

A randomized controlled trial to evaluate the impact of an educational DVD on cancer patients considering participation in a phase I clinical trial.

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Background: Informed consent for phase I trials is controversial; gaps in patient (pt) knowledge regarding the purpose of these studies are central to this debate. This study assessed the impact of viewing an educational DVD on pt knowledge and satisfaction in cancer pts newly referred to a phase I trials clinic.

Methods: Prior to physician (MD) appointment, 49 pts were randomly assigned to view either an educational DVD (n=22) which provided information about phase I trials, or a placebo DVD (n=27) which described research achievements by local scientists. Upon completion of DVD viewing, pts completed a self-administered questionnaire addressing their understanding of phase I trials (knowledge) and their satisfaction with the DVD (perception). The interviewing MD (n=8), who was blinded to the intervention, also rated the pt's understanding of phase I trials upon completion of the clinic appointment.

Results: The mean pt age was 56 and 61% were male. Prior to attending the phase I clinic, most pts (86%) had previously heard of clinical trials, but only 49% were aware of phase I trials. Pts who viewed the educational DVD were less likely to believe that the goal of phase I trials is to determine the efficacy of a new drug ($p=0.019$), more likely to correctly assess that drugs undergoing phase I evaluations have not been thoroughly studied in humans ($p=0.003$), and less likely to believe that phase I drugs have proven activity against human cancers ($p=0.008$). More pts who viewed the educational DVD than the placebo DVD agreed/strongly agreed that the DVD provided useful information ($p<0.001$), believed that they had a good knowledge of phase I trials ($p=0.031$), felt that the DVD helped them decide whether to enter a phase I trial ($p=0.011$), and perceived that they would have more questions for their physicians as a result of watching the DVD ($p=0.017$). No statistically significant differences in MD satisfaction was observed.

Conclusions: Exposure to an educational DVD increased both objective measures of pt knowledge as well as pt satisfaction regarding participation in phase I clinical trials. The educational DVD did not significantly impact MD perception of pt understanding.

Character Count = 1988