

THE UNIVERSITY *of York*



**NHS**  
Wrightington, Wigan and  
Leigh Teaching Hospitals  
NHS Foundation Trust

Reverse or Anatomical replacement for Painful Shoulder Osteoarthritis,  
Differences between Interventions (RAPSODI)

## Blinding Guidance for Sites



[ytu-rapsodi@york.ac.uk](mailto:ytu-rapsodi@york.ac.uk)



[@RAPSODI\\_Trial](https://twitter.com/RAPSODI_Trial)

# Why do we need to blind patients?

The **purpose** of blinding patients (and outcome assessors at 24 months) to their total shoulder replacement (TSR) is to **maintain objectivity** in data collection.

- This will **minimise the potential for introducing bias** by either the patient or outcome assessor.
- A **patient** who trusts in the effectiveness of a specific intervention **may unconsciously or intentionally perceive or detect an enhanced or diminished treatment effect**, i.e. they may overestimate or underestimate the effect of their intervention when providing data.
- **Outcome assessors** who are aware of the treatment used may **unconsciously or intentionally alter their assessment in the knowledge of the treatment** that the patient has received.

# Who is blinded on RAPSODI?

✓ Patients

✓ Outcome assessors at 24 months

✓ Qualitative interviewers

✗ Surgeons

✗ Physiotherapists

✗ Research nurses/associates



We understand that it will be a challenge to maintain blinding of patients.



**The aim is to mitigate the risk** of this happening. When it does occur, it will be reported on (and considered in the analysis) at the end of the study.



**Unblinding** is likely to occur **equally in both groups which would minimise any effect on the study findings**, but we need to monitor this.

# RAPSODI Blinding Overview

- When randomised into the trial, the **patient will consent to be blinded** to the type of replacement they will receive.
- Patients will be **unblinded** to the type of TSR they have had **after the independent outcome assessment** of their shoulder Range of Movement and Strength (24-month time point) and completion of the 24-month patient questionnaire (primary end-point).
- If a **patient does become unblinded** to their treatment allocation, this will be **recorded** (see the '*Unblinding*' CRF in Folder 2.4 of your ISF).
- **Unblinding will be monitored** throughout the trial and **reported during analysis**.
- If a **patient is unblinded** they will **stay in the trial** and be followed up as usual.

# Blinding-related Trial Documents

## Provided in your electronic ISF:

- *'Managing Blinding Checklist'* (ISF folder '13 - Miscellaneous\13.1 Recruitment strategies - posters, web links, letters')
- *'Participant Status and Blinding Log'* (ISF folder '8 - Participant logs and consent forms\8.3 Participant status and blinding log')
- *'Unblinding CRF'* (ISF folder '2 - Study protocol and key documents\2.4 Current CRFs')

## Provided online on YTU's website:

- This *'Blinding Guidance for Sites'*

## Posted to you after you randomise a patient:

- A4 brown envelope with a RAPSODI label (You can put trial paperwork in this envelope which can then be kept in the patient's paper notes)
- RAPSODI sticker for the front cover of patient paper notes

(An example of what the RAPSODI label and sticker look like is in the *'Managing Blinding Checklist'* document.)

# Blinding documents - '*Managing Blinding Checklist*'

The main purpose of the '*Managing Blinding Checklist*' is to describe **site-wide** strategies you can implement to minimise risk of unblinding at every stage of the trial process and acts as a checklist which you can complete.

We will ask you to return this to us periodically so we can monitor how it is going implementing blinding at each site.

This '*Managing Blinding Checklist*' also:

- Acts as a **reminder for the strategies** which you could implement **for each patient**, which are also listed in the '*Participant Status and Blinding Log*' (explained in the following slide).
- Has space for you to **add any feedback** about blinding so that when we ask you to return this to us you can note here anything that you would like to tell us.
- Gives you an **example of what the RAPSODI label and sticker** look like that we will send you that you can use to alert colleagues to the blinded patient (if you use paper patient notes).
- Shows you what the **RAPSODI 'blinding card'** looks like which we send patients after they are randomised. This is laminated and wallet-sized. It could serve as a reminder to patients about being blinded which they can show healthcare professionals they meet during their follow up period.

