

BMJ Open Dual mobility versus conventional total hip arthroplasty in femoral neck fractures (DISTINCT): protocol for a registry-nested, open-label, cluster-randomised crossover trial

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ABSTRACT

Introduction Hip fractures treated with total hip arthroplasty (THA) are at high risk of prosthesis instability, and dislocation is the most common indication for revision surgery. This study aims to determine whether dual mobility THA implants reduce the risk of dislocation compared with conventional THA in patients with hip fracture suitable to be treated with THA.

Methods and analysis This is a cluster-randomised, crossover, open-label trial nested within the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). The clusters will comprise hospitals that perform at least 12 THAs for hip fracture per annum. All adults age ≥ 50 years who meet the Australian and New Zealand Hip Fracture Registry guidelines for THA will be included. The intervention will be dual mobility THA and the comparator will be conventional THA. Each hospital will be allocated to two consecutive periods, one of dual mobility THA and the other of conventional THA in random order, aiming for an average of 16 patients eligible for the primary analysis per group (32 total per site), allowing different recruitment totals between sites. Data will be collected through the AOANJRR and linked with patient-level discharge data acquired through government agencies. The primary outcome is dislocation within 1 year. Secondary outcomes include revision surgery for dislocation and all-cause, complications and mortality at 1, 2 and 5 years. If dual mobility THA is found to be superior, a cost-effectiveness analysis will be conducted. The study will aim to recruit 1536 patients from at least 48 hospitals over 3 years.

Ethics and dissemination Ethics approval has been granted (Sydney Local Health District - Royal Prince Alfred Hospital Zone (approval X20-0162 and 2020/ETH00680) and site-specific approvals). Participant recruitment is via an opt-out consent process as both treatments are considered accepted, standard practice. The trial is endorsed by the Australia and New Zealand Musculoskeletal Clinical Trials Network.

Trial registration number ACTRN12621000069853.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a multicentre, registry-nested trial with a cost-effective design requiring minimal changes to standard practices, maximising generalisability.
- ⇒ The crossover design reduces between-cluster variations.
- ⇒ Dislocations and adverse events were captured at the site level and with linked administrative data and not direct patient contact.
- ⇒ Patient-reported outcomes (eg, pain, function and quality of life) were not collected.
- ⇒ Surgeons and patients were not blinded to treatment allocation.

INTRODUCTION

Hip fractures are the most serious and costly fall-related injury suffered by older people, affecting more than 18 700 Australians at a cost of \$A908 million in 2016.^{1 2} Nearly half (45%–50%) of hip fractures occur in the subcapital (femoral neck) region, of which the majority are displaced.³ Displaced femoral neck fractures have a high rate of failure with internal fixation⁴ and are therefore treated with arthroplasty,⁵ which involves either complete or partial replacement of the hip joint. Hip fracture practice guidelines recommend total hip arthroplasty (THA) over hemiarthroplasty (HA) for independently mobile, active patients with minimal comorbidities prior to injury.^{6–8} THA is increasingly being used in Australia to treat femoral neck fractures compared with HA, increasing from 19.7% to 26.4% of arthroplasties between 2000 and 2016.^{9 10}

Currently, there are several prosthesis options available to orthopaedic surgeons

performing THA for hip fractures. In Australia, conventional THA designs that substitute the ball of the hip joint with a metal femoral prosthesis and the acetabular socket with a static metal and polyethylene cup are the most commonly used.¹¹ THA lacks the inherent stability of the natural hip joint and dislocation may occur.¹² Dislocation involves separation of the prosthetic femoral head from the acetabular cup and is the most common complication after THA for hip fracture. Accumulated evidence from randomised controlled trials reports a dislocation rate of 4.8%,¹³ but this may underestimate the true incidence. Observational studies using arthroplasty registry data suggest an overall dislocation incidence of 8.4%¹⁴ following THA for hip fracture, approximately two to three times higher than when THA is performed electively for osteoarthritis.¹⁵ Dislocations are associated with significant additional hospital costs and decreased patient quality of life,^{16 17} and require closed reduction of the prosthesis to restore the patient's ability to ambulate. More than half of patients who experience recurrent dislocations will require revision surgery to prevent further episodes of hip instability.^{18 19} In Australia, recurrent dislocations in patients with hip fracture are the most common reason for revision surgery in the first 5 postoperative years.¹¹

