Baseline Case Report Form

Participant Study No

TWICS

Theophylline with Inhaled Corticosteroids

Theophylline With Inhaled CorticoSteroids

CONFIDENTIAL

This study is funded by the
NIHR Health Technology Assessment Programme

Date of assessment | D D / M M / Y Y Y Y

Section A – Demographic information

A1 Date of birth | D D / M M / Y Y Y Y

A2 Sex | Male ☐ | Female ☐

A3 Weight (kg) | ____

A4 Height (cm) | ____

A5 Smoking status | Current smoker ☐ | Ex-smoker ☐

*A "**current smoker**" is defined as someone who is a current smoker or who has given up within the last 12 weeks. An "**ex smoker**" is defined as someone who has given up smoking more than 12 weeks ago.*

A6 Age started smoking | ____

A7 If ex-smoker, age stopped smoking | ____

A8 Average number of cigarettes per day | ____

A9 Identified in | Primary care ☐ | Secondary care ☐

Section B – Post-bronchodilator lung function

LABA within 8 hours, SABA within 2 hours. If necessary, assess lung function 15 minutes after administration of the participant's own SABA.

B1 FEV_1 (litres) | ____

B2 FVC (litres) | ____

Section C – COPD history & current respiratory treatment

C1 Number of exacerbations in previous year requiring treatment with antibiotics and/or oral corticosteroid ☐

C2 Date of recovery from most recent exacerbation M M / Y Y Y Y

C3 Number of exacerbations in previous year requiring hospitalisation ☐

Current treatment for COPD

C4 Inhaled short acting beta 2 agonist Yes ☐ No ☐

C5 Inhaled combined ICS LABA Yes ☐ No ☐

If yes: name, device & strength …….....

Dose ……. puffs per day

Approximate start date M M / Y Y Y Y

C6 Inhaled short acting anti-muscarinic Yes ☐ No ☐

C7 Inhaled ICS Yes ☐ No ☐

If yes: name, device & strength …….....

Dose ……. puffs per day

Approximate start date M M / Y Y Y Y

C8 Inhaled non-combination LABA Yes ☐ No ☐

C9 Inhaled LAMA Yes ☐ No ☐

C10 Nebulised ipratropium As required ☐ Regular use ☐ No ☐

C11 Nebulised short acting beta 2 agonist As required ☐ Regular use ☐ No ☐

C12	Oral mucolytics	Yes ☐	No ☐
C13	Oral leukotriene antagonists	Yes ☐	No ☐
C14	Long-term antibiotics	Yes ☐	No ☐

If yes: name ……

Dose ……. mg

Times per day ☐

Section D – Co-morbidities

Record whether the patient has been diagnosed with any of these conditions; and if so, whether they are on medication for this.

	Co-morbidities			*If yes, is the patient on current medication for this condition?*	
D1	Asthma	Yes ☐	No ☐	Yes ☐	No ☐
D2	Bronchiectasis	Yes ☐	No ☐	Yes ☐	No ☐
D3	Ischaemic heart disease (MI, angina)	Yes ☐	No ☐	Yes ☐	No ☐
D4	Hypertension (treated)	Yes ☐	No ☐	Yes ☐	No ☐
D5	Diabetes Mellitus	Yes ☐	No ☐	Yes ☐	No ☐
D6	Osteoporosis	Yes ☐	No ☐	Yes ☐	No ☐
D7	Anxiety or depression treated in last 5 years	Yes ☐	No ☐	Yes ☐	No ☐
D8	Cerebrovascular event (stroke, TIA)	Yes ☐	No ☐	Yes ☐	No ☐

Section E – Other regular medication

E1 Is the patient prescribed long-term tricyclic antidepressants? Yes ☐ No ☐

E2 List all prescribed medication that the patient is currently taking.

- Include any medication listed in section D or in E1 above.
- Exclude any medication listed in section C above.

Drug	Dose	Frequency

Follow-up Case Report Form

Participant Study No

Follow-up time-point: **Six months** ☐ **Twelve months** ☐

TWICS

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Date of assessment D D / M M / Y Y Y Y

Section A – Smoking status & weight

A1 Smoking status — Current smoker ☐ Ex-smoker ☐

*A "**current smoker**" is defined as someone who is a current smoker or who has given up within the last 12 weeks. An "**ex smoker**" is defined as someone who has given up smoking more than 12 weeks ago.*

A2 Weight _____ kg

Section B – Post-bronchodilator lung function

LABA within 8 hours, SABA within 2 hours). If necessary, assess lung function 15 minutes after administration of the participant's own SABA.

