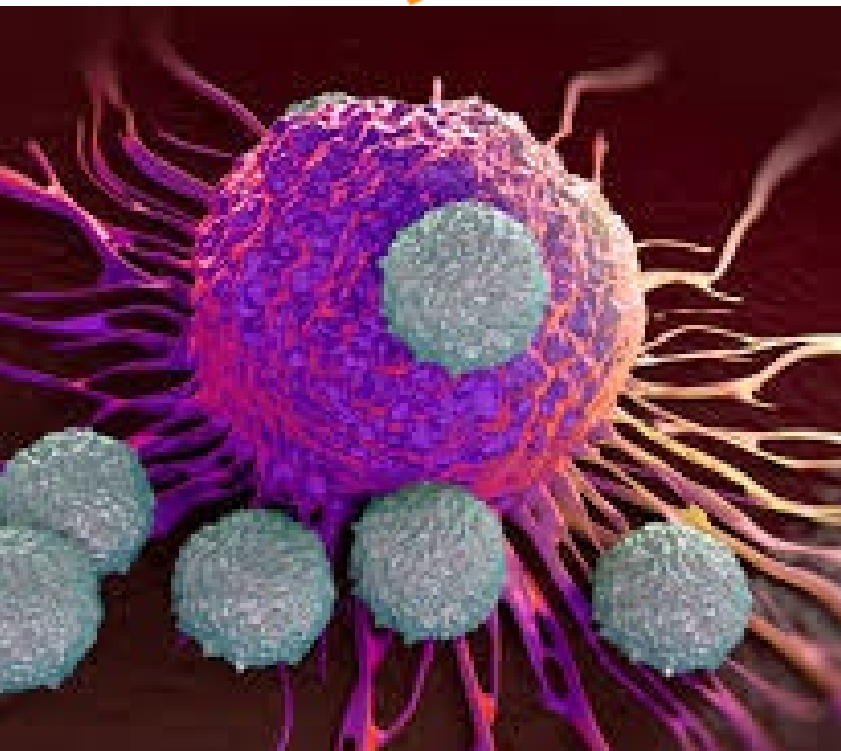
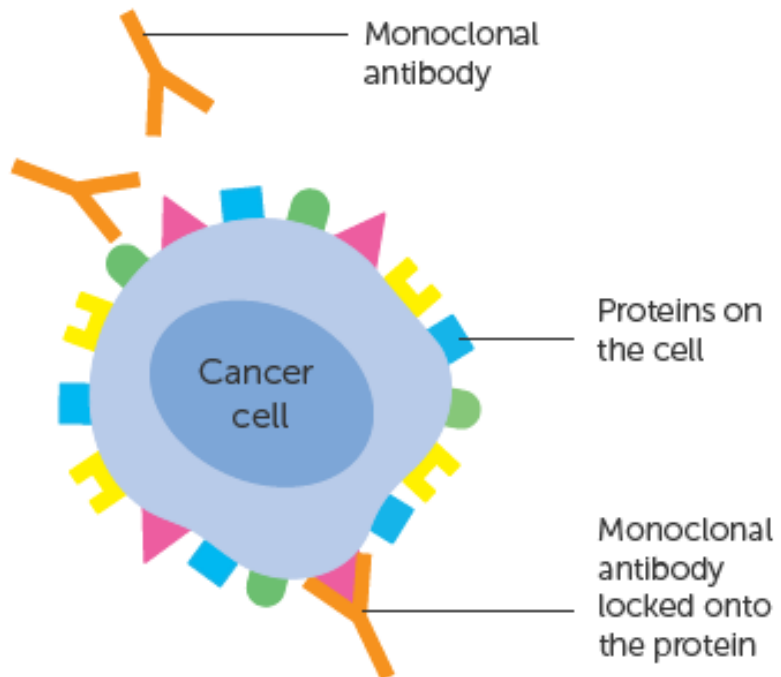
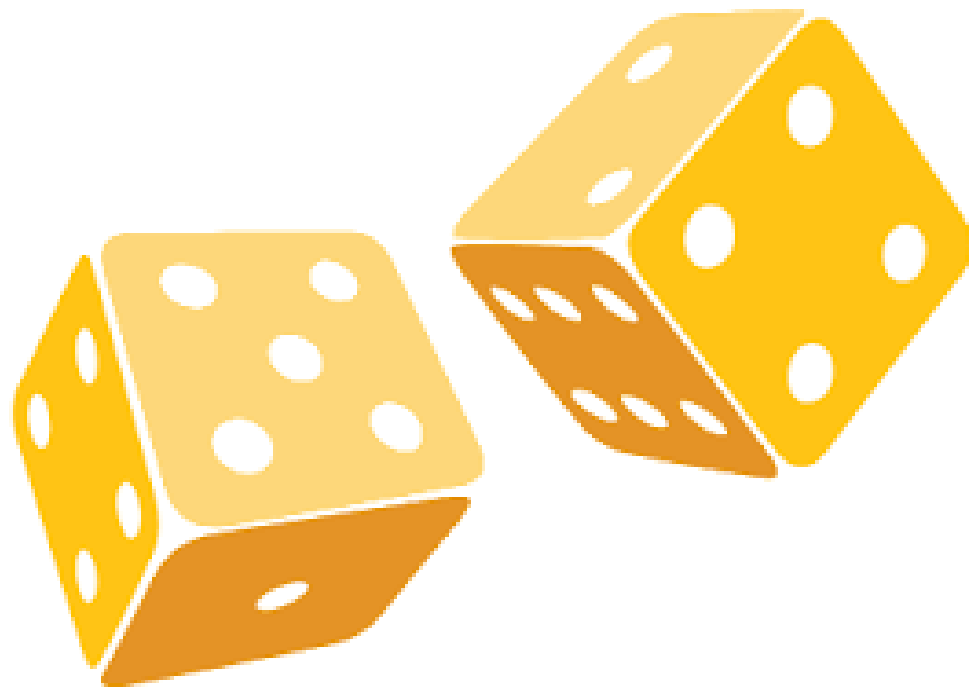






