/15378	6.7	6.2	4.2-14.3
Unknown	20/15378	0.0	0.0	0.0-1.7

†results exclude 22 randomised patients who withdrew their data

Table S3 Characteristics of respondents†

Characteristics (self-reported)	Active (n=5,808)	Opportunistic (n=1,973)	All (n=7,781)
Age (years); median (Q1, Q3)	58.0 (49.4, 67.1)	59.4 (49.4, 68.3)	58.3 (49.4, 67.4)
Sex (male); n(%)	3,011 (51.8)	956 (48.5)	3,967 (51.0)
Ethnicity; n(%)			
White	4,710 (81.1)	1,568 (79.5)	6,278 (80.7)
Mixed	55 (1.0)	23 (1.2)	78 (1.0)
Asian	350 (6.0)	114 (5.8)	464 (6.0)
African Caribbean	229 (3.9)	44 (2.2)	273 (3.5)
Other	61 (1.1)	15 (0.8)	76 (1.0)
Missing	403 (6.9)	209 (10.6)	612 (7.9)
Smoking status; n(%)			
Never smoker	1,344 (23.1)	562 (28.5)	1,906 (24.5)
Ex-smoker	2,708 (46.6)	820 (41.6)	3,528 (45.3)
Current smoker	1,535 (26.4)	465 (23.6)	2,000 (25.7)
Missing	221 (3.8)	126 (3.4)	347 (4.5)
Pack years; median(IQR)	17.6 (7.5, 31.2)	18.0 (8.3, 30.7)	17.6 (7.6, 31.0)
General health; n(%)			
Very good/good	3,390 (58.4)	1,105 (56.0)	4,495 (57.8)
Fair	1,763 (30.4)	627 (31.8)	2,390 (30.7)
Very bad/bad	391 (6.7)	118 (6.0)	509 (6.5)
Unknown	264 (4.6)	123 (6.2)	387 (5.0)
Comorbidities (ever been told by physician)			
Asthma; n(%)	815 (14.0)	307 (15.6)	1,122 (14.4)
COPD/chronic bronchitis/emphysema; n(%)	287 (4.9)	70 (3.5)	357 (4.6)
Heart disease; n(%)	355 (6.1)	132 (6.7)	487 (6.3)
Heart failure; n(%)	115 (2.0)	38 (1.9)	153 (2.0)
Diabetes; n(%)	673 (11.6)	252 (12.8)	925 (11.9)
Stroke; n(%)	153 (2.6)	40 (2.0)	193 (2.5)
Depression; n(%)	1,042 (17.9)	334 (16.9)	1,376 (17.7)
Respiratory symptoms triggering an invite for spirometry:			
Dyspnoea (MRC 2+); n(%)	2,346 (40.4)	796 (40.3)	3,142 (40.4)
MRC grade 2; n(%)	2,277 (39.2)	763 (38.7)	3,040 (39.1)
MRC grade 3; n(%)	1,117 (19.2)	380 (19.3)	1,497 (19.2)
MRC grade 4; n(%)	698 (12.0)	244 (12.4)	942 (12.1)
MRC grade 5; n(%)	297 (5.1)	93 (4.7)	390 (5.0)
Chronic cough; n(%)	752 (13.0)	174 (8.8)	926 (11.9)
Chronic phlegm; n(%)	589 (10.1)	138 (7.0)	727 (9.3)
Wheezing; n(%)	2,272 (39.1)	717 (36.3)	2,989 (38.4)
Any of the above respiratory symptoms; n(%)	3,264 (56.2)	1,077 (54.6)	4,341 (55.8)