Due to concerns about dislocation, orthopaedic surgeons are increasingly using an alternative THA design that features a mobile rather than static articulating polyethylene liner between the prosthetic femoral head and the acetabular cup.⁹ The mobile polyethylene liner of the 'dual mobility' THA theoretically increases prosthetic hip stability by increasing the effective head to neck ratio and jump distance (ie, head displacement required for dislocation) compared with conventional THA, as well as by allowing an increased range of motion of 10°–15° in all directions before dislocation occurs.²⁰ Dual mobility THA therefore may have the potential to reduce the incidence of dislocation when THA is used for hip fracture. The benefits of preventing dislocation are therefore twofold. First, patients are less likely to experience difficulties in self-care and anxiety associated with recurrent dislocation.¹⁶ Second, increased implant stability would reduce the cost burden associated with treatment of dislocation.

Clinical and arthroplasty registry studies are divided as to whether dual mobility THA reduces the incidence of dislocation and subsequent revision surgery. A recent systematic review of nine retrospective studies reported an incidence of dislocation of 1.5% for dual mobility THA when used for femoral neck fracture at a mean follow-up of 2.5 years.²¹ This compares to a dislocation rate of 4.8% for conventional THA at 2 years.¹³ In a meta-analysis, the authors reported a 74% lower risk of dislocation in three studies that directly compared dual mobility with conventional THA. However, these studies were judged to be at moderate to serious risk of bias.²¹ Arthroplasty registries do not show a clear reduction in revision surgery with the use of dual mobility THA for femoral neck fracture. An analysis of the Nordic Arthroplasty Register Association

(NARA) data, which featured a propensity score-matched cohort of 9040 patients with hip fracture (4520 dual mobility and 4520 conventional THA) from Denmark, Norway and Sweden, reported that dual mobility reduces the incidence of all-cause revision by 25% and revision for dislocation by 55% at a median follow-up of 2.4 years (range 0–14 years).²² However, two additional registry studies, one from the Netherlands (1122 dual mobility and 10735 conventional THA patients)²³ and the other from Australia (1778 dual mobility and 8582 conventional THA),²⁴ did not observe a similar benefit when large femoral heads (≥ 32 mm) were used in conventional THA.

Study rationale

In Australia, the cost of dual mobility implants is 1.5–2 times higher than conventional THA acetabular implants using publicly available government prosthesis rebate data.²⁵ There is a need to determine whether dual mobility is both an effective and cost-effective treatment strategy for reducing the incidence of dislocation and subsequent revision surgery in patients with femoral neck fracture when compared with conventional THA. Both dual mobility and conventional THAs are considered standard care in Australia, with dual mobility implants constituting approximately 25% of THAs performed for femoral neck fracture in 2019.¹¹

Objectives

Primary objective

The primary objective of this study is to determine whether dual mobility THA is superior to conventional THA in femoral neck fractures in reducing the risk of hip dislocation in the first postoperative year.

Secondary objectives

1. To compare the revision rates (for dislocation and all-cause) for dual mobility THA and conventional THA at 1, 2 and 5 years postoperatively.
2. To compare the complication rates (unplanned reoperation or readmission) associated with dual mobility THA and conventional THA in the first postoperative year.
3. To compare the mortality rates between dual mobility THA and conventional THA at 1, 2 and 5 years postoperatively.
4. To perform a cost-effectiveness analysis comparing dual mobility THA and conventional THA at 1 year postoperatively if dual mobility THA is found to be superior to conventional THA in reducing the risk of hip dislocation.

METHODS AND ANALYSIS

Study design

DISTINCT (Dual mobility verSus conventional Total hip arthroplasty In femoral Neck fractures, a registry-nested, open-label, Cluster-randomised crossover Trial) is a pragmatic, superiority, open-label, cluster-randomised

