

DRAFT3-CASP Screening/Randomisation Procedure

This guide runs through the screening and randomisation procedure from start to finish and details what to do if you need to randomise manually through RRAMP in the event that REDCap doesn't work.

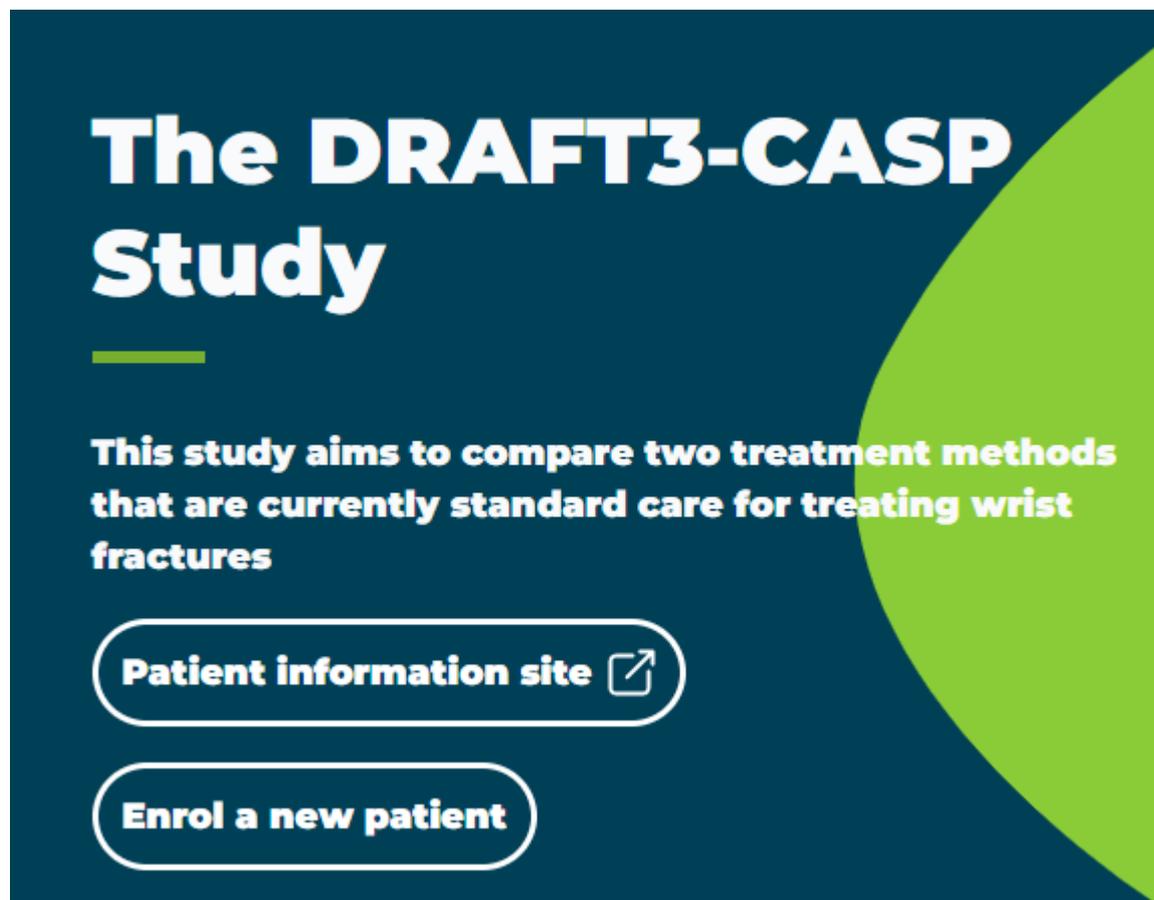
If you are struggling at any point throughout the randomisation process please either call the Trial Manager Heather on 01865 (2)23113 or the Trial Administrator Elli on 01865 612709 so that we can help you. Alternatively, you can contact the study team in the DRAFT3 Whatsapp group.

DO NOT TRY TO RANDOMISE PATIENTS DIRECTLY INTO REDCAP (i.e. NOT VIA THE WEBSITE) - THIS WILL NOT WORK.