†results exclude 22 randomised patients who withdrew their data

Figure S1 CONSORT diagram: Cluster RCT

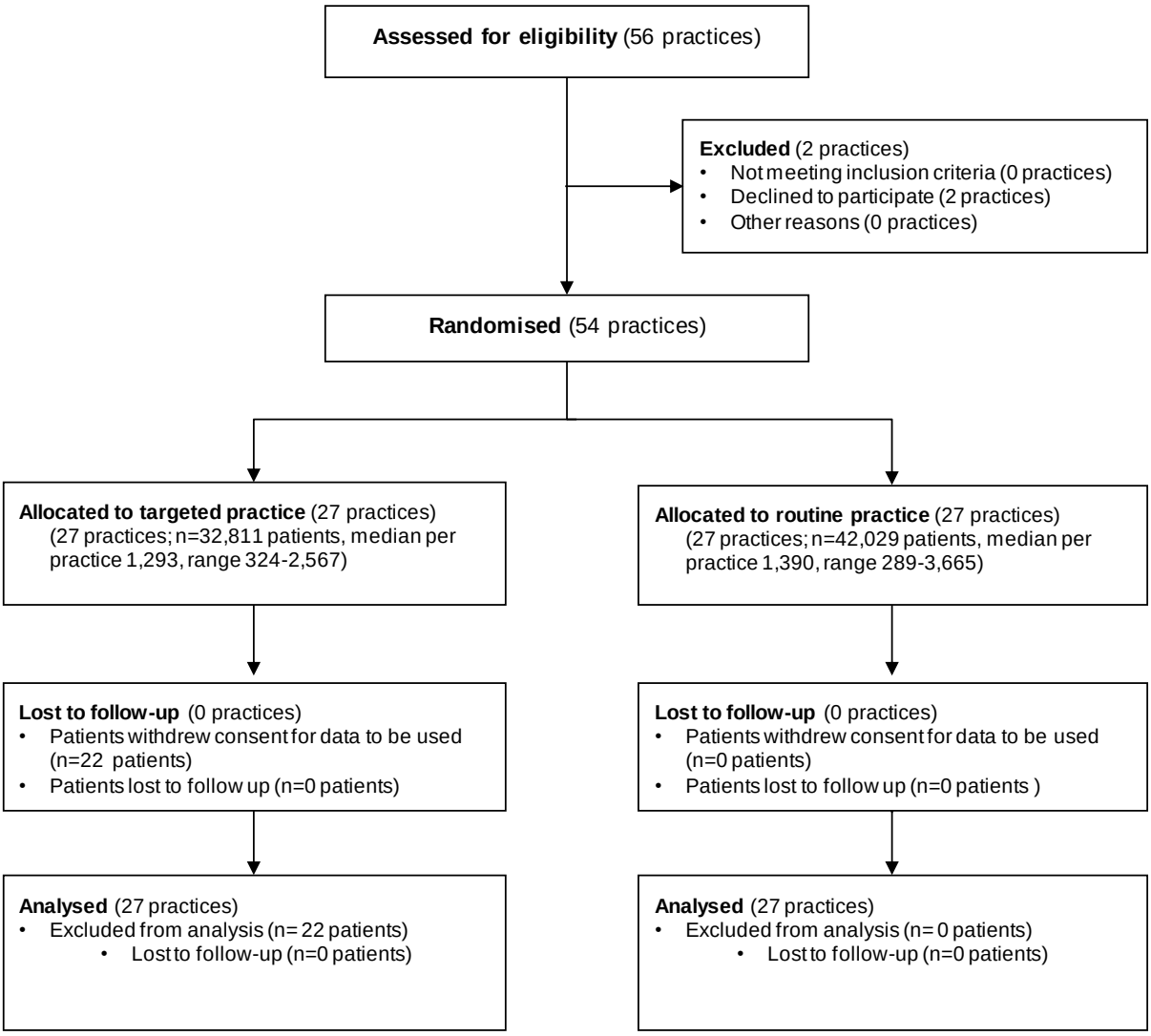
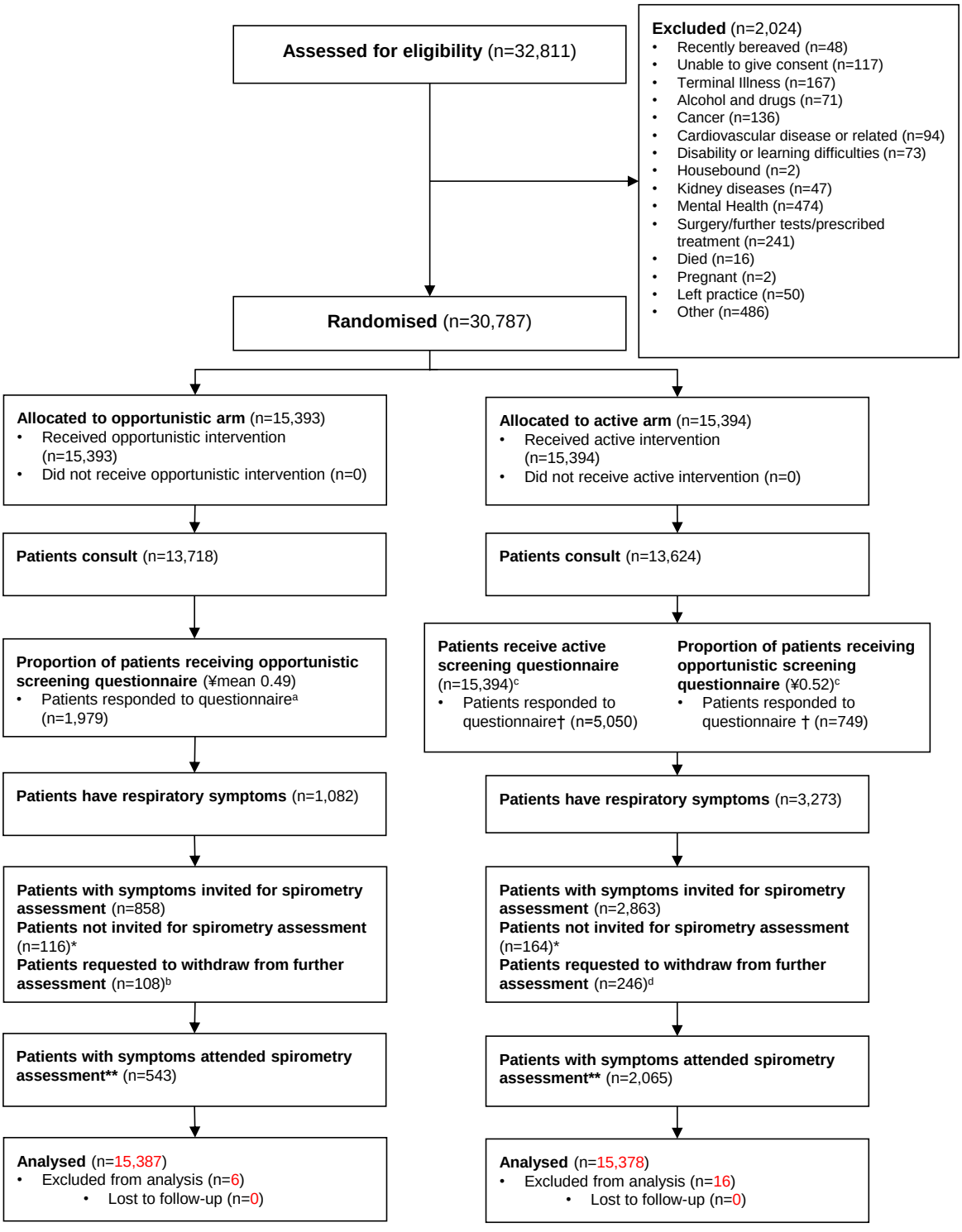
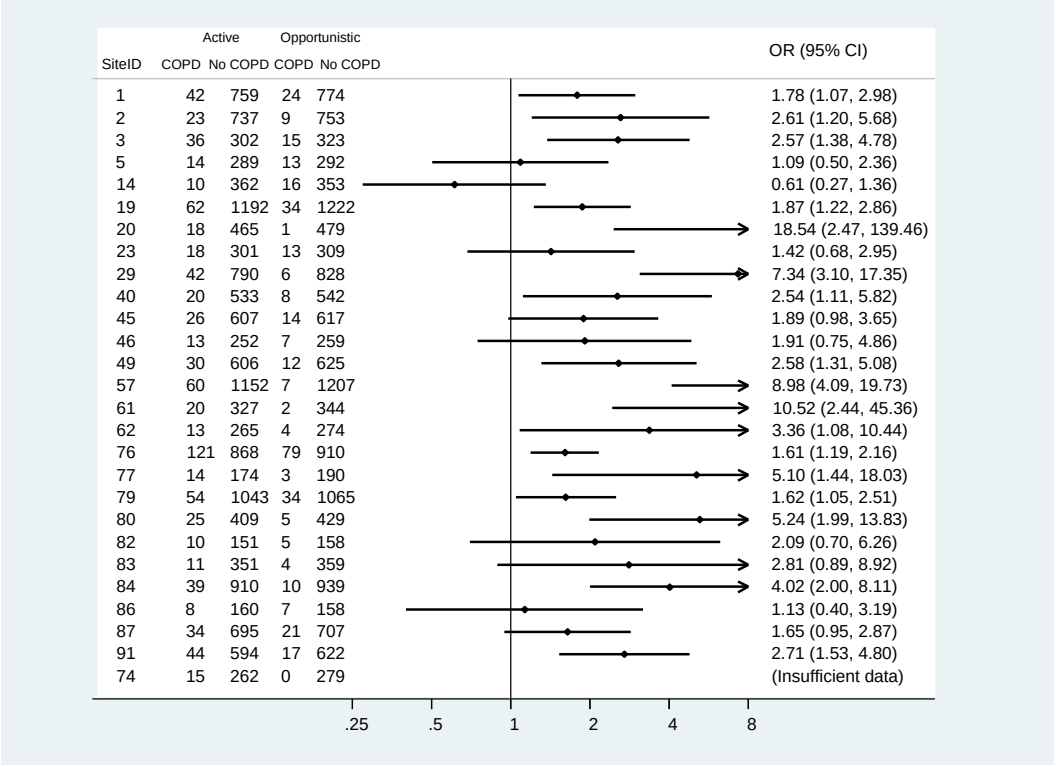


