A RANDOMISED 2x2 TRIAL OF COMMUNITY VERSUS HOSPITAL REHABILITATION, FOLLOWED BY TELEPHONE OR CONVENTIONAL FOLLOW UP; IMPACT ON QUALITY OF LIFE, EXERCISE CAPACITY AND USE OF HEALTHCARE RESOURCES



Case Report Form

Patient ID

Date of Questionnaire

Pre Rehab

<u>Also need MRC Breathlessness (blue), SF36 (lemon), EQ5D</u> (green), CRQ(cream), Resource Use and Socioeconomic (pink)

<u>Check Data</u>

Subject initials





North/South

Hosp no

Delete one

ID number from database

Inclusion criteria

Diagnosis of COPD	Yes/no
MRC grade 3 dyspnoea	Yes/no
Informed consent	Yes/no
Access to telephone	Yes/no
Willing/motivated to make lifestyle changes	Yes/no
Can hear and understand	Yes/no
Prognosis not under 2 years from any disease	Yes/no
No requirement for oxygen therapy	Yes/no
Stable or controlled cardiac disease	Yes/no
No musculoskeletal problems precluding exercise	Yes/no

Patients GP

Has the subject had any exacerbations requiring a change in usual respiratory treatment in the last 4

weeks

Yes/no

If yes outcome is to return to waiting list on database

Bronchodilator

Give 2 puffs Salbutamol and/or 2 puffs Atrovent Forte

via Volumatic (10 tidal breath technique) time



Incremental Shuttle test

Level walked

Distance walked in metres

Estimated VO2 max in ml/min/Kg

[4.19+(0.025*distance walked)]

85% of VO2 max for endurance walk in ml/min/Kg

[Estimated VO2 max*0.85]

Endurance shuttle level calculated

Starting SpO2	
Lowest SpO2	
Starting Heart Rate	
Highest Heart Rate	



Worksheet for Incremental Walk

(Strike through each 10 m length performed)

1	2	3							
4	5	6	7						
8	9	10	11	12					
13	14	15	16	17	18				
19	20	21	22	23	24	25			
26	27	28	29	30	31	32	33		
34	35	36	37	38	39	40	41	42	
43	44	45	46	47	48	49	50	51	52
<u>Heig</u> l	<u>nt and</u>	weight	<u>-</u>						

Height in metres

Weight in Kg

Mid upper arm muscle circumference

Distance to mid point in mm

Mid upper arm circumference in mm

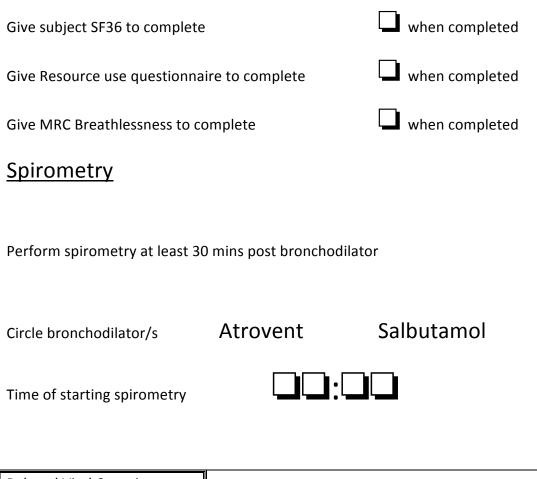
Triceps skin fold thickness in mm





Calculated mid upper arm muscle circumference (calculated by database)

First Questionnaires



FEV ₁	
FVC	
1.00	
PEF	
1 61	

Current Medication

medication	route	number	frequency

Second questionnaires

Interviewer filled CRQ

when completed

Self fill Eq5D

when completed

Endurance walk

Level set

Distance walked in metres

How long was the walk in minutes

Was the walk stopped because level too low

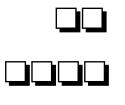
If so increase by 2 levels and recommence

Starting SpO2	
Lowest SpO2	
Starting Heart Rate	
Highest Heart Rate	

Worksheet for Endurance Walk

(Strike through each 10 m length performed)

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	17	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48	49	50
51	52	53	54	55	56	57	58	59	60
61	62	63	64	65	66	67	68	69	70
71	72	73	74	75	76	77	78	79	80
81	82	83	84	85	86	87	88	89	90
91	92	93	94	95	96	97	98	99	100





Yes/No



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<u>EQ-5D</u>

Patient ID

Date of Questionnaire

✓ for	timepoint
	Pre Rehab
	Post Rehab
	Rehab plus 6 months
	Rehab plus 12 months
	Rehab plus 18 months
	Withdrawal from study

EUROQOL[©] HEALTH QUESTIONNAIRE

Here are some simple questions about your health in general. By ticking one answer in each group below, please indicate which statements best describe your own health state TODAY.