# De klassieke RCT kent uitdagingen



Time consuming



40% premature termination



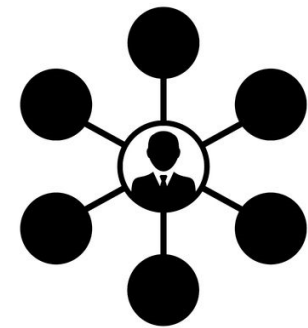
Disappointment / drop-out



Limited generalisability



Complicated Informed  
Consent



Multiple innovations  
for same condition

# De Innovatiepoli – integratie van onderzoek en zorg



## Informed consent

Gebruik van klinische gegevens

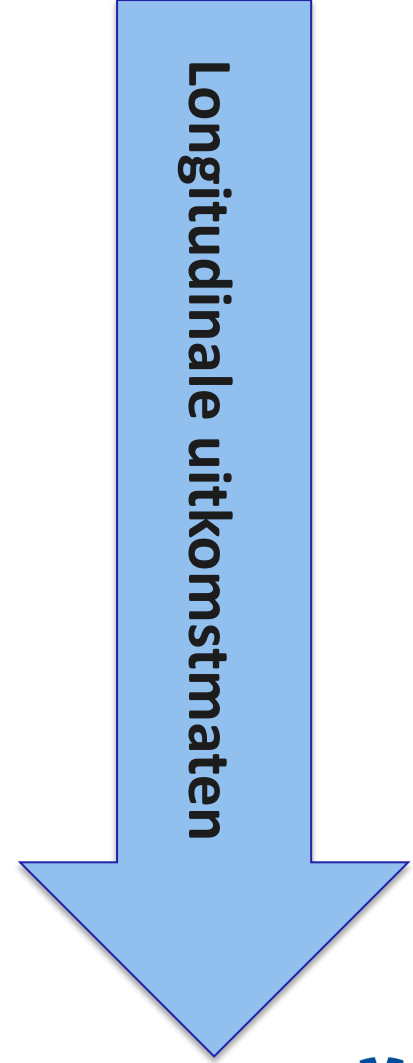
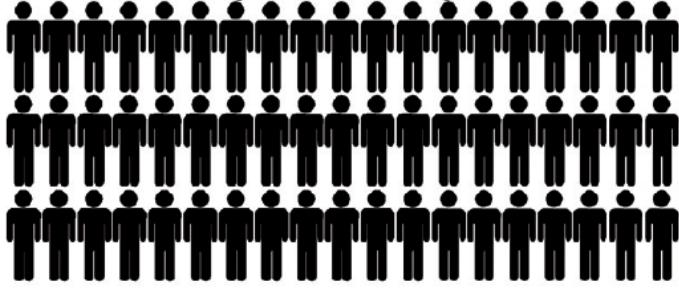
Biobank

