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What are the best ways to improve shared decision-making for all patients booked for surgery?

Submission date
15/06/2023

Recruitment status
No longer recruiting

Registration date
11/07/2023

Overall study status
Ongoing

Last Edited
30/06/2025

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Over 5 million people decide to have surgery each year. These decisions are important and life-changing. Shared decision-making (SDM) is the recommended way for patients and professionals to make joint decisions about care by talking about personal preferences and values. Unfortunately, SDM does not happen for everyone. Patients say they want to be more involved in decisions. Improving SDM is therefore a research priority. We don't know how to improve SDM at a big (organisational) scale, or for under-served groups (e.g. deprived (poor) or elderly people and ethnic-minority groups). We also need better ways to measure SDM. Our research will find these answers and create a new way to improve SDM.
The aim of this study is to create a new way (an 'intervention') for patients to measure their experience of SDM on a big scale, to feedback this experience to care teams, and change what patients and professionals do before surgery to improve care.

Who can participate?
1. Patients over the age of 18 years who have been booked for planned surgical procedures at participating hospitals
2. Healthcare professionals working in participating Trusts
3. Members of the wider community over the age of 18 years who are disproportionately affected by poor SDM and outcomes of surgery: those that are economically disadvantaged, from minority ethnic groups, and in older age. Ethnicity is expected to focus on British Asian /South Asian populations as the most common minority group in the UK, however, this will be informed in discussions with stakeholders and patient and public representatives.

What does the study involve?
The researchers will interview people in Bristol and Bradford to find out how to create an intervention that is inclusive of underserved groups. Next, they will have meetings for patients and professionals to agree on the best ways to measure SDM and its impact. The researchers plan to create and test their intervention in different settings and explain how it works to improve patient care. A scientific study will then test if the intervention makes any difference to patients and the health service compared to usual care.

What are the possible benefits and risks of participating?
The study will develop knowledge about how to improve SDM for under-served groups and will find ways to measure SDM and its impact. This will help the health service and other researchers to improve SDM for surgery.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
March 2022 to June 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Christin Hoffmann, c.hoffmann@bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
292800

Protocol serial number
CPMS 48738, IRAS 292800

Study information

Scientific Title
Development, pilot, and evaluation of a decision support intervention that uses real-time feedback of patients' experience of shared decision-making to change patient and professional decision-making processes before adult elective surgery and to improve patient and health service outcomes

Acronym
ALPACA

Study objectives
It is possible to co-develop a decision support intervention that uses real-time monitoring and feedback of patients' experience of shared decision-making to change patient and professional decision-making processes before adult elective surgery to improve patient and health service outcomes

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/06/2023, North West - Liverpool Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)2071048118, +44 (0)20 7104 8222, +44 (0) 2071048016; liverpoolcentral.rec@hra.nhs.uk), ref: 21/NW/0091

Approval to monitor patients' experience of SDM in routine clinical practice was initially approved through a quality improvement proposal at North Bristol NHS Trust (reference: Q80008). This was then incorporated into a larger programme of work, where all processes were

approved through the appropriate governance framework (Consent & SDM Programme Board, reporting to the Clinical Effectiveness & Audit Committee). Ethical approval required to conduct interviews with NHS patients and professionals was granted by the NHS HRA North West - Liverpool Central Research Ethics Committee (reference: 21/PR/0345).

Study design
Multi-centre mixed-methods co-development study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Any patients requiring surgical treatment

Interventions
The overall aim of this project is to develop, pilot, and evaluate a decision-support intervention that uses real-time feedback of patients' experience of SDM to change patient and professional decision-making processes before adult elective surgery and improve patient and health service outcomes.

There are three phases with the following objectives:

Phase 1: Assess the feasibility, usability and acceptability of implementing a system to monitor SDM for surgery automatically and in real time.
Phase 2: Co-develop and refine the intervention with patients and professionals to understand how the intervention works, for whom, and in what context.
Phase 3: Evaluate the effectiveness, cost-effectiveness, and implementation of the intervention to improve patient and health service outcomes in the English NHS.

Intervention development and evaluation will be conducted according to Medical Research Council guidelines. Qualitative findings will be reported in accordance with COREQ (Consolidated criteria for reporting qualitative studies) guidelines.

