

What influences patients participation in an RCT comparing surgical interventions? (TREND)

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Background: recruitment

- Adequate patient recruitment key condition clinical trials
- Recruitment often challenging
- Consequences of inadequate patient recruitment
 - Decreased power potential relevant effects
 - Longer duration with higher costs
 - External validation might be affected

Background: TREND study

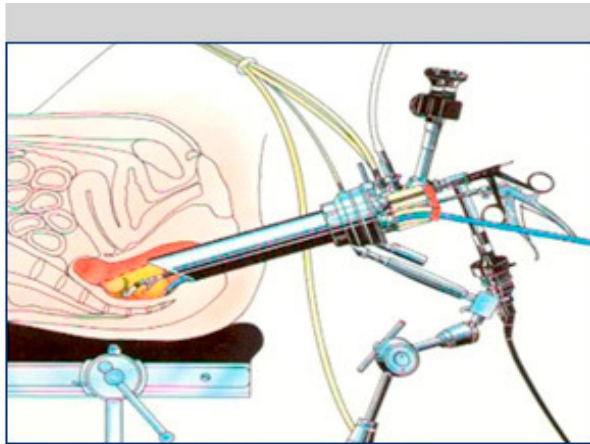
- Gastroenterology: currently many RCTs comparing therapeutic endoscopy and minimally invasive surgery
- TREND study¹: RCT comparing transanal endoscopic microsurgery versus endoscopic mucosal resection for large rectal adenomas
- Sample size TREND 184 patients
- Recruitment in TREND study slower than expected

¹ Van den Broek JC, de Graaf EJR, Dijkgraaf MGW et al. Transanal endoscopic micorsurgery versus endoscopic mucosal resection for large rectal adenomas (TREND study). BMC Surgery 2009.



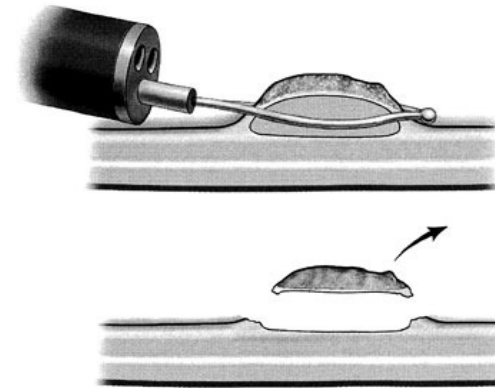
Background: TREND study

- Transanal endoscopic microsurgery



- General anesthesia
- Hospital admission 1-4 days
- Possible higher morbidity rate

- Endoscopic mucosal resection



- Mild sedation
- No hospital admission
- Possible higher recurrence rate

Aim

- Identify barriers and motives for participation in the TREND study
 - a study comparing transanal endoscopic microsurgery versus endoscopic mucosal resection for large rectal adenomas

Methods - participants

- Semi-structured interviews (qualitative)
- Patients counseled for participation in TREND study invited
 - 14 participants; 11 non-participants
 - 5 hospitals
- Overall consent rate eligibles TREND 58%

Methods - interviews

Interviews

- Main motive for (non-)participation in TREND study (open)
- Potential other barriers and motivations presented by interviewer (semi-structured)

Topic list

- Information: counseling, written information, timing
- Design: randomization
- Intervention and intervention-related therapy (anesthesia, relapse, admission)
- Personal benefit / altruism
- Concerns
- Organizational aspects
- Influence partner, health professional and acquaintances
- Importance and experience with scientific research/ hospital

