



# Participant Questionnaire

## STARFISH

A randomised controlled trial of STeroid Administration Routes For Idiopathic Sudden sensorineural Hearing loss

Site:	_____
TNO:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Initials:	<input type="checkbox"/> <input type="checkbox"/>
Year of birth:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Time point of completion:	<input type="checkbox"/> Baseline - Date: DD/MMM/YYYY <input type="checkbox"/> 6 weeks - Date: DD/MMM/YYYY <input type="checkbox"/> 12 weeks - Date: DD/MMM/YYYY

Please return to Birmingham Clinical Trials Unit (BCTU) on completion using the pre-paid envelopes provided:

STARFISH Trials Office  
 Birmingham Clinical Trials Unit (BCTU)  
 Public Health Building Y17  
 University of Birmingham  
 Edgbaston  
 Birmingham  
 B15 2TT



Thank you for agreeing to take part in the STARFISH trial, a study aimed to find the best route of steroid administration for treating ISSNHL.

Please read all the questions carefully and complete all sections in this form. If you have any queries or would like someone to assist you, please do not hesitate to ask a member of the research team.

Perception of hearing loss

Using your own words, please describe your impressions and symptoms that you remember as you first developed sudden hearing loss.

*Please summarise in three words below:*

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

### SSQ12 Instructions

**The following questions inquire about aspects of your ability and experience hearing and listening in different situations.**

For each question, put a mark, such as a cross (x), **anywhere** on the scale shown against each question that runs from 0 through to 10. Putting a mark at **10** means that you would be **perfectly** able to do or experience what is described in the question. Putting a mark at **0** means you would be quite **unable** to do or experience what is described.

As an example, question 1 asks about having a conversation with someone while the TV is on at the same time. If you are well able to do this then put a mark up toward the right-hand end of the scale. If you could follow about half the conversation in this situation put the mark around the mid-point, and so on.

We expect that all the questions are relevant to your everyday experience, but if a question describes a situation that does not apply to you, put a cross in the "not applicable" box. Please also write a note next to that question explaining why it does not apply in your case

**Please check one of these options:**

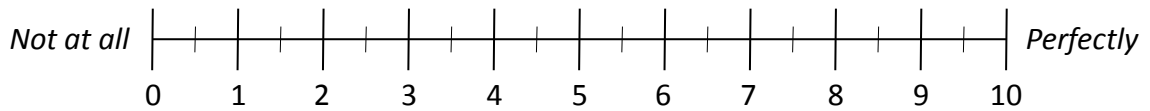
- I have **no** hearing aid/s
- I use **one** hearing aid (**left ear**)
- I use **one** hearing aid (**right ear**)
- I use **two** hearings aids (**both ears**)

**If you have been using hearing aid/s, please indicate for how long:**

**Left ear**  
 \_\_\_\_\_ years  
 \_\_\_\_\_ months  
 or \_\_\_\_\_ weeks  
 N/A

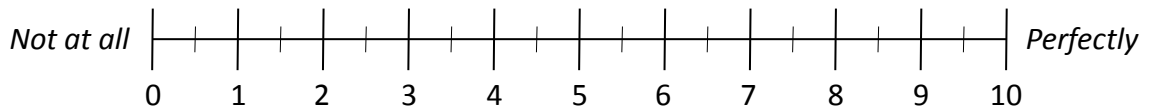
**Right ear**  
 \_\_\_\_\_ years  
 \_\_\_\_\_ months  
 or \_\_\_\_\_ weeks  
 N/A

1. You are talking with one other person and there is a TV on in the same room. Without turning the TV down, can you follow what the person you're talking to says?



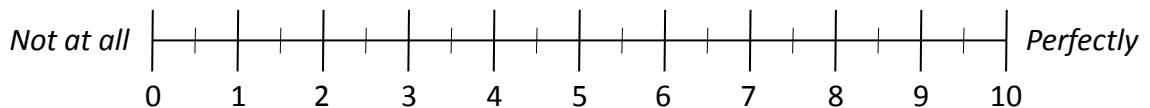
Not applicable

2. You are listening to someone talking to you, while at the same time trying to follow the news on TV. Can you follow what both people are saying?



Not applicable

3. You are in conversation with one person in a room where there are many other people talking. Can you follow what the person you are talking to is saying?



Not applicable

4. You are in a group of about five people in a busy restaurant. You can see everyone else in the group. Can you follow the conversation?



Not applicable

5. You are with a group and the conversation switches from one person to another. Can you easily follow the conversation without missing the start of what each new speaker is saying?



