



■ WRIST & HAND

A qualitative study exploring clinicians' views on clinical trials in thumb carpometacarpal joint osteoarthritis

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Aims

Osteoarthritis (OA) affecting the thumb carpometacarpal joint (CMCJ) is a common painful condition. In this study, we aimed to explore clinicians' approach to management with a particular focus on the role of specific interventions that will inform the design of future clinical trials.

Methods

We interviewed a purposive sample of 24 clinicians, consisting of 12 surgeons and 12 therapists (four occupational therapists and eight physiotherapists) who managed patients with CMCJ OA. This is a qualitative study using semi-structured, online interviews. Interviews were audio-recorded, transcribed verbatim, and analyzed using thematic analysis.

Results

A total of 14 themes were developed, six of which were developed relating to the clinical management of CMCJ OA: 1) A flexible 'ladder' approach starting with conservative treatment first; 2) The malleable role of steroid injection; 3) Surgery as an invasive and risky last resort; 4) A shared and collaborative approach; 5) Treating the whole person; and 6) Severity of life impact influences treatment. The remaining eight themes were developed relating to clinical trial barriers and facilitators: 1) We need to embrace uncertainty; 2) You are not losing out by taking part; 3) It is difficult to be neutral about certain treatments; 4) Difficult to recruit to 'no treatment'; 5) Difficult to recruit to a trial comparing no surgery to surgery; 6) Patients are keen to participate in research; 7) Burden on staff and participants; and 8) A enthusiasm for a variety of potential trial arms.

Conclusion

Our findings contribute to a better understanding of how clinicians manage thumb CMCJ OA in their practice settings. Our study also provides useful insights informing the design of randomized clinical trials involving steroid injections and surgery in people with thumb CMCJ OA.

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Introduction

Thumb carpometacarpal joint (CMCJ) osteoarthritis (OA) is a common condition which results in pain and reduction in function and quality of life.¹⁻³ The majority of thumb CMCJ OA pain is managed in primary care settings or by referral to musculoskeletal services, which are largely run by physiotherapists or occupational therapists.⁴ Therapy-based interventions vary and often include patient education, analgesia, exercises, joint protection, assistive devices, splints, and

steroid injections.^{4,5} Our previous work has demonstrated that this treatment appears fairly common across the UK, although there are variations regarding the use of steroid injections.⁴

There is a limited qualitative research exploring the impact of thumb CMCJ OA.⁶⁻⁸ A small number of qualitative studies have been carried out relating to therapists' perceptions of CMCJ OA: these studies have focused on joint instability⁹ and referral process, assessment, and effectiveness of particular

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Table I. Characteristics of therapists interviewed.

Sex	Professional role	Work setting	Administer steroid injections?
Male	Consultant physiotherapist	Community	Yes
Female	Hand therapist (OT)	Hospital	No
Female	Hand therapist (OT)	Hospital and Community	Yes
Female	Hand therapist (OT)	Hospital	Yes
Female	Hand therapist (PT)	Hospital and Community	Yes
Male	Consultant physiotherapist	Community	Yes
Female	Senior hand therapist (PT)	Community	Yes
Female	Advanced physiotherapist	Primary Care	Yes
Female	Advanced physiotherapist	Hospital	No
Male	Hand therapist (OT)	Hospital	Yes
Female	Advanced clinical practitioner (PT)	Community	Yes
Female	Physiotherapist	Hospital	Yes

OT, occupational therapist; PT, physiotherapist.

Table II. Characteristics of hand surgeons interviewed.

Professional role	Sex	Work setting	Experience, yrs
Consultant	Male	Hospital	5 to 10
Consultant	Female	Hospital	< 5
Consultant	Female	Hospital	5 to 10
Consultant	Male	Hospital	5 to 10
Consultant	Male	Hospital	25 to 30
Consultant	Male	Hospital	< 5
Consultant	Male	Hospital	5 to 10
Consultant	Male	Hospital	5 to 10
Consultant	Female	Hospital	5 to 10
Consultant	Male	Hospital	20 to 25
Consultant	Male	Hospital	15 to 20
Consultant	Female	Hospital	5 to 10

interventions.^{10,11} There are no qualitative studies that have explored clinicians' approach to managing CMCJ OA. Our aim was to explore the approach of clinicians to the management of CMCJ OA in order to inform potential clinical trials.