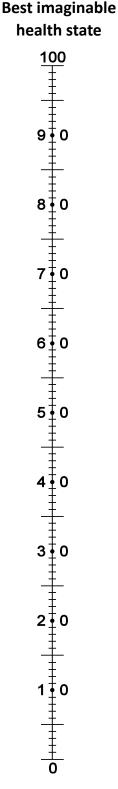
(Please circle <u>one</u> number)

1.	Mobility	
	I have no problems in walking about	1
	I have some problems in walking about	2
	I am confined to bed	3
2.	Self-care	
	I have no problems with self-care	1
	I have some problems washing or dressing myself	2
	I am unable to wash or dress myself	3
3.	Usual Activities	
	I have no problems with performing my usual activities	1
	(e.g. work, study, housework, family or leisure activities) I have some problems with performing my usual activities	2
	I am unable to perform my usual activities	3
4.	Pain/Discomfort	
	I have no pain or discomfort	1
	I have moderate pain or discomfort	2
	I have extreme pain or discomfort	3
5.	Anxiety/Depression	
	I am not anxious or depressed	1
	I am moderately anxious or depressed	2
	I am extremely anxious or depressed	3

6. To help people say how good or bad their health is, we have drawn a scale (rather like a thermometer) on which the **best state** you can imagine is marked by **100** and the **worst state** you can imagine is marked by **0**.

We would like you to indicate on this scale how good or bad **your own health is today**, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad **your current health state** is.

Your own health state today



Worst imaginable health state

THANK YOU FOR FILLING IN THIS QUESTIONNAIRE.

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<u>SF-36 v2</u>

Patient ID

Date of Questionnaire

✓ for timepoint		
	Pre Rehab	
	Post Rehab	
	Rehab plus 6 months	
	Rehab plus 12 months	
	Rehab plus 18 months	
	Withdrawal from study	

HEALTH STATUS QUESTIONNAIRE

The following questions ask you about your health, how you feel and

how well you are able to do your usual activities.

If you are unsure how to answer a question, please give the best answer you can.

OVERALL HEALTH

1. <u>In general</u>, would you say your health is:

(Please circle <u>one</u> number only)

Excellent	. 1
Very good	.2
Good	
Fair	.4
Poor	. 5

2. Compared to <u>one year ago</u>, how would you rate your health in general <u>now</u>?

(Please circle <u>one</u> number only)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

Yes. No. not Yes. ACTIVITIES limited a limited a limited at lot little all Feeding yourself 1 2 3 a. Getting up from a chair b. 2 3 1 C. Bathing or dressing yourself 1 2 3 d. Walking in your home 1 2 3 Walking 100 yards e. 1 2 3 f. Walking half a mile 2 3 1 Walking more than a mile g. 1 2 3 Bending, kneeling or stooping h. 1 2 3 Climbing one flight of stairs i. 2 3 1 Climbing several flights of stairs j. 2 1 3 Lifting or carrying groceries k. 2 3 1 L Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling 2 3 1 or playing golf m. Vigorous activities, such as running, lifting heavy objects, participating in 2 3 1 strenuous sports

(Please circle one number on each line)

4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Were limited in the kind of work or other activities	1	2	3	4	5
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

(Please circle one number on each line)

5. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time	
a.	Cut down on the amount of time you spent on work or other activities	1	2	3	4	5	
b.	Accomplished less than you would like	1	2	3	4	5	
C.	Did work or other activities less carefully than usual	1	2	3	4	5	

(Please circle <u>one number on each line</u>)

6. During the <u>past 4 weeks</u>, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(Please circle <u>one</u> number)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. How much bodily pain have you had during the past 4 weeks?

(Please circle <u>one</u> number)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

(Please circle <u>one</u> number)

Not at all	1
A little bit	2
Moderately	3
Quite a bit	
Extremely	5
and continue	

YOUR FEELINGS

9. These questions are about how you feel and how things have been with you during <u>the past 4 weeks</u>. (For each question, please give the one answer that comes closest to the way you have been feeling.)

	w much of the time during e <u>past 4 weeks</u> :	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a.	Did you feel full of life?	1	2	3	4	5
b.	Have you been very nervous?	1	2	3	4	5
C.	Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d.	Have you felt calm and peaceful?	1	2	3	4	5
e.	Did you have a lot of energy?	1	2	3	4	5
f.	Have you felt down-hearted and depressed?	1	2	3	4	5
g.	Did you feel worn-out?	1	2	3	4	5
h.	Have you been happy?	1	2	3	4	5
i.	Did you feel tired?	1	2	3	4	5

(Please circle one number on each line)

HEALTH IN GENERAL

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional</u> problems interfered with your social activities (like visiting friends, relatives etc.)?

