

Patient preferences on decentralised clinical trial approaches

A focus group study to identify attributes

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Purpose

To identify the drivers (attributes) for participation in clinical trials with different decentralisation levels in persons living with type 2 diabetes mellitus (T2DM).

Background

- Decentralised clinical trials move away from conventional in-person study-site-visits to the participant's environment by using innovative digital technologies.
- Centering of trial activities around participants:
 - Promises easier trial access & less burden for participants,
 - but will also result in less face-to-face contact with health-care-professionals.
- Little is known about the drivers for participation in clinical trials with different decentralisation levels.

Methods



Step 1: Literature search

- Identification of attributes from literature
- Iterative discussion rounds with researchers to narrow down to the most important attributes



Step 2: Focus groups

- Pilot focus group session with three participants
- Focus group sessions in the Netherlands, Austria and Germany
- Around six participants with T2DM per group
- Nominal group technique to prioritise attributes for a discrete choice experiment



Idea generation



Round-robin



Clarification



Ranking

Results

Step 1: Attributes for clinical trial participation identified in the literature

30 identified attributes condensed to nine attributes



Location of trial activities



Travel time per visit



Study measurement complexity



Use of digital technologies



Frequency of trial visits



Type of contact with health care professionals



Data collection



Entire duration of the trial



Risk and safety IMP

Step 2: Preliminary results from pilot focus group session - 15 identified attributes

Attributes from literature

Location (1)*

Time spent (2)*

Flexibility-timing (3)*

Actual tasks (TODOs) (4)*

Training

Innovation

Data collection

Risk and safety of the trial product

Type of contact with health care professionals

Completely new attributes

Personal and community benefits (5)*

Referral

Support network system

Trial security

After trial treatment

Remuneration

*Ranking of the top five most important attributes

Conclusion

- ✓ Focus groups are essential to identify relevant attributes.
- ✓ A transparent and predefined methodology is important.
- ✓ Drivers for participation in clinical trials are important, e.g. to design future patient-centric clinical trials and to increase participation in clinical trials.
- ✓ Next steps: finalise focus groups and elicitation of preferences within a discrete choice experiment based on attributes & levels identified in this study.