B1 FEV_1 (litres) _____

B2 FVC (litres) _____

Section C – Current treatment for COPD/respiratory conditions

C1 Inhaled short acting beta 2 agonist — Yes ☐ No ☐

C2 Inhaled combined ICS LABA — Yes ☐ No ☐

If yes: name, device & strength …….....

Dose ……. puffs per day

Approximate start date M M / Y Y Y Y

C3 Inhaled short acting anti-muscarinic — Yes ☐ No ☐

C4 Inhaled ICS Yes ☐ No ☐

If yes: name, device & strength ……

Dose ……. puffs per day

Approximate start date | M | M | / | Y | Y | Y | Y |

C5 Inhaled non-combination LABA Yes ☐ No ☐

C6 Inhaled LAMA Yes ☐ No ☐

C7 Nebulised ipratropium As required ☐ Regular use ☐ No ☐

C8 Nebulised short acting beta 2 agonist As required ☐ Regular use ☐ No ☐

C9 Oral mucolytics Yes ☐ No ☐

C10 Oral leukotriene antagonists Yes ☐ No ☐

C11 Long-term antibiotics Yes ☐ No ☐

If yes: name ……

Dose ……. mg

Times per day | |

Section D – Other regular medication

Is the patient on current medication for:

D1	Asthma	Yes ☐	No ☐
D2	Bronchiectasis	Yes ☐	No ☐
D3	Ischaemic heart disease (MI, angina)	Yes ☐	No ☐
D4	Hypertension	Yes ☐	No ☐
D5	Diabetes Mellitus	Yes ☐	No ☐
D6	Osteoporosis	Yes ☐	No ☐
D7	Anxiety or depression	Yes ☐	No ☐
D8	Cerebrovascular event (stroke, TIA)	Yes ☐	No ☐
D9	Is the patient prescribed long-term tricyclic antidepressants?	Yes ☐	No ☐

D10: List all prescribed non-respiratory medication that the patient is currently taking.

- Include any medication listed in section D above, and any other medication.
- Exclude any medication listed in section C above.

Drug	Dose	Frequency

Section E – COPD exacerbations since last study visit?

Has the participant had any exacerbations since last study visit?

Yes ☐ No ☐

If yes, how many exacerbations [ ] *Describe all exacerbations below*

Exacerbation 1

Approximate date of onset: D D / M M / Y Y Y Y

Approximate date of recovery: D D / M M / Y Y Y Y Not yet recovered ☐

Type of Treatment: (select all that apply)

Increased use of SABA ☐ Increased/ started nebulised bronchodilator ☐ Oral corticosteroid ☐

Antibiotics ☐ Oxygen ☐ Other ☐

If other, give details [ ]

Location of Treatment: (select all that apply)

Treated at home ☐

If yes

Number of days treated at home [ ]

Care by services to prevent hospitalisation ☐

If yes

Number of days care provided [ ]

Admitted to hospital ☐

If yes

Number of days in hospital [ ]

*** USE CONTINUATION SHEET IF MORE THAN ONE EXACERBATION ***

Section F – Emergency hospital admissions since last study visit

Other than any hospitalisations described in section E, has the patient had any ***non-COPD*** emergency hospital admissions last study visit?

Yes ☐ No ☐

If yes, how many admissions ☐ *Describe all admissions below*

Admission 1

Approximate date of admission: D D / M M / Y Y Y Y

Approximate date of discharge: D D / M M / Y Y Y Y Not yet discharged ☐

Hospital:

Reason:

Admission 2

Approximate date of admission: D D / M M / Y Y Y Y

Approximate date of discharge: D D / M M / Y Y Y Y Not yet discharged ☐

Hospital:

Reason:

USE CONTINUATION SHEET IF MORE THAN TWO HOSPITALISATIONS

Section G – Other health service use since last study visit

Use this section to record health service use not previously recorded in sections E or F above. Please enter '0' if service has not been used

Inpatient services	***Number of admissions***	***Total number of inpatient days***
General medical ward		
Long stay ward		
Other: ……..		
Other: ……..		