Procedure

To begin the screening and randomisation procedure, go to the draft3-casp website at the below link.

www.draft3casp.org



On this page, click the 'Enrol a new patient' button.

Log in to RedCap



This will take you to another page where you can enter the generic password, which will be sent to you in your **greenlight activation email**. Once you submit the password, it will open the REDCap screening form.

Demographics

Site name <small>* must provide value</small>	<input type="text"/>
Date of screening <small>* must provide value</small>	03-04-2023 <input type="text"/> Today D-M-Y
Date of injury <small>* must provide value</small>	<input type="text"/> Today D-M-Y
Sex at birth <small>* must provide value</small>	<input type="text"/>
Age on day of screening <small>* must provide value</small>	<input type="text"/>
To which of these ethnic groups does the patient consider they belong? <small>* must provide value</small>	<input type="text"/>
Index of Multiple Deprivation Score - please calculate using the patients postcode with the tool below	<input type="text"/>
Get IMD Score (https://kadoorie.octru.ox.ac.uk/IMDTool/)	
If the patient does not live in England, please select the option 'not a resident of England'. <small>* must provide value</small>	

Choose your site name from the drop down and fill in all of the remaining information on the screening form.

IMD 2019 Decile Lookup tool

The IMD Postcode search is a tool whereby the user can find the Index of Multiple Deprivation decile group for a valid postcode.

Post code: IMD Decile: 1

Please note:

- The search currently only works for postcodes within England.
- The following datasets are used in the IMD postcode search:
 - Office of National Statistics - Indices of Multiple Deprivation 2019. Contains public sector information licensed under the [Open Government Licence v3.0](#).
 - Open Geography Portal - Postcode to Output Area to Lower Layer Super Output Area to Middle Layer Super Output Area to Local Authority District (November 2022) Lookup in the UK. Contains public sector information licensed under the [Open Government Licence v3.0](#).
- Oxford Trauma does not guarantee the accuracy or integrity of the data.

To enter the IMD score, follow the link provided. Please use this tool specifically, if you use google it will give you a different scale that won't work.

Inclusion Criteria

For this patient to be eligible for this study, the next questions, A1-A3, must have the answer 'Yes'

A1. Is the patient willing to provide informed consent? Yes

* must provide value No

Not applicable reset

A2. Is the patient aged 16 years or older? Yes

* must provide value No

reset

A3. Does the patient have a fracture of the distal radius which, in the opinion of the treating clinician, does not require a manipulation of the fracture?

* must provide value

Patient does not want to be part of a research project

Patient does not want to complete questionnaires

Treatment preference

No reason given

Other

Why is the patient not willing to provide informed consent?

* must provide value

Exclusion Criteria

For this patient to be eligible for this study, the next questions, B1-B3, must have the answer 'No'

If the patient has a treatment preference or doesn't want to take part for another reason, tick no to A1 and specify using the dropdown that will pop up.

Inclusion Criteria

For this patient to be eligible for this study, the next questions, A1-A3, must have the answer 'Yes'

A1. Is the patient willing to provide informed consent?
 * must provide value
 Yes
 No
 Not applicable
 reset

A2. Is the patient aged 16 years or older?
 * must provide value
 Yes
 No
 reset

A3. Does the patient have a fracture of the distal radius which, in the opinion of the treating clinician, does not require a manipulation of the fracture?
 * must provide value
 Yes
 No
 reset

If the patient was not approached, you can select 'Not applicable' for question A1. You can then select 'no' to "Was the patient approached to join this study?" which will pop up a bit further down the form underneath the exclusion criteria. **Please select this option if the patient is ineligible for any other reason as only eligible participants should be approached for consent.** Always ensure to complete the entire screening form.

Has the patient previously been approached to join the DRAFT3-CASP study?
 * must provide value
 Yes
 No
 Unknown
 reset

Was the patient approached to join this study?
 * must provide value
 Yes
 No
 reset

Why was the patient not approached to join this study?
 * must provide value

Name of person screening
 * must provide value

Dropdown menu options:
 Research staff not available
 Internet/administrative problems
 Clinical decision that a splint would be inappropriate
 Clinical decision that a cast would be inappropriate
 Other

It will ask you whether the patient has previously been approached for the DRAFT3-CASP study – as the study recruitment will last a while there is a chance that a patient might break their wrist (or the other one) again. These patients can't be recruited into the study again.

