

## 1 Introduction

- Optimal treatment for stage III-N2 non-small cell lung cancer (NSCLC) requires surgical or non-surgical multi-modality treatment.
- Studies have failed to demonstrate superiority of either approach.
- Evidence exploring patient/carer quality of life across the different treatment pathways is limited.
- Data describing the N2 population in the United Kingdom (UK), and the proportion of patients with resectable disease is also limited.

## 2 Methods

- Feasibility randomised controlled trial (RCT) recruiting from eight UK sites.
- Clinical data was collected for all N2 patients discussed at participating multi-disciplinary team (MDT) meetings.
- Patients randomised to surgical or non-surgical treatment approach.
- Aimed to recruit 66 patients and their carers (later revised to 42 due to COVID-19 related delays).
- Patient/carer questionnaire data was collected at baseline, weeks 6, 9, 12 and month 6.
- Patient/carer/MDT interviews at end of study.
- Declining patients also interviewed
- Feasibility outcomes include recruitment rate; participant retention; treatment fidelity.

## 3 Results

- 276 patients with stage III-N2 NSCLC were assessed for eligibility; **224 (81%) were ineligible.**
- Of the 52 patients deemed eligible, seven declined a research consultation (e.g., had a strong treatment preference and did not wish to discuss the study, therefore not approached), 17 patients formally declined.
- Of the 45 patients approached, **28 (62%) patients and nine of their carers consented.**
- COVID-19 delayed site opening and impacted recruitment.
- No patients swapped or withdrew from their treatments; 13 (46%) patients completed 6-month questionnaires.**
- Feasibility metrics for recruitment, attrition and treatment fidelity were met (amber rating) but with significant challenges.**

