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Baseline Participant Questionnaire

If you need to get in touch with the ACTIvATeS Trial research team, please contact:

ACTIvATeS Trial team
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Campus
Coventry
CV4 7AL

Phone: Fax: E-mail:





Please read these instructions before completing the questionnaire:

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us find out if the treatments you receive are helpful for your scoliosis.

<u>Please answer all the questions.</u> Although it may seem that questions are asked more than once, it is still important that you answer every one. We apologise for any repetition but we have used specially designed questionnaires and to assess the treatment you are receiving properly they need to be answered fully.

Please follow the instructions for each section carefully.

<u>Most questions request that you place an X in the box provided</u>. If so, please use an X rather than a tick, so that we can tell when you really meant to choose a particular box.

For example in the following question, if your answer 'yes', you should place an X firmly in the box next to yes.

	Yes	No
Do you drive a car?	X	

Please use a **BLACK or BLUE pen**. Please do not use a pencil.

Please check that you have completed all sections and return your completed questionnaire to the research clinician.

You will be invited to complete another questionnaire in approximately 6 months time.

Please keep a record of any days off school, and hospital or medical procedures you undergo until we see you again.

Please write any notes you have for the research team on the back page.

Section 1:

This section is to find out some general information about you. Please answer the following questions as completely as you can.

1. Date of birth:		2. Female ₁ Male ₂	
//			
3. At what age were you diagnosed	with scoliosis?	1. Do you currently wear a brace	?
years old		Yes 1 No 2	
5. To which of these ethnic groups of	do you consider you bel	ong? (Please place a X in one b	ox only)
White	1	Mixed	5
Indian	2	Pakistani	6
Bangladeshi	3	Black or Black British	7
Chinese	4	Other Ethnic Group	8
6. Onset of puberty:	0.2	Vaa Na	
Girls – have you started your period	5!	Yes 1 No 2	
	If yes, what age:	years old	
Boys – have you noticed any symptopubic hair, voice changes)?	oms of puberty (i.e.	Yes 1 No 2	
	If yes, what age:	years old	

Yes - daily	1
Yes - at least 4-5 times a week	2
Yes - at least 2-3 times a week	3
Yes - at least once a week	4
No - I do not have access to a computer and the internet	5
8. If you answered "yes" to the above question, t the internet (place an X next to all that apply)	hen, where do you have access to a computer and
At home	
At school	
At the library	
At a café	
At a friend or relative's house	
Other (please specify):	

7. Do you have access to a computer and the internet? (please place an X in one box)

Section 2:

1. Please place an 'X' in the box that best describes which hand you use for each activity.

	Always Left	Usually Left	No preference	Usually Right	Always Right
Writing	1	2	3	4	5
Throwing	1	2	3	4	5
Scissors	1	2	3	4	5
Toothbrush	1	2	3	4	5
Knife (without fork)	1	2	3	4	5
Spoon	1	2	3	4	5
Lighting a match (hand that holds match)	1	2	3	4	5
Computer mouse	1	2	3	4	5

Section 3:

The following questions ask about the condition of your back and how it affects you. Please place an X in the box for the best answer to each question. Please only enter one answer for each question.

1. Which one of the following best describes the amount of pain you have experienced during the past 6 months? None 1 Mild Moderate Moderate to severe Severe 2. Which one of the following best describes the amount of pain you have experienced over the last month? None Mild Moderate Moderate to severe Severe 3. During the past 6 months have you been a very nervous person? None of the time A little of the time Some of the time Most of the time All of the time 4. If you had to spend the rest of your life with your back shape as it is right now, how would you feel about it? Very happy Somewhat happy Neither happy nor unhappy Somewhat unhappy Very unhappy

5. What is yo	ur current level of activity?	
	Bedridden	1
	Primarily no activity	2
	Light activities and light sports	3
	Moderate activities and moderate sports	4
	Full activities without restriction	5
6. How do yo	u look in clothes?	
	Very good	1
	Good	2
	Fair	3
	Bad	4
	Very bad	5
7. In the past	6 months have you felt so down in the dumps that n	othing could cheer you up?
	Very often	1
	Often	2
	Sometimes	3
	Rarely	4
	Never	5
8. Do you ex	perience back pain when at rest?	
	Very often	1
	Often	2
	Sometimes	3
	Rarely	4
	Never	

	100% normal	1
	75% normal	2
	50% normal	3
	25% normal	4
	0% normal	5
	the following best describes the appearance of your r the head and extremities?	
	Very good	1
	Good	2
	Fair	3
	Poor	4
	Very Poor	5
11. Which on	e of the following best describes your pain medication	on use for back pain?
	None	1
	Non-narcotics weekly or less (e.g., aspirin, paracetamol, Ibuprofen)	2
	Non-narcotics daily	3
	Narcotics weekly or less (e.g.codydramol, co-codamol)	4
	Narcotics daily	5
12. Does you	r back limit your ability to do things around the house	e?
	Never	1
	Rarely	2
	Sometimes	3
	Often	4
	Very Often	5

9. What is your current level of work/school activity?

13. Have you felt calm and peaceful during the pas	st <u>6 months</u> ?
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
14. Do you feel that your back condition affects you	ur personal relationships?
Not at all	1
Slightly	2
Mildly	3
Moderately	4
Severely	5
15. Are you and/or your family experiencing finance	ial difficulties because of your back?
Severely	1
Moderately	2
Mildly	3
Slightly	4
Not at all	5
16. In the past 6 months have you felt down hearts	ed and blue?
Never	1
Rarely	2
Sometimes	3
Often	4
Very often	5

17. In the last because o	3 months have you taken any days off of work, included back pain?	ding household work, or school
	0 days	1
	1 day	2
	2 days	3
	3 days	4
	4 or more days	5
18. Does your	back condition limit your going out with friends/famil	y?
	Never	1
	Rarely	2
	Sometimes	3
	Often	4
	Very often	5
19. Do you fee	el attractive with your current back condition?	
	Yes, very	1
	Yes, somewhat	2
	Neither attractive nor unattractive	3
	No, not very much	4
	No, not at all	5
20. Have you	been a happy person during the past 6 months?	
	None of the time	1
	A little of the time	2
	Some of the time	3
	Most of the time	4
	All of the time	5

Are you satisfied with the results of your back management	21.	Are you	satisfied w	ith the resu	ilts of vour	back ma	nagement?
------------------------------------------------------------------------------	-----	---------	-------------	--------------	--------------	---------	-----------

Very satisfied	1
Satisfied	2
Neither satisfied nor unsatisfied	3
Unsatisfied	4
Very unsatisfied	5

22. Would you have the same management again if you had the same condition?

Definitely yes	1
Probably yes	2
Not sure	3
Probably not	4
Definitely not	5

Please look carefully at the following pictures that describe spinal shapes. Please place an X in the box below the drawing that looks most like you.

