Patient preferences on decentralized clinical trial approaches

Focus group study to identify attributes

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Conflict-of-interest statement

I have no personal conflict of interest to declare.

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- "www.imi.europa.eu"

Disclaimer

- The research leading to these results was conducted as part of the Trials@Home consortium. This paper only reflects the personal view of the stated authors and neither IMI nor the European Union, EFPIA, or any Associated Partners are responsible for any use that may be made of the information contained herein.

Background - What is decentralization of clinical trials?

" trials that make use of digital innovations and other related methods to make them more accessible to participants"

"moving trial activities to the participant's home or to other local settings"

"minimising or eliminating physical visits to a clinical trial centre"

Adapted from: https://trialsathome.com/trialshome-glossary/

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Objective

What are the drivers for participation in clinical trials?

Research gap: little knowledge about how changes in decentralization of a trial effect preferences for participation.

Aim: determine the drivers (attributes) for participation in clinical trials with different decentralization levels in persons with type-2-diabetes mellitus (T2DM).

The findings will be used to elicit preferences in a discrete-choice-experiment.

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Methods

Step 1: Literature search

- Identification of attributes
- Iterative discussion rounds with researchers

Step 2: Focus groups

- Focus groups in three countries: The Netherlands, Austria and Germany
- Around six participants with T2DM per group
- Duration: 3-4 h
- Nominal group technique

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Methods

Structure of the focus group

Part 1: Informed Consent

Part 2: Background questionnaire

Part 3: Focus group session

A. Introduction

B. Silent generation and round-robin

C. Clarification

D. Ranking

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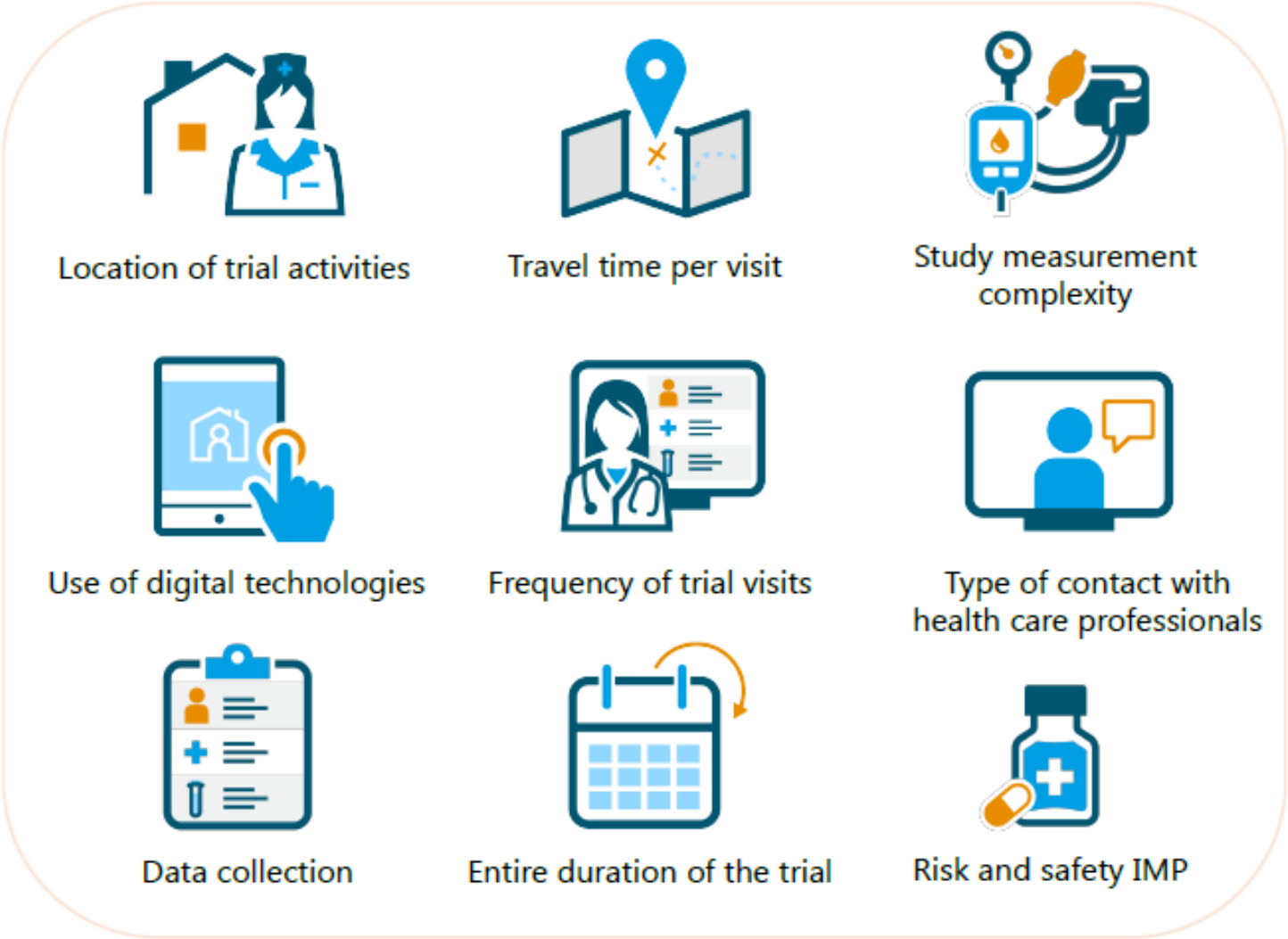
Results from literature

Attributes for clinical trial participation:

30 identified attributes

condensed to nine attributes



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Preliminary results focus group session

Pilot focus group session with three participants: 15 identified attributes

Attributes from the literature
Risk and safety of the trial product
Location
Time spent
Flexibility-timing
Actual tasks (TODOs)
Training
Innovation
Data collection
Type of contact with health care professionals

Completely new attributes
Referral
Support network system
Trial security
After trial treatment
Remuneration
Personal and community benefits

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Preliminary results focus group session

Ranking of the top five most important attributes in the pilot focus group session

Ranking of the attributes	
1	Location
2	Time spent
3	Flexibility – timing
4	Actual tasks (TODOs)
5	Personal and community benefits

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Conclusion

- Focus groups are essential to identify relevant attributes
- Transparent and predefined methodology is important
- Drivers for participation in clinical trials are important, e.g.:
  - To design future patient-centric clinical trials
  - To increase participation in clinical trials

Next steps

- Finalize focus group sessions in three countries
- Define a final set of attributes and levels
- Elicitation of preferences within a discrete choice experiment

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Thank you!

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https://trialsathome.com

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