Out-patient services	***Number of appointments***
Hospital day-case admissions	
Hospital out-patient appointments	
A&E – no overnight admission	
Other: ……..	
Other: ……..	

Primary care services	***Number of appointments***
Emergency GP visit	
Routine GP visit	
Community/district nurse	
Hospital at home team	
Other: ……..	
Other: ……..	

Section H – Adverse reactions since the last study visit?

Has the patient experienced any of the following adverse reactions to the study medication? (ie new symptoms or increase of existing symptoms)

Immunological

H1 Anaphylactic / anaphylactoid reaction	Yes ☐	No ☐
H2 Hypersensitivity	Yes ☐	No ☐

Gastrointestinal

H4 Nausea	Yes ☐	No ☐
H5 Reflux	Yes ☐	No ☐
H6 Diarrhoea	Yes ☐	No ☐
H7 Abdominal pain	Yes ☐	No ☐
H8 Gastric irritation	Yes ☐	No ☐
H9 Vomiting	Yes ☐	No ☐

Cardiac

H10 Palpitations	Yes ☐	No ☐
H11 Tachycardia	Yes ☐	No ☐

Psychiatric

H12 Insomnia	Yes ☐	No ☐
H13 Anxiety	Yes ☐	No ☐

Dermatological

H14 Rash	Yes ☐	No ☐
H15 Pruritus (itchiness)	Yes ☐	No ☐

Neurological

H16 Tremor	Yes ☐	No ☐
H17 Headache	Yes ☐	No ☐
H18 Dizziness	Yes ☐	No ☐
H19 Agitation	Yes ☐	No ☐
H20 Convulsions	Yes ☐	No ☐

Other

H21 Hyperuricaemia (acute gout)	Yes ☐	No ☐
H22 Diuresis (increased frequency of urination)	Yes ☐	No ☐
H23 Urinary retention	Yes ☐	No ☐

H24 Any other – please give details Yes ☐ No ☐

If the patient has experienced any adverse events or adverse reactions that meet the criteria for serious, this should be recorded using an SAE form immediately.

H25 If relevant, is the participant pregnant? Yes ☐ No ☐ N/A ☐

Section I – Returned medication

Did the participant return any drug bottles? Yes ☐ No ☐

Drug pack number:		Number of tablets returned	
Drug pack number:		Number of tablets returned	
Drug pack number:		Number of tablets returned	
Drug pack number:		Number of tablets returned	
Drug pack number:		Number of tablets returned	
Drug pack number:		Number of tablets returned	
Drug pack number:		Number of tablets returned	

Disposal of returned medication:

Secondary care: Returned to clinical trials pharmacy * ☐

Primary care: Disposed via Unused Medication Disposal box in practice * ☐

Primary care: Taken by practice staff to local pharmacy for destruction * ☐

Primary care: Advised patient to take them to their local pharmacy for destruction ☐

** certificate of destruction should be completed by clinical trials pharmacy or practice staff*

Section J – At 12 months only

Has the participant spontaneously expressed interest in being prescribed theophylline by their GP? Yes ☐ No ☐

TWICS
Theophylline with Inhaled Corticosteroids

Serious Adverse Event Form

Participant Study Number | | | | | |

FOR TRIAL OFFICE USE ONLY
REPORT NO.

DATE REPORTED TO TRIAL OFFICE
D D M M Y Y Y Y

DO NOT SEND IDENTIFIABLE DATA WITH THIS REPORT

Date of report D D M M Y Y Y Y

Initial report ☐ Follow up report ☐

Participant Details

Initials | | Date of Birth D D M M Y Y Y Y Gender Male ☐ Female ☐ Unknown ☐

Diagnosis **Onset date** D D M M Y Y Y Y

ASSESSMENT OF THE SAE
To be completed by PI or consultant grade delegate, who should also sign the page 6 of the report.