1. Body curve	A	R	A	A	A
	1	2	3	4	5
2. Rib prominence (bump)	W.		W	(J)	
	1	2	3	4	5
3. Flank prominence (bump)					
	1	2	3	4	5
4. Head chest hips					
	1	2	3	4	5
5. Position of head over hips					
	1	2	3	4	5

6. Shoulder level					
7. Shoulder blade rotation		2	3	4	5
8. Shoulder angle		2	3	4	5
9. Head position		2	3	4	5
10. Spine prominence (bump)	1	2	3	4	5

Please tell us how well the following statements apply to you. Please mark the box with an X that most applies to you.

	Not true	A little true	Somewhat true	Fairly true	Very true
11. I want to be more even.	1	2	3	4	5
12. I want to look better in clothes.	1	2	3	4	5
13. I want to have more even hips.	1	2	3	4	5
14. I want to have a more even waist.	1	2	3	4	5

Listed below are a number of statements related to a variety of normal kinds of feelings and bodily reactions. Read each item and decide how well the statement reflects you personally. It's best to go with your first judgement and not to spend too long thinking about any one question.

Place a 'X' in the box that most applies to you.

	Never true	Occasionally true	Sometimes true	Frequently true	Always true
I am aware of my overall body posture.	1	2	3	4	5
I am aware of how far I am bending over when I have to bend to do something.	1	2	3	4	5
3. I am aware of strain in my muscles.	1	2	3	4	5
4. I can provide definite information regarding the specific location and severity of pain/ discomfort in my body when the doctor asks me what symptoms I am having.	1	2	3	4	5
5. I can exert the correct amount of force/ pressure required to do a task even without thinking about it.	1	2	3	4	5
6. I am sensitive to changes in the position of my legs even without looking at them.	1	2	3	4	5
7. I can touch my nose with my index fingers, even with my eyes closed.	1	2	3	4	5
8. I can tell when I should stop doing something (e.g. lifting) before it causes me pain or injury.	1	2	3	4	5
9. I can tell where my hands are located without even looking at them.	1	2	3	4	5
10. I can tell how tired I will be after a task when I first start doing it.	1	2	3	4	5
11. I can feel even the slightest touch (e.g. a small raindrop or an ant crawling) on my skin.	1	2	3	4	5
12. I know my own strength.	1	2	3	4	5

Some kind of problems can make it hard to do many activities, such as eating, bathing, school work, and playing with friends. We would like to find out how you are doing. Please place an X in one box per line unless told otherwise.

1. During the last week was it easy or hard for you to:

	Easy	A little hard	Very hard	Can't do at all
Lift heavy books?	1	2	3	4
Pour a 2 litre bottle of milk?	1	2	3	4
Open a jar that has been opened before?	1	2	3	4
Use a fork and spoon?	1	2	3	4
Comb your hair?	1	2	3	4
Button buttons?	1	2	3	4
Put on your coat?	1	2	3	4
Write with a pencil?	1	2	3	4

2. On average, over the last 12 months, how often did you miss school because of your health?

Rarely	1
Once a month	2
Two or three times a month	3
Once a week	4
More than once a week	5
Do not attend school, etc.	6

3. During the last week how happy have you been with:

	Very happy	Somewhat happy	Not sure	Somewhat unhappy	Very unhappy
How you look?	1	2	3	4	5
Your body?	1	2	3	4	5
What clothes or shoes you can wear?	1	2	3	4	5
Your ability to do the same things your friends do?	1	2	3	4	5
Your health in general?	1	2	3	4	5

4. During the last week, how much of the time

	Most of the time	Some of the time	A little of the time	None of the time
Did you feel sick and tired?	1	2	3	4
Were you full of pep and energy?	1	2	3	4
Did pain or discomfort interfere with your activities?	1	2	3	4

5. During the last week has it been easy or hard for you to:

	Easy	A little hard	Very hard	Can't do at all
Run short distances?	1	2	3	4
Ride a bike?	1	2	3	4
Climb three flights of stairs?	1	2	3	4
Climb one flight of stairs?	1	2	3	4
Walk more than a mile?	1	2	3	4
Walk three blocks?	1	2	3	4
Walk one block?	1	2	3	4
Get on and off a bus?	1	2	3	4

6. How often do you need help from another person for walking and climbing?

Never	Sometimes	About half the time	Often	All the time
1	2	3	4	5

7. How often do you use assistive devices (such as braces, crutches, or wheelchair) for walking and climbing?

Never	Sometimes	About half the time	Often	All the time
1	2	3	4	5

Ω	Durina	tho	lact	WOOK	hac	iŧ	hoon	0261	or	hard	for	VOL	to:
ο.	Duilliu	เมเต	ıası	WCCL	Has	11	חבבוו	casv	UI.	Halu	101	vou	w.

