The challenges of recruiting women with low-risk ductal carcinoma in situ to a randomised controlled trial: the LORIS study experience

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Lay Summary

Background

In ductal carcinoma in situ (DCIS), some cells in the lining of the breast milk ducts are seen as abnormal on mammograms. There are three grades of DCIS - low, intermediate and high. Standard treatment is surgery, often followed by radiotherapy and sometimes endocrine (hormone) therapy. It is unknown whether low or low intermediate grade DCIS will ever become invasive breast cancer, meaning some women are being overtreated.

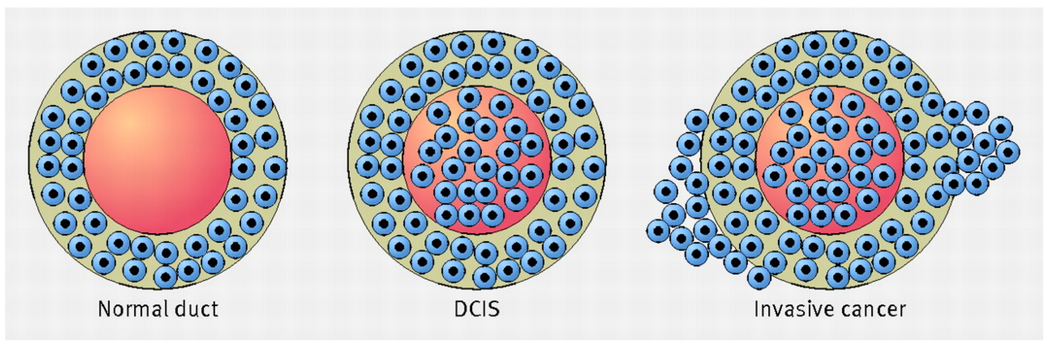

Figure 1: Difference between normal, DCIS and invasive disease[a]

Methods

The **LO**w **RIS**k DCIS (LORIS) trial is testing whether women with low or low intermediate grade DCIS can safely avoid surgery. Women are randomised to surgery or active surveillance (annual mammograms for 10 years). Recruiting into a trial comparing 'something' with 'nothing' is challenging. SHORE-C produced a patient information film to complement written trial materials and provided training to trial staff. We explored the views and experiences of patients invited to take part in LORIS and recruiting staff through surveys, questionnaires and interviews.

Findings

Most patients found the study information clear and useful. Women who agreed to take part in LORIS wanted to help research and/or thought it offered the best treatment option. Those who did not take part were influenced by others or had worries about randomisation. Trial staff noted that low recruitment was due to fewer potential participants than expected and patient preference. Nearly half of trial staff would not join LORIS if they were invited, or encourage loved ones to do so.

Conclusion

To improve recruitment in similar, future trials it is important that all trial staff are fully on board with the trial.

Research Question

Can best practice strategies targeted at patients and recruiting staff, ensure recruitment targets are met and if not, why not?

Methods

- Women aged ≥ 46 years with histologically confirmed low/ intermediate grade DCIS randomised 1:1 surgery or active monitoring
- Figure 2 shows the participant pathway, including information provided at each stage
- Clinical Trials Questionnaire (CTQ) examining reasons for and against participation completed pre-randomisation
- Interviews about decision making and views on trial information post-randomisation

