Report Supplementary Material 11 Baseline Form

THE UNIVERSITY of York

South Tees Hospitals NHS
NHS Foundation Trust

CONFIDENTIAL

United Kingdom Frozen Shoulder Trial (UK FROST)

Baseline form for eligible and consenting patients with a frozen shoulder

Please use a black or blue pen to complete the questionnaire.

This form is for the Research Nurse/Associate to complete with an eligible patient who has consented to take part in the trial

Participant ID Number: | | | | |

Date when questionnaire completed: | | | / | | | / | | | | |
day *month* *year*

Section 1: PROBLEMS WITH YOUR SHOULDER

Please tick (✓) one box for every question.

1. During the past 4 weeks...

How would you describe the **worst** pain you had from your shoulder?

None	Mild	Moderate	Severe	Unbearable
☐	☐	☐	☐	☐

2. During the past 4 weeks...

Have you had any trouble dressing yourself because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transport because of your shoulder? (whichever you tend to use)

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

4. During the past 4 weeks...

Have you been able to use a knife and fork - at the same time?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

5. During the past 4 weeks...

Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

6. During the past 4 weeks...

Could you carry a tray containing a plate of food across a room?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

7. During the past 4 weeks...

Could you brush/comb your hair with the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

8. During the past 4 weeks...

How would you describe the pain you usually had from your shoulder?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

9. During the past 4 weeks...

Could you hang your clothes up in a wardrobe, using the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With great difficulty	No, impossible
☐	☐	☐	☐	☐

10. During the past 4 weeks...

Have you been able to wash and dry yourself under both arms?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

11. During the past 4 weeks...

How much has pain from your shoulder interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

12. During the past 4 weeks...

Have you been troubled by pain from your shoulder in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

Please check back that you have answered each of the previous twelve questions and then continue with the rest of the questionnaire.

The following questions ask about your symptoms as well as your ability to perform certain activities. Please answer *every question*, based on your condition in the last week, by circling the appropriate number. If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* of which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1.	Open a tight or new jar.	1	2	3	4	5
2.	Do heavy household chores (e.g. wash walls, floors).	1	2	3	4	5
3.	Carry a shopping bag or briefcase.	1	2	3	4	5
4.	Wash your back.	1	2	3	4	5
5.	Use a knife to cut food.	1	2	3	4	5
6.	Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

		NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7.	During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

		NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8.	During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*		NONE	MILD	MODERATE	SEVERE	EXTREME
9.	Arm, shoulder or hand pain.	1	2	3	4	5
10.	Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11.	During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand *(circle number)*	1	2	3	4	5

Shoulder Pain Question

Please select the number below that best describes how bad your shoulder pain has been during the past 24 hours. *(Circle one number only).*

0	1	2	3	4	5	6	7	8	9	10
No pain										**Worst possible pain**

Section 2: This section asks about your health in general

Under each heading, please tick the **ONE** box that best 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 to wash or dress 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 ☐

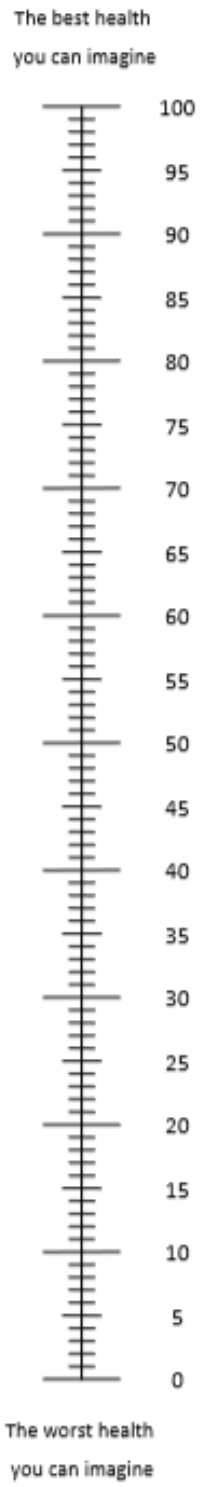
I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.
- The scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.

  0 means the <u>worst</u> 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 below.

YOUR HEALTH TODAY = | | | |

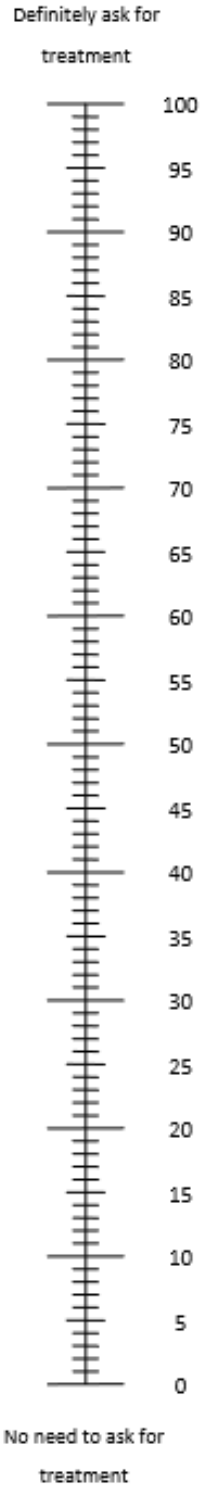


We would like to know to what extent your frozen shoulder symptoms in the past 24 hours would prompt you to ask for further treatment.