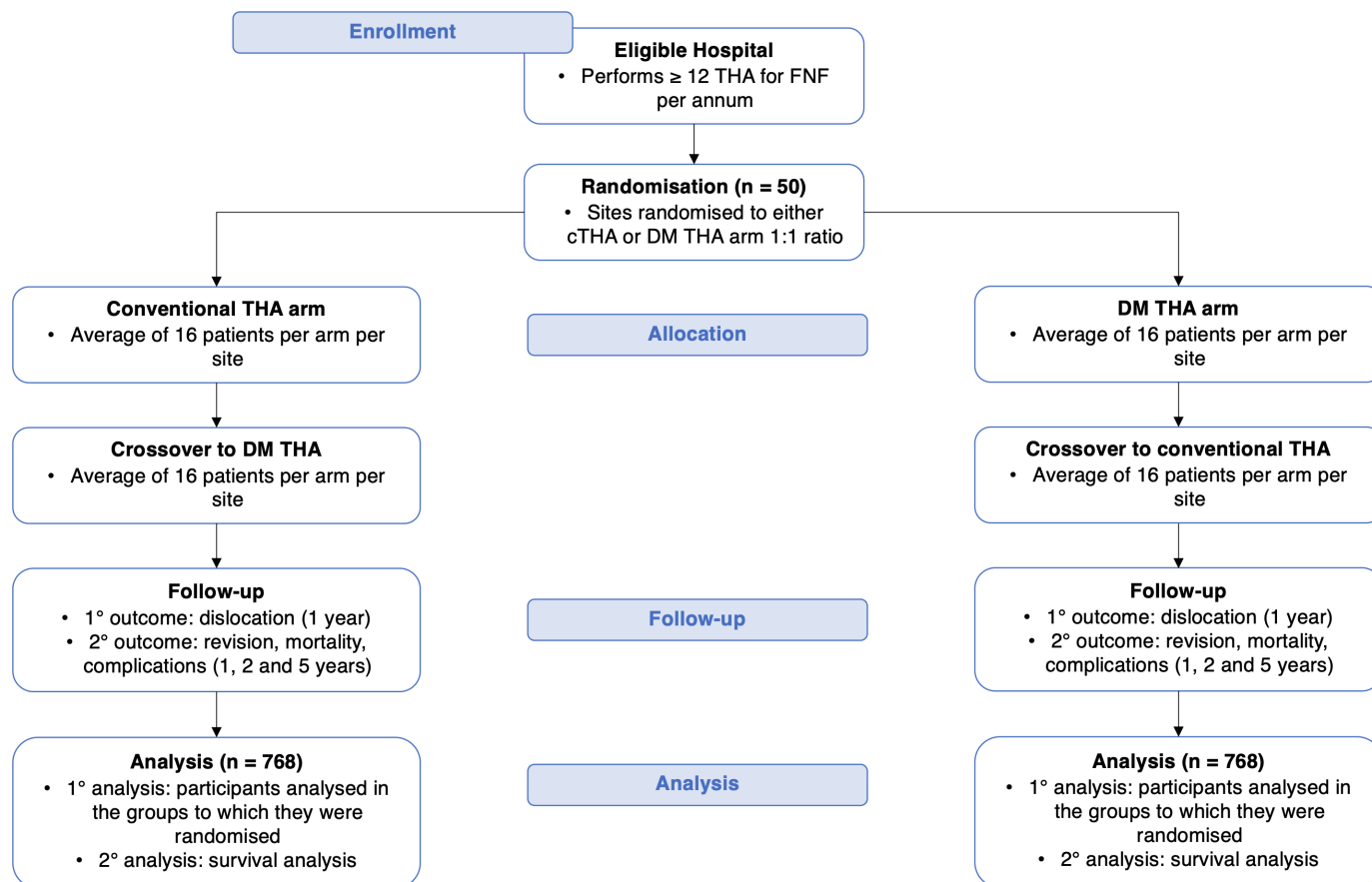


Figure 1 Study flow diagram. cTHA, conventional total hip arthroplasty; DM THA, dual mobility total hip arthroplasty; FNF, femoral neck fracture; THA, total hip arthroplasty.

crossover trial nested within the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). The setting is eligible Australian hospitals (public and private) performing THA for femoral neck fractures. Recruitment commenced on 1 February 2021 and is expected to finish in December 2023. The study flow is depicted in [figure 1](#).

Eligibility criteria

Hospitals will be eligible to recruit for DISTINCT if they performed ≥ 12 THAs for femoral neck fracture in the 2018 reporting period of the AOANJRR. Recruiting sites are required to review and adhere to the study protocol and make no other changes to departmental practices or protocols relevant to the care of patients with hip fractures over the study period. All listed investigators are required to complete Good Clinical Practice (GCP) training prior to the commencement of the study. The chief investigator (IAH) was responsible for approaching and recruiting hospital sites.

