


**RCT's are too often underpowered  
with other serious flaws:**

*Misused as Evidence, negatively influencing  
practice and innovation in Health Care*

**Frans L. Moll**



Universitair Medisch Centrum  
Utrecht



**DISCLOSURES**

“NO DISCLOSURES”

**RCT's from glorification to misuse**




The reason RCT became the golden  
standard to demonstrate Evidence  
even in the MedTech arena



**Controlled Clinical Trials**

- Why was the CCT in the MedTech arena fallen into disgrace?
  - Too often “control” was not genuine “control”
  - Too much risk for “Operator Dependent Self-Importance” or simply, Ego 😊
  - Statistics more important. Sensitivity, Specificity, Positive and Negative Predictive Value, Overall Accuracy etc.
  - Finally the holy-grail : the Randomized Clinical Trial



**Achilles heel of the  
RCT:  
Power Calculation**

- **Logistics & Finance:**  
Impact ideal patient count for valid conclusions.
- **Short Study Duration:**  
Maximize patient numbers and homogeneity to:
  - Avoid external risk factors.
  - Reduce confounding variables.
- **Minimal Patient Numbers:**  
Require **extreme homogeneity** and limit operator bias.
- **Operator Skill Consistency:**  
No significant differences in outcomes based on skill.

**Achilles heel of the  
RCT:  
Power Calculation**

Minimal Numbers versus Maximal  
Numbers in RCT's

- Conclusion with **minimal** numbers is usually: *'more studies'* are needed...
- Conclusion with **maximal** global numbers usually *"subanalysis and substudies needed"* which patients really benefit...
- *In the meantime, inappropriate conclusions circulate*

**Achilles heel of the RCT:**  
**Power Calculation**

*Personalized Medicine should be the current standard of Care*


- But in the MedTech the outcome of a new technique is not only biased for the individual patient characteristics (genetically), but also socio-economic risk factors are confounders
- and last but not least the operator skills of the physician



**RCT's | The Concept of Evidence**

**Rethinking "Evidence-Based" in MedTech**


- **Evidence** should be clear to both the **eye** and the **mind**.
- Our perception isn't as objective as we believe.
- Avoid misusing "**Evidence-Based**" to control healthcare costs.
- **Innovation** in MedTech shouldn't be hindered by RCT flaws or the misuse of evidence.



**Conclusion | Take Home Message**


**The Real Evidence in MedTech**

- **True evidence** lies in relentless pursuit of **superior training** and **smart solutions**.
- Should we reconsider the value of **CCTs** (Controlled Clinical Trials)?



**Gene Strandness**

Hemodynamics for Surgeons



**"Figures Can't Lie but Liars Can Figure"**