Figure S2 CONSORT diagram: nested RCT



¥Estimate from GP systems from flags remaining- NB it is a function of both given out or responded therefore flag removed
†18 questionnaire responses from active participants were received where it is not known if these were postal or opportunistic questionnaires.
a 1 patient without respiratory symptoms withdrew consent for use of all their data
b 5 patients with respiratory symptoms withdrew consent for use of all their data
c 7 patients withdrew consent for all their data without providing questionnaire data
d 8 patients with respiratory symptoms withdrew consent for use of all their data
e 1 patient withdrew consent for use of all their data after spirometry
*some patients did not provide contact information/not contactable
**some patients were invited for spirometry appointment in error (25 and 59 for the opportunistic and active arm respectively) and attended (18 and 43 for the opportunistic and active arm respectively). Spirometry data not included in the analysis.

Figure S3 Effect sizes by practice: active vs opportunistic case finding



Appendix 1

READ codes used for identifying COPD patients

Clinical system:EMIS Web and LV

H31	Chronic bronchitis
H32	Emphysema
H36	Mild chronic obstructive pulmonary disease
H37	Moderate chronic obstructive pulmonary disease
H38	Severe chronic obstructive pulmonary disease
H39	Very severe chronic obstructive pulmonary disease
H3A	End stage chronic obstructive airways disease
H3y	Other specific chronic obstructive airways disease
H3z	Chronic obstructive airways disease