Not applicable

6. You are outside. A dog barks loudly. Can you tell immediately where it is, without having to look?



Not applicable

7. Can you tell how far away a bus or a truck is, from the sound?



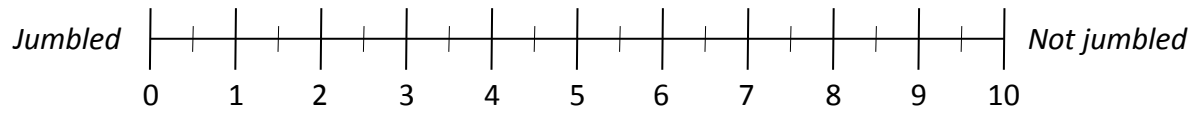
Not applicable

8. Can you tell from the sound whether a bus or truck is coming towards you or going away?



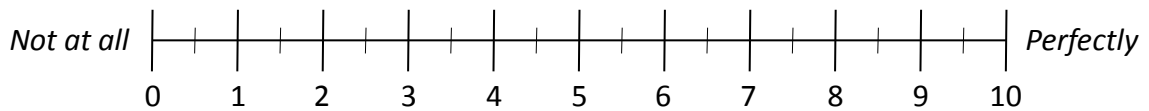
Not applicable

9. When you hear more than one sound at a time, do you have the impression that it seems like a single jumbled sound?



Not applicable

10. When you listen to music, can you make out which instruments are playing?



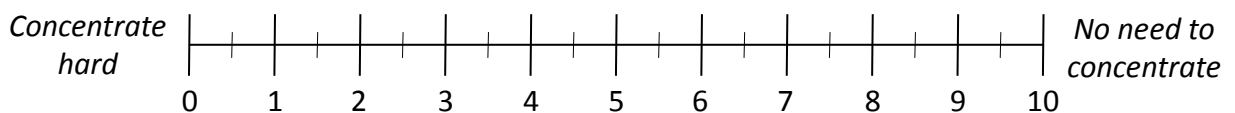
Not applicable

11. Do everyday sounds that you can hear easily seem clear to you (not blurred)?



Not applicable

12. Do you have to concentrate very much when listening to someone or something?



Not applicable

# Vestibular Rehabilitation Benefit Questionnaire

This questionnaire asks about your dizziness on a typical day in the last week - please do not include problems that you think are caused by another condition.

Please answer all of the questions by circling one of the answer options.

<b>Part A - your symptoms</b>						
This section is about how often you experience different feelings.						
1. I feel dizzy						
all of the time	very often	quite often	sometimes	not very often	only very occasionally	never
2. I get a feeling of tingling, prickling or numbness in my body						
all of the time	very often	quite often	sometimes	not very often	only very occasionally	never
3. I have a feeling that things are spinning or moving around						
all of the time	very often	quite often	sometimes	not very often	only very occasionally	never
4. I feel as though my heart is pounding or fluttering						
all of the time	very often	quite often	sometimes	not very often	only very occasionally	never
5. I feel unsteady, as though I may lose my balance						
all of the time	very often	quite often	sometimes	not very often	only very occasionally	never
6. I have difficulty breathing or feel short of breath						
all of the time	very often	quite often	sometimes	not very often	only very occasionally	never
This section is about how dizzy you get when you move around. Please do not circle 'not at all dizzy' if you avoid making the movement - either try the movement or talk to your balance therapist before answering.						
7. Bending over makes me feel						
not at all dizzy	very slightly dizzy	mildly dizzy	moderately dizzy	really quite dizzy	very dizzy	extremely dizzy
8. Lying down and/or turning over in bed makes me feel						
not at all dizzy	very slightly dizzy	mildly dizzy	moderately dizzy	really quite dizzy	very dizzy	extremely dizzy
9. Looking up at the sky makes me feel						
not at all dizzy	very slightly dizzy	mildly dizzy	moderately dizzy	really quite dizzy	very dizzy	extremely dizzy
10. Moving my head <u>slowly</u> from side to side makes me feel						
not at all dizzy	very slightly dizzy	mildly dizzy	moderately dizzy	really quite dizzy	very dizzy	extremely dizzy
11. Moving my head <u>quickly</u> from side to side makes me feel						
not at all dizzy	very slightly dizzy	mildly dizzy	moderately dizzy	really quite dizzy	very dizzy	extremely dizzy

## Part B - how the dizziness is affecting you

Please read each question carefully - some of the statements are phrased to suggest that you have difficulty (for example, 'I have trouble focusing my eyes') and some are phrased to suggest you do not have difficulty (for example, 'I feel comfortable travelling').

