A Systematic Review of Methods used to Conduct Decentralised Clinical Trials

Amy Rogers, Giorgia De Paoli, Selvarani Subbarayan, Rachel Copland, Kate Harwood, Joanne Coyle, Lyn Mitchell, Thomas M MacDonald, Isla S Mackenzie, on behalf of the Trials@Home Consortium

MEMO Research, Ninewells Hospital and Medical School, University of Dundee, UK

Introduction

Objective: To evaluate published data on the design and conduct of decentralised clinical trials (DCTs) using quantitative and qualitative approaches.

Background: DCTs are clinical trials that make use of digital innovations and other related methods to make them more accessible to participants. They aim to reduce the burden of trial participation, boost trial accessibility and recruitment, and improve the generalisability of evidence.

DCTs include fully "remote" trials, where there is no direct in-person interaction between study personnel and participants, as well as "hybrid" trials, where DCT methods are combined with more conventional site-based approaches.

We do not know if DCTs are better for recruitment, retention, or cost than conventional site-based trials.

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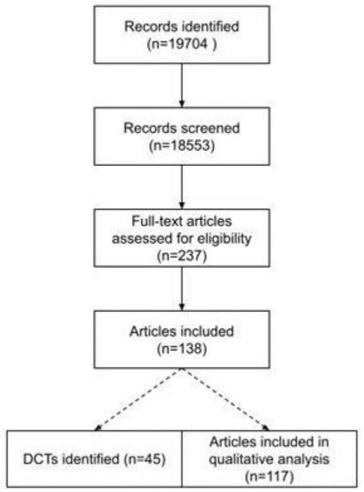
Methods

- Prospectively registered: PROSPERO 2020 CRD42020166710
- Structured searches of academic databases, ClinicalTrials.gov, and relevant websites for publications reporting or discussing DCT methods (11/02/20 - 31/03/20).
- Removal of duplicates
- Title and abstract screening
- Full-text screening
- Structured data extraction forms
    a. Quantitative
    b. Qualitative
- Analysis
    a. Descriptive statistics
    b. Thematic analysis

Flow Diagram



See full paper for detailed PRISMA flow diagram

Quantitative Results

Key findings:

- DCTs using various operational and technological approaches have been used in many therapeutic areas and patient groups.
- There is insufficient evidence to demonstrate a benefit of any DCT methods in terms of recruitment, retention, or cost.

The 45 DCTs identified were widely heterogeneous in design and reporting. Meta-analysis of the effect of DCT methods on the primary recruitment outcome (number of randomised participants) was therefore not appropriate, and summary statistics only were generated.

- 14 fully remote, 18 hybrid
- Median 375 participants (range 10- 39,876)
- 87% UK or N. America based
- 7 DCTs with participants in 2 or more countries

Many different technologies and operational solutions used to achieve decentralisation:

postal	telephone	email	websites
smartphone apps	routinely collected data	usual healthcare provider	home nursing
telemedicine	self-sampling kits	digital images	direct-to-participant IMP
wearable devices	e-consent	incentives	bring-your-own-device
bluetooth connected devices	eDiaries	courier delivery	3rd party ID verification

Qualitative Results

Key finding:

- The convenience of at-home participation must be balanced against transferring burden to study participants.

117 sources published between 1988 and 2020

25 Facilitators
34 Barriers
28 Advantages
25 Disadvantages
9 Patient experiences
7 Stakeholder Opinions

Themes: value, burden, safety, equity

Conclusions

- Technological improvements and proposed benefits in trial efficiency and participant-centredness have led to increasing adoption of DCT methods.
- The COVID-19 pandemic has accelerated DCT adoption.
- We found insufficient published evidence to confirm if DCTs are better for recruitment, retention, or overall trial cost.
- We identified advantages, disadvantages, facilitators, and barriers which should be considered when adopting or developing DCT methods.
- Further exploration of patients' and stakeholders' perceptions and experiences should be conducted to ensure that DCTs are beneficial for all.