Phase 1 will use mixed methods to examine the feasibility and usability of a novel system to monitor SDM of surgical patients in real time. The study will conduct interviews and focus groups with diverse stakeholders (patients, professionals, members of the wider community) to explore views on real-time feedback of patients' experience of SDM to improve outcomes for patients. Recruitment will focus on under-served groups (economically disadvantaged, minority ethnic, and older age) to inform the development of an inclusive intervention. This phase will also apply principles of behavioural/organisational change to inform the initial development of programme theory.

Phase 2 of this programme will co-develop and refine the decision-support intervention with patients and professionals. It is anticipated that this intervention will include methods for 1) efficient, real-time evaluation of SDM by patients at scale, 2) timely feedback of experiences of SDM to care teams before surgery, and 3) activities to support meaningful change in decision-making processes before surgery to improve patient/health service outcomes.
Co-development of the intervention will be achieved by understanding contexts in which the

intervention will be delivered through consultation with patient and professional stakeholders and refining programme theory through focus groups with patient and/or professional stakeholders in local, specific contexts. Following this, the intervention will be piloted in new collaborating surgical specialties and hospitals not involved in the development process. The potential impact of the intervention will be explored using qualitative and quantitative methods, and the scope (population inclusion/exclusion) will be defined.

Phase 3 will evaluate the effectiveness, cost-effectiveness, and implementation of the intervention. Evaluation will be undertaken from a pragmatic, real-world effectiveness perspective, designed in collaboration with the NIHR Bristol Trials Centre and stakeholders. A cluster design is planned because contamination needs to be avoided at an individual patient /clinician level. Mixed qualitative and quantitative process evaluation is planned throughout in accordance with MRC guidelines to understand the function of the intervention and mechanisms of action in context. A run-in period is planned where the intervention is delivered prior to randomisation without the active ingredients defined in the programme theory. It will likely involve real-time evaluation of patients' experience of SDM without any form of feedback to clinical teams. Internal pilot to full trial progression criteria will be set out in advance using recommended guidelines.
Implementation is planned by identifying and mapping key stakeholders relevant to implementation, and co-creating a strategy for implementation and long-term sustainability of the intervention involving official bodies and policymakers (e.g. GMC, NICE, medical royal colleges).

Intervention Type
Mixed

Primary outcome(s)
Patients' experiences of shared decision making measured using the CollaboRATE and SHARED-Q10 at baseline (upon surgery booking) and follow-up (before surgery)

Key secondary outcome(s))
Will be established during the study

Completion date
30/06/2026

Eligibility

Key inclusion criteria
All patients over the age of 18 years who have been booked for planned vascular, gastrointestinal, urological, neurosurgical, gynaecological, breast, cardiac and orthopaedic surgical procedures at participating hospitals will be eligible to participate.

Healthcare professionals working in participating Trusts will be eligible for inclusion. Specifically, this includes professionals that
1. Booked eligible patients for surgery
2. Are involved in SDM discussions with eligible patients
3. Have overall responsibility for eligible patients' care
Professional participants may include surgeons, anaesthetists, nurses, perioperative care physicians and allied health professionals.

Members of the wider community over the age of 18 years will be eligible to take part. Included will be people who are disproportionately affected by poor SDM and outcomes of surgery: those that are economically disadvantaged, from minority ethnic groups, and in older age. Ethnicity is expected to focus on British Asian/South Asian populations as the most common minority group in the UK, however, this will be informed in discussions with stakeholders and patient and public representatives.

Participant type(s)
Patient, Health professional, Population, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
117

Key exclusion criteria
1. Patients under the age of 18 years
2. Without capacity to consent for medical procedures
3. Undergoing unplanned (emergency) surgery or endoscopic procedures

There are no specified exclusion criteria for healthcare professional participants or members of the wider community

Date of first enrolment
01/10/2023

Date of final enrolment
19/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital

Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
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United Kingdom
BD9 6RJ

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The researchers will make pseudo-anonymised datasets available via the University's Research Data Repository, data.bris to bona fide researchers, subject to a legally binding data access agreement. Any applications to access data will involve a case-by-case review by the University of Bristol Data Access Committee. Qualifying researchers will be required to sign a data access agreement and closely liaise with study team members to ensure that the data they plan to make public are sufficiently anonymised. Generally, data will be made available for non-commercial use, only for the purpose of health and care research and with appropriate approvals in place (e.g. research ethics or national equivalent).

IPD sharing plan summary
Stored in non-publicly available repository, Published as a supplement to the results publication, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative study	10/04/2024	06/02/2025	Yes	No
Results article		27/06/2025	30/06/2025	Yes	No
Protocol article	Study website	18/01/2024	19/01/2024	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes