

# WHITE 12-DUALITY: An investigation of people 65 years and over with a broken hip to determine whether using a hip replacement with modified mobility (Dual mobility cup) can reduce the rate of hip dislocation in the first year after hip fracture surgery

<b>Submission date</b> 16/08/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/08/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Every year around 70,000 people in the UK break their hip. Hip fractures are a common and very serious injury in older people, similar in impact to a major stroke. We will investigate two treatments for one specific type of hip fracture. Currently, surgeons use one of two types of total hip replacement, which is an operation to replace both the ball and socket of the hip joint. One type uses a small ball within the socket, in the other the ball is enclosed within a larger plastic ball; we do not know which is the better treatment.

We will investigate which of these treatments gives a better result for people aged 65 years and over with a hip fracture from 30 hospitals across the UK. We want to look at whether people have had any complications after their surgery, particularly dislocation, where the ball comes out of the socket. We will ask people how they feel and how active they are a year after their fracture. We will also work out the cost of the two treatments – for the individual, for the health service and in terms of social support in the following year.

We have previously tried to answer this important question in a pilot study. We concluded that it wasn't possible to carry out the necessary study since it would need to be very large and expensive. Since then, there has been greatly increased use of the alternative type of hip replacement without any evidence. In this study we will work in collaboration with other international partners so that taken together we will be able to answer the question more quickly and at a cost that is reasonable.

### Who can participate?

Patients aged 65 years and over with a displaced intracapsular hip fracture who meet the accepted criteria for consideration of a total hip replacement as per current NICE guidance.

### What does the study involve?

To compare the two treatments properly we think we will need 1600 people to take part overall, we anticipate that 450 will come from the UK part of the study. If people agree to take part, they will be placed into one of two groups through a process called randomisation which makes sure that the groups are similar and the comparison is fair. After their operation everyone will have the usual ward care, rehabilitation and follow up that is standard practice at their hospital.

The researchers will ask participants about any complications from the surgery, their health, walking ability and other daily activities, as well as any additional costs. Answers will be collected at the time of the surgery, at 4 and 12 months after the injury; the results from the two groups will then be compared.

### What are the possible benefits and risks of participating?

The risks of hip surgery include infection, blood clots, damage to nerves and blood vessels in the surgical area, and the risks associated with the anaesthetic. For hip replacement surgery, there is a risk of dislocation and of further fracture around the implant. The risks are not altered by taking part in this study.

### Where is the study run from?

University of Oxford (UK)

### When is the study starting and how long is it expected to run for?

April 2022 to September 2024

### Who is funding the study?

National Institute for Health and Care Research National Institute for Health and Care Research Research for Patient Benefit programme (NIHR RfPB) (UK)

### Who is the main contact?

DUALITY Study Team, white12-duality@ndorms.ox.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Miss Kate Herbert

### Contact details

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
2020-003719-83

**Integrated Research Application System (IRAS)**  
287755

**Protocol serial number**  
IRAS 287755, CPMS 53416, RFPB - NIHR203115

## **Study information**

### **Scientific Title**

World Hip Trauma Evaluation 12: Dual mobility versus standard articulation total hip replacement in the treatment of older adults with a hip fracture (DUALITY)

### **Acronym**

WHITE 12-DUALITY

### **Study objectives**

To establish whether the risk of dislocation after total hip replacement (THR) surgery performed for femoral neck fracture is reduced after the use of dual mobility versus standard articulation THR

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 14/01/2021, Berkshire Research Ethics Committee (Berkshire South Central REC, Easthampstead Baptist Church, Southill Road, Bracknell, RG12 7NS, UK; +44 (0)2071048138; berkshire.rec@hra.nhs.uk), ref: 20/SC/0452

### **Study design**

Pragmatic multicentre two-arm randomized controlled superiority comparison with parallel economic analyses and follow-up

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Displaced intracapsular hip fracture

### **Interventions**

WHiTE 12-DUALITY is a randomised comparison appended to the World Hip Trauma Evaluation (WHiTE ) Platform. WHiTE is a platform trials framework, designed to efficiently deliver multiple randomised comparisons of interventions for patients aged 60 years and over with a hip fracture. The platform and its appended randomised comparisons are governed by one single set of ethical and regulatory approvals and an explicit legal basis and processing purpose for the use of patient-level data. The Platform affords a common core dataset and documentation.