Methods

Study design. We conducted a qualitative study using semi-structured face-to-face interviews with 24 clinicians, including 12 surgeons and 12 physiotherapists and occupational therapists who regularly treat people with thumb CMCJ OA (Tables I and II).

Our qualitative study team included a hand surgeon (BJFD) with over ten years' clinical experience and qualitative research training, a physiotherapist (CS) trained in qualitative research methods, and an anthropologist qualified as a physiotherapist (FT). BJFD conducted all the interviews and led the data analysis. FT and CS played a collaborative role in analysis.

We followed the CONSolidated criteria for REporting Qualitative research (COREQ) checklist to report our findings (see Supplementary Table i).¹²

Sampling and data collection. We aimed to include a purposive sample of clinicians with a range of years in

clinical practice, from different work settings (community- or hospital-based services for therapists, district general hospitals, or tertiary referral units for surgeons) and professional training (specialist hand therapists, physiotherapist or occupational therapists, surgeons), including some with experience in arthroplasty and injection administration. Clinicians were purposefully recruited from a total of 20 centres in the UK. The therapists had previously collaborated with BJFD in a multicentre service evaluation project and were aware of the aim to build the basis for a future clinical trial in this area.⁴ There were no refusals or study dropouts.

There is no predefined or recommended sample size in qualitative research.¹³ Sampling for qualitative research is based on reaching a point where robust and nuanced ideas develop from the data.^{14,15} The issue of data "saturation" is contested, and it can be "unclear how the typical meaning of saturation as 'no new information' has been judged or determined". Most recently, Braun and Clarke¹⁴ argued that the concept of saturation is incompatible with an interpretive approach to thematic analysis. Other studies in this area have included a sample size ranging from three to nine participants.^{9,16}

Between 2020 and 2021, BD conducted online interviews with surgeons and therapists on the Teams platform (Microsoft, USA). Despite being a surgeon, BJFD feels that he is in a position of equipoise regarding the role of surgical and non-surgical interventions in CMCJ OA, although it must be acknowledged that researchers inevitably bring their personal experiences and views into the analysis. The interview schedule was developed based on a previous work that has described the CMCJ OA care pathways in the UK.⁴ It covered five topics of interest relating to general management approach, the role of exercise, surgery and steroid injection, and clinical trial design (Table III). All participants provided verbal consent before the start of each interview. Interviews were audio-recorded and field notes were made. The interviews were transcribed by a professional transcription company and

Table III. Summary of interview schedule.

Section	Components
Introduction	Greeting, summary of context of interview and consent
1	General approach to management
2	Role of exercise therapy
3	Role of steroid injections including specific prompts relating to timing and use in trial
4	Role of surgery including specific prompts relating to timing and use in trial
5	Barriers and facilitators to clinical trials in CMCJ OA <ul style="list-style-type: none"> ■ Steroid injection trial design including potential comparators ■ Views about surgery versus no surgery trial Views on specific surgical interventions trials including joint arthroplasty and trapeziectomy
End	Any further thoughts and thanking participant

CMCJ, carpometacarpal joint; OA, osteoarthritis.

BJFD checked for accuracy by reviewing the transcripts against the audio recordings. The transcripts were then uploaded as Word documents (Microsoft) and organized on NVivo qualitative data analysis software (version 12; QSR International, USA). Participants were given a £50 gift voucher to acknowledge their participation and time for taking part in the interviews. All audio recordings and transcripts were anonymized using non-identifiable study codes.