	Easy	A little hard	Very hard	Can't do at all
Stand while washing your hands and face at a sink?	1	2	3	4
Sit in a regular chair without holding on?	1	2	3	4
Get on and off a toilet or chair?	1	2	3	4
Get in and out of bed?	1	2	3	4
Turn door knobs?	1	2	3	4
Bend over from a standing position and pick up something off the floor?	1	2	3	4

9. How often do you need help from another person for sitting and standing? (Cross (x) one box.)

Never	Sometimes	About half the	Often	All the time
1	2	3	4	5

10. How often do you use assistive devices (such as braces, crutches, or wheelchair) for sitting and standing?

Never	Sometimes	About half the time	Often	All the time
1	2	3	4	5

	ticipate in recreational outdoor activitie ng, hiking, jogging)	s with other kids the same age? (F	or example:
Yes, easily	Yes, but a little hard	Yes, but very hard	No
1	2	3	4
If you answered	"no" to Question 11 above, was your a	activity limited by: (Cross (x) to all t	hat apply)
	Pain?		
	General Health?		
	Doctor or parent Instructions?		
	Fear the other kids won't like you?		
	Dislike of recreational outdoor activitie	s?	
	Activity not in season?		
	cipate in games or sports with other kindstball, catch, skipping, touch rugby, hop Yes, but a little hard	scotch)	ag, basketball No
1	2	3	4
If you answered	"no" to Question 12 above, was your a	ctivity limited by: (Cross (x) to all th	nat apply)
	General Health?		
	Doctor or parent Instructions?		
	Fear the other kids won't like you?		
	Dislike of games or sports?		
	Activity not in season?		

	ite in competitive level sports with II, soccer, rugby, baseball, swimm		
Yes, easily	Yes, but a little hard	Yes, but very hard	No
1	2	3	4
If you answered "no" to	Question 13 above, was your act	ivity limited by: (Cross (x) to	all that apply)
Pain	?		
Gen	eral Health?		
Doct	or or parent Instructions?		
Fear	the other kids won't like you?		
Disli	ke of competitive level sports?		
Activ	vity not in season?		
14. How often in the l	ast <u>week</u> did you get together and Sometimes	d do things with friends?	r rarely
1	2		3
If you answered "some (Cross (x) to all that ap	times" or "never or rarely" to Ques ply)	stion 14 above, was your ac	tivity limited by
Pair	n?		
Gen	eral Health?		
Doc	tor or parent Instructions?		
Fea	r the other kids won't like you?		
Frie	nds not around?		

15. How often in the last week did you participate in PE or break time?

Often	Sometimes	Never or rarely	No gym or recess
1	2	3	4
If you answered "son (Cross (x) to all that a	netimes" or "never or rarely" to (apply)	Question 15 above, was y	our activity limited by:
Pa	ain?		
G	eneral Health?		
De	octor or parent Instructions?		
Fe	ear the other kids won't like you	?	
Di	islike of PE or break time?		
So	chool not in session?		
Lo	don't attend school?		
16. Is it easy or hard	I for you to make friends with ki	ds your own age?	
Usually easy	Sometimes easy	Sometimes hard	Usually hard

17. How much pain have you had during the last week? (Cross (x) one box.)

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

1

18. During the last week, how much did pain interfere with your normal activities (Including at home, outside of the home, and at school)? (Cross (x) one box.)

Not at all	A little bit	Moderately	Quite a bit	Extremely
1	2	2	4	5

19. What expectations do you have for your treatment? As a result of my treatment, I expect:

	Definitely yes	Probably yes	Not sure	Probably not	Definitely not
To have pain relief	1	2	3	4	5
To look better	1	2	3	4	5
To feel better	1	2	3	4	5
To feel better about myself	1	2	3	4	5
To sleep more comfortably	1	2	3	4	5
To be able to do activities at home	1	2	3	4	5
To be able to do more at school	1	2	3	4	5
To be able to do more play or recreational activities (biking, walking, doing things with friends).	1	2	3	4	5
To be able to do more sports	1	2	3	4	5
To be free from pain or disability as an adult	1	2	3	4	5

20. If you had to spend the rest of your life with your bone and muscle condition as it is right now, how would you feel about it?

Very satisfied	Somewhat satis- fied	Neutral	Somewhat dissat- isfied	Very dissatisfied
1	2	3	4	5

By placing a X in one box in each group below, please indicate which statements best describe your own heath state today.

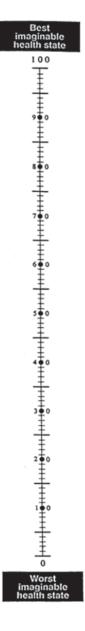
Mobility I have no problems in walking about I have some problems in walking about I am confined to bed 3 Self-care I have no problems with self-care I have some problems washing or dressing myself I am unable to wash or dress myself Usual activities (e.g. work, study, housework, family or leisure activities)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

To help people say how good or bad a health state 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 is your own health today, in your opinion.

Please do this by <u>drawing a line from</u> <u>the box below</u>, to whichever <u>point on</u> <u>the scale indicates how good or bad</u> <u>your current health state is **today**.</u>

Your own health state TODAY



This section asks about how your health interferes with your everyday life. Please read each question carefully and place a X in the box of the answer that best describes your level of ability. You may feel that some of these questions are repeating what we have already asked you, or that they do not apply to you, but it is important that we ask the same questions of everyone, so we would be very grateful if you would answer all the following questions.

1. Which <u>one</u> of the following best describes your usual ability to see well enough to read ordinary newspaper print?			
Able to see well enough without glasses or contact lenses	1		
Able to see well enough with glasses or contact lenses	2		
Unable to see well enough even with glasses or contact lenses	3		
Unable to see at all	4		
2. Which <u>one</u> of the following best describes your usual ability to see well enough friend on the other side of the street?	to recognise a		
Able to see well enough without glasses or contact lenses	1		
Able to see well enough with glasses or contact lenses	2		
Unable to see well enough even with glasses or contact lenses	3		
Unable to see at all	4		
3. Which <u>one</u> of the following best describes your usual ability to hear what was sconversation with at least 3 other people?	aid in a group		
Able to hear what was said without a hearing aid	1		
Able to hear what was said with a hearing aid	2		
Unable to hear what was said even with a hearing aid	3		
Unable to hear what was said, but did not wear a hearing aid	4		
Unable to hear at all	5		