If a question does not apply to you, please circle 'same as before' rather than leaving it out.

12. Compared to before the dizziness, I feel comfortable travelling

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

13. Compared to before the dizziness, I feel confident

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

14. Compared to before the dizziness, I have difficulty looking after myself  
(for example, washing my hair, cleaning my teeth, dressing myself, etc)

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

15. Compared to before the dizziness, I feel comfortable going out alone

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

16. Compared to before the dizziness, I can concentrate and/or remember things

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

17. Compared to before the dizziness, I need to hold on to something for support

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

18. Compared to before the dizziness, I think my quality of life is good

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

19. Compared to before the dizziness, I avoid some activities, positions or situations

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

20. Compared to before the dizziness, I am happy to be on my own

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

21. Compared to before the dizziness, I feel stable in the dark or when my eyes are closed

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less

22. Compared to before the dizziness, I take part in social activities

a lot more      quite a bit more      a little bit more      same as before      a little bit less      quite a bit less      a lot less



# TINNITUS FUNCTIONAL INDEX

Participant TNO:

Please read each question below carefully. To answer a question, select **ONE** of the numbers that is listed for that question, and draw a **CIRCLE** around it like this: **10%** or **1**.

<b>I</b>	<b>Over the PAST WEEK...</b>
<p>1. What percentage of your time awake were you consciously <b>AWARE OF</b> your tinnitus?  <i>Never aware</i> ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◀ <i>Always aware</i></p> <p>2. How <b>STRONG</b> or <b>LOUD</b> was your tinnitus?  <i>Not at all strong or loud</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Extremely strong or loud</i></p> <p>3. What percentage of your time awake were you <b>ANNOYED</b> by your tinnitus?  <i>None of the time</i> ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◀ <i>All of the time</i></p>	
<b>SC</b>	<b>Over the PAST WEEK...</b>
<p>4. Did you feel <b>IN CONTROL</b> in regard to your tinnitus?  <i>Very much in control</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Never in control</i></p> <p>5. How easy was it for you to <b>COPE</b> with your tinnitus?  <i>Very easy to cope</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Impossible to cope</i></p> <p>6. How easy was it for you to <b>IGNORE</b> your tinnitus?  <i>Very easy to ignore</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Impossible to ignore</i></p>	
<b>C</b>	<b>Over the PAST WEEK, how much did your tinnitus interfere with...</b>
<p>7. Your ability to <b>CONCENTRATE</b>?  <i>Did not interfere</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Completely interfered</i></p> <p>8. Your ability to <b>THINK CLEARLY</b>?  <i>Did not interfere</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Completely interfered</i></p> <p>9. Your ability to <b>FOCUS ATTENTION</b> on other things besides your tinnitus?  <i>Did not interfere</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Completely interfered</i></p>	
<b>SL</b>	<b>Over the PAST WEEK...</b>
<p>10. How often did your tinnitus make it difficult to <b>FALL ASLEEP</b> or <b>STAY ASLEEP</b>?  <i>Never had difficulty</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Always had difficulty</i></p> <p>11. How often did your tinnitus cause you difficulty in getting <b>AS MUCH SLEEP</b> as you needed?  <i>Never had difficulty</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Always had difficulty</i></p> <p>12. How much of the time did your tinnitus keep you from <b>SLEEPING</b> as <b>DEEPLY</b> or as <b>PEACEFULLY</b> as you would have liked?  <i>None of the time</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>All of the time</i></p>	

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Please read each question below carefully. To answer a question, select **ONE** of the numbers that is listed for that question, and draw a **CIRCLE** around it like this: **10%** or **1**.