Individual randomised comparisons are not dependent on each other and each will have its unique start and stop dates and publication of results without compromising the integrity of the platform.

Participants will be randomised using block randomisation on a 1:1 basis to Dual Mobility Total Hip Replacement or Standard Total Hip Replacement:

1. Dual Mobility Total Hip Replacement: the cup must be of dual articulation, non-constrained design.
2. Standard Total Hip Replacement: the cup and liner must be of a single articulation, non-constrained design.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

The adjusted risk of dislocation treated by open or closed reduction within 12 months post diagnosis of a hip fracture.

Dislocation events will be obtained through participant-reported complications via medical follow up Case Report Forms and review of the participants' medical records.

### **Key secondary outcome(s)**

1. Reoperation: any surgical procedure performed on the index total hip replacement within 12 months post diagnosis of a hip fracture
2. Implant-related infection within 12 months post diagnosis of a hip fracture: There is no consistent international consensus on the diagnosis of implant-related deep infection. Here, this will be defined clinically by the treating surgical team, as a diagnosis recorded in the participants' medical records.
3. Subjective mobility status measured using the modified New Mobility Score at 6 weeks, 4 and 12 months post-diagnosis of a hip fracture
4. Residential status measured using the UK National Hip Fracture Database Residential Status at 6 weeks, 4 and 12 months post-diagnosis of a hip fracture
5. Mortality risk using death notification up to 12 months post-diagnosis of a hip fracture
6. Risk and pattern of complications measured using a bespoke complications questionnaire and routinely collected hospital data up to 5 years post-diagnosis of a hip fracture
7. Resource use from an NHS and personal social services perspective calculated using a bespoke resource use questionnaire up to 12 months post-diagnosis of a hip fracture

### **Completion date**

01/09/2024

## **Eligibility**

### **Key inclusion criteria**

**Platform inclusion:**

Aged 60 years old and over presenting to a WHiTE recruitment centre for treatment of a hip fracture

**Additional inclusion criteria for DUALITY:**

Adults aged 65 years old and over with a displaced intracapsular hip fracture who meet the accepted criteria for consideration of a total hip replacement as per current NICE guidance

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Lower age limit**

60 years

**Sex**

All

**Key exclusion criteria**

Platform:

Does not meet inclusion criteria

**Additional exclusion criteria for DUALITY:**

1. Delayed fracture surgery (date of presentation to recruitment centre more than seven days prior to the date of randomisation)
2. Pathological or stress fracture of the femoral neck
3. Fracture adjacent to a previous ipsilateral hip implant, such as a previously inserted screw or plate

**Date of first enrolment**

10/09/2022

**Date of final enrolment**

31/08/2023

**Locations****Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre**  
**University Hospital of Wales**  
Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**  
**Royal United Hospital, Bath**  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**Royal Cornwall Hospitals NHS Trust**  
Royal Cornwall Hospital  
Treliske  
Truro  
United Kingdom  
TR1 3LJ

## **Sponsor information**

**Organisation**  
University of Oxford

**ROR**  
<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Research for Patient Benefit Programme

**Alternative Name(s)**

NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Data access requests should be made to Prof. Xavier Griffin (X.griffin@qmul.ac.uk). Requests can be made 2 years after the publication of the trial results. The decision on the level of access granted and the purpose for which it might be made available will be guided by the Oxford Clinical Trials Research Unit and University of Oxford policies regarding data sharing that are in place at the time of the request.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No