

Randomised Controlled Trials and Patient Preferences

Zelen design

Zelen M. A new design for randomized controlled trials. N Engl J Med 1979; 300: 1242-45. Advantage that almost all eligible individuals are included. Allows evaluation of the true effects of offering experimental interventions to patients. Disadvantage that it is an open trial, and statistical power affected if high proportion of participants choose to have the standard treatment.

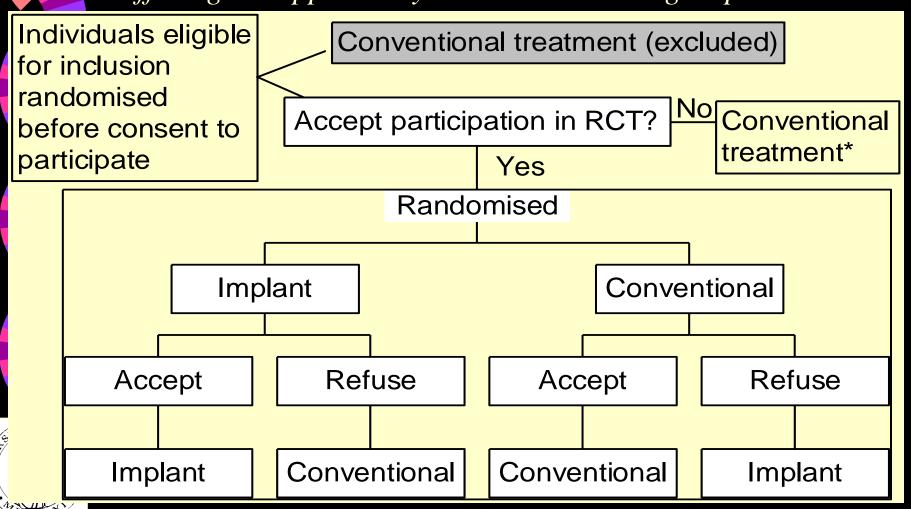
Individuals eligible Conventional treatment (excluded) for inclusion randomised Conventional Accept participation to RCT? before consent to treatment* participate Yes Randomised Conventional **Implant** treatment

conventional treatment, but analysed as if they have received exp. treatm.



Zelen double randomised consent design

Olswchewski et al., 1985. Ethical concerns overcome by offering the opportunity to switch to other group

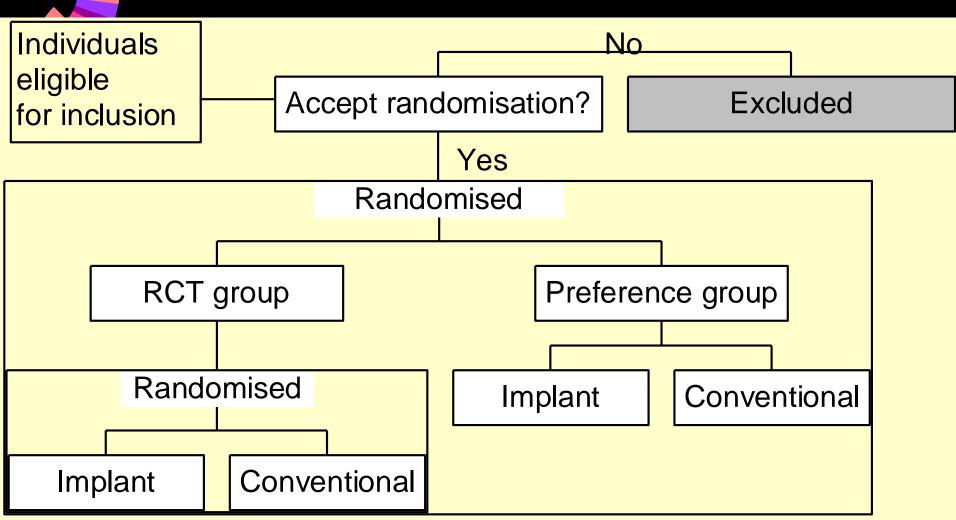


Given conventional treatm., but analysed as if they have received exp. treatm.



Wennberg design

Include individuals who agree to be randomised





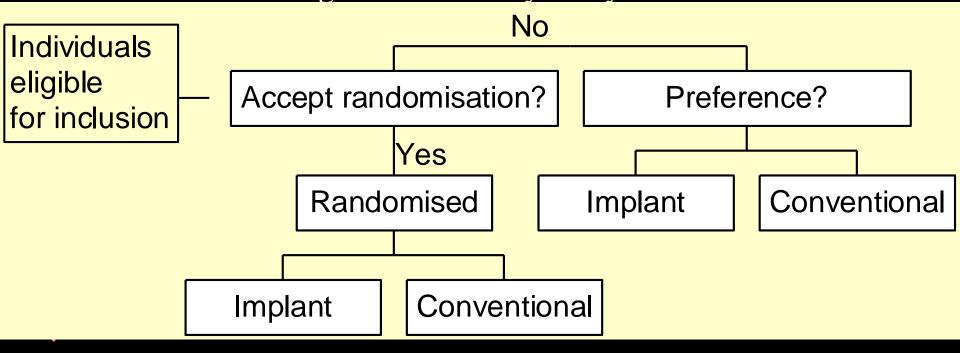
Comprehensive cohort design

Olschewski et al., 1985; Brewing & Bradley, 1989.

All participants are followed up, regardless of randomisation status. Outcomes of RCT and cohort groups can be compared. Ideal where it is likely that many patients will refuse, because patients or operators have a strong preference for one intervention. A disadvantage is no status of

differences in baseline characteristics in the RCT and preference groups.

Satisfaction with existing conditions very likely influence.





Feine & Awad design

Feine J, Awad MA. Community Dent Oral Epidemiol 1998.