<b>A</b>	<b>Over the PAST WEEK, how much has your tinnitus interfered with...</b>	<i>Did not interfere</i>	<i>Completely interfered</i>
		▼	▼
	13. Your ability to <b>HEAR CLEARLY</b> ?	0	10
	14. Your ability to <b>UNDERSTAND PEOPLE</b> who are talking?	0	10
	15. Your ability to <b>FOLLOW CONVERSATIONS</b> in a group or at meetings?	0	10
<b>R</b>	<b>Over the PAST WEEK, how much has your tinnitus interfered with...</b>	<i>Did not interfere</i>	<i>Completely interfered</i>
		▼	▼
	16. Your <b>QUIET RESTING ACTIVITIES</b> ?	0	10
	17. Your ability to <b>RELAX</b> ?	0	10
	18. Your ability to enjoy <b>"PEACE AND QUIET"</b> ?	0	10
<b>Q</b>	<b>Over the PAST WEEK, how much has your tinnitus interfered with...</b>	<i>Did not interfere</i>	<i>Completely interfered</i>
		▼	▼
	19. Your enjoyment of <b>SOCIAL ACTIVITIES</b> ?	0	10
	20. Your <b>ENJOYMENT OF LIFE</b> ?	0	10
	21. Your <b>RELATIONSHIPS</b> with family, friends and other people?	0	10
	22. How often did your tinnitus cause you to have difficulty performing your <b>WORK OR OTHER TASKS</b> , such as home maintenance, school work, or caring for children or others? <i>Never had difficulty</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Always had difficulty</i>	0	10
<b>E</b>	<b>Over the PAST WEEK...</b>		
	23. How <b>ANXIOUS</b> or <b>WORRIED</b> has your tinnitus made you feel? <i>Not at all anxious or worried</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Extremely anxious or worried</i>		
	24. How <b>BOTHERED</b> or <b>UPSET</b> have you been because of your tinnitus? <i>Not at all bothered or upset</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Extremely bothered or upset</i>		
	25. How <b>DEPRESSED</b> were you because of your tinnitus? <i>Not at all depressed</i> ► 0 1 2 3 4 5 6 7 8 9 10 ◀ <i>Extremely depressed</i>		

**HUI23S1UKE<sub>n</sub>.15Q**  
HEALTH UTILITIES INDEX<sup>®</sup> MARK 2 AND MARK 3 (HUI2/3)  
15-ITEM QUESTIONNAIRE FOR  
SELF-ADMINISTERED, SELF-ASSESSED  
"ONE WEEK" HEALTH STATUS ASSESSMENT

This questionnaire contains a set of questions that ask about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, during the past week. To define the past week period, please think about what the date was 7 days ago and recall the major events that you have experienced during this period. Please focus your answers on your abilities, disabilities and how you have felt during the past week.

You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

Please read each question and consider your answers carefully. For each question, please select one answer that best describes your level of ability or disability during the past week. Please indicate the selected answer by circling the letter (a, b, c, ...) beside the answer.

All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

---

1. Which one of the following best describes your ability, during the past week, to see well enough to read ordinary newsprint?
  - a. Able to see well enough without glasses or contact lenses.
  - b. Able to see well enough with glasses or contact lenses.
  - c. Unable to see well enough even with glasses or contact lenses.
  - d. Unable to see at all.
  
2. Which one of the following best describes your ability, during the past week, to see well enough to recognize a friend on the other side of the street?
  - a. Able to see well enough without glasses or contact lenses.
  - b. Able to see well enough with glasses or contact lenses.
  - c. Unable to see well enough even with glasses or contact lenses.
  - d. Unable to see at all.

3. Which one of the following best describes your ability, during the past week, to hear what was said in a group conversation with at least three other people?
- a. Able to hear what was said without a hearing aid.
  - b. Able to hear what was said with a hearing aid.
  - c. Unable to hear what was said even with a hearing aid.
  - d. Unable to hear what was said, but did not wear a hearing aid.
  - e. Unable to hear at all.
4. Which one of the following best describes your ability, during the past week, to hear what was said in a conversation with one other person in a quiet room?
- a. Able to hear what was said without a hearing aid.
  - b. Able to hear what was said with a hearing aid.
  - c. Unable to hear what was said even with a hearing aid.
  - d. Unable to hear what was said, but did not wear a hearing aid.
  - e. Unable to hear at all.
5. Which one of the following best describes your ability, during the past week, to be understood when speaking your own language with people who do not know you?
- a. Able to be understood completely.
  - b. Able to be understood partially.
  - c. Unable to be understood.
  - d. Unable to speak at all.
6. Which one of the following best describes your ability, during the past week, to be understood when speaking with people who know you well?
- a. Able to be understood completely.
  - b. Able to be understood partially.
  - c. Unable to be understood.
  - d. Unable to speak at all.

