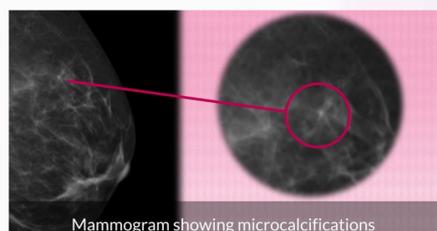


BACKGROUND

LORIS is a multi-centre, RCT of Surgery versus Active Monitoring with annual mammography in patients with low risk ductal carcinoma *in situ* (DCIS). During a 2 year feasibility study potential patients were invited to complete the Clinical Trials Questionnaire (CTQ)¹ and participate in semi structured telephone interviews about the verbal, written and film based trial information. The patient information film in DVD format was produced to complement the patient information leaflets (PIL). It incorporates simple graphics, interviews with clinicians and a Q&A session with women asking the Chief Investigator questions about the trial.



OBJECTIVES were to:-

- ❖ examine the reasons for trial participation/rejection
- ❖ obtain feedback on clarity & usefulness of information sheets & DVD
- ❖ identify potential communication drivers & barriers to recruitment

METHODS

- ❖ participants completed CTQ prior to randomisation
- ❖ CTQ has 16 possible reasons influencing trial decisions
- ❖ agreement/disagreement indicated on a scale 1 to 5
- ❖ most important reason for decision to participate or not chosen
- ❖ SHORE-C researchers contacted consenting patients for interview
- ❖ declining trial participants contacted SHORE-C for interview

INTERVIEWS EXPLORED:-

- ❖ usefulness of the patient information leaflets and DVD
- ❖ attitudes towards LORIS and factors influencing final decision

PARTICIPANTS

- ❖ 41 in feasibility study (surgery n=20, active monitoring n=21)
- ❖ 16 declined LORIS trial
- ❖ 40 (98%) acceptors and 9 (56%) decliners completed the CTQ
- ❖ 35 were interviewed (31 acceptors; 4 decliners)

RESULTS

Age range 48-70 years; 23/35 had a partner; 23 were employed

CTQ

Acceptors & decliners differed sig.(p<0.007) in agreement with 6/16 items

- ❖ trial offered the best treatment available (90% v 0%)
- ❖ benefits of treatment in the trial would outweigh any S/Es (82% v 0%)
- ❖ either treatment in the trial would be suitable for me (75% v 0%)
- ❖ wanted to help the doctor's research (100% v 50%)
- ❖ feel others will benefit from results of the trial (100% v 67%)
- ❖ family or friends wanted me to join the trial (50% v 0%)

Main reason for:-

- ❖ Joining LORIS The trial offered best treatment available (13/40; 33%)
- ❖ Declining LORIS The idea of randomisation worried me (4/9; 44%)

INTERVIEWS:- Who introduced the trial first?

- ❖ Surgeon (77%); Radiologist (17%); Research nurse (91%)
- ❖ Majority (91%) said their decision to join LORIS was not influenced by HCPs

Never heard of DCIS before. Surgeon explained it & told me about the LORIS Study. I was told to have a good think about it. At the next appointment I decided to go for the trial.

Both surgeon and nurse were very good at explaining the trial. Gave me a lot of info to read & the DVD

Information sheets & DVD

91% read pre biopsy leaflet ; 86% registration leaflet; 97% randomisation sheet

PILs and DVD were easy to understand (91%; 96%) & very useful (83%; 84%)

The DVD backed up everything written down, was easy to digest, common sense & no confusion whatsoever

PIL was very comprehensive, very open but not biased.

- ❖ 29% said that the PILs & 40% the DVD had helped them make a decision

It helped confirm to me why you are doing the research, why it is so important and necessary.

- ❖ 73% watched DVD with family and friends

My daughter encouraged me to enter the study after we watched the DVD

My husband found it really useful and informative as he had not researched about DCIS

- ❖ Q&A session on the DVD was a favoured section (52%)



Doctors spoke in layman's terms and provided extremely clear answers

Q & A - so brilliant, exactly what you want to ask, made the process feel normal



SUMMARY

- ❖ LORIS patient information sheets and DVD appear to help understanding
- ❖ being randomised obviously a disincentive to some
- ❖ family & friends influence trial participation, HCPs did not
- ❖ seeing other women articulate concerns & asking questions was helpful
- ❖ DVD content has been made available on LORIS & SHORE-C websites & YOU Tube

Reference

1. Jenkins & Fallowfield, British Jn Cancer 2000, 82,;1783-1788