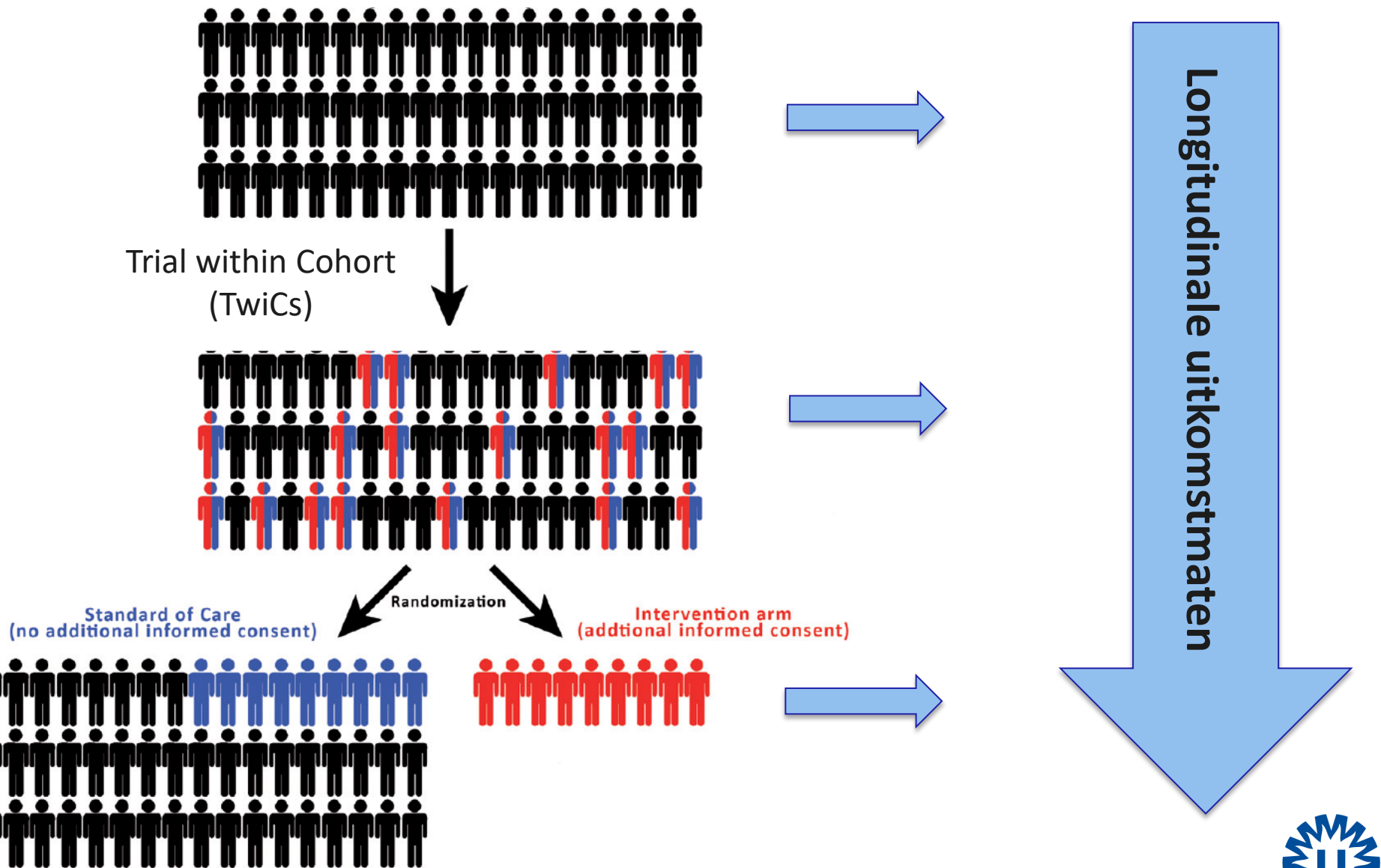
Patient reported outcomes

.....

## Broad consent for randomization

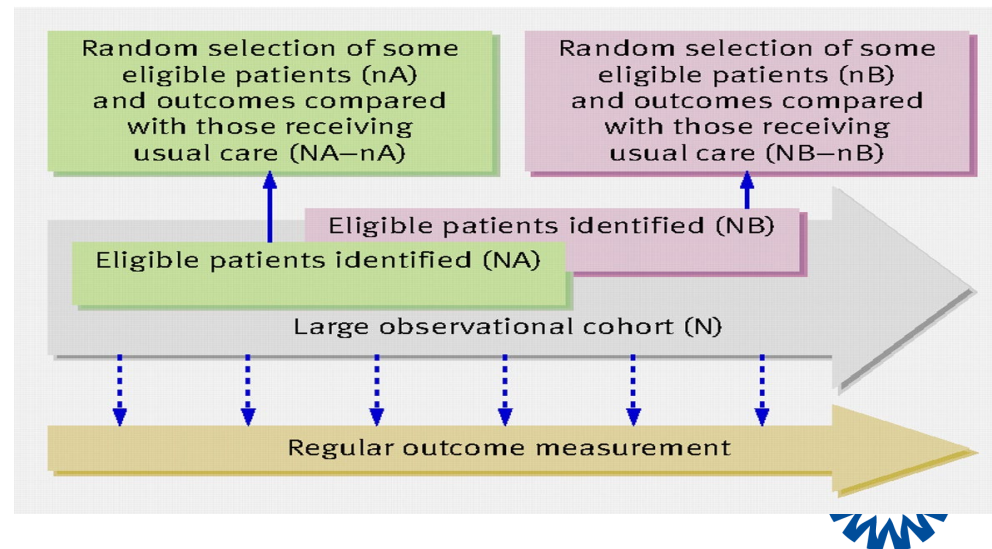






# Potentiele voordelen

- Patient-centred informed consent
  - Efficiëntere inclusie
  - Meer representatieve onderzoekspopulatie
- Geen / nauwelijks contaminatie in controlegroep
- Platform voor meerdere trials



Efficacy of Dose-Escalated Complete Tumor Response in Locally Advanced Rectal Cancer: A Phase 2 Randomized

Alice M. Couwenberg, MD, PhD,\* Maaïke Berbee, MD, PhD,† Miange René Arensman, MD,‡ Mihaela G. Frank J. Wessels, MD, PhD,§ Joan Jeanine Roodhart, MD, PhD,\*\* Or Sieske Hoendervangers, MD,\* Jer