7. Which one of the following best describes how you have been feeling during the past week?
- a. Happy and interested in life.
  - b. Somewhat happy.
  - c. Somewhat unhappy.
  - d. Very unhappy.
  - e. So unhappy that life was not worthwhile.
8. Which one of the following best describes the pain and discomfort you have experienced during the past week?
- a. Free of pain and discomfort.
  - b. Mild to moderate pain or discomfort that prevented no activities.
  - c. Moderate pain or discomfort that prevented some activities.
  - d. Moderate to severe pain or discomfort that prevented some activities.
  - e. Severe pain or discomfort that prevented most activities.
9. Which one of the following best describes your ability, during the past week, to walk?  
Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches or a walker.
- a. Able to walk around the neighbourhood without difficulty, and without walking equipment.
  - b. Able to walk around the neighbourhood with difficulty; but did not require walking equipment or the help of another person.
  - c. Able to walk around the neighbourhood with walking equipment, but without the help of another person.
  - d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighbourhood.
  - e. 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.
  - f. Unable to walk at all.

10. Which one of the following best describes your ability, during the past week, to use your hands and 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.

- a. Full use of two hands and ten fingers.
- b. Limitations in the use of hands or fingers, but did not require special tools or the help of another person.
- c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person).
- d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools).
- e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools).
- f. 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).

11. Which one of the following best describes your ability, during the past week, to remember things?

- a. Able to remember most things.
- b. Somewhat forgetful.
- c. Very forgetful.
- d. Unable to remember anything at all.

12. Which one of the following best describes your ability, during the past week, to think and solve day to day problems?

- a. Able to think clearly and solve day to day problems.
- b. Had a little difficulty when trying to think and solve day to day problems.
- c. Had some difficulty when trying to think and solve day to day problems.
- d. Had great difficulty when trying to think and solve day to day problems.
- e. Unable to think or solve day to day problems.

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

16. Overall, how would you rate your health during the past week?
- a. Excellent.
  - b. Very good.
  - c. Good.
  - d. Fair.
  - e. Poor.
17. How did you complete the questionnaire? Please select the one answer that best describes your situation.
- a. By myself, without any help from anyone else.
  - b. By myself, except someone else circled the answers on the questionnaire form for me.
  - c. With the help of someone else.
  - d. This questionnaire was completed by a family member, without help from the subject or patient.
  - e. This questionnaire was completed by a nurse or other health professional, without help from the subject or patient.  
Please specify type of health professional: \_\_\_\_\_
  - f. This questionnaire was completed by another person, without help from the subject or patient.  
Please specify relationship to subject or patient: \_\_\_\_\_



**ABOUT YOUR OVERALL QUALITY OF LIFE**

Please indicate which statements best describe your overall quality of life at the moment by placing a tick (✓) in **ONE** box for each of the five groups below.

**1. Feeling settled and secure**

- I am able to feel settled and secure in **all** areas of my life
- I am able to feel settled and secure in **many** areas of my life
- I am able to feel settled and secure in **a few** areas of my life
- I am **unable** to feel settled and secure in **any** areas of my life

<input type="checkbox"/>	4
<input type="checkbox"/>	3
<input type="checkbox"/>	2
<input type="checkbox"/>	1

**2. Love, friendship and support**

- I can have **a lot** of love, friendship and support
- I can have **quite a lot** of love, friendship and support
- I can have **a little** love, friendship and support
- I **cannot** have **any** love, friendship and support

<input type="checkbox"/>	4
<input type="checkbox"/>	3
<input type="checkbox"/>	2
<input type="checkbox"/>	1

**3. Being independent**

- I am able to be **completely** independent
- I am able to be independent in **many** things
- I am able to be independent in **a few** things
- I am **unable** to be at all independent

<input type="checkbox"/>	4
<input type="checkbox"/>	3
<input type="checkbox"/>	2
<input type="checkbox"/>	1

**4. Achievement and progress**

- I can achieve and progress in **all** aspects of my life
- I can achieve and progress in **many** aspects of my life
- I can achieve and progress in **a few** aspects of my life
- I **cannot** achieve and progress in **any** aspects of my life

<input type="checkbox"/>	4
<input type="checkbox"/>	3
<input type="checkbox"/>	2
<input type="checkbox"/>	1

**5. Enjoyment and pleasure**

- I can have **a lot** of enjoyment and pleasure
- I can have **quite a lot** of enjoyment and pleasure
- I can have **a little** enjoyment and pleasure
- I **cannot** have **any** enjoyment and pleasure

<input type="checkbox"/>	4
<input type="checkbox"/>	3
<input type="checkbox"/>	2
<input type="checkbox"/>	1

Please ensure you have only ticked **ONE** box for each of the five groups.

Thank you for completing this questionnaire and for your support of the STARFISH trial.