Clinical system: System One

H3	COPD read codes in a cluster

READ codes used for identifying ever-smokers

Clinical system:EMIS Web and LV

1372	Trivial smoker - < 1 cigarette per day
1373	Light smoker - 1-9 cigarettes per day
1374	Moderate smoker - 10-19 cigarettes per day
1375	Heavy smoker - 20-39 cigarettes per day
1376	Very heavy smoker - 40+ cigarettes per day
1377	Ex-trivial smoker - < 1 cigarette per day
1378	Ex-light smoker - 1-9 cigarettes per day
1379	Ex-moderate smoker - 10-19 cigarettes per day
137A	Ex-heavy smoker - 20-39 cigarettes per day
137B	Ex-very heavy smoker - 40+ cigarettes per day
137C	Keeps trying to stop smoking
137F	Ex-smoker - amount unknown
137G	Trying to stop smoking
137H	Pipe smoker
137J	Cigar smoker
137K	Stopped smoking
137M	Rolls own cigarettes
137N	Ex-pipe smoker
137O	Ex-cigar smoker
137P	Cigarette smoker
137Q	Smoking started
137R	Current smoker
137S	Ex-smoker

137T	Date ceased smoking
137V	Smoking reduced
137X	Cigarette consumption
137Y	Cigar consumption
137Z	Tobacco consumption NOS
137a	Pipe tobacco consumption
137b	Ready to stop smoking
137c	Thinking about stopping smoking
137d	Not interested in stopping smoking
137e	Smoking restarted
137f	Reason for restarting smoking
137g	Cigarette pack-years

Clinical system:
System One

Ub0oo	Tobacco smoking behaviour

TargetCOPD POSTAL QUESTIONNAIRE TO PATIENTS

PATIENT ID_____

Thank you for taking the time to fill in this questionnaire. Your input is very valuable so please complete as many questions as you are able and return in the reply-paid envelope. Alternatively you may complete this form online at

https://www.pc-crtu.bham.ac.uk/Target

Please try to answer every question with the closest answer possible by ticking the appropriate box.

SECTION 1: YOUR LUNG HEALTH

1. (a) Do you usually have a cough (either during the day, or night, or first thing in the morning)?

   Yes ☐

   No ☐ **(If No, go to Q2)**

   (b) Do you usually cough like this on most days for 3 consecutive months or more during the year?

   Yes ☐ → If yes, for how many years have you had this cough? .....years

   No ☐

   (c) Does the weather affect your cough? Yes ☐ No ☐

2. (a) Do you ever cough up phlegm from your chest when you don't have a cold

   Yes ☐

   No ☐ **(If No, go to Q3)**

   (b) Do you usually bring up phlegm from your chest (either during the day, or night, or first thing in the morning)? Yes ☐ No ☐

(c) Do you bring up phlegm on most days for 3 consecutive months or more during the year?

Yes ☐ → If yes, for how many years have you had trouble with phlegm? ..... years

No ☐

3. Have you had wheezing or whistling in the chest in the past 12 months?

   Yes ☐ → If yes, how frequently do you wheeze?

   Occasionally ☐ More often ☐

   No ☐

4. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?

   Yes ☐ No ☐

5. Do you get short of breath walking with other people of your own age on level ground or have to stop for breath after about 15 minutes when walking at your own pace?

   Yes ☐ No ☐

6. Do you have to stop for breath after walking about 100m or after a few minutes on level ground?

   Yes ☐ No ☐

7. Are you too breathless to leave the house, or breathless while dressing or undressing?

   Yes ☐ No☐

8. Can you lie flat at night?

   Yes ☐

   No ☐ → If no, how many pillows do you need **in total**?.....

9. Do you have or have you had any allergies?

Yes ☐

No ☐ **(If No, go to Q11)**

10. If yes, what type of allergies? (tick any that apply)

Hay fever ☐ Eczema ☐ Skin allergies ☐ Allergic rhinitis (nose/eye symptoms) ☐

Food allergies ☐ Other ☐ (please specify)…….....……

11. Do you usually have a blocked or running nose? Yes ☐ No ☐

12. Over the last year has your breathing kept you from doing as much as you used to? Yes ☐ No ☐

SECTION 2: YOUR GENERAL HEALTH AND CIRCUMSTANCES

13. How would you describe your health in general?

Very good ☐ Good ☐ Fair ☐ Bad ☐ Very bad ☐

14. Has a doctor ever said you have (please tick any that apply):

Asthma	☐	High blood pressure	☐
COPD	☐	Diabetes	☐
Chronic bronchitis	☐	Stroke	☐
Emphysema	☐	Lung cancer	☐
Heart disease	☐	Tuberculosis	☐
Heart failure	☐	Depression	☐

