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Can an independent consultation and feedback program for patients and surgeons help to optimize decisions on which materials are used for joint replacement surgeries?

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Registration date 08/01/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/03/2021	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee and hip replacement surgery involves replacing worn bones and cartilage with artificial materials. There is a wide range of cost associated with these materials, but also issues of safety and side effects to consider. Patients and surgeons should both be involved in selecting the most appropriate surgical procedure and materials used. This study aims to investigate a program that helps doctors and patients make informed and cost-effective decisions.

Who can participate?
The study recruits both orthopedic (joint) specialists and adult patients who are waiting for hip or knee joint replacement surgery

What does the study involve?
Hospitals will be randomly allocated into one of two groups. Patients and doctors in the intervention arm will receive 18 months' access to an independent consultation and feedback intervention program designed by the study on the basis of routine medical services. Hospitals in the control group will continue as usual.

What are the possible benefits and risks of participating?
For patients, the benefits of participation may include reduced medical costs, more complete and accurate clinical history recording and more reasonable and transparent clinical decision-making and better health outcomes. For patients, the risks of participation may include increased risk of privacy exposure and more psychological pressure in communicating with doctors.
For doctors, the benefits of participation may include better doctor-patient relationships, reduced deficiencies and moral hazards in decision-making, improved patient trust of patients and better standardization of medical practices.The study risks for doctors may include increased workload and longer time spent in clinical decision-making.

Where is the study run from?
The First Affiliated Hospital of University of Science and Technology of China

When is the study starting and how long is it expected to run for?
June 2018 to June 2023

Who is funding the study?
Key Research and Development Projects of Anhui (China) and the Fundamental Research Funds for the Central Universities (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Smartphone and web-based independent consultation and feedback for joint replacement surgeries: a randomized controlled trial

Acronym
ICFS

Study objectives

Independent consultation and feedback system (ICFS) can optimize clinical decisions on use of medical materials for patients needing joint replacement surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2019, Biomedical Ethics Committee of the University of Science and Technology of China (17 Lujiang Road, Hefei, Anhui, China; +86-(0)551-62282931; ahslyyllwyh@163.com), ref: 2019-N(H)-213

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Hip or knee joint replacement surgery

Interventions
The study utilizes a quasi-RCT design involving patients needing joint replacement surgery and the corresponding orthopedic surgeons selected, from hospitals of Anhui province, randomized into equal intervention and control arms. The intervention arm receives 18 months' access to an independent consultation and feedback intervention program designed by the study on the basis of the routine medical services; while the control arm receives routine medical services.

The intervention consists of two main components targeting patients and doctors.
For patients, the intervention has four parts:
1. PI1 (option assessment). PI1 contains a cost-benefit evaluation aid. The objectives of PI1 is to help patients make a relatively systematic evaluation of the alternative diagnosis and treatment procedures, including medical materials (MMs) use. The intervention contents of PI1 include materials to:
1.1. Display to patient diagnosis/treatment alternatives (especially options of MM use) and corresponding advantages, disadvantages and indications
1.2. Provide problem-solving cases so as to eliminate the problems and doubts that patients may have regarding their current conditions and MMs use
1.3. Provide structured cost-utility rating scale to help patients systematically evaluate different joint replacement procedures/MMs on their physiological, psychological and social functions
1.4. Provide easy-to-understand cost-utility evaluation summaries to help comparison and selection of different treatment/MM options
2. PI2 (facts review and confirmation). The intervention contents of PI2 include materials to:
2.1. Remind the patient of the importance of reporting and recording accurate symptoms and medical history
2.2. Provide a relatively 'private' and 'independent' environment for patients to check and supplement information on their symptoms and medical history without being affected by relatives, friends, doctors, etc.
2.3. Ask patient to perform at least twice a 'facts review and confirmation', once before

