Achilles Tendinopathy Management study

6 month Questionnaires

Participant initials:	
Participant Trial Number:	
Hospital site code:	
Date sent to participant:	d d – m m m – y y y y
Trial Tendon:	

Please complete all questions on all pages if you can.
Please return this questionnaire booklet to the below address using the pre-paid envelope provided:

ATM trial office,
Warwick Clinical Trials Unit,
Division of Health Sciences,
Warwick Medical School,
The University of Warwick,
Coventry, CV4 7AL

We appreciate your participation within the trial.
Many thanks in advance.

Instructions

Please read these instructions and follow the instructions for each section carefully.

Please answer ALL the questions. Although it may seem that the questions are asked more than once, it is still important that you answer every one.

Please use a BLACK or BLUE pen. Please do not use a pencil.
Please check that you have completed all sections.

For each section, if you are asked to put a tick in the box, please use a tick rather than a cross. For example in the following question, if your answer to the question is yes, you should place a tick firmly in the box next to yes.

Example

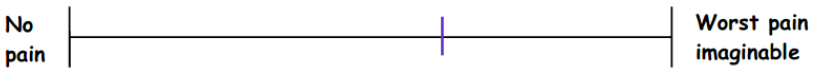
Do you drive a car? Yes ☑ No ☐

When asked a question that has a scale, such as that shown below, please tick the box above the number that represents your answer to the question.

For example, do you have pain when stretching the Achilles tendon fully over the edge of a step?

			✓								no pain

Similarly, when asked to complete the visual analogue scale below, please mark the line with a vertical line to show your pain, such as that below.



If you have received treatment in both tendons, please answer questions based on your worst tendon.

If there are any questions that you do not understand, please ask a member of the research team or the ATM trial office who will be happy to help.

GLOSSARY OF TERMS

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Gait cycle = walk

Achilles tendon loading sports = sports where predominately running takes place, such as football, tennis etc.

Heel raises = rise up on your toes with your knees straight and your body tall.

Blinding = you will not know the treatment that you have received

Medical condition update

Participant Trial Number: | | | | **Hospital site code:** | | | | |

What is the date you are completing this? d d – m m m – y y y y

1. In the past three months, have you been diagnosed with any new medical conditions? ☐ **No** ☐ **Yes**

If **Yes**, please provide details ……

2. In the past three months, have you been actively trying to become pregnant, became pregnant or breastfeeding? ☐ **No** ☐ **Yes** ☐ **N/A**

3. In the past three months, have you sustained any new injuries? ☐ **No** ☐ **Yes**

If **Yes**, please provide details ……..

4. Have your current medications changed since you received the trial injection? ☐ **No** ☐ **Yes**

5. If **Yes** was answered to **Q4**, please explain what has changed including dose and number of times taken daily?

Medication: ..... Dose: ..... Number of times taken daily: .....
Medication: ..... Dose: ..... Number of times taken daily: .....
Medication: ..... Dose: ..... Number of times taken daily: .....

6. In the past three months, have you received any of these other NHS or private treatments for your Achilles tendon pain? ***Please tick all that apply and enter a number for sessions.***

	Treatment		**If Yes, number of sessions**
	No	**Yes**	
Injections	☐	☐	
Physiotherapy	☐	☐	
Surgery	☐	☐	
Acupuncture	☐	☐	
Podiatry	☐	☐	
Prescribed insoles	☐	☐	
Other	☐	☐	

If **Other**, please provide details……..

Complications form – trial tendon

Participant Trial Number: | | | | **Hospital site code:** | | | | |

1. You previously reported the following complications:

For office use

1 ☐ bruising at the injection site
2 ☐ fainting episode associated with tendon injection treatment
3 ☐ an infection diagnosed by a doctor
4 ☐ mild discomfort associated with tendon injection treatment
5 ☐ bleeding associated with tendon injection treatment
6 ☐ swelling
7 ☐ skin discolouration
8 ☐ allergic reaction
☐ Other *please specify* ……

☐ N/A If N/A is ticked, please turn to the next page

2. For any of those ticked as **Yes** above, have you received any treatment?

☐ **Yes** ☐ **No**

2.a. If **Yes**, what treatment ……..
……
……

3. Had this/ Have these (that are ticked **Yes** to in Q1) now resolved?

☐ **Yes** ☐ **No**

3.a.. If **No**, please detail ……..
……
……

4. Are there any other details: ……...
……
……

FOR OFFICE USE ONLY

Do any of the events detailed above meet the definition of an SAE? ☐ **Yes** ☐ **No**

If Yes, please notify the Trial Coordinator to initiate the completion of an SAE form.