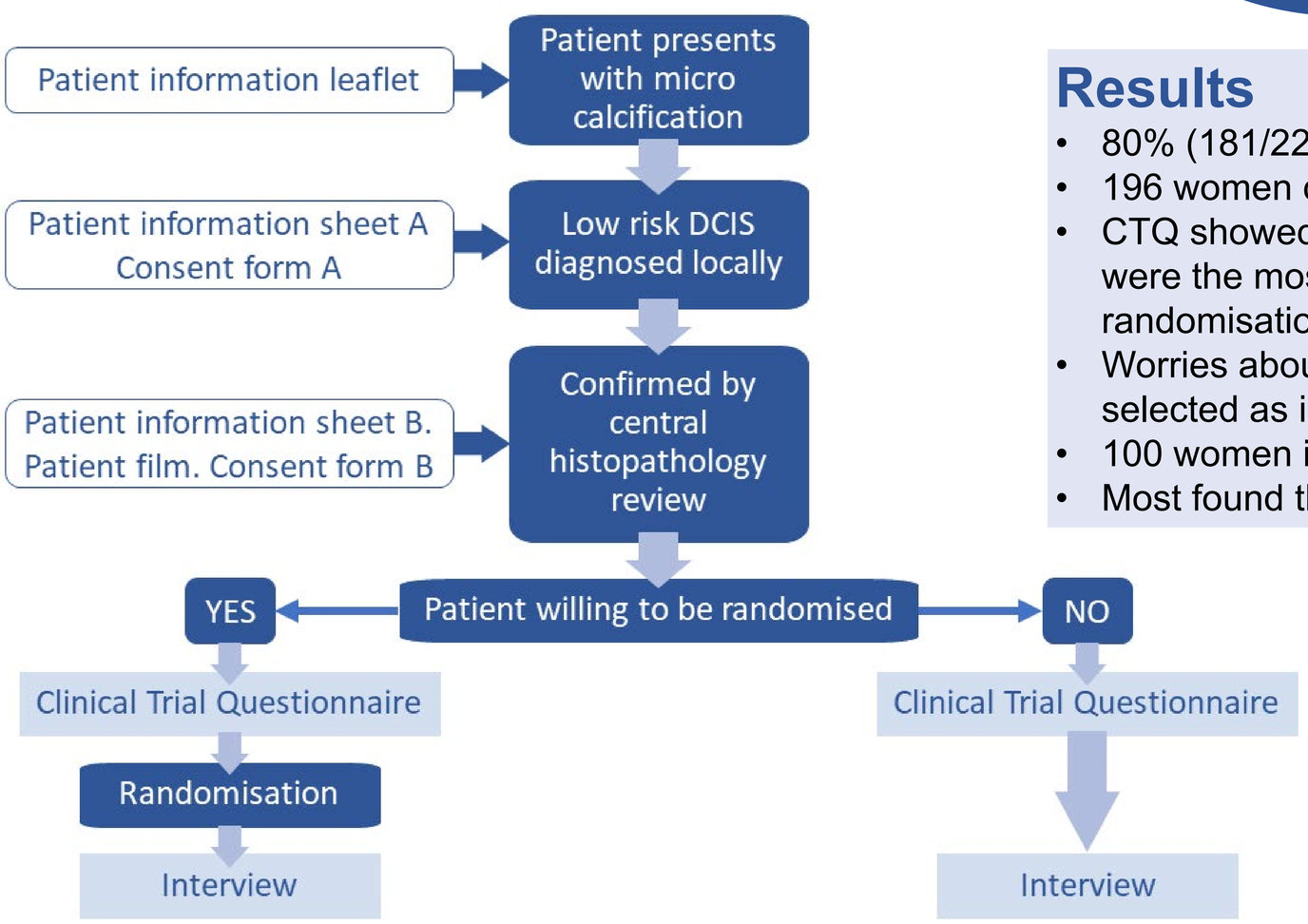

Figure 2: Participant pathway

- Initially, 4 communication workshops held for recruiting staff
- A year into the main trial, surveys and semi-structured interviews with recruiting staff explored recruitment challenges and based on these, some sites were offered refresher site initiation visits and communication workshops

I hope that anything I do helps, not just for my family, but all women

I thought getting yearly rather than three yearly mammograms was a good idea. Getting checked more often was the main reason.

Results

- 80% (181/227) of eligible women agreed to be randomised
- 196 women completed CTQ, 175 acceptors and 21 decliners
- CTQ showed altruism and the belief that the trial offered the best treatment were the most frequently selected important reasons for accepting randomisation
- Worries about randomisation and influences of others were most frequently selected as important reasons for declining
- 100 women interviewed, 89 acceptors and 11 decliners
- Most found the study information provided clear and useful

- Communication workshops, attended by 37 trial staff, improved knowledge and confidence
- Only 45/87 (52%) trial staff said that they would join LORIS if eligible or encourage family or friends to do so
- Most common recruitment barriers staff identified were low numbers of eligible patients and patient preference

Conclusion

- Recruitment to LORIS was challenging despite the use of best practice strategies aimed at both patients and recruiting staff
- There was a lower number of eligible patients than anticipated
- The influence of the opinions of salient others was an important reason for declining trial entry
- All staff communicating with potential patients need to be in equipoise and fully support the study to enhance recruitment in similar future trials

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References: Wheelwright, S., Matthews, L., Jenkins, V. et al. Recruiting women with ductal carcinoma in situ to a randomised controlled trial: lessons from the LORIS study. Trials 24, 670 (2023). https://doi.org/10.1186/s13063-023-07703-4. [a]Nicola, L.P.B., et al., Ductal carcinoma in situ of the breast. BMJ, 2012. 344: p. e797.