Ethics approval. The study protocol was reviewed by the local institutional review board (University of Oxford's Clinical Trials and Research Governance department), who approved the study and stated that project did not require formal Research Ethics Committee approval as it was activity preparatory to research according to the UK Health Research Authority's algorithm. All methods were carried out in accordance with local research governance protocols.

Analysis. Data were analyzed by BJFD and CS and reviewed by FT. Data collection and analysis occurred simultaneously, and a systematic iterative approach of thematic analysis was used. The data for the 12 therapists and the 12 surgeons was analyzed separately to allow comparison.

The trustworthiness of our findings hinged on a collaborative approach to research rigour, involving members of the research team and our patient and public involvement (PPI) representatives.¹⁷ First, BJFD and CS independently coded the data from the interview transcripts. Second, codes were discussed by BJFD and CS within the context of the field notes, and codes were grouped into themes with a common essence. FT contributed to the analysis by reviewing the categories and themes and providing insights and additional perspectives. Through team meetings, BJFD, CS, and FT discussed and revised the categories and themes until agreement on the final themes was reached. We then combined the themes from both interview sets (surgeons and therapists).

Patient and public involvement. The study was designed, analyzed, and written up with input from a patient representative who helped to develop the interview schedule, and also provided feedback on the final themes and manuscript write-up.

Results

Six themes were developed relating to the approach of clinicians to the clinical management of thumb CMCJ OA in a potential clinical trial: 1) A flexible 'ladder' approach starting with conservative treatment first; 2) The malleable role of steroid injection; 3) Surgery as an invasive and risky last resort; 4) A shared and collaborative approach; 5) Treating the whole person; and 6) Severity of life impact influences treatment. Eight main themes were developed relating to clinical trial barriers and facilitators: 1) We need to embrace uncertainty; 2) You are not losing out by taking part; 3) It is difficult to be neutral about certain treatments; 4) It is difficult to recruit to 'no treatment'; 5) Difficult to recruit to a trial comparing no surgery to surgery; 6) Patients are keen to participate in research; 7) Burden on staff and participants; and 8) A enthusiasm for a variety of potential trial arms. A summary of these findings is illustrated in Figures 1 and 2 and Table IV.

Clinical management of CMCJ OA

A flexible 'ladder' approach. This theme describes a sequential, flexible and staged ladder-like approach to the management of thumb CMCJ OA and a preference for non-invasive non-surgical interventions as the first line of treatment. Clinicians preferred to start with the basic "conservative" non-invasive treatments first and this model of care was repeatedly described using terminology such as "step ladder" or "ladder" to communicate the preference for this sequential and staged approach.

I say to them, 'We don't treat as per escalator, we treat as per ladder'. We go up simple first. [Therapist]

Simple 'conservative' non-surgical interventions started with basic analgesics and then moved onto therapy based interventions such as splints, patient education, activity modification and exercises. This ladder approach was something that clinicians felt patients also preferred. The basis for this was explained as being the minimally-invasive nature of non-surgical interventions and their lack of recovery 'down time'. This flexible ladder-based approach was described as balancing the management of the patient's symptoms with the potential negative impacts of interventions.

I lay out to them a ladder if you like, of care and of management and they can go up the ladder, they can go up and stop, it's about managing their symptoms and balancing management of their symptoms with the potential side effects and complications. [Therapist].

