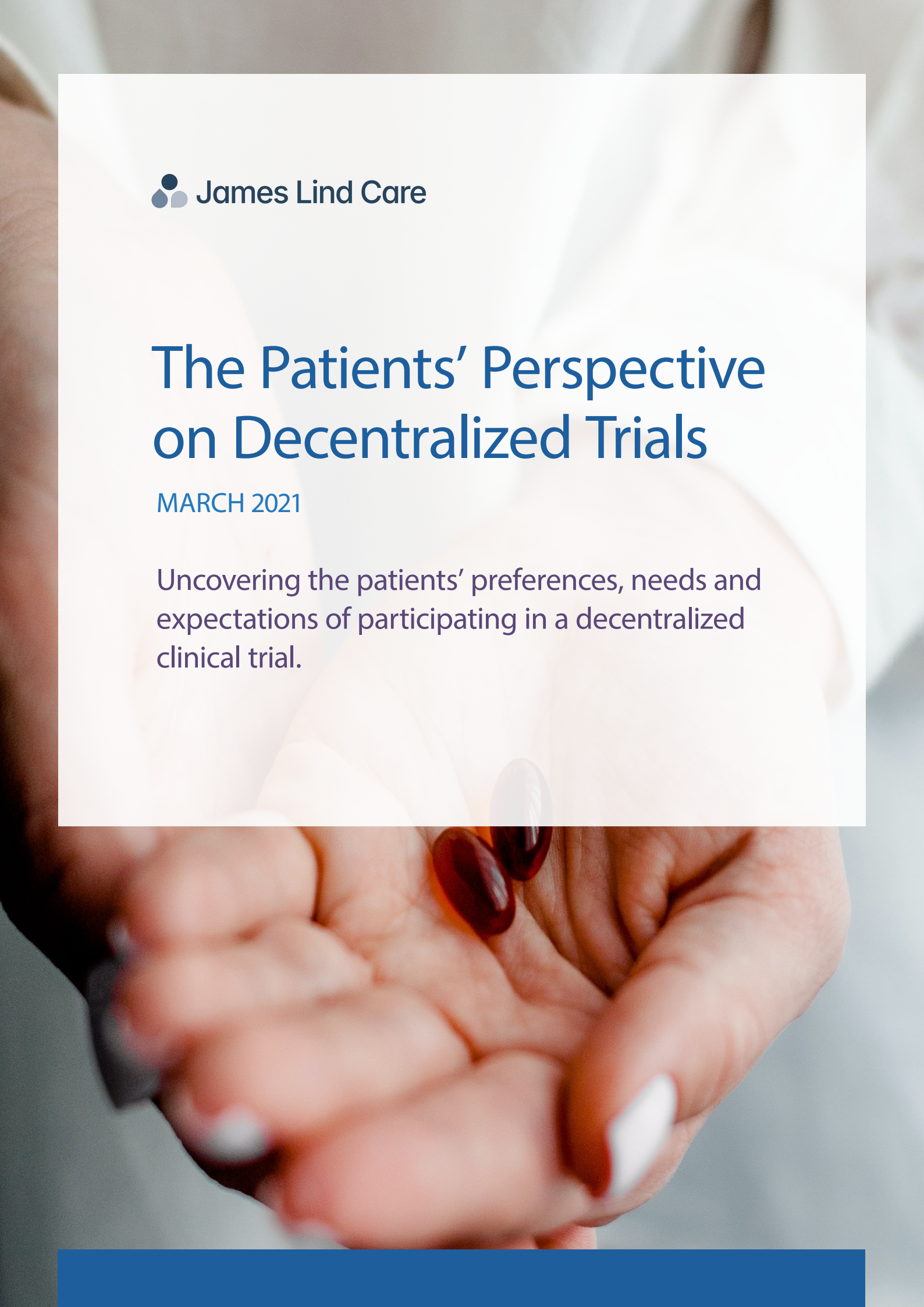





The Patients' Perspective on Decentralized Trials

MARCH 2021

Uncovering the patients' preferences, needs and expectations of participating in a decentralized clinical trial.