Heike I  
Esther I  
Joost T.  
Wilhelm  
Helena

The impact of retractor SPONGE-assisted laparoscopic surgery on duration of hospital stay and postoperative complications in patients with colorectal cancer (SPONGE trial): study protocol for a randomized controlled trial

Alice M. Couwenberg<sup>1\*</sup>, Maarten J. P. Burbach<sup>1</sup>, Anke B. Smits<sup>2</sup>, Marco Van Vulpen<sup>1</sup>, Wilhemina M. U. Van Grevenstein<sup>3</sup>, Peter G. Noordzij<sup>4</sup> and Helena M. Verkooijen<sup>5</sup>

International Journal of  
Radiation Oncology  
biology • physics

www.redjournal.org

Circulating tumor DNA guided adjuvant chemotherapy in stage II colon cancer (MEDOCC-CrEATE): study protocol for a trial within a cohort study

S. J. Schraa<sup>1†</sup>, K. L. van Rooijen<sup>1†</sup>, D. E. W. van der Kruijsen<sup>1</sup>, C. Rubio Alarcón<sup>2</sup>, J. Phallen<sup>3</sup>, M. Sausen<sup>4</sup>, J. Simmons<sup>4</sup>, V. M. H. Coupé<sup>5</sup>, W. M. U. van Grevenstein<sup>6</sup>, S. Elias<sup>7</sup>, H. M. Verkooijen<sup>7</sup>, M. M. Lacle<sup>8</sup>, L. J. W. Bosch<sup>2</sup>, D. van den Broek<sup>9</sup>, G. A. Meijer<sup>2</sup>, V. E. Velculescu<sup>3</sup>, R. J. A. Fijneman<sup>2†</sup>, G. R. Vink<sup>1†</sup>, M. Koopman<sup>1††</sup> and And on behalf of the PLCRC-MEDOCC group

Stereotactic Body Radiation  
Conventional Radiation Therapy  
Bone Metastases—A Phase 2  
Controlled Trial Within a  
Port

,\* Joanne M. van der Velden, MD, PhD,†  
... .. D,\*

hyperbaric oxygen  
patients with late

MD, PhD‡

The effects of exercise  
of patients with breast  
UMBRELLA Fit study):  
randomized controlled

radiation toxicity (HONEY trial): a trial  
protocol using a trial within a cohort  
design