4	Which <u>one</u> of the following best describes your usual ability to hear what was said in a conversation with one other person in a quiet room?	
	Able to hear what was said without a hearing aid	1
	Able to hear what was said with a hearing aid	2
	Unable to hear what was said even with a hearing aid	3
	Unable to hear what was said, but did not wear a hearing aid	4
	Unable to hear at all	5
5	. Which <u>one</u> of the following best describes your usual ability to be understood when spe your own language with people who do not know you?	aking
	Able to be understood completely	1
	Able to be understood partially	2
	Unable to be understood	3
	Unable to speak at all	4
6	. Which <u>one</u> of the following best describes your usual ability to be understood when spe with people who know you well?	aking
	Able to be understood completely	1
	Able to be understood partially	2
	Unable to be understood	3
	Unable to speak at all	4
7	Which one of the following best describes how you usually feel?	
	Happy and interested in life	1
	Somewhat happy	2
	Somewhat unhappy	3
	Very unhappy	4
	So unhappy that life was not worthwhile	5

8.	Which one of the following best describes your usual level of pain and discomfort?	
	Free of pain and discomfort	1
	Mild to moderate pain or discomfort that prevented no activities	2
	Moderate pain or discomfort that prevented some activities	3
	Moderate to severe pain or discomfort that prevented some activities	4
	Severe pain or discomfort that prevented most activities	5
a	Which one of the following best describes your usual ability to walk?	
٥.	(Note: Walking equipment refers to mechanical supports such as braces, cane, crutches, or a	walker.)
	Able to walk around the neighbourhood without difficulty, and without walking equipment	1
	Able to walk around the neighbourhood with difficulty, but did not require walking equipment or the help of another person	2
	Able to walk around the neighbourhood with walking equipment, but without the help of another person	3
	Able to walk only short distances with walking equipment, and required a wheel-chair to get around the neighbourhood	4
	Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighbourhood	5
	Unable to walk at all	6

10. Which one of the following best describes your usual ability to use your hands & fingers?

(Note: Special tools refers to hooks for buttoning clothes, gripping devices for opening jars or lifting small items, and other devices to compensate for limitations of hands or fingers.)

	Full use of two hands and ten fingers	
	Limitations in the use of hands or fingers, but did not require special tools or the help of another person	2
	Limitations in the use of hands or fingers, independent use of special tools (did not require the help of another person)	3
	Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with the use of special tools)	4
	Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with the use of special tools)	5
	Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)	6
11.	Which one of the following best describes your usual ability to remember things?	
	Able to remember most things	1
	Somewhat forgetful	2
	Very forgetful	3
	Unable to remember anything at all	4
12.	Which one of the following best describes your usual ability to think & solve day to day proble	ms?
	Able to think clearly and solve day to day problems	1
	Had a little difficulty when trying to think and solve day to day problems	2
	Had some difficulty when trying to think and solve day to day problems	3
	Had great difficulty when trying to think and solve day to day problems	4
	Unable to think or solve day to day problems	5

13. Willich one of the following best describes your usual ability to perform basic activities?	
Eat, bathe, dress and use the toilet normally	1
Eat, bathe, dress or use the toilet independently with difficulty	2
Required mechanical equipment to eat, bathe, dress or use the toilet independently	3
Required the help of another person to eat, bathe, dress or use the toilet	4
14. Which one of the following best describes how you usually feel?	
Generally happy and free from worry	1
Occasionally fretful, angry, irritable, anxious, or depressed	2
Often fretful, angry, irritable, anxious or depressed	3
Almost always fretful, angry, irritable, anxious or depressed	4
Extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help	5
15. Which one of the following best describes your usual level of pain or discomfort?	
Free of pain and discomfort	1
Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities	2
Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities	3
Frequent pain or discomfort, frequent disruption of normal activities. Discomfort required prescription narcotics for relief	4
Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities	5

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
17. How did you complete the questionnaire? Please select the one answer that best described situation.	cribes your
By myself, the patient/subject, without any help from anyone else	1
By myself, the patient/subject, except <u>someone else circled</u> the answers on the questionnaire form for me	2
By myself, the patient/subject, but with the help of someone else	3
This questionnaire was completed by a family member, <u>without help</u> from the subject/patient	4
This questionnaire was completed by a nurse or other health professional, without help from the subject or patient	
Please specify type of health professional:	5
This questionnaire was completed by another person, without help from the subject/patient Please specify relationship to subject or patient:	6

16. Overall, how would you rate your usual health?

This section asks about any health or social care you have accessed in the last 3 months.

Have you used or had contact with any of the following community based health or social care services in the <u>last 3 months?</u>

Yes

1

No

If yes, please complete the table below:

Community based health or social care services	Used or had contact with in the last 3 months (please place a X in the box)?	Number of times in the last 3 months
GP (family doctor), surgery visit	Yes 1 No 2	
GP (family doctor), home visit	Yes 1 No 2	
GP (family doctor), phone/email	Yes 1 No 2	
Practice or district nurse	Yes 1 No 2	
Physiotherapist	Yes 1 No 2	
Occupational therapist	Yes No	
Orthotist	Yes 1 No 2	
Social worker	Yes No	
Any other community based health or social care services? Please specify:	Yes ₁ No ₂	
Please specify:	Yes 1 No 2	
Please specify:	Yes ₁ No ₂	

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If yes, please com	plete the table bel	ow:			
Name of hospital:	Type of ward: (e.g. children's ward)		/ nights did stay?	Reason for stay: (e.g. to have an operation)	If you had an operation please state what type:
3. Have you visited	an NHS hospital	as an outpa	tient in the	ast 3 months? Yes	1
o. Have you would	an morning	ao an oatpa		No	2
If yes, please comp	olete the table bel	ow:			-
	spital department lace a X in the bo			Name of hospital	Number of visits in the last 3 months
Orthopaedic/spinal		No ₂			
Paediatric clinic	Yes 1	No ₂			
Emergency departr	ment Yes 1	No ₂			
Physiotherapy depa	artment Yes	No ₂			
Orthotics/bracing d	epartment				
	Yes 1	No ₂			
Other department	Yes	No ₂			
Please specify:					
Other department	Yes	No ₂			
Please specify:					