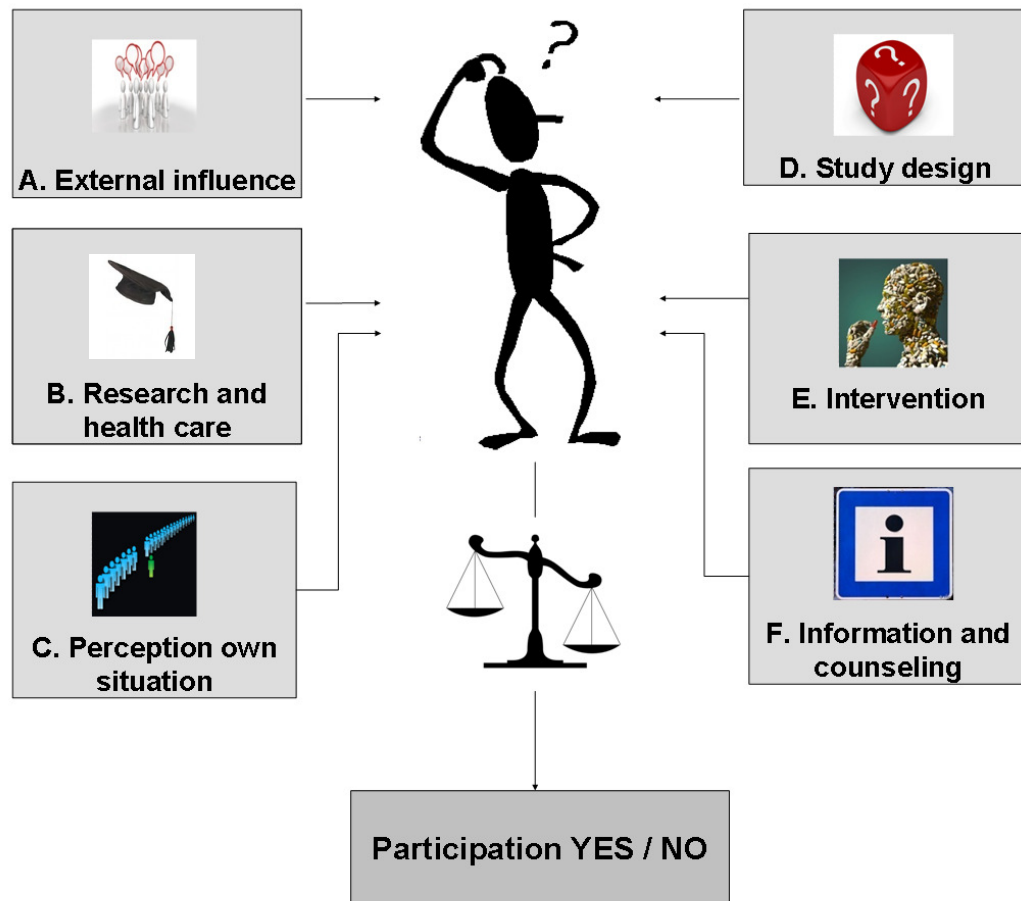
Methods - analysis

- Analysis using constant comparison
 - interviews and analysis parallel (update topic list)
- Coding by two independent researchers (MaxQDA)
 - start with marking transcribed text
 - code subthemes
 - code main themes

Results – participants

- 18 potential participants interviewed
 - 11/14 invited participants consented interview (79%)
 - 7/11 invited non-participants consented interview (64%)
- Age 54 – 84 years
- Reasons for refusing the interview were
 - “don’t feel like it” (1)
 - “over 80” (2)
 - “gets nervous from all the research” (1)
 - not contacted (3)

Results – main themes



Results - motives

- Key motive for trial participation (all participants)
 - Contribution to medical science and future clinical practice
- Other (conditional) motives:
 - Satisfactory counseling
 - Sufficient time to reflect
 - The sense that participation was completely voluntary

Results – motives

Quote participant, contribution to medical research

‘Look, for me it’s pleasant, not only for myself but also for the future to contribute to medical research. That’s what I think is important in general.’

Quote participant, contribution to medical research

‘The main reason is simply numbers tell the tale. The more you know, the better the treatment can be. Yes, just to improve medical quality. I hope to.’

Results - barriers

- Key barriers non-participants
 - A distinct preference for either therapeutic endoscopy (n=4) or minimally invasive surgery (n=3), due to the intervention or intervention-specific characteristics like type of sedation.
- Equipoise not always fully understood
- Most non-participants felt contributing to research was important, but treatment preference dominated

Results - barriers

Quote non-participant, preference surgery

“Ehm, for that aspect. There was another reason, how well can you remove them? Because there is an indication that ultimately these polyps could lead to colon cancer. I wanted to have them removed properly. And then you’d think, they are of course removed completely when removed surgically.”

Results - barriers

Quote non-participant, preference endoscopy

“I had such a clear preference for endoscopy that I did not want to take part in the lottery.... I found a big plus that I would not undergo surgery and related anesthesia and hopefully would recover quickly”

Results - decision making

- Family members (or partner) were consulted in about half of all decisions
- We noticed that in older people logistical issues seemed more apparent as a barrier
- Study characteristics as randomization, insurance and ethical approval hardly influenced decision making

Conclusion

- Key motive participation: contributing to medical science
 - Key barrier participation: distinct preference for either of the interventions
 - Equipoise not always fully understood
 - Risk perception and decision making individual
- In RCTs comparing similar endoscopic and surgical strategies, individually tailored counseling is important