Patients will be eligible for participation in the trial if they meet the Australian and New Zealand Hip Fracture Registry (ANZHFR) criteria for treatment of a displaced femoral neck fracture with THA,⁸ specifically able to walk independently out of doors with no more than use of a stick prior to the fracture, not cognitively impaired, and medically fit for anaesthesia and the procedure. No

maximum age limits will be applied, but patients must be aged ≥ 50 years.

Patients will be excluded if they meet the criteria for HA according to the ANZHFR guidelines (displaced femoral neck fracture in a patient with dementia or other significant cognitive impairment and/or permanent resident of a residential aged care facility),⁸ suffer a pathological fracture due to tumour or have a pre-existing bony deformity requiring a custom or non-standard prosthesis for management. Additionally, many patients with minimally displaced fractures and some with displaced fractures may be managed with internal fixation, but these patients will not be included.

Rationale for study design

As both treatment arms are considered standard, common and accepted treatment for management of femoral neck fracture in Australia without specific consent, we elected for a cluster-randomised design. A cluster design simplifies trial administration at sites by allowing for an opt-out consent process. This is the same opt-out consent process that governs the collection of patient operative data collected by the hospital and provided to the AOANJRR. An individually randomised superiority trial comparing dual mobility with conventional THA (WHiTE Two) has previously been attempted but was deemed unfeasible due to poor patient recruitment in this patient population.²⁶

Another individually randomised superiority trial (DUALITY) is currently recruiting in Sweden, with results not expected until 2026.²⁷ The risks of both the intervention and the comparator are similar and discussed as part of the standard surgical consent process for THA. A specific patient-level study consent for DISTINCT was deemed not required by the ethics committee as it would require an additional consent process apart from consent for surgery and make entry into the research difficult, likely incomplete and potentially confusing for patients. A qualitative analysis of participants recruited for the WHITE Two trial confirms these concerns, with many patients describing high levels of physical and emotional stress due to femoral neck fracture and the urgent nature of the surgery being barriers to participating in a research project.²⁸ All study participants will receive a copy of the participant information form (online supplemental material), which describes the study rationale, the study procedures and the opt-out process in lay terms.

Second, by randomising the hospital to a sequence of dual mobility and conventional THA, the crossover design will provide site principal investigators adequate notice after randomisation to provide training in study procedures, as well as ensure appropriate implants are available for allocation. It will also allow adequate time for all site investigators to undergo GCP training prior to commencement of recruitment,²⁹ a requirement for the ethical conduct of clinical trials in Australia. There will be no training for the surgical procedure as this will be done according to usual practice in each hospital. Standardising practice within a cluster to a single prosthesis for a period will minimise contamination between study arms and improve study adherence. Using each site to recruit both arms of the study minimises variance inflation from any within-cluster correlation. All eligible patients from each site will be included (as the site is the unit of randomisation), minimising selection bias.

Treatment groups and randomisation

Each hospital site will be allocated to consecutive periods of standard protocol of dual mobility THA and standard protocol of conventional THA for management of displaced femoral neck fractures, with the order of the two periods determined by randomisation at a 1:1 ratio using a computer-generated sequence. Allocation will occur 1 month (range: 3–6 weeks) prior to site commencement to allow introduction of local protocols and supply of implants. Randomisation will be performed by statisticians at the South Australian Health and Medical Research Institute (SAHMRI), independent of the study investigators, using simple randomisation without the use of blocks or stratification. Sites will not be blinded to group allocation after randomisation; however, statistical analysis and interpretation will be blinded.

Patients will be informed of the trial by the treating surgeon at the time of consent for surgery but will not be required to provide individual consent to the trial, as both surgical implants represent standard practice and

randomisation is not at the patient level. Each site will adhere to the initially randomised protocol for a period based on surgical volume, aiming for a site average of 16 patients eligible for the primary analysis per group (32 total per site). Fast recruiting sites will be allowed to recruit until up to 25 patients per group have been registered into the trial by the AOANJRR. Slow recruiting sites may be crossed over prior to recruiting 16 patients so that a similar number of patients can be recruited to each group prior to recruitment ending in December 2023. THA using both dual mobility and conventional designs will be performed as per standard surgical technique according to surgeon preference, using the same surgical approach and method of fixation (cemented or uncemented) for both treatment groups. For the conventional THA group, surgeons will be required to use a large femoral head (≥ 32 mm) unless patient anatomy does not allow. Lipped liners are permissible in the conventional THA group, but constrained liners are not permitted as they are not indicated for primary joint replacement in patients with displaced femoral neck fracture and have unique modes of failure that may confound analysis. For the dual mobility THA group, all cementless designs (with and without screw holes) are permissible. Surgical approach can vary by surgeon, but individual surgeons must maintain the same surgical approach for both study groups. If a posterior approach is used, a capsular repair will be performed, as well as a repair of the short external rotators.