Date Chief Investigator made aware of AEs/ SAEs : d d – m m m – y y y y

Complications form – non-trial tendon

Participant Trial Number: | | | | **Hospital site code:** | | | | |

1. You previously reported the following complications:

For office use

1 ☐ bruising at the injection site
2 ☐ fainting episode associated with tendon injection treatment
3 ☐ an infection diagnosed by a doctor
4 ☐ mild discomfort associated with tendon injection treatment
5 ☐ bleeding associated with tendon injection treatment
6 ☐ swelling
7 ☐ skin discolouration
8 ☐ allergic reaction
☐ Other *please specify* ……

☐ N/A If N/A is ticked, please turn to the next page

2. For any of those ticked as **Yes** above, have you received any treatment?

☐ **Yes** ☐ **No**

2.a. If **Yes**, what treatment ……..
……
……

3. Had this/ Have these (that are ticked **Yes** to in Q1) now resolved?

☐ **Yes** ☐ **No**

3.a.. If **No**, please detail ……..
……
……

4. Are there any other details: ……...
……
……

5. Have any contact details changed since the last appointment? ☐ **Yes** ☐ **No**

If **Yes**, please complete the **Change of Contact details form on the next page**.
If **No**, please continue to the next page.

FOR OFFICE USE ONLY

Do any of the events detailed above meet the definition of an SAE? ☐ **Yes** ☐ **No**

If Yes, please notify the Trial Coordinator to initiate the completion of an SAE form.

Date Chief Investigator made aware of AEs/ SAEs : d d – m m m – y y y y

Change of Contact Details Form

Participant Trial Number: | | | | **Hospital site code:** | | | | |

Title: ……**First Name:** ……**Surname**……

Address
Address line 1: ……
Address line 2: ……
Address line 3: ……
Address line 4: ……
Address line 5: ……
Postcode: ..……

Telephone
Home: ……Mobile: ……Work: ……
Best time to contact: .....
Email: ……@……

Please provide details of two people who would be willing to be contacted by the research team in case your address changes. Note: please could you notify the contacts listed below that their details have been shared

Contact 1

Title: ……**First Name:** ……
Surname:……

Address
Address line 1:……
Address line 2: ……
Address line 3: ……
Address line 4: ……
Address line 5: ……
Postcode: ..……

Telephone
Home: ……
Mobile: ……
Relationship:……

Contact 2

Title: ……**First Name:** ……
Surname:……

Address
Address line 1:……
Address line 2: ……
Address line 3: ……
Address line 4: ……
Address line 5: ……
Postcode: ..……

Telephone
Home: ……
Mobile: ……
Relationship:……

GP DETAILS
Doctor/Surgery Name: ……
Address: ……
Telephone: ……

Please turn over.

The VISA-A questionnaire:

An index of the severity of Achilles tendinopathy

Participant Trial Number: | | | | **Hospital site code:** | | | | |

The VISA-A questionnaire: An index of the severity of Achilles tendinopathy

IN THIS QUESTIONNAIRE, THE TERM PAIN REFERS SPECIFICALLY TO PAIN IN THE ACHILLES TENDON REGION

1. For how many minutes do you have stiffness in the Achilles region on first getting up?

100 mins | | | | | | | | | | | 0 mins

2. Once you are warmed up for the day, do you have pain when stretching the Achilles tendon fully over the edge of a step? (keeping knee straight)

strong severe pain | | | | | | | | | | | no pain

3. After walking on flat ground for 30 minutes, do you have pain within the next 2 hours? (if you are unable to walk on flat ground for 30 minutes because of pain, score 0 for this question).

strong severe pain | | | | | | | | | | | no pain

The VISA-A questionnaire:

An index of the severity of Achilles tendinopathy

Participant Trial Number: | | | | **Hospital site code:** | | | | |

4. Do you have pain walking downstairs with a normal gait cycle?

strong severe pain | | | | | | | | | | | | no pain

5. Do you have pain during or immediately after doing 10 (single leg) heel raises from a flat surface?

strong severe pain | | | | | | | | | | | | no pain

6. How many single leg hops can you do without pain?

0 | | | | | | | | | | | | 10

7. Are you currently undertaking sport or physical activity?

- ☐ Not at all
- ☐ Modified training ± modified competition
- ☐ Full training ± competition but not at same level as when symptoms began
- ☐ Competing at the same or higher level as when symptoms began