Yes

No

2. Have you stayed overnight in an NHS hospital in the <u>last 3 months?</u>

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Test or investigations (please pl	lace a X in the box	()		Number of times in the la 3 months
X-Ray	Yes	₁ No	2	
MRI	Yes	₁ No	2	
CT-Scan	Yes	₁ No	2	
Blood Test	Yes	₁ No	2	
Other tests or investigations Please specify:	Yes	₁ No	2	
Other tests or investigations	Yes	₁ No	2	
	(e.g. painkillers s	uch as i	- bup	profen or paracetamol) by
lave you been prescribed any medicines to by the NHS in the last three months? Yes 1 No 2 es, please provide details:	(e.g. painkillers si	uch as i	- bup	profen or paracetamol) by
lave you been prescribed any medicines be by the NHS in the last three months? Yes 1 No 2 es, please provide details:	(e.g. painkillers si	uch as i	bup	Number of times it was prescribed in the last 3 month
ave you been prescribed any medicines e by the NHS in the last three months? Yes 1 No 2 s, please provide details:	(e.g. painkillers si	uch as i	bup	Number of times it was pro
lave you been prescribed any medicines e by the NHS in the last three months? Yes 1 No 2 es, please provide details: Medicine prescribed	(e.g. painkillers si	uch as i	bup	Number of times it was pro
Have you been prescribed any medicines are by the NHS in the last three months? Yes 1 No 2 es, please provide details: Medicine prescribed 1.	(e.g. painkillers si	uch as i	bup	Number of times it was pro

4. Have you had any tests or investigations at an NHS hospital in the <u>last 3 months</u>?

1.							
2.							
3.							
4.							
7. Have your parents paid for any private healthcare (e.g. consultation with private orthopaedic consultant) because of your health in the <u>last 3 months</u> ? Yes No 2 If yes, please provide details.							
Type of private healthcare (e.g. visit to a spinal surgeon or physiotherapy treatment)	Number of visits in the last 3 months	Total cost paid by your parents	Total cost paid by medical insurance				
1.							
2.							
3.							
4.							
	<u> </u>						

6. Have you been provided with any equipment (e.g. brace or special chair) by the NHS in the last three

Number of items in the last 3 months

months?

Yes

If yes, please provide details:

Type of equipment provided

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₁ No

8. Have your parents paid for any medicines (e.g. painkillers such as it cause of your health in the in the <u>last three months?</u>	ouprofen or paracetamol) be-
Yes No	
If yes, please provide details:	
Type of medicine privately paid for	Cost in the last 3 months (to the
(e.g. paracetamol)	nearest pound)
1.	
2.	
3.	
4.	
9. Have your parents paid for any special equipment (e.g. brace or spering the last three months? Yes No 1 If yes, please provide details:	
Type of equipment paid for	Cost in the last 3 months (to the nearest pound)
1.	
2.	
3.	
4.	

1. Are you in full-time education?	Yes	No	2
If yes, then please complete questions 2- 4. If no, please p	roceed to Question	5.	

2. What year are you in at school or college? _____

3. Have you used any additional educational services because of problems with your health in the last 3 months?

Yes

No

If yes, please provide details.

This section asks about education and employment

		_	
Additional education servic	es		Number of times in the last 3 months
Contacts with school nurse	Yes No	1	
Contacts with school counselor	Yes No	1	
Extra help in school (mentor, teac assistant)	hing Yes No	1	Total number of hours week:
Any other additional educational s	Yes No	2	

	Yes	No 2	
If yes, how long were you off school for? Total number of dates and the school for?	ays		
Proceed to question 7 below.			
5. If you are not in full-time education, which of these best describes	your situatio	n?	
Activity during the day	that be	x in the box st describes situation	K
In an apprenticeship (e.g to be a plumber, hair-dresser, etc.) or government supported training			1
Employee/Self-employed			2
Employee on sick leave			3
Unpaid employment (e.g. voluntary job)			4
Unemployed			5
Other (e.g. excluded from school)			6
6. Have you been off work because you were sick in the <u>last 3 month</u> If yes, how long were you off work for? Total number Have you lost any earnings from your job due to sickness? If yes, please estimate the amount lost in the <u>last 3 months</u> (to	er of days Yes	1 No	22
7. Do you have a job at the weekend and/or in the holidays?	Yes	, No	2
If yes, have you been off sick in the last 3 months from this job?	Yes	1 No	2
If yes, how long were you off work for? Total number			_
Have you lost any earnings from your job due to sickness?	Yes	1 No	2
If yes, please estimate the amount lost in the last 3 months (to	the neares	st pound) £_	

4. Have you been off school because you were sick in the <u>last 3 months</u>?

Section 11

This section is for your parent to complete

)

2. What is your employment status? (Please place an X in the box that best applies to you).

Employed	1
Sheltered employment	2
Unemployed	3
Student	4
Housewife/husband	5
Retired	6
Other	7

If unemployed: month/year last in paid employment

____ / ___ _

m m y y

If employed: Hours worked per week (on average)

3. What is your annual income? (Please place an X in the box that best applies to you).

Up to £5,199	1
£5,200 up to £10,399	2
£10,400 up to £15,599	3
£15,600 up to 20,799	4
£20,800 up to 25,999	5
£26,000 up to £31,199	6
£31,200 up to £36,399	7
£36,400 up to £51,599	8
£52,000 and above	9

Is this before or after tax?

Before After

4. How many days have you been absent from work in the <u>last 3 months</u> ?	
Of these, how many were due to your child's health?	
5. Has your child's health affected your working ability?	Yes ₁ No ₂
If yes: How many hours less have you worked per week due to your child's health?	
6. If you have a partner: What is his/her employment st	atus?
Employed	1
Sheltered employment	2
Unemployed	3
Student	4
Housewife/husband	5
Retired	6
Other	7
	/
If unemployed: month/year last in paid employment	m m y y
If employed: Hours they work per week (on average)	

	Up to £5,199	1		
	£5,200 up to £10,399	2		
	£10,400 up to £15,599	3		
	£15,600 up to 20,799	4		
	£20,800 up to 25,999	5		
	£26,000 up to £31,199	6		
	£31,200 up to £36,399	7		
	£36,400 up to £51,599	8		
	£52,000 and above	9		
ls	this before or after tax?	Before	1 After	2
8.	How many days have they been absent from work in the <u>last 3 months</u> ?	ı 		-
	Of these, how many were due to your child's health?	?		-
9.	Has your child's health affected their working ability?	Yes 1	No 1	
	If yes: How many hours less have they worked per week due to your child's health?			-

7. What is your partner's annual income?

10. Did you spend any money on travel to access hea services or visit the hospital as a result of your ch health in the <u>last 3 months</u> ?	
If yes, please provide details:	
	Total cost in the last 3 months (£)
Car park fees	
Petrol/fuel costs	
Public transport fares	
Taxi fares	
Other (please specify):	
11. In the <u>last 3 months</u> , have you incurred any other	additional expenditure due to your child's health $_{ m 1}$ No $_{ m 2}$
If yes, please record any additional expenditures	incurred over the last 3 months
Type of additional expenditure (e,g, exercise equipment or special clothing)	Total cost in the last 3 months (£)
1.	
2.	
3.	
4.	
4.	