Other medical condition (please specify)

……

15. Have you ever had a paid job?

Yes ☐ Please state the occupation you have been employed in most of your life

…….....

.....
.....

Please describe what you do/did in this job

…….....

.....……

……

……

……

No ☐

16. Have you ever worked in a job which exposed you to vapours, gas, dust or fumes?

Yes ☐

No ☐ **(If No, go to Q18)**

17. If yes, for how many years have you been exposed?

.....

18. (a) Have you ever smoked as much as one cigarette a day (or one cigar a week or an ounce of tobacco a month) for as long as one year? Yes ☐ No ☐ **(If No, go to Q19)**

(b) How much do/did you smoke a day?

.....cigarettes/day .....cigars/week.....oz or .....g tobacco/week

(c) How old were you when you started smoking?.....

(d) Do you still smoke?

Yes ☐ **(If Yes, go to Q19)**

No ☐

(e) How old were you when you finally stopped smoking?.....

19. In most weeks, how many hours per week are you exposed to other people's tobacco smoke? .....

20. What is your current height without shoes? …… metres **or** ……feet.....inches

21. What is your current weight without shoes? …….kg **or**……stone…..pounds

22. Please indicate your date of birth: …….

23. Sex: Male ☐ Female ☐

24. How would you class your ethnic group? (Please tick one)

White
English/Welsh/Scottish/Northern Irish/British ☐
Irish ☐
Gypsy/Irish Traveller ☐
Any other white background ☐

Mixed / multiple ethnic groups
White & Black Caribbean ☐
White & Black African ☐
White & Asian ☐
Other mixed ☐

Asian / Asian British
Indian ☐
Pakistani ☐

Bangladeshi ☐
Chinese ☐
Any other Asian background ☐

Black / African / Caribbean / Black British
African ☐
Caribbean ☐
Any other Black / African / Caribbean background ☐

Other ethnic group
Arab ☐
Other ☐
Prefer not to say ☐

SECTION 3: CONTACT INFORMATION

25. Title……. First name…….....……

Surname

……..……..……...

26. Address……

……

……

……

…….....

27. Postcode…….....……

……

28. Telephone number

Home:…….....……

Mobile:…….....……

……

29. Email address……...……

…

30. You may be invited for further assessment; to help us schedule these appropriately please indicate your preferred appointment times (tick any when you are available)

Monday	morning	☐	afternoon	☐	evening	☐
Tuesday	morning	☐	afternoon	☐	evening	☐
Wednesday	morning	☐	afternoon	☐	evening	☐
Thursday	morning	☐	afternoon	☐	evening	☐
Friday	morning	☐	afternoon	☐	evening	☐
Saturday	morning	☐	afternoon	☐	evening	☐

THANK YOU FOR TAKING THE TIME TO FILL OUT THIS QUESTIONNAIRE!

PLEASE RETURN AS INDICATED USING EITHER THE REPLY-PAID ENVELOPE OR ONLINE AT

https://www.pc-crtu.bham.ac.uk/Target

Appendix 3 Cost questionnaire

Including patient costs in the TargetCOPD results

Please read the following information, which outlines why we are asking you to fill in this questionnaire.

The aim of the questionnaire:

Inviting people to attend spirometry (lung assessment) as part of a screening programme costs large sums of money. However, very little is known about the *hidden* costs of these assessments to the health service and to individuals taking part. An estimation of the costs would be incomplete if we did not consider the cost to the patients when attending for assessment. The information we get from this questionnaire will help us to find out this valuable information, and will be included in the TargetCOPD study results.