Postoperative treatment will be standardised across study sites according to the following requirements:

- ▶ All patients will be able to weight-bear as tolerated without restriction postoperatively.
- ▶ Splinting, such as Charnley abduction pillows, will not be used routinely.
- ▶ Education and information around hip precautions will be consistent across study groups.
- ▶ Each site will use the same local rehabilitation protocols for both treatment arms.

Adherence

Adherence to the study protocol will be determined using standard AOANJRR data forms, completed by the surgical team at the time of surgery. The AOANJRR has completeness for more than 98% of arthroplasty procedures performed in Australia via standard forms submitted for both primary and revision procedures,³⁰ and this process will remain unchanged. Bimonthly meetings of site principal investigators will occur to discuss study recruitment and identify barriers to study adherence. Sites will be provided written monthly updates on recruitment numbers, as well as protocol violations. Where protocol violations occur, site principal investigators will be required to provide a reason for the violation. AOANJRR staff will monitor the number of data forms received and provide 1-month notice of the crossover date. Crossover and completion will be arranged before more than 25 cases have been recorded in the study arm.

Table 1 Data collection and timepoints

Time point	Data collection	Variables
Pre-operative	Age	> 50 years old.
	Gender	Male, female.
	Side	Right, left, bilateral.
	ASA grade	ASA I–V.
	BMI	Underweight (<18.50), normal (18.50–24.99), pre-obese (25.00–29.99), obese class 1 (30.00–34.99), obese class 2 (35.00–35.99), obese class 3 (≥40).
	Surgical approach	Posterior, lateral*, anterior.
	Acetabular implant	Conventional liner, dual mobility liner.
	Femoral implant	Stem type (polished or matte), fixation (use of cement).
	1 year	Dislocation
Revision surgery		AOANJRR hip form.
Complications (via site reporting and state-level hospital data).		Site reporting or linked data.
Mortality		Linked data to national death index.
2 years and 5 years	Revision surgery	AOANJRR hip form.
	Mortality	Linked data to national death index.

*Includes anterolateral approach.

AOANJRR, Australian Orthopaedic Association National Joint Replacement Registry; ASA, American Society of Anesthesiologists Physical Status Classification System; BMI, body mass index.

Prior to crossover, site principal investigators will undertake an audit of all patients enrolled in the trial to ensure that all patients are eligible for inclusion in the primary analysis as per the study protocol.

Data collection methods

Data collection will occur at baseline and at 1, 2 and 5 years. Baseline demographic data (age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) Physical Status Classification grade, as well as both acetabular and femoral implant types, surgical approach, and laterality of THA will be via standard (currently routine) forms submitted to the AOANJRR for primary joint replacement (table 1).

Primary outcome

For the primary outcome of dislocation within 1 year of the index THA, data will be captured by site reporting and data linkage. Participating sites are required to notify the principal investigators of all dislocations related to the surgery as they become aware via a standardised adverse event proforma. To capture dislocations, study data will be linked with hospital-level data acquired through state governments or the Australian Institute of Health and Welfare using unique patient identifiers. Patients will be considered to have dislocated the prosthetic hip joint if a site investigator reports evidence of a dislocated hip, or linked data report an emergency department presentation, admission diagnosis or procedure for hip dislocation. For patients who have bilateral prosthetic hip joints, site investigators will be contacted to determine laterality of the dislocated

hip. If laterality cannot be determined for dislocations captured by data linkage, dislocations that occur within the first postoperative year will be assumed to be related to the most recent hip arthroplasty procedure where the patient has a pre-morbid contralateral hip prosthesis.