# Blinding documents – RAPSODI Label and Sticker

## Example of RAPSODI label to put on brown envelope (which goes in patient's paper notes, if you still use paper notes):

We will send you a brown A4 envelope which you can put this RAPSODI label on and keep it in the patient's paper notes with the trial paperwork in, to help alert colleagues at your site to the blinded patient. This envelope does not need to be sealed.



**This patient is participating in the RAPSODI-UK trial of shoulder replacements for painful osteoarthritis**

This patient has consented to be **blinded as to which type of shoulder replacement they have received** ('anatomic' or 'reverse') until they have completed the study.

If you have any questions please speak to:

PI/Co-PI Name: \_\_\_\_\_

Contact details: \_\_\_\_\_

## Example of RAPSODI sticker for cover of patient's paper notes (if you still use paper notes):

This RAPSODI sticker is designed to be put on the front of patient's paper medical notes to alert colleagues at your site to them being a blinded patient. You can add the date in the space provided on the label to help identify when the patient should be kept blinded until.

If a patient becomes unblinded please add the date this occurred to this sticker if possible.



This RAPSODI trial participant should be kept blinded about their type of shoulder replacement. It is expected that the patient will be kept blinded until at least 26 months from randomisation

i.e. \_\_/\_\_/\_\_\_\_ This date should be recorded by the designated person at site.

York Trials Unit ([ytu-rapsodi@york.ac.uk](mailto:ytu-rapsodi@york.ac.uk)) will confirm when the patient can be unblinded.

Please record the date when the patient was unblinded \_\_/ \_\_/ 20 \_\_

# Blinding documents - *'Participant Status and Blinding Log'*

The main purpose of the *'Participant Status and Blinding Log'* is to act as a **reminder of the strategies you can implement for each patient** on RAPSODI and (if you wish) **record which strategies you have implemented for each patient** (though this is not mandatory). These strategies are also listed in the *'Managing Blinding Checklist'* described in the previous slide.

How you can use the Log:

1. Familiarise yourself with the 'per-participant' blinding strategies listed on the *'Blinding Confirmation'* tab of the Log and in the Checklist.
2. When randomising a patient, consider how these strategies could be implemented for that patient, and (if you wish) log which strategies you implement along the way.
3. You can use this Log to help you complete the periodic surveys we will send to you during the trial to monitor how these strategies are being implemented.
4. You can also note on this Log where a patient is going for their follow up appointment and if they are going out of area for physiotherapy or to a community physiotherapist, this could help alert you to any need to communicate with different team about a patient's being blinded.



# Blinding documents – ‘Unblinding CRF’

1. Complete this ‘Unblinding CRF’ when a patient becomes unblinded to their treatment allocation.
2. Please add as much detail as possible to the form so that we can monitor this and improve the process.
3. Return this CRF in a prepaid envelope to YTU.
4. If you are using the ‘*Participant Status and Blinding Log*’, **update the ‘Blinding Confirmation’** tab of the to note that they are unblinded.
5. Add the **date unblinding occurred** to the **RAPSODI blinding alert sticker** on the patient’s paper notes if possible.

**NOTE: Unblinded patients will remain the trial** unless they request otherwise.

## RAPSODI-UK Trial: Participant Un-blinding Form

Please complete this form when a participant has become un-blinded. Please also complete the ‘Blinding checklist’ tab on the ‘Participant Status Log’ spreadsheet to confirm which blinding strategies were implemented for this participant.

Participants who are unblinded should remain in the trial unless they become unblinded because they have withdrawn from the trial. If this occurs, trial, please complete the “Change in Circumstance” CRF.

Participant ID:       Date un-blinding occurred:  /  /      
Day Month Year  
 (if exact date not known please enter the month and year)

### 1. Reason the participant was un-blinded (please cross all boxes that apply)

- Clinical need for the participant to know
- Participant insisted on knowing their allocation
- Participant overheard a conversation between clinicians
- Participant saw their notes, X-rays or other paperwork
- Participant unblinded themselves (for example, the participant had been on the waiting list for a reverse shoulder before being enrolled on the trial and told that the shape of their shoulder would change)
- Participant withdrew from the trial
- Other (please specify)

We understand that it is a challenge to maintain blinding and would like to gather further information to see what can be done to make it more effective.