If the patient wasn't approached for the study, please select no to this question and select the reason from the dropdown – this is where you will record if research staff were not available or due to clinician decisions/treatment preferences. If it is unknown whether the patient was approached, please select 'unknown'.

PATIENT IS INELIGIBLE FOR THIS STUDY

Is the patient willing to be approached to take part in qualitative interviews?

Yes

No

* must provide value

reset

Consent to Contact Form

The information on this form will allow us to contact you to discuss taking part in an interview for the DRAFT3-CASP interview study only

This information will be deleted when the study has ended

1. I understand that a member of the research team from the University of Oxford may contact me about taking part in an interview to explore my experience of injury and recovery and have supplied my contact details.

Yes

No

reset

* must provide value

Date:

04-04-2023

D-M-Y

* must provide value

Signature:

* must provide value

 [Add signature](#)

Name of Person Taking Consent:

* must provide value

Date:

04-04-2023

D-M-Y

* must provide value

Signature:

* must provide value

 [Add signature](#)

Form Version & Date: V1.0 17Nov2022

Submit

If this is ticked, the patient will not be eligible but they can still take part in the qualitative interviews. If you tick yes to 'Is the patient willing to be approached to take part in qualitative

interviews' and press submit, it will take you to the Consent to Contact Form so that you can collect the contact details without having to consent them into the main study.

Exclusion Criteria

For this patient to be eligible for this study, the next questions, B1-B3, must have the answer 'No'

B1. Is the injury more than 2 weeks old? Yes No reset
* must provide value

B2. Is the fracture open with a Gustilo and Anderson grading greater than 1? Yes No reset
* must provide value

B3. Is the patient unable to adhere to trial procedures? (e.g. patients with permanent cognitive impairment, or other concomitant severe injuries e.g. head injury) Yes No reset
* must provide value

Why is the patient unable to follow the trial procedures or to complete the questionnaires?
* must provide value

Patient has permanent cognitive impairment
 Other concomitant severe injuries e.g. head injury
 Patient does not have sufficient English skills
 Other

PATIENT IS INELIGIBLE FOR TRIAL

If the patient has a cognitive impairment, concomitant severe injuries, insufficient English or cannot adhere for any other reason, then tick no to B3 and specify using the dropdown. (N.B. Treatment preference is not a reason that a patient is unable to follow trial procedures).

Submit this form and it will take you to the consent form.

7. I understand that my General Practitioner may be contacted in order to provide information about my health status. I agree reset
* must provide value