Secondary outcomes

Secondary outcomes include revision surgery, complications and mortality. Revision surgery data will be obtained from the AOANJRR at 1, 2 and 5 years. Revision surgery is defined as any removal, exchange or addition of one or more components to the primary THA. Revision surgery indications include dislocation, infection, loosening, lysis, implant breakage (stem and acetabular) and fracture.³¹ Non-revision-related complications, such as any unplanned reoperation or readmission related to the surgery, will be measured by site reporting and data linkage. Specifically, complication data will be collected up to 12 months postsurgery and the time of each complication will be recorded. Complications will be categorised as follows:

- ▶ Readmission related to the original surgery or associated treatment.
- ▶ Reason for readmission: infection, wound dehiscence, wound bleeding, stiffness, fracture and other (non-joint) surgery.
- ▶ Reoperation on the same joint: closed reductions performed in the emergency department under sedation or any joint procedure performed in an operating theatre.

► Death (measured by routine linkage between the AOANJRR and the National Death Index).

A cost-effectiveness analysis will be conducted if dual mobility THA is found to be superior to conventional THA.

Sample size

The HEALTH trial, a recent large randomised controlled trial of 1495 patients from 80 institutions in 10 countries, reported a 4.7% incidence of dislocation in the 2 years following conventional THA for hip fracture in patients aged ≥ 50 years.³² A systematic review and meta-analysis of randomised controlled trials that included the HEALTH trial comparing conventional THA with HA reported an incidence of dislocation of 4.8% for THA.¹³ For the DISTINCT study, we anticipate an overall dislocation rate of 4%–5% at 1 year based on these data. The most recent systematic review of three retrospective observational studies of dual mobility THA performed for hip fracture reported an incidence of dislocation of 1.5% compared with 7.6% in conventional THA, but did not detect a difference in reoperation rates.³³ A matched-pair analysis from NARA reported 25% reduction in all-cause revision (HR 0.75, 95% CI 0.62 to 0.92) and a 55% reduction in the risk of revision for dislocation (HR 0.45, 95% CI 0.30 to 0.68).²² With estimated dislocation rates of 6% and 3% for conventional THA and dual mobility THA, respectively, a cluster-randomised trial using at least 48 clusters would require an average of 16 patients per group, per cluster (n=1536 patients in total), with a coefficient of variation of cluster sizes of 0.5, 80% power and a significance level of 5% (intracluster correlation=0.01, interperiod correlation=0.008).^{34 35} As the outcome is the difference in proportions of cases with dislocation within 1 year of follow-up, regardless of mortality, no adjustment for death or loss to follow-up has been made. The study will recruit an average of 16 patients per group (32 total), per cluster. This sample size would provide 90% power for a higher event rate of 8% and 4% for the two groups.

Statistical analysis

The analysis for the primary outcome will test between-group difference in the proportion of cases sustaining a dislocation of the affected hip within 1 year postoperatively. The primary analysis will use cluster summary methods, weighted by cluster size to account for unequal cluster sizes.³⁶ Analyses will be reported both unadjusted and adjusted for hospital type (public or private). These methods estimate the treatment effect using cluster-level differences and have been shown to be adequate for cluster-randomised crossover trials with rare outcomes and the intracluster and interperiod correlation coefficients expected in this trial.³⁷ Multiple imputation for missing data will use joint modelling to account for clustering.³⁸ Participants will be analysed in the groups to which they were randomised. Sensitivity analyses will compare the unadjusted primary outcome based on their allocation, treatment received (as-treated) and

per-protocol grouping. Survival analysis will be performed using Kaplan-Meier curves and the log-rank test, clustered by site, to determine any differences in the timing of dislocations based on the groups to which patients were randomised and separately based on the treatment received (as-treated).

Subgroup analyses of the primary outcome will test for differences in treatment effect based on surgical approach (posterior, lateral or anterior), femoral head size (< 32 mm or ≥ 32 mm), conventional liner type (standard or lipped), obese (BMI ≥ 30) or non-obese (BMI < 30), and gender (male, female). The subgroup analyses will use cluster summaries by subgroup weighted by size, with an interaction term between subgroup and treatment sequence. Tests for differences between subgroups will account for multiple testing. The rationale for inclusion of the above subgroups is based on prior observational studies demonstrating a higher risk of dislocation associated with the posterior surgical approach,^{19 22 39 40} smaller femoral head sizes (< 32 mm),^{23 24} obesity^{9 41} and male sex.⁴² Lipped liners have been shown to be protective against revision for dislocation when THA is performed for osteoarthritis.^{43 44} A higher all-cause revision risk was observed (HR 1.40, 95% CI 1.21 to 1.61, $p < 0.001$) for THA performed for femoral neck fracture in the private sector. However, this difference became non-significant once the analysis was adjusted for prostheses with a higher than anticipated rate of revision, indicating that outcomes are similar when comparing like for like prostheses. Treatment group differences for each secondary outcome (all-cause revision, revision for dislocation, death, reoperation and readmission) will be estimated using cluster summary methods as described above. Estimates will be reported both unadjusted and adjusted for hospital status.