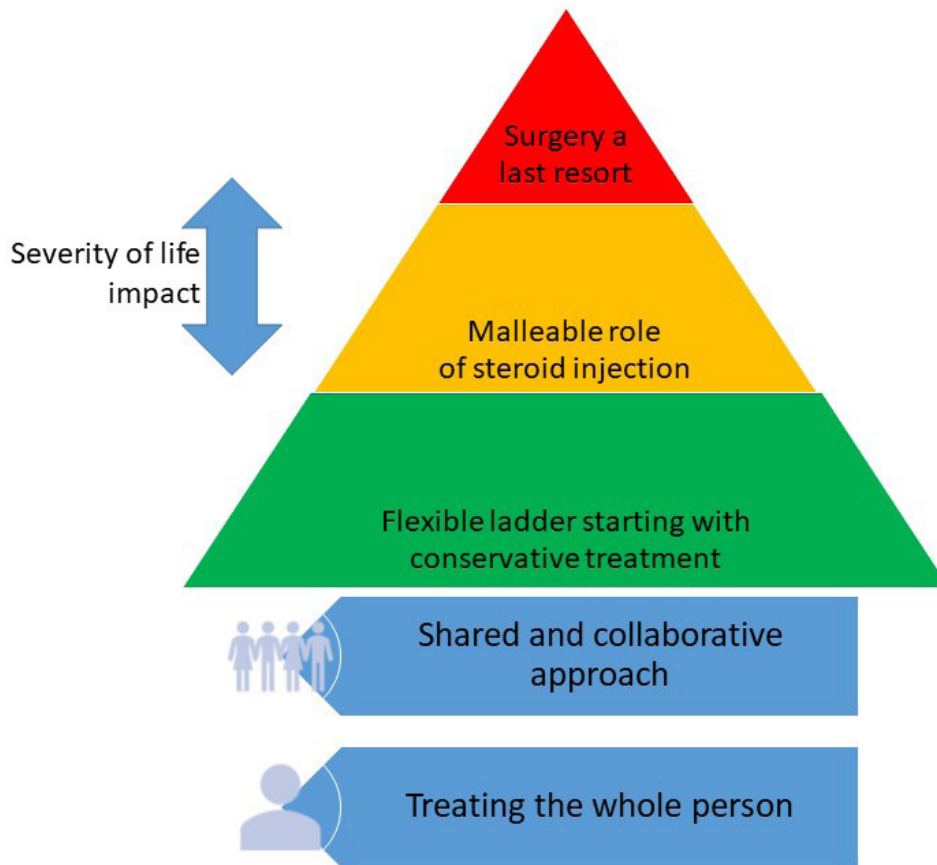


Fig. 1

A diagram depicting the key themes developed relating to the clinical management approach.

The malleable role of steroid injections. This theme describes the malleable role of steroid injections within the overall ladder approach. Although steroids are considered “invasive”, clinicians also described how they encountered clinical situations where steroids were chosen as a first-line of treatment. For example, steroid injections would be of value in people with ‘severe pain’ and needed ‘immediate’ or ‘instant’ pain relief in such situations.

But when it comes to using injections, when it’s unbearable pain, then injection would be the first-line of treatment. [Therapist]

Clinicians preferred to use steroid injections as part of a package of care as an “adjunct” to other interventions such as activity modification and exercise therapy rather than a stand-alone intervention. Steroid injections were also used as a first line “two-pronged” approach with the aim of engaging the patient in “conservative” multimodal treatment once their pain had subsided.

So, for some people, what I tend to do is a two-pronged attack, I guess. So potentially list them for a steroid injection, but say, ‘Look, while you’re waiting for that steroid injection to happen, let’s get you through to the hand therapist, they can give you

lots of advice and information, to try and maximize the effects of that steroid.’ And they tend to buy into that as an idea. [Therapist]

Surgery as an invasive and risky last resort. This theme describes the role of surgery on the ladder as a last resort intervention. Surgery was described by clinicians as effective but very much a last resort, generally only to be considered when all conservative treatment methods have been used and failed.

If they’ve exhausted conservative measures, and they are still symptomatic, we’ll look at some kind of surgery with them. [Surgeon]

Though clinicians considered surgery as an effective option, they also perceived it to be highly invasive. Two influential factors were the long and painful recovery period and concerns about the likelihood of a successful outcome. The extended recovery period from surgery contrasted with the quick recovery from steroid injection, implying that surgery was seen as the opposite to a ‘quick fix’ with a relatively long recovery.