8. I agree to take part in the DRAFT3-CASP study. I agree reset
* must provide value

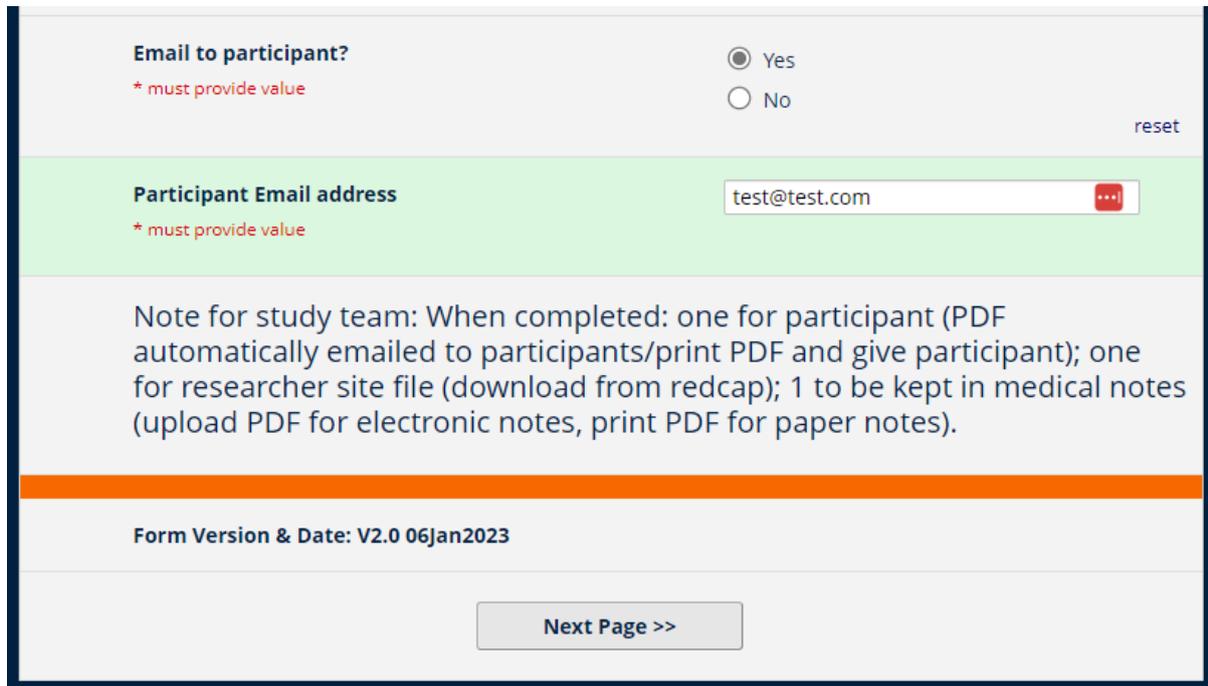
9. I agree to be approached by a member of the research team from the University of Oxford to take part in the optional study participant interviews.
* must provide value

I am happy to be contacted about these interviews
 Please do not contact me about these interviews

Sorry consent is not valid

The consent will not be valid until it has been signed so don't worry about the Sorry consent is not valid message because it should go away once the form is valid and complete. The patient can also

choose to take part in the optional qualitative interviews at this point by selecting 'I am happy to be contacted about these interviews' to question 9. This has no bearing on being a part of the main study or the questionnaires for this.



Email to participant?
* must provide value

Yes
 No

reset

Participant Email address
* must provide value

test@test.com

Note for study team: When completed: one for participant (PDF automatically emailed to participants/print PDF and give participant); one for researcher site file (download from redcap); 1 to be kept in medical notes (upload PDF for electronic notes, print PDF for paper notes).

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Next Page >>

If the patient would like the consent form to be emailed to them, tick Yes to 'Email to participant' and enter their email address below. **NOTE: Please make sure the patient double-checks this email address as if the consent form is sent to another person this could constitute a serious data breach.** If the patient does not want the consent form to be emailed to them, tick no to this and then make sure you print the consent form off on the next screen to give a copy to the patient.

Consent Form

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

1 of 2

Consent Form

Page 1

**DRAFT3**
DISTAL RADIUS ACUTE FRACTURE TRIAL
CAST VS SPLINT

Oxford Trauma and Emergency Care
NDORMS
Trauma Unit, Kadoorie Centre
John Radcliffe Hospital, OX3 9DU
01865 223113
Draft3-casp@ndorms.ox.ac.uk

I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous Page

Submit

Tick to certify the document is correct, if it isn't go back to << Previous page and correct the information. If it is, submit the consent form and it will take you to the contact details form.

Email Address	<input type="text"/>
Mobile Number (without spaces)	<input type="text"/>
Landline Number (including area code)	<input type="text"/>
Please provide either a mobile or a land line number	
<p>Is the participant happy to receive a link to the study questionnaires by email and/or SMS text message?</p> <p><small>* must provide value</small></p> <p><input type="radio"/> Yes</p> <p><input checked="" type="radio"/> No</p> <p style="text-align: right;">reset</p>	
<p>Please advise the participant we will therefore contact them by phone or post to complete the study questionnaires</p>	

Enter the patient’s contact details carefully. If the patient doesn’t have the ability to receive SMS messages or emails, or they just don’t want them, select No to ‘is the participant happy to receive the questionnaires by email and/or SMS text message?’ This will prompt us to follow them up by phone and/or post.