New data reveals that patients are welcoming the upcoming of decentralized trials. This report provides insights into some very important precautions to take in order to make decentralized trials work and some scenarios that must be prevented.

874 answers from community members in Europe

Our findings are based on online survey and in-depth interviews with our community members in The United Kingdom, and Denmark.



Patients welcome new trial design, but worry about technology

Decentralized trials are embraced by the majority of patients. Only 12% prefer the classical concept, involving purely face-to-face visits, and an astonishing 92% of patients are willing to wear digital equipment.

On the other hand, decentralized trials may compromise patient centricity which threatens to raise the dropout rate, not lower it. Among those hesitant (52%) to participate, 36% worry about technical issues and 24% are concerned about missing the frequent face-to-face visits with experts. These visits provide them with valuable insight into their conditions and an important sense of recognition and purpose.

This report focuses on the five essential patient aspects when deciding whether to shift to a decentralized trial design:

PREFERRED DESIGN:	What kind of trial design do patients prefer?
MOTIVES:	What are the main motivators for participation?
IMPACT:	How does a decentralized trial impact participants' motivation
CONCERNS:	What are patients' concerns related to decentralized trials?
SERVICES:	What services should be offered to enforce retention?



Key findings

1. **PREFERRED DESIGN**
Decentralized trials are the most favorable model with only 12% preferring the classical design.

2. **MOTIVES FOR PARTICIPATION**
Purpose is strong and so is personal benefit.

3. **DECENTRALIZATION LOWERS MOTIVATION**
Maintaining motivation and retention is more difficult in decentralized trials.

4. **CONCERNS MAY INCREASE DROP-OUT RATES**
Patients worry about managing the wearables and taking on a greater responsibility.

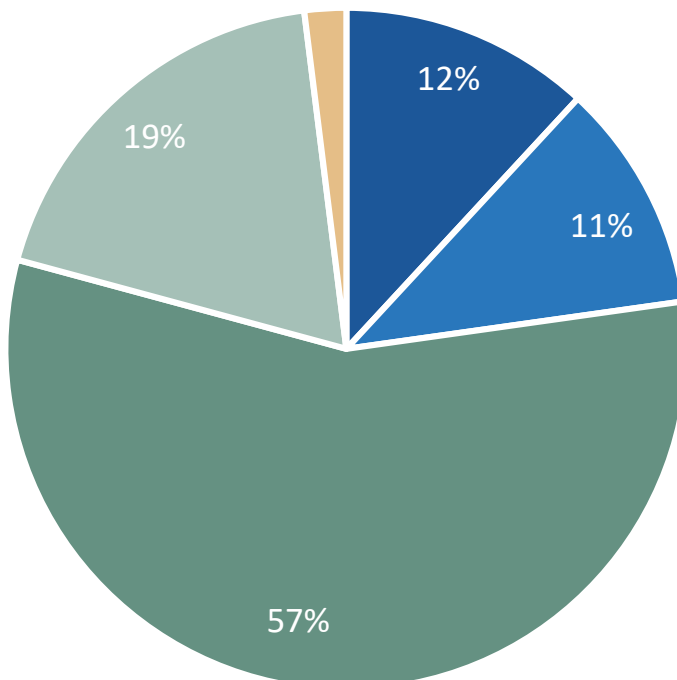
5. **SERVICES AS A SOLUTION**
Establishing reassurance and making patients feel safe. E.g., via relation to nurse and access to expert if worried



Preferred design

Patients embrace the idea of decentralized trials:

- 57% prefer participating mostly from home with only a few site visits
- 19% prefer a virtual trial design, participating entirely from home
- Less than one in 8 prefer the classical clinical trials model.