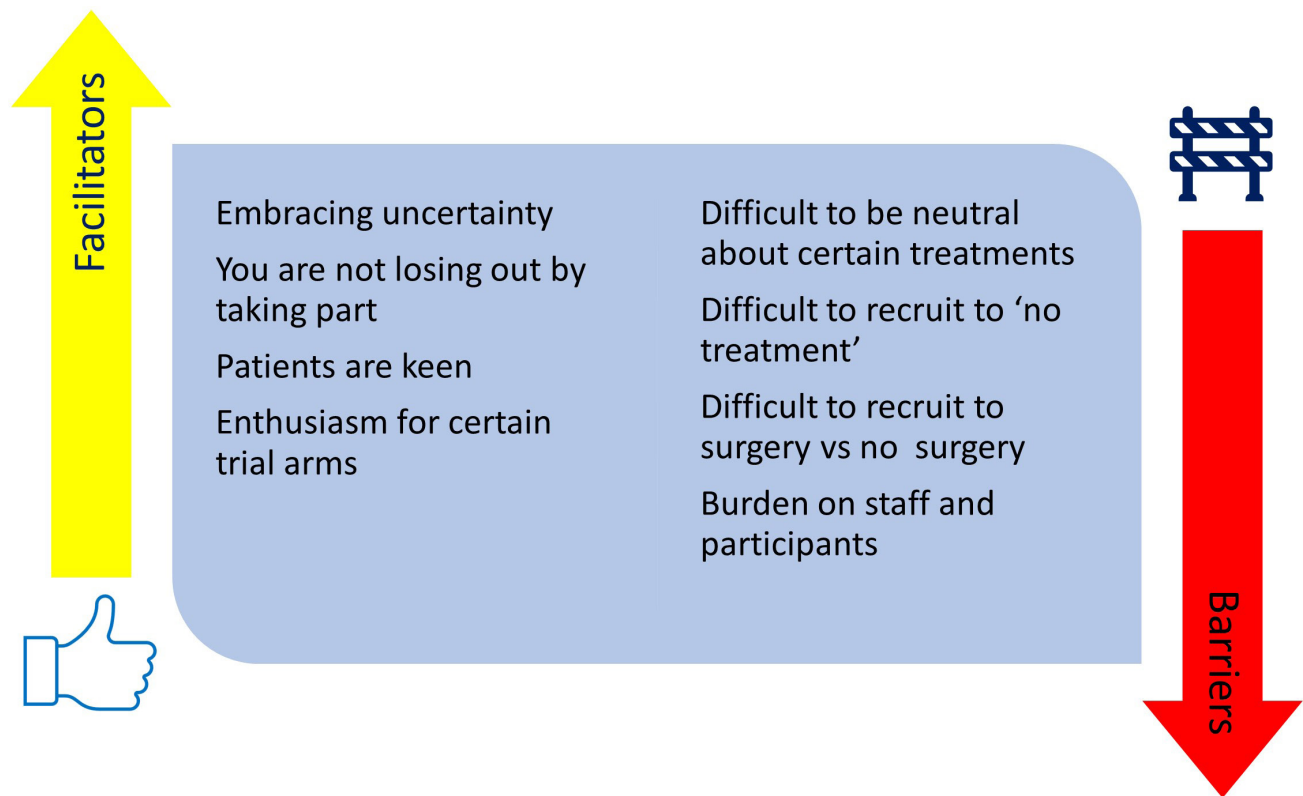


Fig. 2

A diagram depicting the key themes develop relating to trial barriers and facilitators.

Thumb surgery is renowned for being really painful, it takes ages to recover from, people often have decreased grip after it.
[Therapist]

Clinicians also had concerns about the outcomes and potential complications after surgery, which included persistent pain and weakness. The lack of improvement in grip and pinch strength after surgery was also a concern. The presence or development of an adduction deformity was felt to negatively influence outcome; consequently, surgeons felt this was an indication for earlier surgical intervention. Clinicians also expressed their concern about the inability of surgery to restore power and get people back to manual jobs.