Email Address	<input type="text"/>
Mobile Number (without spaces)	<input type="text"/>
Landline Number (including area code)	<input type="text"/>
Please provide either a mobile or a land line number	
<p>Is the participant happy to receive a link to the study questionnaires by email and/or SMS text message?</p> <p><small>* must provide value</small></p> <p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p style="text-align: right;">reset</p>	
<p>If yes to receiving a link electronically, please indicate their preferred mode of contact</p> <p><small>* must provide value</small></p>	
<p>If we need to contact the participant by phone</p>	

- Email
- Text (SMS) Message
- Email AND Text Message

If the patient would prefer to complete the follow-ups electronically, select Yes to this question and then choose the specific contact using the dropdown that will pop up. Once all information has been entered, submit this form.

DRAFT3-CASP: Cast vs Splint

The following questionnaires relate to your health and wrist function today

Form Version: V1.0 17Nov2022



Resize font: 

EQ-5D-5L

Page 1 of 6

Please click the **ONE** box that best describes your health **TODAY**.

It will then ask the patient the same questions but regarding their wrist and general health **after** their injury (i.e. Today).

Resize font:  [Survey Queue](#)

PROMIS Bank v2.0 - Upper Extremity

Are you able to carry a heavy object (over 10 pounds /5 kg)?

- Without any difficulty
- With a little difficulty
- With some difficulty
- With much difficulty
- Unable to do

reset

The PROMIS questionnaire is a variable questionnaire which asks questions based on the answers that the patient enters (i.e. it will not ask them if they can lift a heavy object if they cannot lift a light one).

<p>What is your height in cm?</p> <p>* must provide value</p>	<input type="text"/> Please visit: https://www.thecalculatorsite.com/conversions/common/meters-to-feet-inches.php
<p>What is your weight in kg?</p> <p>* must provide value</p>	<input type="text"/> Please visit: https://www.thecalculatorsite.com/conversions/common/kg-to-stones-pounds.php
<p>Form Version & Date: V1.0 17Nov2022</p>	
<input type="button" value="Submit"/>	

In the baseline CRF, it will ask the patient for their weight and height, which cannot be left blank - their best guess is fine. There is a link to a converter if the patient needs this.

**DRAFT3-CASP: Cast vs Split
Randomisation Form**

Please confirm that the participant is eligible for this study before proceeding according to the following criteria:

The participant may enter the study if ALL of the following apply:

- Participant is willing and able to give informed consent for participation in the study.
- Aged 16 years or above.
- Presenting with a fracture of the distal radius which, in the opinion of the treating clinician, does not require a manipulation of the fracture.

The participant may not enter the study if ANY of the following apply:

- Present to research team more than 2 weeks post-injury
- The fracture is open (Gustilo and Anderson >1)
- They are unable to adhere to trial procedures, e.g. patients with permanent cognitive impairment, or other concomitant severe injuries e.g. head injury

Can you confirm that the participant is eligible for this study?

* must provide value

Yes
 No

reset

Participant Initials

* must provide value

Participant Date of Birth

* must provide value

 D-M-Y

Date of Consent

* must provide value

 D-M-Y

Once the patient submits their final baseline form it will take you to the randomisation form. Firstly it will ask you to double check the patient's eligibility for the study. If this is no, please stop the randomisation and contact the trial management team.

Once you have clicked on the 'Submit' button we will try to randomise for you; this could take up to 60 seconds, so please do not click on the submit button again.

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Submit

Fill in the rest of the form and press submit. REDCap will then talk to the randomisation platform (RRAMP) in the background, which may take up to a minute, so please be patient.

**DRAFT3-CASP: Cast vs Splint
Randomisation Check**

Sorry, there appears to have been a problem randomising this participant!

Please log on to RRAMP - <https://rramp-test.octru.ox.ac.uk> and randomise by hand, then return to this screen.

