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WILLINGNESS OF POSTMENOPAUSAL WOMEN TO PARTICIPATE IN A STUDY INVOLVING LOCAL VAGINAL OESTROGEN TREATMENT AS AN ADJUNCT TO PELVIC ORGAN PROLAPSE SURGERY - LOTUS FEASIBILITY TRIAL.

Hypothesis / aims of study
To identify the motivations for, and barriers to, recruitment and participation in clinical trial among postmenopausal women with pelvic organ prolapse intending to have surgical management.

Study design, materials and methods
A qualitative study design in which twenty women participating in the trial and one focus group interview was conducted. Women were encouraged to discuss and explore their willingness to participate in the study, their views of the use of hormone replacement therapy, menopause, pelvic organ prolapse and its effect on quality of life, the use of a placebo and their views on clinical trials. In addition, we explored reason as to why postmenopausal women decline participation. Qualitative content analysis was performed to develop a series of coding units from the interview process. We identified key descriptive themes within the qualitative data. The coding categories were systematically approached and data analysis conducted. Thematic analysis, involving a rigorous process of qualitative coding, enabled iterative development and validation of emergent themes

Results
Participants identified that they were inclined to participate in a clinical trial when clear, accurate and respectful communication; empathic, non-judgemental, professional support; timely access to further testing and appointments and seamless interactions with services were provided. Altruism and trust in the doctor were seen as the most important reasons for accepting entry to a trial, whereas preference for the doctor choosing treatment rather than randomization were themes emerging from women who declined entry into the trial.
'*I participated in the hope it helps another woman in the future'*
'Study was easy to understand' ' Interview 18

Unertainity about their feeling on whether they wanted to use local oestrogen and fear of developing cancer due to trial drug was another major barrier to recruitment. Postmenopausal women expressed they were dependant on either a relative or friend to bring them to appointment was a factor that prevented them for participation.
' I would have participated but I need my friend to bring me to the clinic. If you could reimburse my taxi fare I would gladly participate' - Focus group 4
'I would rather like to know whether I am getting the oestrogen cream or not, I prefer not to have placebo' -Focus group 3
' I have heard on the tele the side effects of HRT, my own doctor is hesitant to keep me on oestrogen for long term. I wish there was some clear guidance'-Focus group 7

Interpretation of results
There is a range of personal and social aspects underlying the decision to participate in a trial. The results from the study show that patients are generally very willing to participate in studies. The type of trial and probably communication style of doctor or nurse explaining the study exerts a considerable influence on patients' preparedness to accept or decline participation.

Concluding message
Qualitative analysis has identified the themes motivating women were: Altruism, clear and transparent information and potential health benefits.Themes identified in women who declined participation were: Lack of time, uncertainty regarding hormone replacement treatment, fear of cancer, dependant on others due to age.

Disclosures
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