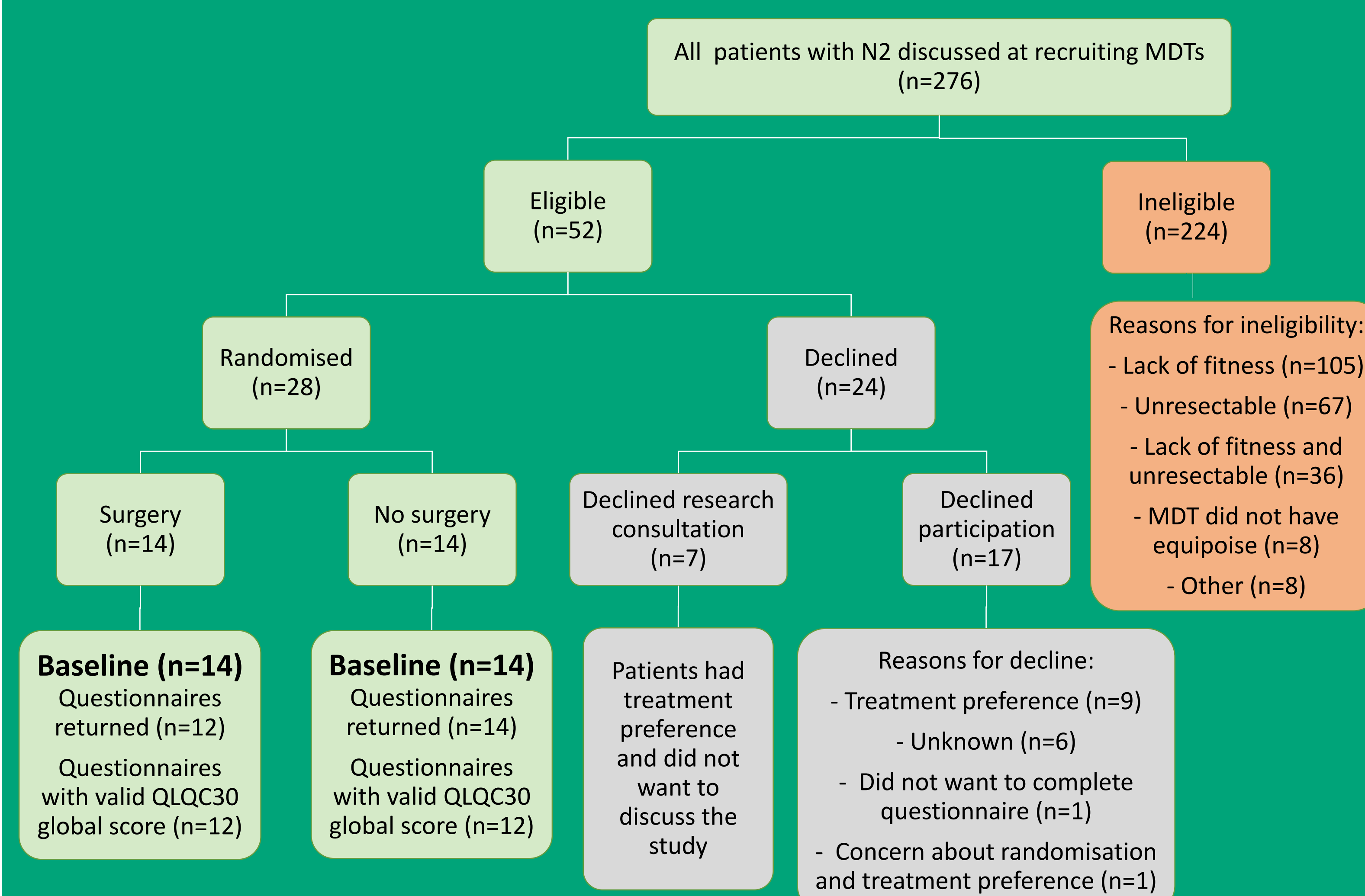


Figure 1. Flow of patients through study recruitment

## Qualitative interviews

Twelve consenting patients, two consenting carers, four declining patients and 20 MDT members were interviewed. Declining patients discussed care experience, individual patient attitudes and decision making. Results from remaining interviews are presented below.

"I wasn't prepared for the level of pain. I thought pain killers would kill it or numb it...I had a lot of problems with breathing as well." Patient, Surgical arm

"I was very lucky I didn't have any real side effects of the treatment, only the tiredness...I think if you put too much in, I think people would think oh I've not got to fill another one of these, I've got all these questions." Patient, non-surgical arm

"If it's a morning appointment, I'll book the morning off work and if they're running late and I'll have to ring work and tell them I won't make it in the afternoon either. That's the only thing that bothers me really." Carer

"If they are of a good performance status then any difficulty in recruitment is generally clinician based, not wanting to recommend the trials." Surgeon

"I think if they were a bit older, they kind of wanted the radiotherapy route rather than surgery, if they were a bit younger, they wanted the surgery route." Respiratory physician

"I think on a case-by-case basis you'll always find that there's a difference in opinion. Generally, I think if they are suitable for surgery we would still try and get them into surgery, and I think if you've got a super fit person in front of you then we might tend as a whole MDT not to put them into PIONEER in the chance that they end up going for the... having the non-surgical treatment." Oncologist