Seriousness criteria: (tick all that apply)

Resulted in death ☐ Life-threatening ☐ Hospitalisation/Prolongation of hospitalisation ☐

Persistent/Significant Disability/Incapacity ☐ Congenital anomaly/ Birth defect ☐ Other medically important condition ☐

Relationship to Study Drug: None ☐ Possible ☐ Probable ☐ Definite ☐

Severity: Mild ☐ Moderate ☐ Severe ☐

Expectedness: (*complete if possibly, probably or definitely related to study drug; refer to expected events listed in SmPC*) Expected ☐ Unexpected ☐

If Resulted in Death:

Date of Death: D D M M Y Y Y Y

Cause of Death:

Action taken: Drug withdrawn ☐ Dose reduced ☐ Dose increased ☐

Dose not changed ☐ Unknown ☐ Not applicable ☐

Outcome: Recovered ☐ Recovered with sequelae ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Fatal ☐

Date of Recovery D D M M Y Y Y Y

Serious Adverse Event Form

Participant Study Number | | | | | |

Event Narrative	**Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form**

Protocol Treatment(s):

Did the patient take any study medication? Yes ☐ No ☐ If Yes,

Start date | D | D | M | M | Y | Y | Y | Y |

Stop date | D | D | M | M | Y | Y | Y | Y |

Did the subject have to be unblinded? Yes ☐ No ☐

Participant Study Number | | | | | |

Ongoing Medical History
Provide details of ongoing medical history below. Include other illnesses present at time of event, previous study emergent adverse events, and pre-existing medical conditions (*including their COPD*). If additional space is necessary, use further copies of this page. If start or end-dates are unknown or partially known, note this – the abbreviation uk is acceptable (for example: uk or uk/2014 or uk/12/2014)

	Condition	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Tick if still ongoing	Medication Required
1				☐	☐ Yes ☐ No
2				☐	☐ Yes ☐ No
3				☐	☐ Yes ☐ No
4				☐	☐ Yes ☐ No
5				☐	☐ Yes ☐ No
6				☐	☐ Yes ☐ No
7				☐	☐ Yes ☐ No
8				☐	☐ Yes ☐ No
9				☐	☐ Yes ☐ No
10				☐	☐ Yes ☐ No

Participant Study Number | | | | | |

Concomitant Medications

Give details of all concomitant medications, including those taken prior to onset of the SAE and any being used to treat the SAE. If additional space is necessary, use further copies of this page. If start or end-dates are unknown or partially known, note this – the abbreviation uk is acceptable (for example: uk or uk/2014 or uk/12/2014).

	Medication	Start Date (DD/MM/ YYYY)	End Date (DD/MM/ YYYY)	Tick if ongoing	Dose	Frequency	Route	Indications	Suspect Drug (tick)	Interaction with study drug (tick)
1				☐					☐	☐
2				☐					☐	☐
3				☐					☐	☐
4				☐					☐	☐
5				☐					☐	☐
6				☐					☐	☐
7				☐					☐	☐
8				☐					☐	☐
9				☐					☐	☐
10				☐					☐	☐

Relevant Tests -
List only relevant confirmatory test results for event(s), for example from blood tests, diagnostic imaging. Please include normal ranges and any comments about the test or its result.

	Test	Date (DD/MM/YYYY)	Result	Normal Range-Low	Normal Range-High	Comments
1						
2						
3						
4						
5						

Rechallenge Information

1. Did the reaction abate after stopping suspected drug? ☐ Unknown ☐ Yes ☐ No ☐ N/A

2. Did the reaction reappear after re-introduction of suspect drug? ☐ Yes ☐ No ☐ N/A

Primary Source Please give details of the person completing this SAE form	
Name:	Email address:
Address:	
Telephone number:	Fax number:
Qualification: Physician ☐ Pharmacist ☐ Other Health Professional ☐ Trial Team ☐	

To be signed by the Principal Investigator or designee
This is the person who has completed the assessment section on page 1 of this form. If the assessment has not yet been made, the report should NOT be signed.

I am the Principal Investigator Yes ☐ No ☐

If No, please state designation

I confirm that this is a SAE

Name: (PRINT) _____

Signature: _____

Date: | D | D | M | M | Y | Y | Y | Y |

Completed SAE forms should be scanned and emailed to twics@abdn.ac.uk, s.c.cotton@abdn.ac.uk and kareninnes@abdn.ac.uk or faxed to 01224 438165. If you do not receive an acknowledgement, please resend or contact the trial team.