(Please circle one number)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
а.	I seem to get ill more easily than other people	1	2	3	4	5
b.	I am as healthy as anybody I know	1	2	3	4	5
C.	I expect my health to get worse	1	2	3	4	5
d.	My health is excellent	1	2	3	4	5

(Please circle one number on each line)

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CoHoRT Study

Resource Use and Socio-economic Questions

Patient ID

Date of Questionnaire

Pre Rehabilitation

Q1	What is your sex?	Male
		Female
Q2	What is your date of birth?	/ / 19
Q3	What is your marital status?	Single (never married)
	(please tick <u>one</u> box)	Married (first marriage)
		Re-married
		Separated (but still legally married)
		Divorced
		Widowed
Q4	What is your ethnic group?	White
	(please tick <u>one</u> box)	British
		Irish
		Any other White background
		(please write in)
		Mixed □ □ □
		White and Black African
		White and Asian
		Any other Mixed background
		<i>Continued on next page, please turn over</i>

		Asian or Asian British	
		Indian	
		Pakistani	
		Bangladeshi	
		Any other Asian background	
		(please write in)	-
		Black or Black British	
		Caribbean	
		African	
		Any other Black background	
		(please write in)	
		Chinese or other ethnic grou	
		chinese of other ethnic grou	
		Chinese	
			- -
		Chinese	- -
		Chinese Any other	- -
		Chinese Any other	- -
Q5	What type of accommodation	Chinese Any other	
Q5	What type of accommodation does your household occupy?	Chinese Any other (please write in)	
Q5		Chinese Any other (please write in)	
Q5	does your household occupy?	Chinese Any other (please write in) A whole house or bungalow that is	
Q5	does your household occupy?	Chinese Any other (please write in) A whole house or bungalow that is Detached	
Q5	does your household occupy?	Chinese Any other (please write in) A whole house or bungalow that is Detached Semi – detached	

Q6	Does your household own	Owns Outright		
	or rent the accommodation?			_
	(please tick <u>one</u> box)	Owns with a mortg	age or loan	
		Pays part rent and	part mortgag	le 🗌
		(shared ownership)		
		Rents		
		Lives here rent free	9	
Q7	Does your accommodation	Yes, in some or all	rooms	
	have central heating?	No		
Q8	How many cars or vans are owned,			
	or available for use, by one or more	0		
	members of your household?	1		
		2		
		3		
		4 or more		
Q9	Do you do any work as an	Yes, full time		(please go to Q11)
	Employee, or on a Government			
	sponsored training scheme, as	Yes, part time		(please go to Q11)
	self-employed/freelance, or in your			
	own/family business?	No		(please go to Q10)

Q10	f NO, are you Retired?		
		Student?	
		Looking after home/family?	
		Permanently sick/disabled?	
		None of the above?	
		(please go to Q12)	
Q11	If you are in paid employment, how		
G	many days have you had off work in		days
	the last month on account of your health?		uays
Q12	Please could you tell me how many times	GP telephone advice	
	you have used any of the following services	GP surgery consultations	
	in the last month.	GP home visits	
		Walk in centre	
		NHS Direct	
		District nurse visits	
		Health visitor visits	
		Social worker visits	
		Hospital	
		Home help	
	Any other profe	essional visitor or service (Please spec	ify)

Q13	Do you receive help with your daily Activities from a relative or friend?	Yes [No [Go to Q14 End of questionnaire
Q14	If YES, on average, how much time per day/per week do they spend?		hours per day days per week
	Now please go to Q15		
Q15	What would that person have been		
	doing as their main activity if they had	Housework	
	not been helping and/or caring for you?	Childcare	
		Caring for a relative or frien	d 🗌
		Voluntary work	
		Leisure activities	
		Attending school or univers	sity
		On sick leave	
		Paid work	
		Other (please specify)	
	If you answer to this question is paid work, please go to Q16, otherwise stop here.		
Q16	What is your carer's occupation?		

THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.

We would like you to tell us something about your breathlessness over the last 24 hours. If you don't do something because you are too breathless to even think of doing it please \checkmark "Yes"

As soon as you \checkmark "No" in the shaded grey area you may stop answering questions.

		Yes	No
1	Are you short of breath on strenuous exercise?		
2	Are you short of breath when hurrying on the level		
	or		
	walking up slight hills		
3	Does shortness of breath make you walk slower than most people of your age on the flat		
	Or		
	Have you had to stop for breath after a mile or so (or after 15 minutes) on the level at your own pace due to shortness of breath		
4	Have you been stopping for breath after walking 100 yards (or after 4 minutes) on the level at your own pace		
5	Have you got short of breath after walking a few yards at your own pace		
	Or		
	Did getting undressed last night make you short of breath		