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Using AI to predict breast cancer recurrence and guide treatment decisions

Submission date 05/02/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/02/2025	**Overall study status** Completed	
Last Edited 06/02/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Breast cancer recurrence remains a significant concern for patients and clinicians alike. Current prediction methods, although robust, can be complex and may not fully support individualized treatment decision-making. To improve personalized care, an artificial intelligence-clinical decision support system (AI-CDSS) has been developed to predict the risk of breast cancer recurrence using patient-specific clinical and pathological data. This system is intended to assist clinicians in discussing prognosis and treatment options with patients. The primary aim of this study is to evaluate whether the use of AI-CDSS in treatment planning improves patient satisfaction and confidence in treatment decisions. Secondary aims include assessing the impact of the tool on patients' understanding of their recurrence risk, decisional conflict, and quality of life.

Who can participate?
Adult patients (aged 18 years or older) newly diagnosed with early-stage breast cancer who are facing treatment decisions (e.g., choice of surgical approach, adjuvant therapy options) are eligible for participation.

What does the study involve?
Participants will be randomly assigned to one of two groups:
• Intervention Group: Patients receive treatment planning that is guided by the AI-CDSS. In this arm, clinicians use the AI tool to generate a personalized recurrence risk prediction that informs the treatment discussion.
• Control Group: Patients receive standard treatment planning without the aid of the AI-CDSS.
Following the treatment consultation, all participants will complete a series of survey questionnaires assessing satisfaction with the decision-making process, understanding of recurrence risk, confidence in the chosen treatment, and quality of life. Surveys will be administered at baseline (pre-consultation) and at follow-up time points (1 month, 3 months, and 6 months after treatment initiation).

What are the possible benefits and risks of participating?
Participation in this study offers meaningful benefits. Intervention group participants gain access to AI-generated personalized recurrence risk assessments and treatment insights for

their care planning. Additionally, all participants contribute valuable feedback that helps enhance decision-support tools for future breast cancer care. There are no risks associated with participation in this study, as patient care will continue to be guided by established clinical judgment and standards, with the AI tool serving solely to support—not replace—the decision-making process.

Where is the study run from?
The study is being conducted at Tri-Service General Hospital, which has agreed to implement and test this new technology.

When is the study starting and how long is it expected to run for?
December 2024 to October 2025

Who is funding the study?
Tri-Service General Hospital

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Impact of an artificial intelligence-clinical decision support system on patient satisfaction and confidence in treatment decision-making for breast cancer recurrence prediction: a randomized controlled trial

Acronym
Breast Recurrence Intelligent Decision Guidance Engine (BRIDGE)

Study objectives
Primary Hypothesis:
The AI-CDSS will significantly improve patient satisfaction and confidence in treatment decision-making at baseline, 1, 3, and 6 months post-consultation compared to standard care.

Secondary Hypothesis:
The AI-CDSS will enhance patients' understanding of their recurrence risk, reduce decisional conflict, and improve quality of life, as measured at baseline, 1, 3, and 6 months after the consultation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/12/2024, Institutional Review Board of Tri-Service General Hospital (No.325, Sec.2, Cheng-Kung Rd. Neihu, Taipei City, 114202, Taiwan; +88687923311 ext 17763; tsghirb@ndmctsgh.edu.tw), ref: B202005044

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Breast cancer

Interventions
This randomized controlled trial evaluates the impact of an artificial intelligence-clinical decision support system (AI-CDSS) on breast cancer treatment planning. Participants are randomly assigned using a computer-generated sequence to ensure balanced allocation and reduce selection bias. The total duration of the intervention spans the initial treatment planning consultation, with follow-up assessments extending for six months.
In the Intervention Group, clinicians integrate the AI-CDSS into the treatment planning consultation. The system processes patient-specific clinical data to generate personalized risk predictions for breast cancer recurrence and to propose tailored treatment recommendations. These AI-generated outputs facilitate shared decision-making between the clinician and the patient. Follow-up questionnaires are administered at baseline (pre-consultation) and 1, 3, and 6 months post-consultation to evaluate outcomes such as patient satisfaction, understanding of recurrence risk, decisional conflict, and overall quality of life.
In the Control Group, participants receive treatment planning and counseling based solely on conventional clinical protocols, without the assistance of the AI-CDSS. Follow-up assessments in this arm are conducted at the same time points (baseline, 1, 3, and 6 months post-consultation) to directly compare the outcomes between the two study arms.

Intervention Type
Other

Primary outcome(s)
Patient satisfaction and confidence in treatment decision-making will be measured using the Satisfaction with Decision Scale (SWD) at baseline (pre-consultation) and 1, 3, and 6 months after the treatment consultation

Key secondary outcome(s)
The following secondary outcomes will be evaluated using validated questionnaires administered at baseline, 1, 3, and 6 months after the treatment consultation:
1. Patient understanding of recurrence risk measured using the Fear of Progression Questionnaire-12 (FoP-Q-12), to determine how well patients comprehend their individualized breast cancer recurrence risk
2. Decisional conflict measured using the Decisional Conflict Scale (DCS), which evaluates factors such as clarity of options and ease of decision-making
3. Quality of life measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)

Completion date
15/10/2025

Eligibility

Key inclusion criteria
1. Female patients aged 18 years or older
2. Newly diagnosed with early-stage (Stage 0–II) breast cancer
3. Eligible for multiple treatment options (e.g., surgical and adjuvant therapies)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Previous history of invasive cancer or breast cancer recurrence
2. Patients whose tumors are hormone receptor-negative or show HER2 overexpression on immunohistochemical staining
3. Cognitive or language barriers that preclude completing the surveys
4. Patients who are enrolled in other interventional trials that might interfere with the study outcomes

Date of first enrolment

01/03/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Taiwan

Study participating centre
Tri-Service General Hospital
No. 325, Sec. 2, Chenggong Rd., Neihu Dist.
Taipei City
Taiwan
114202

Sponsor information

Organisation
Tri-Service General Hospital

ROR
https://ror.org/007h4qe29

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tri-Service General Hospital

Alternative Name(s)
Sānjun Zongyīyuàn, Tri-Service General Hospital, Taiwan, TSGH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/02/2025	No	Yes