If people are working I always counsel that it can affect their grip strength and may impact on their ability to carry out their job. Although the pain might be better, they may functionally struggle a little bit more. [Therapist]

A shared and collaborative approach. This theme is about managing OA in a patient-clinician partnership: taking the time to take a joint decision, empowering patients to

self-manage their OA, and ultimately taking the time to make the decision about surgery together.

I think with thumb base arthritis like with any arthritis, it's very much up to the patients really what they want to tolerate ... I definitely am an advocate of shared decision making when it comes to things like arthritis and I've found it's very individual.
[Surgeon]

This process of getting patients involved in their care and to build understanding by explaining the 'what and the why' of the interventions was seen as pivotal in this shared process:

Getting people on board and understanding is a key part of all treatment. [Surgeon]

Although this shared and collaborative process might take an investment of time, clinicians felt that it was worthwhile because building a patient's understanding was a vital part of engaging them in their treatment. This approach was framed as progress in comparison to the older, more paternalistic model in which medical

Table IV. The themes illustrated by a narrative exemplar.**Themes relating to the management of CMCJ OA**

1. A flexible 'ladder' approach starting with conservative treatment first	'I say to them, 'We don't treat as per escalator, we treat as per ladder'. We go up simple first.'
2. The malleable role of steroid injection	'So, it can be used alongside. So, once the injection therapy has shown that the pain levels are under control, we need to put the other measures in place after that'
3. Surgery as an invasive and risky last resort	'If they've exhausted conservative measures, and they are still symptomatic, we'll look at some kind of surgery with them'
4. A shared and collaborative approach	'Getting people on board and understanding is a key part of all treatment'
5. Treating the whole person	'It's all about self-help, it's all about self-management, it's all about lifestyle change'
6. Severity of life impact influences treatment	'And then, what is the importance of determining the level of intrusion? The importance of determining the level of intrusion is to influence your threshold to convert to surgical treatments'
Themes relating to barriers and facilitators to a clinical trial	
1. We need to embrace uncertainty	'When you explain to them that we genuinely don't know what best practice is and what we should be doing, a lot of happy are quite happy to accept that and to help. '
2. You are not losing out by taking part	'So long as they know very clearly your reasons for doing the study and know that they're not losing out.'
3. It is difficult to be neutral about certain treatments	'But it is so difficult to have everyone in the patient's pathways maintain enough equipoise to not bias your results. '
4. It is difficult to recruit to 'no treatment'	'You know, you might randomly choose you get nothing, they're going to sit there and say, "Well, this is basically pretty rubbish." Aren't they?'
5. Difficult to recruit to a trial comparing no surgery to surgery	'I think it would be harder to recruit at the stage where they've done all those treatments.'
6. Patients are keen to participate in research	'But it amazed me at how patients were just happy to be involved in research, and be involved in trials, and they were happy to be randomized'
7. Burden on staff and participants	'I think it is going to be the other aspects of the trial that you'll find difficult to engage people on. I find that people who are... maybe people who are less able to commit time, so your working category of people.'
8. An enthusiasm for a variety of potential trial arms	'I think an injection trial would be really interesting. It's just, as the question I asked you, I don't quite know what the best way of doing it is'

CMCJ, carpometacarpal joint; OA, osteoarthritis.

professionals did not engage patients in the decision making process:

The days of the doctor or the medical staff as infallible sources of information are long gone, and I think it's our responsibility to try, as far as possible, to set the risks and benefits out to enable the patients to make decisions. [Therapist]

Clinicians described wanting to help educate and engage patients in their treatment, and ultimately enable the patient to make their own decisions:

I tell them, 'I am not deciding for you', I make that clear from the very start, 'you have to have your own authority for your own condition. [Surgeon]

Treating the whole person. This theme incorporates the importance of treating the person in a holistic manner. Therapists described how they individualized treatment in order to tackle specific functional problems:

I think now at a later stage of my current career, it's more related to function in combination with the latter. So, if somebody was having difficulty lifting a cup or undoing a jar, then my rehab would be based around the functional tasks, less about kind of isolated thumb extension or reduction or progressive exercise in that regard. [Therapist]

The favouring of the more holistic biopsychosocial approach by therapists was consistent, and the biomedical model was generally seen as dated and outmoded. Therapists very much saw their role as influencing lifestyle change in a holistic manner:

It's all about self-help, it's all about self-management, it's all about lifestyle change, it's not just "this is your MSK condition, this is a bio-model of what's going on, this is what you need to do." It's about the whole person and kind of people, smoking cessation and changing your alcohol habits, changing your exercise habits. So, I think we're in quite a good position to do that. [Therapist]

The influence of life impact on treatment decisions. This theme describes clinicians' views about how the severity of the life impact of thumb CMCJ OA influenced the treatment approach. The multiple and diverse impacts of thumb CMCJ OA in terms of pain, function, quality of life, social life, and mental health were described. Clinicians feel that patients chose to manage their own symptoms and tended to delay surgery. However, clinicians recognized a variation in what they felt different patients were willing to tolerate. Clinicians described how some patients could become truly miserable as the impact became all-encompassing in their lives:

It's not all of them, it's a small cohort where it makes their lives miserable. It's because it affects them day to day, every day, all day long, whatever they're doing with their hands; eating, drinking, doing their job, driving their car, writing, everything they do is affected by it. [Surgeon]

The treatment ladder was not felt to be a rigid and was described by clinicians as being flexible to the individual patient's needs and expectations. The degree of impact of thumb CMCJ OA upon patients was described as a key element for consideration when it came to titrating the ladder to the individual patient:

I think that's one of the fascinating things about it is, it's all very well in my head having a ladder of treatment but the patients need to pop in and pop off at different points because they have individual demands, if you like, and individual expectations and needs. [Therapist]

Surgeons described ways in which they explored the impact of symptoms and the level of 'intrusion' in order to determine when surgery should be offered. The impact on patients' lives in terms of stopping them do what they want to do was felt to be a key aspect of this. The presence of 'pain and misery' was described as an indication for considering surgery:

I would say, 'Are you in pain and misery?', and if they are, we're then looking at surgery. [Surgeon]

Barriers and facilitators to a clinical trial in CMC OA

We need to embrace uncertainty. This theme describes the importance of embracing uncertainty in clinical trials. This applied to trial participants and participants emphasized the value of clearly communicating uncertainty about treatment outcomes. It also incorporated the importance of ensuring that the clinicians and research team appreciate clinical uncertainty. Participants described how the preconceived opinions of potential trial participants might inhibit recruitment because they feel that a particular intervention works. Clinicians felt that communicating the genuine clinical uncertainty to patients was vital in recruiting patients.

When you explain to them that we genuinely don't know what best practice and what we should be doing, a lot of happy are quite happy to accept that and to help. [Therapist]

Clinicians described the importance of linking together the communication of genuine uncertainty, the explanation of how this uncertainty was the reason for the study, and how the fundamental motivation for a trial was trying to improve patient care.

We don't actually know [which treatment is the most effective], we're trying to improve our practice and we don't actually know if this works, so this is the reason for the study. [Therapist]

You are not losing out by taking part. This theme described the importance of explaining to potential

participants that they would not be losing out by taking part in the trial.