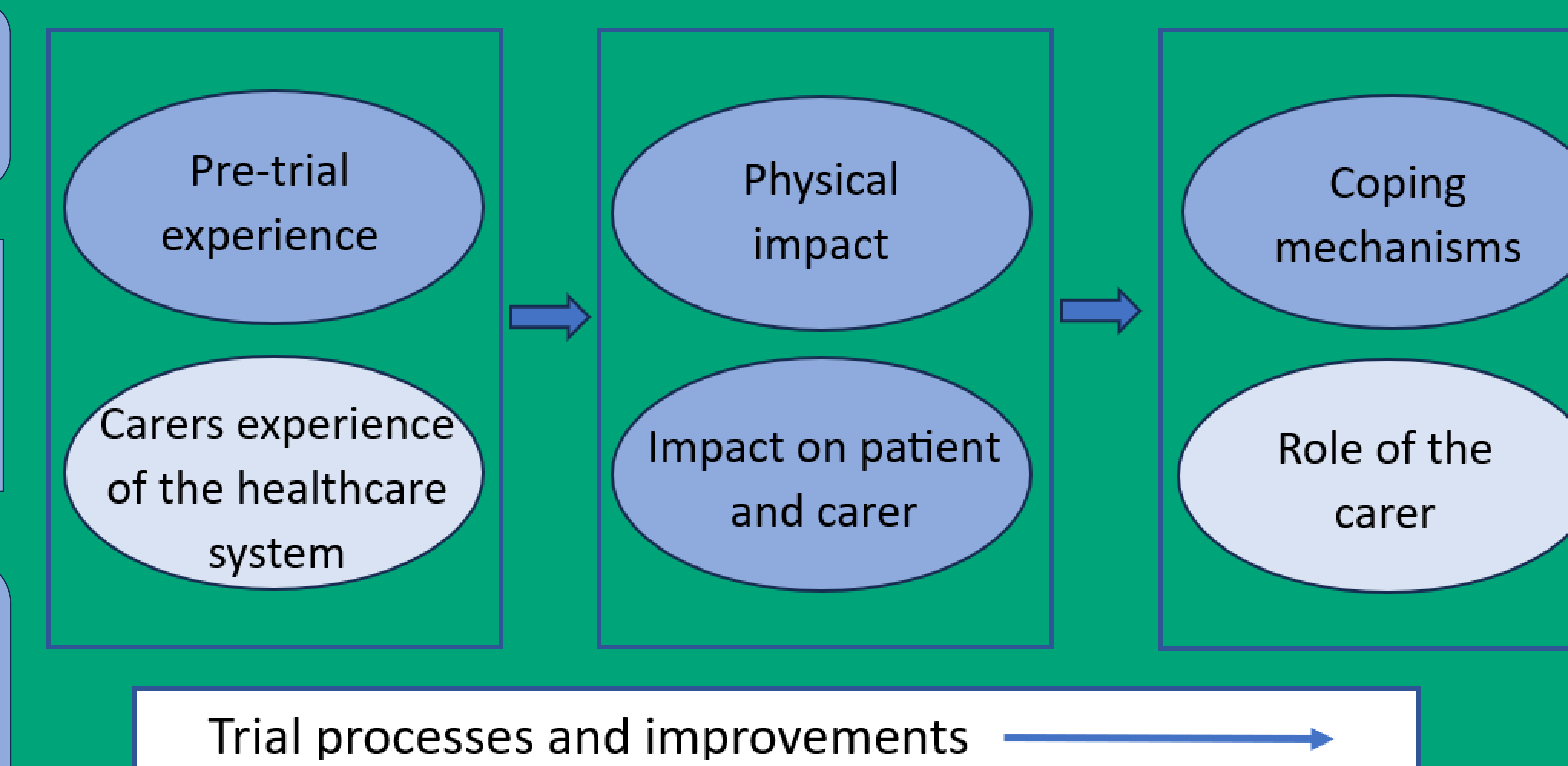


Figure 2. Themes from semi-structured interviews with patients and carers

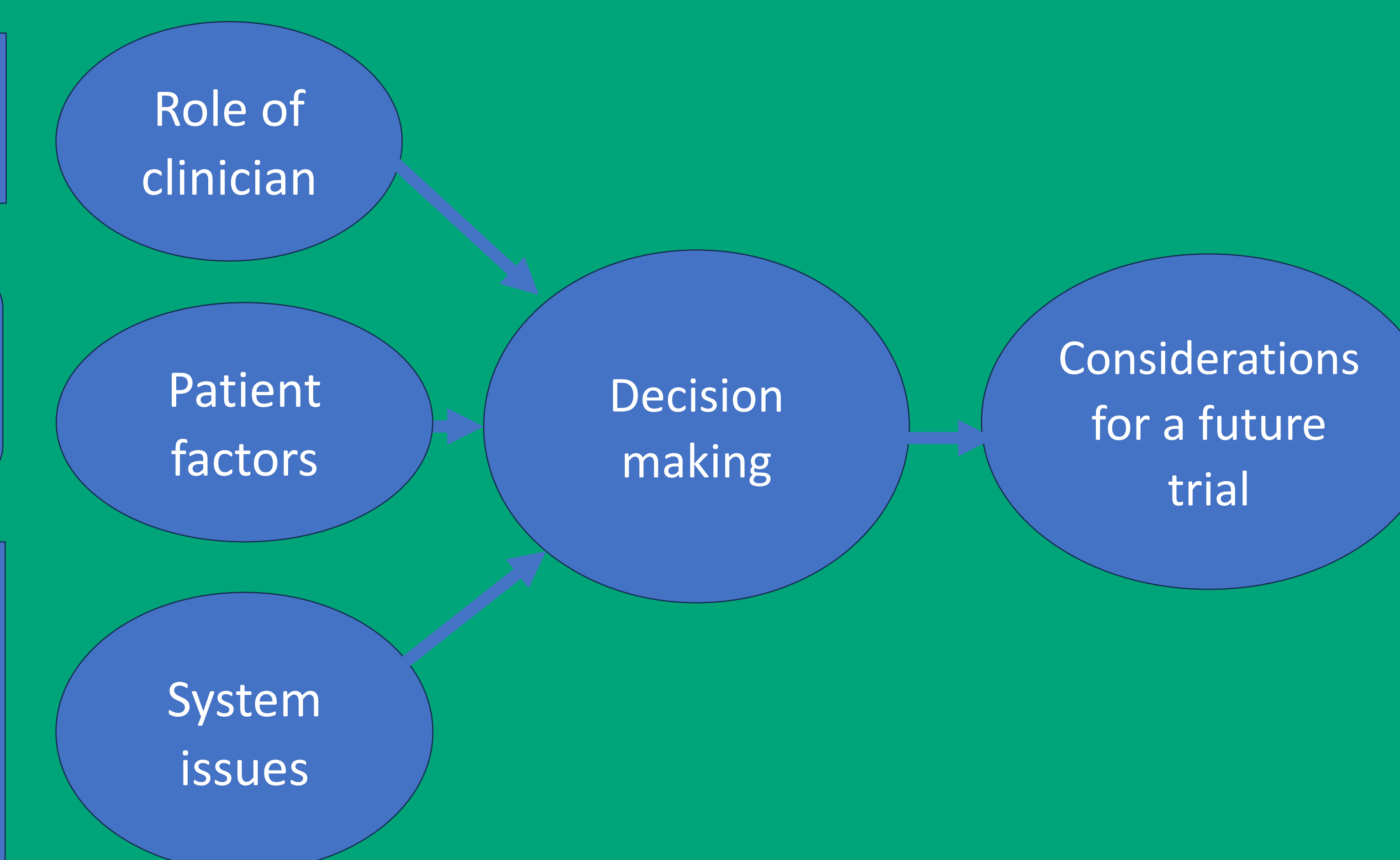


Figure 3. Themes from semi-structured interviews with MDT members

## 4 Conclusion

Despite challenges (site opening delays and fewer eligible patients than anticipated); 28 patients were successfully recruited, and clinical data was collected on 248 patients with N2 disease. Requirements for a fully powered trial (with modifications) were met. Qualitative data gave useful insights into recruitment challenges and points for consideration for a future trial.

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