You will need the following information

1. Participant REDCap Record ID
2. Participant Initials
3. Participant Date of Birth
4. Date of Consent

The participant is:

- willing and able to give informed consent for participation in the study.
- aged 16 years or above.
- presenting with a fracture of the distal radius which, in the opinion of the treating clinician, does not require a manipulation of the fracture.
- The injury is less than two weeks post-injury
- The fracture is not open (Gustilo and Anderson = 1)
- able to adhere to trial procedures

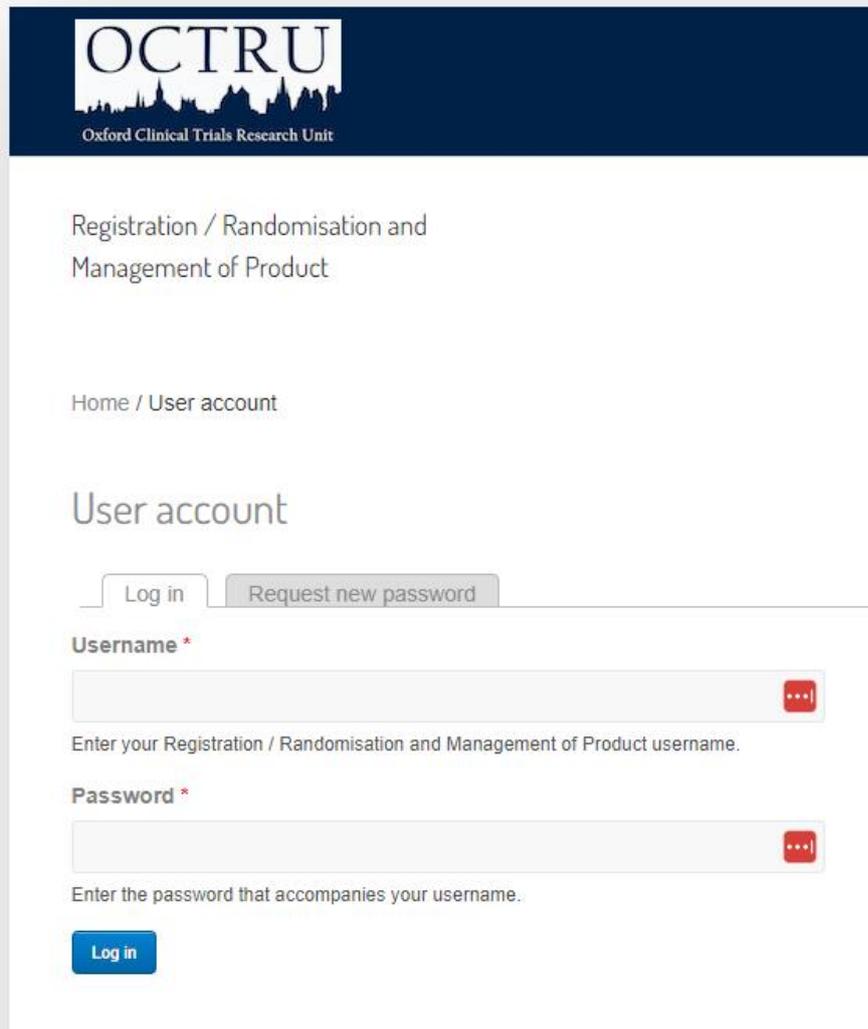
The participant is less than 50 years old

The person who confirmed eligibility was: sgds

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Submit

If the process is not successful, you will see the Randomisation Check page and will need to manually randomise the patient via RRAMP.



OCTRU
Oxford Clinical Trials Research Unit

Registration / Randomisation and
Management of Product

Home / User account

User account

Username *

Enter your Registration / Randomisation and Management of Product username.

Password *

Enter the password that accompanies your username.

To do this, follow the link <https://rramp.octru.ox.ac.uk> and enter your RRAMP login. (This login should have been requested during set up of your site. If you do not have access and would like it for possible use in the future, please email draft3-casp@ndorms.ox.ac.uk. If you do not have access and are in the process of randomising a patient, please either call the Trial Manager Heather on 01865 (2)23113 or the Trial Administrator Elli on 01865 612709 so we can do it for you).

RECRUITING

AFTER-FULL
DRAFT3-CASP

On your home page, click on the DRAFT3-CASP project. You may have multiple studies in your list depending on the studies you are involved in.