That is the end of this questionnaire.

Please check that you have completed all sections and return your completed questionnaire to the research clinician.

You will be asked to complete another questionnaire in approximately 6 months.

Thank you very much for your time.



Baseline Assessment Form

If you need to get in touch with the ACTIvATeS Trial research team, please contact:

ACTIVATES Trial team
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Campus
Coventry
CV4 7AL





Section 1: This section relates to information about the participant provided from x-ray that you will need to collect prior to the assessment appointment.

Please ensure you have entered <u>the participant's ID number</u> on the front cover of this form.

1. Date of x-ray									
	D	D	M	М	Y	Y	Υ	Υ	

2. Curve characteristics

Type of curve (Place an X in the appropriate answer)	Apex of curve (specify level or levels as appropriate)	Cobb angle (degrees)	Direction of curve (= left) = right
Single 1			
Double 2			
Curve balance	Coronal plane distance from S1 to plumb line C7 plumbline left of S1 = L C7 plumbline right of S1 = R	L / R (please circle)	mm
(Central Sacral Vertebral Line	Sagittal plane distance from S1 to plumb line C7 plumbline anterior to S1 +ve C7 plumbline posterior to S1 -ve	+ / - (please circle)	mm

_	01			
-5	SKE	IETAI	mati	Iritv

Please circle the number that indicates the Risser sign for this patient (from x-ray report).

0 1 2 3 4 5

Section 2: This section is to ensure the research team have sufficient details about the assessment that you are performing.

1. Da	te you	are c	om	pletin	g th	is ass	essm	ent:						n comple ur clock)		i
D	D	1	M	М		Υ	Υ	Υ	Υ			Н	Н	М	M	
;	3. Cen	tre:								_	4. Res	earch cl	inician's	name:		
L																

Section 3: Line bisection test

Equipment:

Line bisection test papers (13 in total including example - labelled in order of testing)

Pen

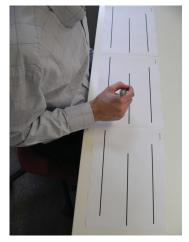
Table or similar wide enough for three A4 sheets in a line (landscape orientation)

Set up:

Patient sitting at table or desk.

Procedure:

Refer to manual for full details of testing procedure. There are two tests - one using 3 sets of straight lines and the other using 1 line on a drawing of a body. The position (left, centre or right), hand (left or right) and order of testing is described on the top of each sheet. Place one sheet down at a time and then remove it before placing the next one. The photos below illustrate the position of the sheets - in reality, only one sheet will be down at any one time.







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Instructions:

Straight line

"I am going to put a sheet of paper in front of you with 3 lines on it. I want you to draw a line where you think the middle of each line is. Try to be as exact as possible"

"You will do this 3 times with your right hand and 3 times with your left. I will place the sheets in different positions. Please mark the lines with the sheet in this position - do not move it from where I put it."

Body line

"I am going to put a sheet of paper in front of you with 1 line on it. I want you to draw a line where you think the middle of the line is. Try to be as exact as possible"

"You will do this 3 times with your right hand and 3 times with your left. I will place the sheets in different positions. Please mark the lines with the sheet in this position - do not move it from where I put it."

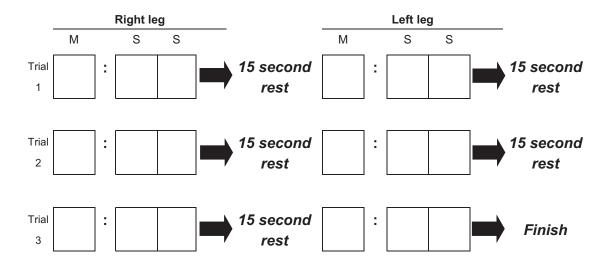
Section 4: Physical details

1. Height and weight

Standing height	cm	Weight	k
Sitting height	cm	If possible u	se the same
Chair height (floor to seat)	cm	stadiometer, so each	

2. Balance - Timed dynamic standing balance test

Test legs alternately (R - L - R - L - R - L) with a 15 second rest in between each leg to reduce fatigue.



kg

Section 5: Laterality discrimination (Recognise programme)

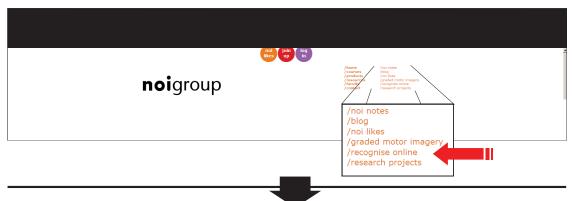
Equipment:

Computer with internet access

Set up:

Patient sitting at table/desk in front of computer.

1) Connect to the internet and navigate to the NOI Recognise website (www.noigroup.com/recognise).

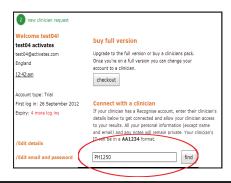


2) Login using 3-digit participant ID number (e.g. 004@activates.com)

Enter password ('peter')

Enter 'PH1250' in 'Connect with a clinician' box.





3) Click '/connect' to confirm clinician. Click on recognise' in menu top right of screen.





4) Choose options for hand or back test as detailed in manual. Refer to manual for full details.

Order of testing is provided over leaf.