Preferred trial design

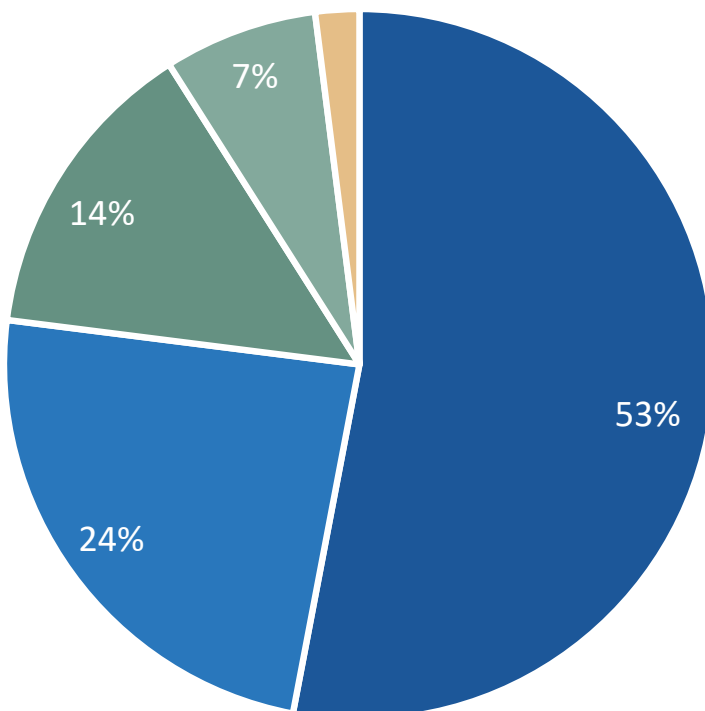
- CLASSICAL: All visits at site
- MODERN: Most visits at site
- DECENTRALIZED: Most visits at home
- VIRTUAL: All visits at home
- None of the above



Motives for participation

Patients enroll in a trial and stay engaged for a number of reasons, but 4 major motives exist. Motives can be categorized as being either altruistic or related to personal benefit.

Dismissing any of them will have great consequences for both enrolment and retention.



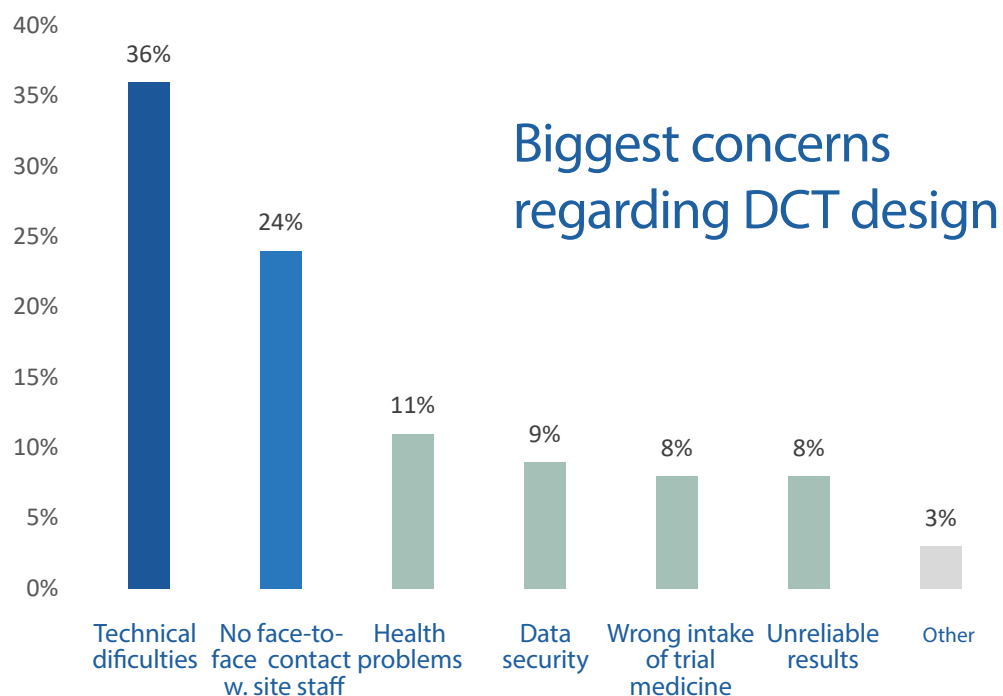
What is the most important reason for you to participate in a clinical trial?

