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) and participate in structured telephone interviews about the verbal, written and film based 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%)
- feel others will benefit from results of the trial (100% v 67%)
- family or friends wanted me to join the trial (50% v 0%)
- feel the trial was important and necessary (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
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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 whatever
- PIL was very comprehensive, very open but not biased

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

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

SUMMARY
- 29% said that the PILs & 40% the DVD had helped them make a decision
- 73% watched DVD with family and friends
- Q&A session on the DVD was a favoured section (52%)

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