

Fire, floods and pestilence: challenges of delivering an RCT comparing a group exercise and education intervention with usual care in the time of COVID-19.

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Background

In February 2020 recruitment started for CLEAT, an NIHR funded single-centre randomised control trial comparing an 8-week *group* exercise and education programme (CHAIN) to usual physiotherapy care for hip osteoarthritis.

Methods

The Plan

- Recruit 10 cohorts of around 30 participants (total 256)
- Block randomisation to either 1-1 standard physiotherapy care or CHAIN (held at leisure centre)
- Assess for performance, pain and quality-of-life pre- and post-intervention (in person), then 3 months later (remote)

The Reality

- COVID-19 pandemic postpones study (cohort 1 cancelled)
- Impacts access to healthcare and leisure centre, trial staff health, people's willingness to participate
- As recruitment picks up, fire closes CHAIN venue temporarily
- Local floods hamper travel to assessments

Mitigation Measures Adopted

- Self-referral to physiotherapy – no need to access GP services
- Allocation method allowed groups with fewer participants
- Smaller group sizes and primary outcome completion rate meant smaller sample needed (90% power maintained)
- Flexible study visits allowed for illness or bad weather
- Telephone completion of primary outcome when necessary
- Close monitoring of compliance to CHAIN

Results

- Recruitment completed within planned timeframe
- 221 participants randomised into further 11 cohorts
- 8/11 cohorts attended median of 7+ CHAIN sessions (see Fig 1)
- CHAIN attendance varied more in later cohorts
- Primary outcome completion range 83-100% per cohort

Conclusion

For early cohorts (during COVID restrictions) treatment and other activities were limited, patients were more available. Later cohorts, patients were "too busy" to commit to an 8-week programme at a set time. Post-COVID culture now favours "on demand" rather than scheduled events (e.g. online vs traditional exercise class), which needs to be considered for future trials.

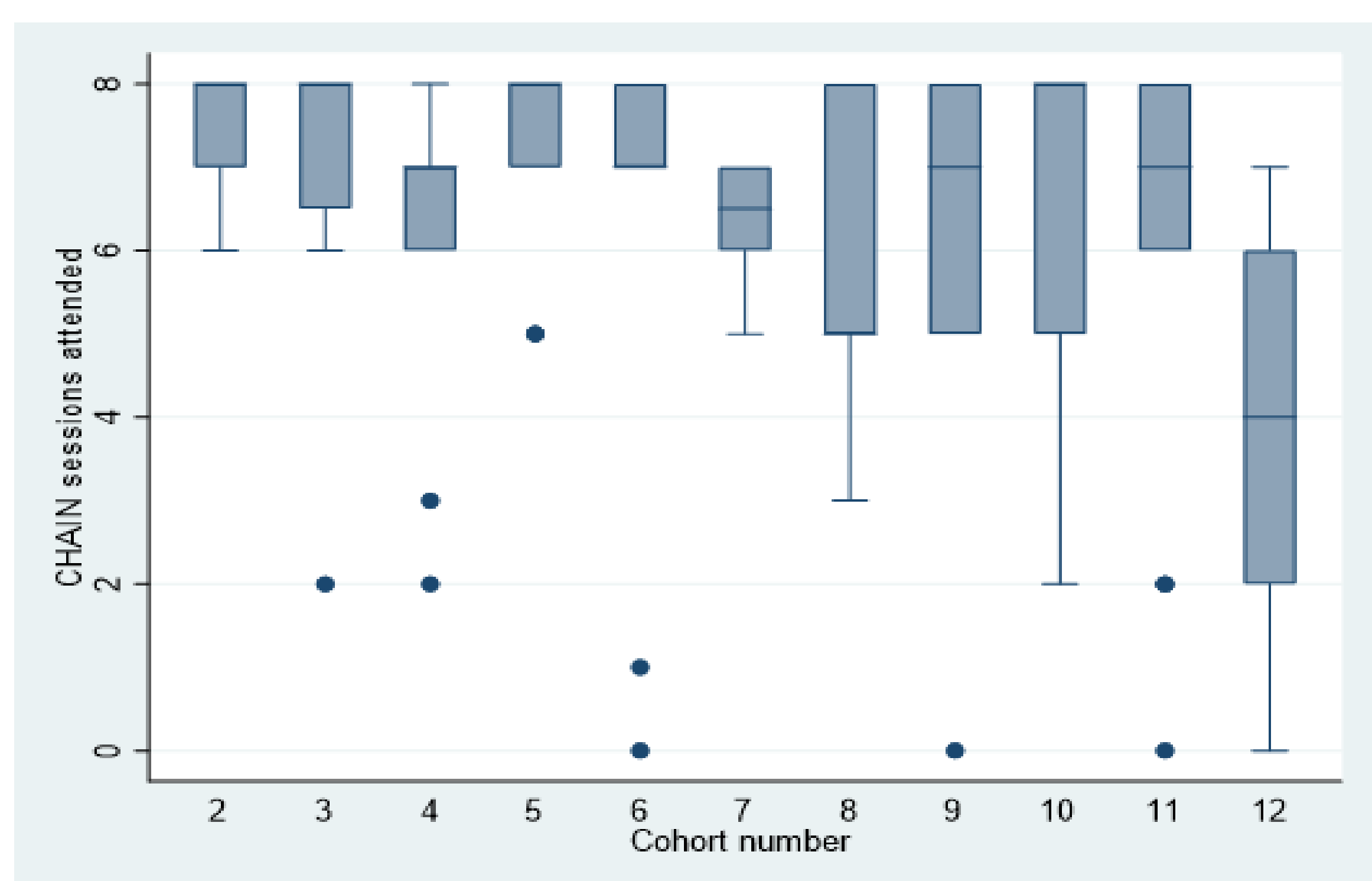


Figure 1: Box plot of CHAIN sessions attended per cohort

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