If dual mobility THA is found to be superior to conventional THA, a within-trial cost-benefit analysis from an Australian healthcare system perspective will be conducted to determine the 12-month cost-benefit of dual mobility compared with conventional THA, determined by the benefit to cost ratio. The upfront cost of THA implants, which includes the cost of the prosthetic equipment (femoral head and acetabular cup), the surgical procedure and the index hospital and intensive care unit stay, will be estimated for each type of THA using trial records, linked health administrative data and unit cost data obtained from the Australian Prostheses List and Independent Hospital Pricing Authority (IHPA). Benefits from hip dislocations avoided over 12 months will be monetised. Comparison of dual mobility with conventional THA will include any cost savings of revision surgeries and related follow-up hospital and community care from reduced dislocation in the first 12 months, which will be measured with linked health administrative data and valued with IHPA hospital price weights. If the benefit to cost ratio is greater than 1, dual mobility THA will be considered of value. Due to the skewed distribution of costs, a non-parametric bootstrapping exercise will be carried out as a robustness check of the results.^{45–48} The

probability that dual mobility is cost-beneficial compared with conventional THA will be calculated as the proportion of bootstrap simulations that return a positive net monetary benefit (ie, simulated benefit > simulated cost).

Data management, monitoring and sharing

The AOANJRR is a listed Federal Quality Assurance Activity and is responsible for data collection, management, analysis and storage. The AOANJRR already collects data on almost all joint replacement procedures performed in Australia. Operative data are completed at the time of surgery on a registry form. These forms are collated regularly by the hospital and sent to the registry for data entry into the secure registry central database. The AOANJRR central database is housed and managed by the SAHMRI. This process will remain unchanged. Data will be made available to investigators on trial completion. De-identified data sets and dictionaries will be made available for further research after trial completion and dissemination of the results by peer-reviewed journal publication on request of the chief investigator (IAH).

A separate trial management committee will be established to monitor data management and quality. A separate safety monitoring committee will not be established, and no stopping rules will be used as both interventions are commonly used and recommended treatments and as such no interim analysis will be performed. This will reduce the chance of early stopping due to spurious findings. Adverse events will be monitored by the trial management committee.

Patient and public involvement

On 15 November 2018, we conducted a focus group with a convenience sample of five patients who had recently undergone THA (three for fracture, two elective) at two participating hospitals (St George and Sutherland). While the main concern patients had during their recovery was the risk of an infection, all patients specifically recalled the risk of dislocation and the recommended precautions and all reported these as a major source of anxiety. Patients were 'particularly careful' and most thought their hip was 'going to pop out' if they performed normal activities, such as gardening, cutting their toenails or driving. Two patients mentioned they were 'chastised frequently' by hospital staff for 'doing the wrong thing'. Most patients voluntarily opted to use walking aids or held handrails to specifically mitigate dislocation risk and not 'upset' the joint. All patients agreed dislocation following hip replacement was an important issue and supported an experimental trial to reduce that risk. The issue of prosthesis novelty was specifically raised, with a single patient expressing concern about having a prosthesis with a shorter track record than 'standard' THA. Patients wanted to 'move forward with innovations' and did not express concern when asked about consent, considering it unnecessary, particularly given that dual mobility THA is approved and is used routinely in many centres (without any specific consent). Patient involvement was

sought for the study design and writing of the protocol (MR, patient consumer advocate). There are no plans to disseminate the study results to study participants as there are no provisions for the AOANJRR to directly contact patients and this would breach the terms of reference under which the AOANJRR functions as a quality assurance activity. Study participants can access a lay summary of the AOANJRR annual reports online, free of charge.

Study governance

The day-to-day management of the trial will be the responsibility of the AOANJRR. Other expert subgroups may be established throughout the project to advise on specific elements and make recommendations should the need arise.

