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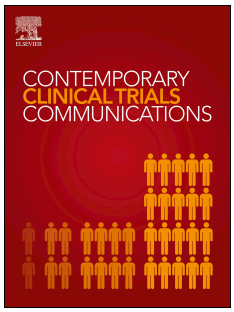

Building clinical trials around patients: Evaluation and comparison of decentralized and conventional site models in patients with low back pain

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ACCEPTED MANUSCRIPT

Building clinical trials around patients: Evaluation and comparison of decentralized and conventional site models in patients with low back pain

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Abstract

Clinical trials are slow and costly, built around the research centers that study local participants. Building clinical trials around patients in their homes and community through remote visits and monitoring could enhance recruitment and increase convenience for participants. This study evaluated different trial settings, a decentralized arm via telemedicine centre (virtual study conduct), a conventional arm via health clinic (onsite study conduct) and a mixed model arm. Acute low-back pain patients (20 -65 years) were recruited to this non-interventional trial in Switzerland. The study consisted of a screening period and a 2-week data collection period using direct data capture (eSource), electronic informed consent form (eICF), electronic diary (eDiary) and wearable actigraphy sensor.

A higher number of patients were enrolled in the decentralized arm (N=18) compared to the conventional arm (N=5) and none in the mixed model arm. The decentralized arm consisted of a diverse population with increased participation from rural areas. In the decentralized arm 89% of enrolled patients completed the study compared to 60% in the conventional arm. All the patients reported satisfaction with the use of eICF, eDiary and remote visits; whereas patients reported a lower level of satisfaction with the wearable sensor.

The decentralized setting was operationally feasible and well accepted by patients. Faster recruitment and improved access to patients was observed in the decentralized arm. This study supports broader adoption of the decentralized model in clinical trials, though further investigations in larger interventional trials are needed to confirm the benefits from this patient-centric approach.

Keywords: **Decentralized clinical trial, eHealth, patient-centric trial, access to trials, recruitment**

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