- To contribute to the development of new medicine
- To help other patients to receive better treatment in the future
- To receive a better medical treatment for my own illness
- To be in contact with and receive treatment from specialized medical staff
- Other reason



Concerns may increase drop-out rates

92% would be willing to use digital equipment such as sensors or smartwatches. Despite this, 52% have worries regarding participating in a clinical trial where all contact with research staff takes place digitally.



Patients' primary worry with decentralized designs is their capability of managing the wearables and technical equipment for remote monitoring. This involves tracking their health, symptoms and adverse events which may cause them to feel solely responsible for their health in a decentralized trial design.

The second biggest concern is lacking regular visits and personal meetings with the study team, which provide reassurance and information to the participants.



Decentralization lowers motivation

Decentralized trials considerably lower one of the four main motives for participation: The benefit of being in contact with and receiving treatment from specialized medical staff. When the number of visits with experts decreases, the patients lose a significant motivator.

The patient's sense of purpose and personal value may diminish over time, due to the lack of continuing appreciation showed by site staff in the classical design.



Birgit Hauggaard
Research Nurse

"It is very important for patients to form a relationship with a consistent expert or nurse. This allows patients to feel appreciated and reminded of their purpose for volunteering, motivating them to continue with the trial. If we don't find a way to maintain this connection in decentralized trials, drop-out rates may surge."



Solutions

Most patients request a trial design with a high degree of decentralization, involving fewer face-to-face visits at study sites.

In order to reduce the risk of high drop out rates, dedicated staff are required to reinstate the participants' permanent sense of purpose, personal value and health security. This can



be achieved by offering a series of participant directed services:

1. **Education** on how to use the technology upon enrolment. Ideally with follow up calls or virtual meetings during the first days and weeks.
2. **Monthly retention calls from a consistent nurse.** This will help patients to remain motivated, remind them of their valued contributions and provide the opportunity to create a relationship with a nurse/expert.
3. **Provide contact to experts** so that patients can still gain knowledge on their disease, as well as receiving a sense of security. Reassurance is needed so they know they are not completely alone if experiencing side effects.



Conclusions

Decentralized trials can be the concept of the future

Patients are ready to abandon the classical trial model, and express willingness to wear technical equipment. More participation from home is favored but requires technical education and new retention services.

Decentralization delivers both convenience and barriers

The vast majority of patients like the idea of not having to travel to sites, and they are willing to wear digital equipment. However, there are some barriers, which need to be handled. If not taken care of properly, decentralized trials could have the exact opposite effect on patient enrolment and retention than intended.

Dropout rates risk rising

The lack of personal contact with specialized health care staff at sites, risks leaving the patient worried and demotivated, eventually leading to increased drop-out rates. Mitigating solutions should be offered to balance the risk of drop-outs.

Cost reductions require patient retention services

Decentralized trials provide an opportunity to reduce costs as less site resources are used. However, reducing site involvement may lead to lowered motivation, eventually making participants drop out. Therefore, sponsors may need to offer regular calls from nurses, and provide access to specialists and education for the use of wearables.

For further data analysis,
please contact Henrik Vincentz
(+45 2889 7575)
henrikvincentz@jameslindcare.com

About James Lind Care

James Lind Care is a clinical trial specialized European patient organization facilitating national on-line patient communities and collaborate with sponsors to guide patients in their clinical trial engagement.

Due to our many members and unique international character, James Lind Care can take action on the issues confronting patient centricity in clinical trials, such as understandable communication, gentle protocol design, and attentive enrolment.

James Lind Care
Købmagergade 60
1150 København K
Danmark
jameslindcare.com