ETHICS AND DISSEMINATION

The study received Human Research Ethics Committee (HREC) approval from the Sydney Local Health District - Royal Prince Alfred Hospital Zone (approval X20-0162 and 2020/ETH00680), which is a lead ethics committee in Australia. The study was registered with the Australian New Zealand Clinical Trials Registry prospectively prior to trial commencement and can be viewed at <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=381041&isReview=true>. The trial protocol has been endorsed by the Australia and New Zealand Musculoskeletal Clinical Trials Network. All participating hospitals have received site-specific ethical approval. Site-specific approvals for each participating hospital have been granted from the following ethics committees: Albury Wodonga Health (SSA/65795/AWHEC-2021-256332), Blacktown Hospital (2020/STE03234), Box Hill Hospital (S21-006-65795), Cabrini Hospital (Malvern) (02-08-10-20), Cairns Hospital (SSA/2020/QCAIRNS/65795), Calvary Adelaide (20-CHRECF009), Coffs Harbour Base Hospital (2020/STE03821), Concord Repatriation General Hospital (2020/STE03235), Epworth Healthcare Richmond (EH2020-620), Fiona Stanley Hospital (RGS0000004025), Flinders Medical Centre (2020/GEM00829 | 2020/SSA01136), Footscray Hospital (Western Health) (SSA/65795/WH-2020-228955), Frankston Hospital (SSA/65795/PH-2020), Gold Coast Hospital and Health Service (Gold Coast University and Robina) (SSA/2021/QGC/65795), Gosford Hospital (2020/STE03236 and CCLHD ref no: 0820-104C), Greenslopes Private Hospital (RG2020.181b), Hornsby Ku-ring-gai Hospital (2020/STE03237), Ipswich Hospital (SSA/2020/QWMS/65795), John Flynn Private Hospital (RG2020.181), John Hunter Hospital (2020/STE03238), Joondalup Health Campus (RG2020.181c), Latrobe Regional Hospital (SSA/65795/LRH-2020-230782), Launceston General Hospital (23019), Liverpool Health Service (2020/STE03239), Logan Hospital (65795), Lyell McEwin Hospital (2020/GEM01121 | 2020/SSA00908), Maroondah Hospital (S21-006-65795), Mater Hospital Brisbane (Public) (MSSA/

MRGO/65795), Mater Private Hospital Brisbane (MSSA/MRGO/65795), Northern Beaches Hospital (2021/NBH/002), Royal Adelaide Hospital (2020/GEM00829 | 2020/SSA00571), Royal Hobart Hospital (23019), Royal North Shore Hospital (2020/STE03823), Royal Perth Hospital (RGS0000004025), Royal Prince Alfred Hospital (HREC Lead) (2020/STE01591), Sir Charles Gairdner Hospital (RGS0000004025), St George Hospital (2020/STE03242), St Vincent's Public Hospital (Sydney) (2020/STE04302), Sunshine Coast University Hospital (SSA/2020/QSC/65795), Sutherland Hospital (2020/STE03240), The Alfred Hospital (SSA/65795/Alfred-2020-230377), Canberra Hospital (2020.STE.00242), The Prince Charles Hospital (SSA/2020/QPCH/65795), The Prince of Wales Hospital (2020/STE03241), The Royal Melbourne Hospital (2020.376), The Wesley Hospital Brisbane (2020.16.326), Townsville University Hospital (SSA/QTHS/65795), University Hospital Geelong Barwon Health (SSA/65795/VICBH-2020-230376), Wagga Wagga Base Hospital (2020/STE03822), Westmead Hospital (2020/STE05169) and Wollongong Hospital (2020/STE04303).

The trial meets the guidance criteria for an opt-out consent process and all other ethical requirements as per the National Statement on Ethical Conduct in Human Research.⁴⁹ As patients will be treated with the standard protocol for both dual mobility and conventional THA, this study poses no foreseeable risk, harm or discomfort to patients beyond what is normally experienced with a femoral neck fracture.

Dissemination will be by peer-reviewed journal publication, conference presentation and through media. All study findings will be reported regardless of statistical significance or the size or direction of effect. Authorship for principal papers will be by the members of the writing committee and the DISTINCT Study Group (consisting of all investigators according to the authorship guidelines of the International Committee of Medical Journal Editors).

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