### 2. When did the un-blinding occur?

(a) After randomisation but before the day of surgery:

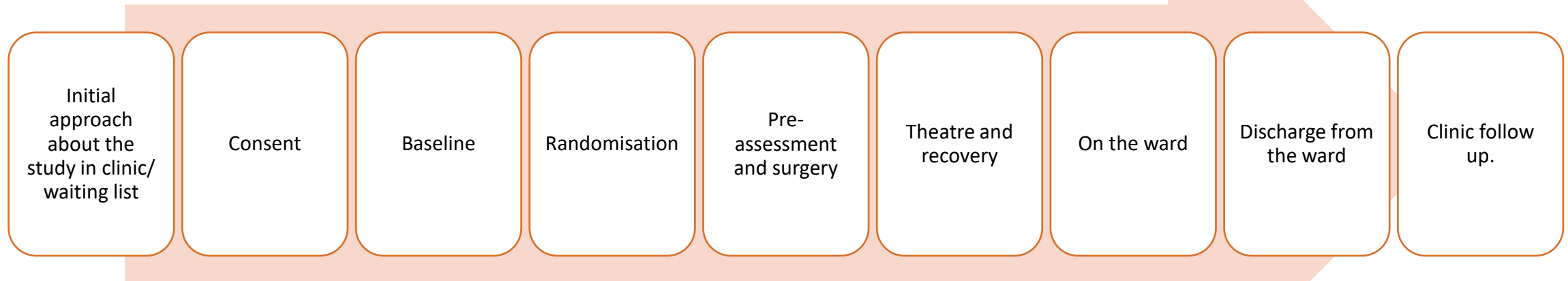
# RAPSODI Blinding Procedure *(also see Trial Site Manual)*

1. First please **familiarise yourself with the guidance** about blinding in the *'Trial Site Manual'* and this *'Blinding Guidance for Sites'* and the recommended blinding strategies in the *Checklist* and *Log*:
  - **'Managing Blinding Checklist'** (ISF folder *'13 - Miscellaneous\13.1 Recruitment strategies - posters, web links, letters'*)
  - **'Participant Status and Blinding log'** (ISF folder *'8.3 Participant status and blinding log'*)
2. **Start implementing the blinding strategies** from the *Checklist* and *Log*, especially consider some of the tasks which might take time and/or negotiation with different departments. In doing this please **consider the patient pathway at your site** and the visits/circumstances/departments etc where unblinding might occur.
3. **Record on the *'Managing Blinding checklist'*** which site-wide strategies have been implemented.
4. Please **respond to feedback requests from the trial team** and **return the *Checklist*** when asked so we can monitor blinding and help future research.
5. Once a patient completes their 24-month patient questionnaire **and** independent assessment of ROM/strength, the patient can be unblinded (**YTU will confirm this**).
6. If a **patient is unblinded**, please complete the ***'Unblinding CRF'*** and return to YTU.

# How to keep patients blinded

Every strategy to help maintain blinding on RAPSODI is listed in the *'Managing Blinding Checklist'* and *'Participant Status and Blinding Log'*.

The main thing to remember about the blinding guidance is that we recommend that you **consider every part of the patient journey at your site:**



# How to keep patients blinded

The 2 most common reasons for unblinding occurring so far on RAPSODI are:

- **Discussions on wards** – please remember to be careful not to mention the type of replacement when talking to the patient and colleagues.
- **Discharge/outpatient letters** – please do not specify the type of shoulder replacement on these letters since the patient receives them.

# How to keep patients blinded

- Ensure all **research staff have read the Trial Site Manual** and this **guidance document**
- **Raise awareness of the trial to all staff and departments** – consider the places and people that come into contact trial patients, especially in theatre, ward, physio, clinic, junior doctors, clinic staff, registrars, etc. you can point them toward this guidance on [YTU's website](#).
- **List patients as a 'RAPSODI-UK Total Shoulder Replacement'** on documentation and theatre/clinic lists where possible, but ensure that theatre/logistics staff are aware of the type of replacement, so components are available on the day of surgery
- Add **RAPSODI stickers on patient paper notes**, if possible, to signal patient's involvement in the trial.
- Add **electronic 'flags'/alerts on patient notes**, if possible, to signal patient's involvement in the trial.
- Can a **'WhatsApp' group be used to communicate with rotating doctors** about blinded patients?
- If your site has **separate aTSR or rTSR leaflets** about care that patients will receive, please **provide patients with the generic leaflet distributed by YTU** (which is the preferred leaflet to use at all sites).
- **Inform physiotherapists about the generic rehabilitation leaflet** (explaining both types of replacement) given to patients to ensure the patient isn't given a replacement-specific leaflet which would lead to them being unblinded.
- **Ensure the outcome assessor** for shoulder range of movement and strength at 24 months is **blinded** to the patient's treatment allocation.
- **On wards, staff put "RAPSODI Trial Blinded Patient" on the whiteboard** (or wherever the patients are listed) to remind ward staff, physios, and rotating doctors coming to ward that patients are blinded.