Instructions:

Hand test - Left or Right hand

"When you start the programme, there will be a series of images of the hand in different positions. I want you to try and guess whether it is the left or the right hand."

"Press the 'a' or 'd' key (or use arrow keys) on the keyboard to make your choice as quickly as possible. You only get one chance for each picture. The computer will tell you at the end how many you got correct. It will also time you to see how long it takes to make your decision. Try to do the test as guickly and accurately as possible."

"Follow the instructions on the screen."

Trunk Test - moving towards the Left or Right

"When you start the programme, there will be a series of images of the trunk in different positions. I want you to try and guess in which direction the body is moving - to the left or to the right.

"Press the 'a' or 'd' key (or use arrow keys) on the keyboard to make your choice as quickly as possible. You only get one chance for each picture. The computer will tell you at the end how many you got correct. It will also time you to see how long it takes to make your decision. Try to do the test as quickly and accurately as possible."

"Follow the instructions on the screen."

Test order

- 1. Back
- 2. Hands

Section 6: Position matching

Equipment:

Inclinometer

Blindfold goggles

Eyeliner pencil or similar (to mark measuring point)

Set up:

- 1) Patient sitting on stool or bed (no back or arm rest) with feet flat on floor and arms crossed across chest so fingers are touching opposite shoulders.
- 2) Mark measuring position on skin at C7/T1 (see skin marking protocol for locating this point). Draw a line perpendicular to the spine through this point. You will use this to align the inclinometer when measuring.
- 3) Place blindfold goggles on patient and ensure they cannot see.

Procedure:

Do a practice to familiarise the patient with the test procedure.

Maximum Side Flexion

- 1) Ask patient to sit in upright position facing straight ahead with arms crossed over chest. Place the inclinometer against the skin marker at C7 and 'zero' the device.
- Ask the patient to bend to one side as far as possible while keeping their legs and hips still.
 Measure the angle and record to nearest degree.

1/2 side flexion

- 1) Instruct patient as to the testing procedure (i.e. attempting to match 1/2 way position).
- 2) Use the same setup as previously.
- 3) In upright position, place the device and zero it.
- 4) Ask patient to bend sideways slowly to what they consider to be 1/2 of their full side flexion ROM. Ask the patient to hold this position and to 'memorise' it. Measure the angle to the nearest degree and record it. The aim is to return to this 1/2 way position.
- 5) Return to start position.
- 6) Ask patient to return to their '1/2 way' position. Re-measure and record the angle on the display.
- 7) Repeat this 3 times for that side.

Repeat the above procedures for the other side. The actual order of testing has been randomised (see results table).

Instructions:

Max ROM

"Sit comfortably with your arms across your chest like this. I will put a blindfold over your eyes so you can't see and then ask you to bend sideways like this."

"To start, you need to face straight ahead and sit comfortably - this is your start position. When I say go back to the start, this is the position you need to return to."

"I will ask you to bend to the side as far as you can and then return to sitting straight. I will be looking at the device and writing down how far you bend. To give me time to write them down, you need to stay in the position until I say."

"Bend your head and body together as far to the [L/R] as possible - hold that position. Return to the start position."

1/2 ROM

"Now bend your body to the [L/R] to a point you think is 1/2 way between the start position and the furthest you can go - hold that position. I want you to memorise this position because I am going to ask you to repeat it."

"Return to the start position - now try and go back to the 1/2 way position again."



1. mark the position of C7.



2. place the device on the line & zero inclinometer.



3. measure & record the angle at either full or 1/2 side flexion.

Max Left	Please 'zero' the device in	r	Max side flexion Left		
	neutral.				degrees
		1/2 Left		1/2 Left	
1	Please 'zero'	1.1	Return to neutral	1.2	
1/2 Left	the device in neutral.	degrees	& then repeat		degrees
		1/2 Left		1/2 Left	
2	Please 'zero'	2.1	Return to neutral	2.2	
1/2 Left	the device in neutral.	degrees	& then repeat		degrees
	<u> </u>	1/21-6		1/21-6	
	Please 'zero'	1/2 Left 3.1	Return to neutral	1/2 Left 3.2	
3 1/2 Left	the device in neutral.	degrees	& then repeat		degrees

Right

Max Right	Please 'zero' the device in neutral.	N	lax side flexion Righ	t degrees
1 1/2 Right	Please 'zero' the device in neutral.	1/2 Right 1.1 degrees	Return to neutral & then repeat	1/2 Right 1.2 degrees
2 1/2 Right	Please 'zero' the device in neutral.	1/2 Right 2.1 degrees	Return to neutral & then repeat	1/2 Right 2.2 degrees
3 1/2 Right	Please 'zero' the device in neutral.	1/2 Right 3.1 degrees	Return to neutral & then repeat	1/2 Right 3.2 degrees

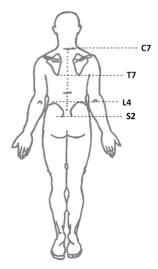
Location of apex (point 8) e.g. T4

to indicate which part of the spine the localisation & 2 point discrimination tests occur



Remember to mark the points on the back prior to testing in sections 7 & 8. See the Skin marking protocol in the manual for full details.

- The apex is defined as the most lateral vertebra of the curve.
- Identify the spinal level that corresponds to this point from the x-ray/ imaging study.
- Using whichever landmark is easiest from the list below, count up or down to find this point.
- Remember, there are 5 Lumbar, 12 thoracic & 7 cervical vertebrae.



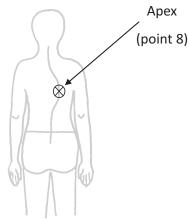
C7 = most prominent point at base of neck (doesn't disappear on extension).

T7 = at same level as bottom point of scapulae

L4 = at same level (or just above) as line between both iliac crests.

S2 = same level as the PSIS (dimples either side of base of spine)

 Once identified, mark out the testing points using the template.



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Section 7: Localisation

Equipment:

Monofilament 10g

Chart showing skin markings 1-15 (use chart appropriate to location of curve apex)

Set up:

- Patient lying face down on plinth with face looking through face hole. Place flat pillow under stomach.
- 2) Patient's back marked up as previously described with 15 testing locations.