To be signed by the Chief Investigator or designee in the event of a SUSAR

I am the Chief Investigator Yes ☐ No ☐

If No, please state designation

I confirm that this is a SUSAR

Name: (PRINT) _____

Signature: _____

Date: | D | D | M | M | Y | Y | Y | Y |

Quality of Life Questionnaire

Participant Study No

Baseline ☐
6 months ☐
12 months ☐

TWICS

Theophylline with Inhaled Corticosteroids

Quality of Life Questionnaire

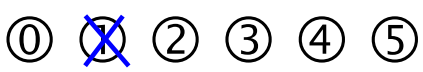
CONFIDENTIAL

This study is funded by the NHS NIHR
Health Technology Assessment Programme

ISRCTN27066620
EudraCT 2013-001490-25

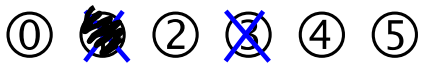
HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting a cross in the appropriate circle or box. Please print your answers carefully within the boxes like this:



OR **x**

If you make a mistake, shade out the wrong box completely and mark the correct one like this



Eg if you ticked “1” but meant to tick “3”

Please try to complete the whole questionnaire.

There are no right or wrong answers.

You do not have to answer any question if you do not want to.

Thank you for your help.

Section A – The COPD Assessment Test (CAT)

For each item below, please mark (X) in the box that best describes you currently. Be sure to select one response for each question.

Example I am very happy	⓪	~~①~~ X	②	③	④	⑤	I am very sad
A1 I never cough	⓪	①	②	③	④	⑤	I cough all the time
A2 I have no phlegm (mucus) in my chest at all	⓪	①	②	③	④	⑤	My chest is completely full of phlegm (mucus)
A3 My chest does not feel tight at all	⓪	①	②	③	④	⑤	My chest feels very tight
A4 When I walk up a hill or one flight of stairs I am not breathless	⓪	①	②	③	④	⑤	When I walk up a hill or one flight of stairs I am very breathless
A5 I am not limited in doing any activities at home	⓪	①	②	③	④	⑤	I am very limited doing activities at home
A6 I am confident leaving my home despite my lung condition	⓪	①	②	③	④	⑤	I am not at all confident leaving my home because of my lung condition
A7 I sleep soundly	⓪	①	②	③	④	⑤	I don't sleep soundly because of my lung condition
A8 I have lots of energy	⓪	①	②	③	④	⑤	I have no energy at all

On this, and the subsequent page of the questionniare, the EQ-5D -3L questionnaire was reproduced in full.

Section C – Breathlessness

Please mark (X) the box that best describes your degree of breathlessness related to activities.

Degree of breathlessness related to activities

Not troubled by breathlessness except on strenuous exercise ☐

Short of breath when hurrying or walking up a slight hill ☐

Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace ☐

Stops for breath after walking about 100 metres or after a few minutes on level ground ☐

Too breathless to leave the house, or breathless when dressing or undressing ☐

Section D – Date

Please write in the date that you completed this questionnaire:

THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

Once you have completed the questionnaire, please give it back to the research nurse, or return it in the pre-paid envelope provided to the following address:

TWICS Trial Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
3rd floor, Health Sciences Building
Foresterhill, Aberdeen AB25 2ZD

Tel: 01224 438193 or 01224 438178
Fax: 01224 438165
twics@abdn.ac.uk

Participant Study Number

TWICS

Theophylline with Inhaled Corticosteroids

Follow-up questionnaire

Side effects and exacerbations (flare-ups)

CONFIDENTIAL

This study is funded by the NHS NIHR
Health Technology Assessment Programme

Please try to complete the whole questionnaire.

There are no right or wrong answers.

You do not have to answer any question if you do not want to.

Thank you for your help.

1. Since we were last in contact with you (on ……)
have you experienced any side-effects of the study tablets? Yes ☐ No ☐

If yes, please describe these side effects:

Can we contact you to discuss these side-effects? Yes ☐ No ☐

2. Since we were last in contact with you (on ……) have you experienced any exacerbations, or flare-ups of your COPD? Yes ☐ No ☐

If yes, please tell us about each exacerbation. We would like to know how long it lasted, what treatment you had, and whether you needed to go into hospital or had care at home from a community team (eg COPD nurse) to prevent hospitalisation.