# How to keep patients blinded

- Please **do not show** patients their **radiographs**.
- If the patient asks about which replacement they have had, please remind them that **they have consented to be blinded** to the procedure type they have received and will be informed on completion of their two-year follow-up.
- A patient can be **unblinded** if there is a **clinical need to know** or they **no longer wish to be blinded** or **take part** in the study.

Patients will receive this wallet-sized laminated card that they can show to healthcare professionals to alert them they are in an active trial and are blinded to treatment allocation



**This patient is participating in the RAPSODI-UK trial of shoulder replacements for painful osteoarthritis**

Dear Health Professional, your patient has consented to be **blinded as to which type of shoulder replacement they have received** ('anatomic' or 'reverse') until they have completed the study.

If you have any questions please email the trial team on [ytu-rapsodi@york.ac.uk](mailto:ytu-rapsodi@york.ac.uk)

# Feedback and Advice from sites

In June 2023 we conducted the **first review of blinding** on the RAPSODI trial.

Sites suggested the following:

- **On wards, staff put “RAPSODI Trial Blinded Patient” on the whiteboard** (or wherever the patients are listed) to remind staff and physios, and rotating doctors coming to ward that patients are blinded.
- **‘WhatsApp’ groups are helpful to alert ward staff and rotating doctors to blinded patients.** Remind new staff and rotating doctors about the trial and the potential for working with blinded.
- Wherever you **document the type of TSR** (and can’t change this) **can you add notes/alerts** to signal they are a blinded patient?
- If your **patients go out of area for their physio**, have you thought about **how to keep them blinded**. Can you communicate to the community physio that they are blinded?
- Can the **discharge letter be completed on day of randomisation** so that whoever randomises the patient completes it to avoid busy ward staff accidentally unblinding the patient?
- Can the **research staff speak to the ward staff face-to-face** about trial patients?
- Can the **theatre list be blinded**?
- **If staff can’t edit the patient electronic record** or theatre list so it doesn't state the type of replacement, **can a ‘note’ be added** to alert staff to the blinded patient?

# Unblinding Reporting Process

## Intentional unblinding:

- Patients will only be unblinded earlier if there is a **clinical need to know** or they **no longer wish to be blinded** or **no longer wish to take part** in the study.

## Accidental unblinding:

- If a patient does become unblinded to their treatment allocation, this will be recorded and reported on during analysis. They will stay in the trial and be followed up as usual.
- Please **report both types of unblinding** to us on the Unblinding CRF
- If a **crossover** between treatments occurs the patient **does not need to be unblinded**.



# Gathering ROM and Strength Blinded at 24 months

## Before the appointment

- Unblinded research staff will need to alert the blinded Outcome Assessor to the patient and provide them with the RAPSODI 24-month ROM and Strength CRF.
- The blinded Outcome Assessor will need to familiarise themselves with this blinding guidance and associated sections of the Trial Site Manual.
- The blinded Outcome Assessor should avoid looking through patient electronic or paper notes in case this unblinds them.

## During the appointment

- The blinded Outcome Assessor is advised to alert the patient that they do not know which replacement they have had and need to remain blind to this until the assessment is completed.

# Monitoring blinding

We will monitor blinding on a 6-monthly basis as part of a Study Within A Trial (SWAT) we are conducting on RAPSODI.

The monitoring will involve:

1. A regular **survey** asking about how implementing blinding has been going
2. We will request sites return their **completed 'Managing Blinding Checklist'**
3. We will also check the completed Unblinding CRFs



# Any questions or feedback on blinding?

Please get in touch at any time if you have any feedback about blinding

[ytu-rapsodi@york.ac.uk](mailto:ytu-rapsodi@york.ac.uk)

**Thank you for all your hard work so far to maintain blinding on RAPSODI!**