Procedure:

- 1) Show the patient the chart and give instructions as to what you will be asking them to do (i.e. guess which site has been touched). Leave the chart so they can see it throughout test.
- 2) As a test, touch each site in turn (1-15) and identify them to the patient. Apply pressure until the wire bends for one second. Repeat 3 times in a row.
- 3) For actual test, each site will be tested twice in random order. The testing order of sites are provided on the result sheet of this form (see next page).

Measurement:

Ask the patient to guess the location - record reported location in box under actual location.

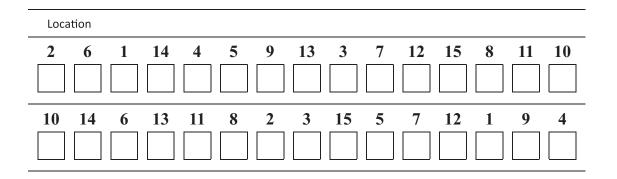
site	12	7	3	13	15	5	8	1	14	11	2	10	9	4	6
Patient says	12	6	3	14	15	5	8	2	14	12	2	11	9	4	5

Instructions:

"Look at the chart with all the numbers on it. I am going to tap you 3 times on your back in these different places and I want you to try and guess which number it is. Each place will be touched more than once. You have only one chance to guess each time - if you are not sure, say the number you think is closest to the place where you feel the touch."

"I am going to start now - please tell me which location you think they are by saying the number from the sheet in front of you."





Section 8: Two point discrimination

Equipment:

Two-point discriminator tool

Set up:

- Patient lying face down on plinth with face looking through face hole. Place flat pillow under stomach.
- 2) Patient's back marked up as previously described using template.

Procedure:

- 1) Show the patient the discriminator tool and give instructions as to what you will be asking them to do (i.e. guess whether they are being touched by one or two points).
- 2) Do a practice by touching them randomly with one or two points on any part of the arm or leg. Apply pressure until the very first blanching of the skin for one second repeat 3 times. Ensure that both points are contacting skin at the same time (NB: the patient is to tell you if they feel two points because the points touched at different times). Ask the patient to guess by saying 'one' or 'two' depending on their perception. If they are unsure, you can repeat the procedure once.
- 3) For actual test, two point discrimination will be conducted at 2 different sites (points 7 & 9). The testing order of sites is provided on the result sheet of this form. Test the first site completely and then test the other site. Testing will take place in 5 mm increments between 10mm and 100mm. The actual order of testing for each distance is randomised (see result sheet).
- 5) <u>Trial 1:</u> Ensure the tool is held parallel to the spine. Test each distance at first site in the order given on the result sheet. Record '1' or '2' in the box underneath for Trial 1. As you look along the row of results for Trial 1, there should be a pattern of 1s at the beginning of the sequence, 2's at the end of the sequence, and possibly a mix of 1's and 2s in the middle.

Trial 1	1	1	1	1	1	1	1	2	1	2	1	1	2	2	1	2	2	2	2	2	2	2	2	2
IIIai I	1	1	1	1	1	T	T		7		1	1			T				_	_	_	_	4	

<u>Trial 2:</u> Re-measure the values between the last two consecutive 1s and the first 2 consecutive 2s inclusive (see example above). Start at the lower end and work up.

<u>Trial 3:</u> Repeat same measures as Trial 2 (see example below) but start at the upper end and work down.

1	Trial 1	1	1	1	1	1	1	1	2	1	2	1	1	2	2	1	2	2	2	2	2	2	2	2	2
T	Trial 2						1	2	2	2	1	1	2	1	2	1	1	2							
ī	Trial 3						2	1	1	2	2	2	2	1	1	2	2	2							

Instructions:

"I am going to tap you on your back 3 times with either one or two points on this device. I want you to tell me whether it is one or two points. I will repeat this many times. If you are not sure I can repeat it."

"I am going to start - please say 'one' when you feel one point and 'two' if you feel two points."

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site 9

7	test order	6	16	23	13	1	21	18	5	17	7	12	22	15	4	8	20	14	3	10	2	9	19	11
form v1.0 22.	distance	10mm	15mm	20mm	25mm	30mm	35mm	40mm	45mm	50mm	55mm	60mm	65mm	70mm	75mm	80mm	85mm	90mm	95mm	100 mm	100 mm	100 mm	1 point	1 point
.11.2012	trial 1																							
	trial 2																							
	trial 3																							

site **7**

	test order	16	18	3	6	12	5	10	8	17	7	22	19	15	13	9	14	4	1	2	20	23	11	21
	distance	10mm	15mm	20mm	25mm	30mm	35mm	40mm	45mm	50mm	55mm	60mm	65mm	70mm	75mm	80mm	85mm	90mm	95mm	100 mm	100 mm	100 mm	1 point	1 point
ISRCTN	trial 1																							
190480705	trial 2																							
	trial 3																							

Section 9: Previous treatment and treatment preferences

1. Has the participant had ar	ny previous treatment for their so	oliosis? Yes 1 No 2										
If yes, then please in	idicate which treatments (Place a	n X in the box for all that apply).										
Physiotherapy												
Scoliosis specific exercis	es Please specify which type of exercises :	scoliosis specific										
	Schroth											
	SEAS											
	ScolioGold Programme	e (Scoliosis SOS Clinic)										
	Does not know											
	Other (Please specify):											
Pilates												
Bracing												
Other	Please specify:											
Other	Please specify:											
		se which treatment they receive, it is										
Please complete the table be	have a preference for one of the	treatments.										
	Please indicate which treatment	Please indicate which treatment										
	the participant would prefer to receive	the parents would prefer their child to receive										
	(Place an X in the box)	(Place an X in the box)										
Physiotherapy advice and education session	1											
A course of physiotherapy												
Equally happy to receive either treatment	Equally happy to receive											

Time that you finished this assessment (24 hour clock):



Please check that all sections have been completed.

Please include a copy of the ISIS scan report when you send this back to the ACTIvATeS centre office.

Please ensure that you have entered <u>the participant's ID number</u> on the front cover of this questionnaire.

Thank you very much for your time.