The VISA-A questionnaire:

An index of the severity of Achilles tendinopathy

Participant Trial Number: | | | | **Hospital site code:** | | | |

8. **Please complete EITHER A, B or C in this question.**

- If you have no pain while undertaking Achilles tendon loading sports please complete Q8 A only.
- If you have pain while undertaking Achilles tendon loading sports but it does not stop you from completing the activity, please complete Q8 B only.
- If you have pain that stops you from completing Achilles tendon loading sports, please complete Q8 C only.

A. If you have no pain while undertaking Achilles tendon loading sports, for how long can you train/ practice?

NIL ☐ 1-10 mins ☐ 11-20 mins ☐ 21-30 mins ☐ >30 mins ☐

OR

B. If you have some pain while undertaking Achilles tendon loading sport, but it does not stop you from completing your training/ practice, for how long can you train / practice?

NIL ☐ 1-10 mins ☐ 11-20 mins ☐ 21-30 mins ☐ >30 mins ☐

OR

C. If you have pain that stops you from completing Achilles tendon loading sports, for how long can you train/ practice?

NIL ☐ 1-10 mins ☐ 11-20 mins ☐ 21-30 mins ☐ >30 mins ☐

ATM

EQ-5D-5L

Health Questionnaire

English version for the UK

Participant Trial Number: | | | | **Hospital site code:** | | | | |

Under each heading, please tick the ONE box that describes your health TODAY.

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable washing or dressing myself ☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

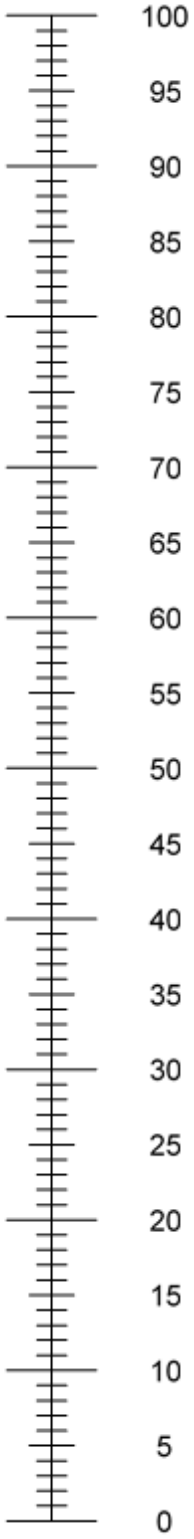
EQ-5D-5L

Health Questionnaire

English version for the UK

Participant Trial Number: | | | | **Hospital site code:** | | | | |

The best health you can imagine



- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.

- Mark an X on the scale to indicate how your health is TODAY.

- Now, please write the number you marked on the scale in the box

YOUR HEALTH TODAY= ☐

The worst health you can imagine

Visual Analogue Score

Participant Trial Number: | | | | **Hospital site code:** | | | | |

VISUAL ANALOGUE SCORE (VAS)

Please place a vertical mark on the line below to indicate how bad you feel your pain is today.

No pain — Worst pain imaginable

Blinding Success Form

Participant Trial Number: | | | | **Hospital site code:** | | | | |

Please indicate with an **tick** which one of the following statements most applies to you:

- ☐ I think I had the autologous platelet rich plasma injection
- ☐ I think I had the placebo imitation injection
- ☐ I am not sure what treatment I received

Future contact

Would you like to receive information about the treatment you were allocated to?

☐ **No** ☐ **Yes**

Would you like to receive a copy of the final results of the study once these have been published?

☐ **No** ☐ **Yes**

Thank you very much for completing these questionnaires.

Please return your questionnaire to the below address
using the pre-paid envelope provided:

ATM trial office,
Warwick Clinical Trials Unit,
Division of Health Sciences,
Warwick Medical School,
The University of Warwick,
Coventry, CV4 7AL

What if I have any questions?

You can contact the research team at any time on the numbers provided in your information sheet. Alternatively, you can contact the ATM trials office at Warwick Clinical trials Unit, The University of Warwick.