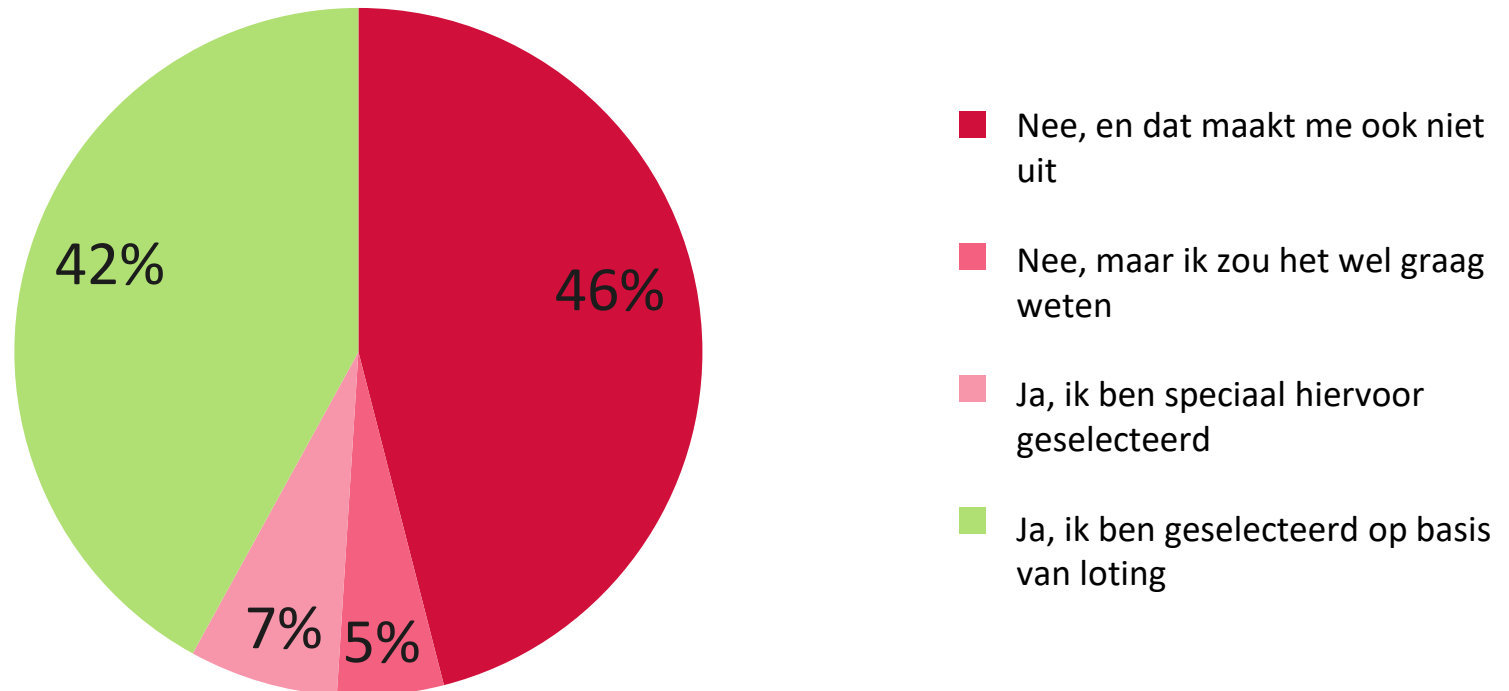
M. C. T. Batenburg<sup>1\*</sup> , H. J. G. D. van den Bongard<sup>1</sup>, C. E. Kleyne<sup>1</sup>, W. Maarse<sup>2</sup>, A. Witkamp<sup>3</sup>, M. Ernst<sup>4</sup>, A. Doeksen<sup>5</sup>, T. van Dalen<sup>6</sup>, M. Sier<sup>5,7</sup>, E. J. P. Schoenmaeckers<sup>8</sup>, I. O. Baas<sup>9</sup> and H. M. Verkooijen<sup>10</sup>

Roxanne Gal<sup>1</sup>, Evelyn M. Monninkhof<sup>1</sup>, Rolf H. H. Groenwold<sup>1</sup>, Carla H. van Gils<sup>1</sup>, Desiree H. J. G. van den Bongard<sup>2</sup>, Petra H. M. Peeters<sup>1</sup>, Helena M. Verkooijen<sup>3</sup> and Anne M. May<sup>1\*</sup>