- This scale is numbered from 0 to 100.
- 0 means that you feel you *do not need* to ask for further treatment for your frozen shoulder
  100 means that you *definitely need* to ask for further treatment.
- Mark an X on the scale to indicate the extent of your frozen shoulder symptoms in prompting you to ask for further treatment.

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

I MARKED THE SCALE AT | | | |



Section 3: It would also help us to know more about you

1. Are you? *(Please cross one box only)*

White British	White Irish	White Other	Black African	Black Caribbean	Black Other
☐	☐	☐	☐	☐	☐

Asian Indian	Asian Pakistani	Asian Bangladeshi	Asian Chinese	Asian Other	White and Black Caribbean
☐	☐	☐	☐	☐	☐

White and Black African	White and Asian	Other mixed background	Other, please state:
☐	☐	☐	☐ _____

2. What is the highest level of qualification you attained or are currently studying for?

(Please cross one box only)

Left school before 16, no school leaving qualifications ☐

Left school at 16, no school leaving qualifications ☐

Left school at 16, with some qualifications e.g. CSE, GCSE, O'Level ☐

Left further education at 18, with some qualifications e.g. NVQ, A Level, AS Level ☐

Degree education e.g. BSc, BA ☐

Higher degree e.g. MA, MSc, PhD ☐

Other vocational/work-related qualifications ☐

Other* ☐

*If 'Other', please state: _____

3. Which of the following best describes your main activity? *(Please cross one box only)*

- Employed full time ☐
- Employed part time ☐
- Self-employed ☐
- Currently unable to work due to poor health ☐
- Unemployed ☐
- Retired ☐
- Carer e.g. looking after family, neighbours, friends ☐
- Studying/student ☐
- Housework ☐
- Other* ☐

*If 'Other', please state: _____

4. If you are employed, which one of the following categories best describes your employment? (*Please select only one answer)*

- ☐ Unskilled manual (e.g. handpacker, dishwasher)
- ☐ Skilled manual (e.g. mechanic, electrician)
- ☐ Unskilled non-manual (e.g. clerk, typist)
- ☐ Skilled non-manual (e.g. manager, teachers, nurses)
- ☐ Professional (e.g. lawyers, doctor, dentists)
- ☐ Other (please describe) _____

5. Are you currently taking steroids for your affected shoulder? *(please cross one box only)* Yes ☐ No ☐

6. Have you had a steroid injection for your affected shoulder? *(please cross one box only)* Yes ☐ No ☐

If 'Yes' a) How many injections have you had? ☐☐

b) How many **weeks** ago was your **last** injection? ☐☐

c) Who gave your **last** injection? General Practitioner ☐ Physiotherapist ☐

7. Have you had physiotherapy for your affected shoulder? *(please cross one box)* Yes ☐ No ☐

If 'Yes' a) Where was the physiotherapy provided? *(please cross one box)*

General Practice ☐ Hospital ☐ Home ☐ Other ☐

b) How many physiotherapy sessions did you have? *(please record number of sessions)* ☐☐

c) Over how many **weeks** did you have your physiotherapy? ☐☐

8. Is it your dominant arm that is affected? *(please cross one box)* Yes ☐ No ☐

9. How many **weeks** have you had your shoulder problem? ☐☐ *weeks*

10. Have you had a similar shoulder problem on the **same** side? *(please cross one box)* Yes ☐ No ☐

11. Have you had a similar shoulder problem on the **opposite** side? *(please cross one box)* Yes ☐ No ☐

12. You have accepted that the treatment you will get for this study is left to chance. However, we would like to know if you had a preference for a treatment before you agreed to take part in the study? *(please cross one box)*

No preference ☐ Physiotherapy ☐ Surgery ☐

If you chose 'Surgery' which type of surgery would you have preferred as described in the patient information leaflet? *(please cross one box)*

Manipulation under anaesthetic ☐ Keyhole surgery ☐ No preference ☐

13. How effective do you think each of the study treatments would be in relieving you of your shoulder symptoms?

	Very ineffective	Fairly ineffective	Can't decide	Fairly effective	Very effective
a. Physiotherapy	☐	☐	☐	☐	☐
b. Manipulation under anaesthetic	☐	☐	☐	☐	☐
c. Keyhole surgery	☐	☐	☐	☐	☐

14. Would you like us to let you know the results of the study? *(please cross one box)* Yes ☐ No ☐

Thank you very much for completing this form – please return to the Research Nurse/Associate.

The rest of this form is for the Research Nurse/Associate to complete

When the baseline form has been completed for an eligible and consenting patient please randomise the patient by contacting York Trial Office on freephone 0800 0566682 during the hours 0900 to 1700 (Mon-Fri) or use the following website www.yorkrand.com (see username and password in the Trial Site Manual).

Please cross the box for which treatment the patient has been randomised to receive:

Physiotherapy ☐ **Manipulation under anaesthesia** ☐ **Keyhole surgery** ☐

Please inform the patient about the treatment they will receive and what will happen next.

To confirm that every aspect of the recruitment of the patient into the trial has been completed please cross a box to indicate that each of the following has been done:

Study Eligibility Form completed	☐
Consent Status Form completed	☐
Four copies of the consent form signed	☐
Baseline Form completed	☐
Contact Details Form completed (posted in a separate envelope)	☐

Please post to York Trials Unit in the freepost envelope: Study Eligibility Form, Consent Status Form, one of the signed Consent Forms, Baseline Form.

Please post the contact details form to York Trials Unit in a separate freepost envelope.

Thank you very much for recruiting this patient and completing the study documentation.