What you need to do:

We would appreciate it if you would take the time to fill in the questionnaire. It shouldn't take longer than 5-10 minutes. Please answer **every** question in the best way you can.

STUDY ID: NAME:

Questionnaire for measuring costs to patients of attending a spirometry assessment clinic

Thinking about your clinic visit for spirometry:

1. Please enter today's date: ____/____/____

2. Where did your spirometry clinic take place? *(Please tick one box)*

Your GP surgery ☐

Other GP surgery ☐

Other ☐

If other, please specify _____

3. What would have been your **main** activity if you had not attended the spirometry clinic?

Paid employment ☐

Looking after relatives ☐

Leisure activities ☐

Housework ☐

Studying at college ☐

Other ☐ *Please specify*_____

If you are in paid employment, please answer question 4, if not go to question 5

4. What arrangements did you make to take time off work? *(Please tick one box)*

Paid absence from work ☐

Unpaid absence from work ☐

Will make the time up ☐

Came to clinic outside work time ☐

Took holiday ☐

Other arrangements ☐

*Please specify*_____

5. How long did it take you to travel to the clinic?

_____ hours _____minutes

6.

a) How did you travel to the clinic? Please tick the **<u>main</u>** (longest in terms of distance) form of transport.

Walking ☐

Private car ☐

Public transport - bus ☐

Public transport - train ☐

Taxi ☐

Other ☐ *Please specify* _____

b) If you travelled by **private car**, were you given a lift by someone else?

Yes ☐ No ☐

c) If you travelled by **private car**, how much was paid in car park fees?

£_____p_____

d) If you travelled by **public transport (bus or train)**, what was the cost of the one-way fare? If you were given a return fare, simply halve it. Put zero if you did not travel by public transport at all or you did not pay a fare.

£_____p_____

e) If you travelled by **taxi** what was the cost of the (one-way) fare? Put zero if you did not travel by taxi at all or you did not pay a fare.

£_____p_____

7. Did anyone accompany you to the clinic **and wait** for you while you received your care?

Yes ☐ No ☐

If yes, did they take time off work? Yes ☐ No ☐

8. If you have other dependants,

Did you pay someone to look after them?

Yes ☐ No ☐ Not Applicable ☐

If yes, how much did it cost ? £_____ p_____

or

Did someone take time off work to look after them ? Yes ☐ No ☐

9. How long did you spend waiting at the clinic **before** your appointment?

_____ hours _____minutes

If you have any comments about your costs for attending the clinic or anything else about this study please write them below.

_____
_____
_____
_____
_____
_____
_____
_____
_____

_____

_____

_____

_____

Thank you for your co-operation and help

Appendix 4: Assumptions and calculations for health economic analysis

Table 1: Unit costs for case-finding

Staff time (including overheads and training)	**Hourly costs (£)**	**Source**
General Practitioner	192.00	PSSRU 2013 [1]
Practice Manager	31.02	NIHR 2011 [2]
Practice Nurse	44.00	PSSRU 2013 [1]
NHS administrator	22.46	NIHR 2011 [2]
NHS receptionist	22.46	NIHR 2011 [2]
Clinical support worker (Band 2)	25.00	PSSRU, 2013 [1]
Stationery (per patient invite)	**Unit cost per item(£)**	
Posting - headed paper, envelopes, stamps	0.48	NIHR 2011 [2]
Return post A5 envelope	0.63	Royal Mail, 2014
GP letter head	0.11	NIHR 2011 [2]
Cost of questionnaire (assumed to be 6 pages)	0.64	NIHR 2011 [2] & Trial data
Text message	0.36	Trial data
Additional unit costs	**(£)**	
Room hire per hour	15.00	Assumption
Travel cost per mile	0.40	Trial data
Spirometry equipment	1,007	Trial data
Laptops	569	Trial data
Disposable Spirett mouthpiece (single use)	0.54	Trial data
Aerochamber spacers (single use)	4.50	Trial data
Salbutomol Inhaler (single use)	4.79	Trial data