SITES	PREVIOUS RANDOMISATIONS	UNBLINDED SUBJECTS	UNBLINDING REQUESTS	REGISTERED USERS	
MANAGE USER EMAIL					
Site Name <input type="text" value="test site"/>		Items per page <input type="text" value="10"/> <input type="button" value="Apply"/>			
SITE	Site IDs	SITE STATUS	NUMBER OF RANDOMISATIONS	LAST SUBJECT RANDOMISED	RANDOMISED BY
DRAFT-CASP : Test Site	TST test_site__88 19642	open to recruitment (12 Aug 2022)	28	Tuesday, 4 April, 2023 - 11:48:34	Heather Barnes

The page should already be on the SITES tab but if it isn't navigate to this tab and then choose your site from the list or type it into the Site Name search bar and click Apply. Click on the grey name of the site to enter.

DRAFT-CASP : Test Site

Please use "Randomise Subject" button to register participants

At the top of the next page, please click the blue 'Randomise Subject' button.

DRAFT-CASP : Test Site

▼ Randomisation

General *

REDCap Record ID *

Can you confirm that the participant is eligible for this study? *

Yes

No

The participant may enter the study if ALL of the following apply: • Participant is willing and able to give informed consent for participation in the study. • Aged 16 years or above. • Presenting with a fracture of the distal radius which, in the opinion of the treating clinician, does not require a manipulation of the fracture. The participant may not enter the study if ANY of the following apply: • Present to research team more than 2 weeks post-injury • The fracture is open (Gustilo and Anderson >1) • They are unable to adhere to trial procedures, e.g. patients with permanent cognitive impairment, or other concomitant severe injuries e.g. head injury

What is the age of the participant? *

< 50

>= 50

Participant initials *

▼ Participant Date of Birth *

E.g., 5 Apr 2023

▼ Date of consent *

Date

E.g., 5 Apr 2023

Name of person who confirmed participants eligibility *

Name of person randomising *

Site *

DRAFT-CASP : Test Site ▼

[Preview](#)

At this point, you will need to enter the REDCap Record ID, confirm that the patient is eligible, whether they are older or younger than 50 and the patient's initials. When you enter the date of birth and date of consent, make sure you enter the date in the format specified. Finally, enter the name of the person confirming eligibility and randomising. Please click the blue 'Preview' button at the bottom of the page and check the details on the following page. You will then need to scroll to the bottom of the following page and click the blue 'Randomise' button.

 • DRAFT-CASP Randomisation *DC-TST-10064* has been created.
• Randomisation successful!
• Subject ID:

DC - TST - 10064

• Randomisation outcome:

Cast

• Please use the link below to navigate to RRAMP page.

DRAFT - CASP

• Subject DC-TST-10064 successfully pushed to REDCap (record ID/screening number: 98).
• Subject DC-TST-10064 successfully pushed to REDCap (record ID/screening number: 98).

If this is successful, RRAMP will confirm the treatment allocation. You will then be able to navigate to the 'Randomisation Outcome' form on REDCap (it should be the last record in the list) and view the randomisation number and treatment allocation.

The treatment allocation is: Splint

The participants randomisation number is: DC-TST-10063

Form Version: V1.0 21Nov2022

Submit

If the randomisation process is successful and you don't need to go through RRAMP, the randomisation outcome form will pop up with the treatment allocation. Please ensure you press submit on this page. Please do not go back in to REDCap manually and complete the Randomisation Check form, this form will appear in sequence if randomisation is unsuccessful.

Survey Queue

Listed below is your survey queue, which lists any other surveys that you have not yet completed. To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title
✔ Completed	Randomisation Outcome – Randomisation

The randomisation is now complete and you can close the survey.

A couple of points to note:

- Please only screen patients that are over the age of 16 and have a confirmed distal radius fracture
- All activities above will occur in the Emergency Department. Once the treatment has been received, the Cast group are then followed up as per usual care, and the splint group are immediately discharged with no planned follow-up
- The only time you will need to go back into the REDCap system directly (i.e. not via the website) is to complete the treatment form, or to answer any unresolved queries raised by the Trial Management team.
- Please only recruit patients via the link on the website at www.draft3casp.org
- If you have any problems, don't hesitate to ask any questions and contact the Trial Management team below:

Draft3-casp@ndorms.ox.ac.uk

01865 223113

DRAFT3 Whatsapp group