Exacerbation 1

What date did the exacerbation start? _____ ***What date did you recover from the exacerbation?*** _____

What treatment did you receive for the exacerbation? (please tick all that apply)

Antibiotics	Oral steroids (prednisolone)	Oxygen	Increased use of inhaler	Started or increased use of nebuliser	Other
☐	☐	☐	☐	☐	☐

Did you have to go into hospital for your exacerbation? Yes ☐ for _____ days No ☐

Did you have care at home from a community team (eg COPD nurse) to try and prevent hospitalisation? Yes ☐ for _____ days No ☐

Exacerbation 2

What date did the exacerbation start? _____ ***What date did you recover from the exacerbation?*** _____

What treatment did you receive for the exacerbation? (please tick all that apply)

Antibiotics	Oral steroids (prednisolone)	Oxygen	Increased use of inhaler	Started or increased use of nebuliser	Other
☐	☐	☐	☐	☐	☐

Did you have to go into hospital for your exacerbation? Yes ☐ for _____ days No ☐

Did you have care at home from a community team (eg COPD nurse) to try and prevent hospitalisation? Yes ☐ for _____ days No ☐

Exacerbation 3

What date did the exacerbation start? _____ ***What date did you recover from the exacerbation?*** _____

What treatment did you receive for the exacerbation? (please tick all that apply)

Antibiotics	Oral steroids (prednisolone)	Oxygen	Increased use of inhaler	Started or increased use of nebuliser	Other
☐	☐	☐	☐	☐	☐

Did you have to go into hospital for your exacerbation? Yes ☐ for _____ days No ☐

Did you have care at home from a community team (eg COPD nurse) to try and prevent hospitalisation? Yes ☐ for _____ days No ☐

Exacerbation 4

What date did the exacerbation start? _____ ***What date did you recover from the exacerbation?*** _____

What treatment did you receive for the exacerbation? (please tick all that apply)

Antibiotics	Oral steroids (prednisolone)	Oxygen	Increased use of inhaler	Started or increased use of nebuliser	Other
☐	☐	☐	☐	☐	☐

Did you have to go into hospital for your exacerbation? Yes ☐ for _____ days No ☐

Did you have care at home from a community team (eg COPD nurse) to try and prevent hospitalisation? Yes ☐ for _____ days No ☐

Thank you for completing this questionnaire

Hull Airway Reflux Questionnaire

Participant Study No

Baseline ☐
6 months ☐
12 months ☐

TWICS
Theophylline with Inhaled Corticosteroids

Theophylline With Inhaled Corticosteroids

QUESTIONNAIRE

CONFIDENTIAL

This study is funded by the NHS NIHR
Health Technology Assessment Programme

ISRCTN27066620
EudraCT 2013-001490-25

HOW TO FILL IN THIS QUESTIONNAIRE

Please circle the appropriate response for each question. Use 0 to indicate no problem and 5 to indicate severe/frequent problem

Coughing	0	1	2	3	4	5

If you make a mistake, shade out the wrong box completely and mark the correct one like this

Coughing	0		2	3	4	5

Eg if you ticked “1” but meant to tick “3”

Please try to complete the whole questionnaire.

There are no right or wrong answers.

You do not have to answer any question if you do not want to.

Thank you for your help.

Please circle the most appropriate response for each question

Within the last MONTH, how did the following problems affect you?						
	0 = no problem					5= severe/ frequent problem
Hoarseness or a problem with your voice	0	1	2	3	4	5
Clearing your throat	0	1	2	3	4	5
The feeling of something dripping down the back of your nose or throat	0	1	2	3	4	5
Retching or vomiting when you cough	0	1	2	3	4	5
Cough on first lying down or bending over	0	1	2	3	4	5
Chest tightness or wheeze when coughing	0	1	2	3	4	5
Heartburn, indigestion, stomach acid coming up (or do you take medications for this, if yes score 5)	0	1	2	3	4	5
A tickle in your throat, or a lump in your throat	0	1	2	3	4	5
Cough with eating (during or soon after meals)	0	1	2	3	4	5
Cough with certain foods	0	1	2	3	4	5
Cough when you get out of bed in the morning	0	1	2	3	4	5
Cough brought on by singing or speaking (for example, on the telephone)	0	1	2	3	4	5
Coughing more when awake rather than asleep	0	1	2	3	4	5
A strange taste in your mouth	0	1	2	3	4	5

Please write in the date that you completed this questionnaire:	

THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

Once you have completed the questionnaire, please give it back to the research nurse, or return it in the pre-paid envelope provided to the following address:

TWICS Trial Office
Centre for Healthcare Randomised Trials (CHaRT)
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