Table 2 Assumptions for training costs for spirometry

Training costs	
Number of tests conducted per clinical support worker (assuming 3721 tests in total and 10 staff required)	372.10
Number of hours training in 1st year per staff member (4 weeks training, plus one day refresher course, assuming 7.5 hour day)	157.50
Number of hours training in subsequent years	7.50
Lifetime of training costs (years)	3
Resource use	**Unit cost (£)**
2 day workshop	350
1 day refresher course	175
Staff time for training	4312.50
Training cost per test	***4.33***

Source: trial data

Table 3: Assumptions for staff time for spirometry

Assumptions		**Value**
Average slots confirmed per day		8.2
Number of tests conducted per day adjusting for 23% DNA rate		6.28
Clinical support worker time per test, assuming a 7.5 hour day (hours)		0.84
Staff cost per test	**Unit cost (£)**	**Total cost (£)**
Clinical support worker	25.00	20.92
Receptionist time (3 minutes)	22.46	1.12
Total		***22.04***

Source: trial data

Table 4 Assumptions for travel costs

Assumptions	**Value**
Average miles travelled to each clinic	7.80
Average number of journeys per full day worked	2.30
Average number of appointments per day	6.28
Miles travelled per clinic attendance	2.85
Cost	**£**
Travel reimbursement per mile	0.40
Cost per clinic attendance	***1.14***

Source: trial data

Table 5 Assumptions for equipment costs

Equipment cost	**Value**
Number spirometry devices	12
Number of laptops & memory sticks	10
Lifespan of fixed equipment (years)	5
Interest rate	3%
Capital Recovery factor	22%
Number of tests conducted over a year	3721
Consumable stock ratio	1.20
Costs	**Cost per case (£)**
Spirometry equipment	0.71
Laptops	0.33
Disposable Spirett mouthpiece (single use)	0.54
Aerochamber spacers (single use)	4.50
Salbutomol Inhaler (single use)	4.79
Cost per test	***10.87***

Table 6: Patient incurred costs: travel and carer costs

Travel costs	**n**	**Cost (£)**
Car parking charges	1710	3.60
Public transport fares	162	156.85
Taxi fares	7	186.06
Not specified	701	
Total travel costs		***346.51***
Travel costs per attendance		***0.13***
Carer costs	**n**	**Cost (£)**
Number paying for care for dependents to attend	11	
Average cost amongst those that reported this (1 person)		18.00
Cost of care (assuming average cost applied to all that paid for care)		198.00
Carer costs per patient attending		***0.07***

Table 7: Patient indirect costs

Paid work	**n**
Number missing paid work	700
Time away from work	**Hours**
Travel time	167.78
Waiting time	57.72
Appointment time	525.00
Total time away from work	750.50
	Cost (£)
Median gross hourly earnings of full-time employees (ONS 2013)	13.03
Estimated costs of missed paid work	9779.01
Indirect cost per patient attending	***3.68***

Cost Sources

[1] PSSRU. Unit Costs of Health and Social Care 2013. University of Kent, 2013. Available from: http://www.pssru.ac.uk/project-pages/unit-costs/2013/

[2] NIHR costing report: http://www.crn.nihr.ac.uk/resources/resource-template/ (Accessed 11th August 2015)

Details of alternative models of care

Three alternative models of care were considered.

1) GP-led model. Band 7 respiratory nurses conduct the spirometry tests. Training costs, travel costs and room hire costs are excluded. The number of reusable spirometry devices are increased from 12 to 28 to ensure there is one device per practice and laptop costs excluded assuming the practice nurse will use the practice computers.

2) Community led-model. As per GP-led model but spirometry provided by a band 5 community nurse supervised by an advanced nurse.

3) Secondary-care model (Tariff-based cost) with spirometry conducted in hospital outpatient appointments. The cost per spirometry attendance is assumed to be charged at the NHS tariff levels for a non-consultant led outpatient respiratory appointment and a spirometry test.