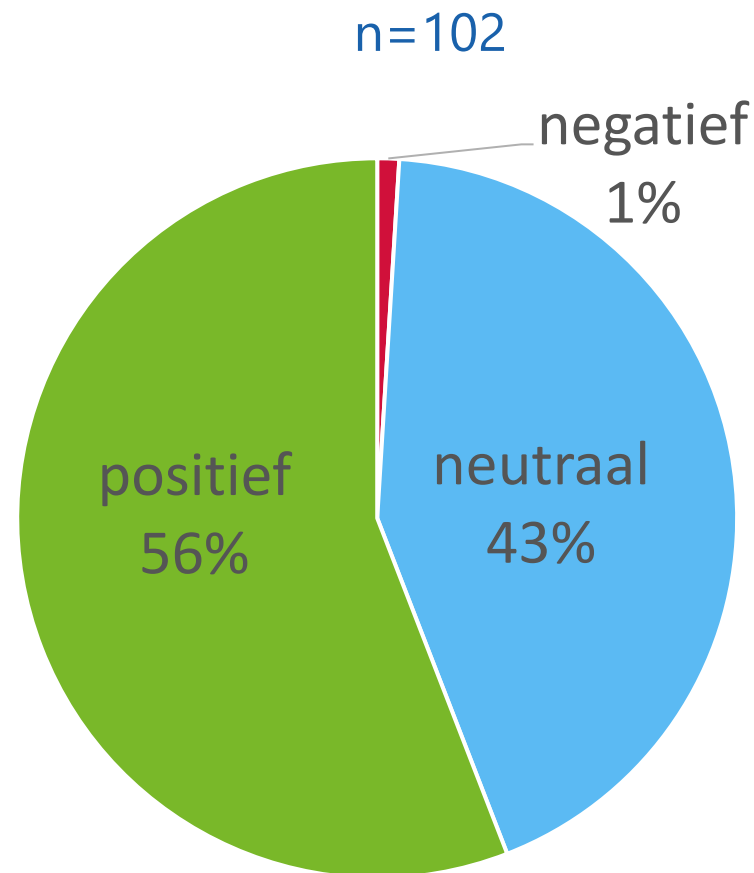


# 'Begrijpt u hoe u bent geselecteerd voor het ondergaan van de experimentele interventie?'

*N=108*



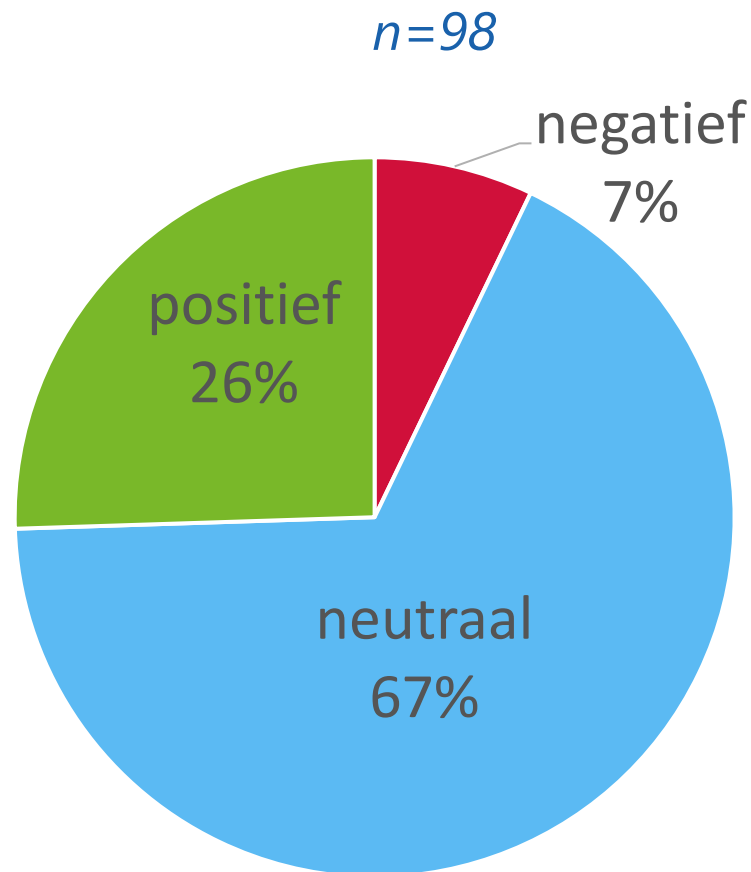
‘Wat vindt u ervan dat u deelnemer aan een controlegroep van experimenteel onderzoek bent geweest?’



Verweij et al. In preparation



'Wat vindt u ervan dat wij u niet apart hebben geïnformeerd toen u ingeloot was voor de controlegroep van experimenteel onderzoek?'



IN THEORY THERE IS  
NO DIFFERENCE BETWEEN  
**THEORY** AND **PRACTICE**  
IN PRACTICE THERE IS

*Yogi Berra*