treatment and MMs use and another 1 week after discharge from hospital
3. PI3 (self-expression). The intervention contents of PI3 include materials to:
3.1. Tell patients which views about doctors/hospitals are misunderstood
3.2. Tell patients to fully and accurately tell doctors about their condition, especially the experiences that doctors can not detect or feel
3.3. Tell patients that they can ask doctors to provide a private environment for discussing their illness
3.4. Tell patients that they can be confident in correcting their symptoms and medical history over time
3.5. Tell patients that they need to straightforwardly speak about their diagnosis, treatment decisions, expectations and difficulties
4. PI4 (Follow-up promotion/aid). The intervention contents of PI4 include materials to:
4.1. Deliver text messages to patient participants every day to mobilize and guide them to taking medicine according doctor's advice, carrying out rehabilitation training, and improving behavior and habits, etc.
4.2. Follow up patients' satisfaction and trust in the doctors and hospitals, the occurrence and severity of complications after MMs use, the degree of recovery of related organ functions, related health behaviors (e.g., physical exercise, smoking and drinking), related quality of life (data collected via EQ-5D-3L scale), etc.

For doctors, the intervention also has four parts:
5. DI1 (Evidence/guideline reminding). The intervention contents of DI1 include materials to:
5.1. Periodically provide literature reviews and the latest reported RCT findings to the doctors
5.2. Remind doctors of the related regulatory norms and guidelines issued by competent authorities and authoritative academic organizations
6. DI2 (Need/preference presentation). The intervention contents of DI2 include materials to:
6.1. Deliver to doctors patients' scores and rankings of various alternative treatment schedules and joint replacement related MMs
6.2. Present to doctors the effectiveness evaluation results on the main related physiological functions, complications, quality of life, etc. at different time points after leaving hospital
6.3. Collect patients' attitudes and satisfaction with joint replacement surgery services
7. DI3 (Diagnosis/treatment audit). The intervention contents of DI3 include materials to:
7.1. Organize authoritative experts to formulate a working 'standardized evaluation index system of joint replacement surgery decisions and MMs use', and deliver the medical records of patients who have undergone joint replacement to the expert group for independent scoring
7.2. Compare doctors' diagnosis and treatment activities to clinical pathways and present the gaps between them
8. DI4 (Performance feedback). The intervention contents of DI4 include materials to:
8.1. Make comparisons of follow-up results (including functional recovery, complications, quality of life, satisfaction, etc.) among different clinical schedules at different time points after leaving hospital
8.2. Periodically (monthly and quarterly) compare the use rate of different types of implant joint MMs and the subsequent patient function-related indicators among doctors
8.3. Perform 'confirmations' twice to compare patient responses with the medical records recorded by doctors

Each of these intervention ingredients is designed to tackle the doctor- and patient-side problems with existing medical materials.

The patients access and interact with the program via a smartphone-based app and the doctors use a web-based clinical support system (CSS).

Intervention Type
Behavioural

Primary outcome(s)
1. Quality-of-life assessed using the EQ-5D-5L scale at 6 months, 12 months and 18 months after discharge
2. Cost of medical materials assessed using questionnaire custom-designed for this study at 6 months after discharge

These data will be used to calculated cost-effectiveness.

Key secondary outcome(s))
1. Peer expert audit score assessed using a custom-designed questionnaire at 6 months after discharge
2. Quality control inspection score assessed using a custom-designed questionnaire at 6 months after discharge
3. Patient awareness rate (treatment schedule, surgical risk, material selection, etc) assessed using a custom-designed questionnaire at discharge, and 6 months, 12 months and 18 months after discharge
4. Patient satisfaction assessed using a custom-designed questionnaire at discharge and 6 months after discharge
5. Total medical expense assessed using a custom-designed questionnaire at 6 months after discharge

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Surgeons:
1. All orthopedic surgeons from the selected hospitals are encouraged to participate in this study

Patients:
1. Awaiting hip or knee joint replacement surgery
2. Have the ability to communicate and make independent decisions
3. Aged 18 years or older

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients unwilling to participate in the study
2. Patients with previous experience of hip or knee joint replacement surgeries
3. Patients unable to communicate clearly and/or make independent decisions

Date of first enrolment
31/12/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of University of Science and Technology of China
Hefei
China
230001

Sponsor information

Organisation
The First Affiliated Hospital of University of Science and Technology of China

ROR
https://ror.org/04c4dkn09

Funder(s)

Funder type
Government

Funder Name
Key Research and Development Projects of Anhui Province

Funder Name
Fundamental Research Funds for the Central Universities

Alternative Name(s)
Fundamental Research Funds for the Central Universities of China, Fundamental Research Fund for the Central Universities

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/03/2021	08/03/2021	Yes	No