So long as they know very clearly your reasons for doing the study and know that they're not losing out. [Surgeon]

Clinicians felt that one possible way to achieve this was to leave the option open for treatment at a later time, or in a different order:

Having treatment, that's what they'd be getting anyway in some way or form. Maybe getting one first, then the other, then the other. They are just getting their treatment slightly different, or in different order. [Therapist]

The idea of not losing out was described as vital in terms of explaining to trial participants that they could cross over to receive treatment at the end of the study if they had not improved:

With this, you're not necessarily losing anything. At the end of the study, if they haven't improved, then you can escalate their treatment as appropriate. [Therapist]

It is difficult to be neutral about certain treatments. This theme describes the challenges of being in equipoise for all the research team. Participants felt that any preconceived opinions of the research team may make a trial difficult and "bias" the results of a study. Some described how clinicians might have fixed ideas about treatment effectiveness, and that this might be problematic in running a successful clinical trial:

It's tricky, because surgeons all have their own little ways of doing things, and that's just the way that they manage their patients. They have their own best practice and what's worked for them in the past. [Therapist]

It's difficult to recruit to "no treatment". This theme describes the importance for potential trial participants of feeling that they are receiving some form of "treatment", whichever trial arm that they are allocated to. As such, participants felt that the way different trial arms were described to patients was very important. In particular, treatment arms described as receiving 'no treatment' were seen as difficult to recruit to because potential trial participants are likely frame 'no treatment' as negative:

You know, you might randomly choose you get nothing, they're going to sit there and say, "Well, this is basically pretty rubbish." Aren't they? [Therapist]

As such, participants described the importance of explaining to potential trial participants that each trial arm was potentially effective, and that even a 'placebo' could be an effective form of treatment.

I think that most people to want to sign up for a trial would want to be signing up to something that they thought "I'm getting one of a number of treatment options" and that treatment option may be the placebo option, but it's at least a treatment option, rather than well basically what you're telling me is don't do anything. [Surgeon]

Some clinicians felt that because of the challenges of recruiting to a "non-treatment" trial arm, interventions

should be offered as a treatment package, rather than as isolated treatments: for example a package that included injections, rather than injection versus no injection.

I don't know if that's what injections anywhere should be. It should be a package, as part of a treatment package. [Therapist]

Difficult to recruit to a trial comparing surgery with no surgery. This theme describes the unique challenges of recruiting to trials comparing surgical and non-surgical interventions, as surgery was framed as a last resort having exhausted all non-surgical measures:

I never push basal thumb surgery ever. I'll always say, 'The longer we can keep your own thumb, the better'. Generally, it's the patient saying, 'Enough is enough. I just want the surgery.' [Surgeon]

There was a sense that a trial of non-surgical intervention versus surgery would be extremely challenging in terms of recruitment to the non-surgical arm, and not of great interest to clinicians.

I think it would be harder to recruit at the stage where they've done all those treatments. [Surgeon]

In contrast, there was great enthusiasm for a trial comparing different types of surgery, in particular, trapeziectomy versus joint arthroplasty. Participants felt this was an area of great uncertainty and that patients would also be keen to take part in such a trial.

I think it's a study that has to be done, absolutely has to be done. [Surgeon]

Patients are keen to participate in research. This theme describes the "keenness" of patients to take part in research. Participants felt that generally, patients wanted to be involved in research and were motivated by altruism in terms of wanting to help others in the longer term. Participants described how they had previously been surprised at patients' willingness to take part in research:

But it amazed me at how patients were just happy to be involved in research, and be involved in trials, and they were happy to be randomized. [Therapist]

Participants described different motivations underlying patients' keenness to take part, which might include elements of altruism combined with self-interest. Participants felt patients were keen to participate and help to answer research questions, if it was clearly explained to them that no one yet knows what the most effective treatment is.

When you explain to them that we genuinely don't know what best practice and what we should be doing, a lot of happy are quite happy to accept that and to help. [Therapist]

Burden on staff and participants. This theme describes different types of burdens upon trial participants and research staff which may make a clinical trial more difficult to carry out. For example, the time and administrative burden for staff, or the time burden for potential trial

participants. Participants felt that it was vital to be provided with adequate time to discuss the trial with potential participants and fill out trial paperwork.

We get half an hour, whatever happens. It doesn't matter what you're doing. And in half an hour, I had to do my normal thing plus all the discussion, the consent forms and it was impossible. I was doing it in my own time. [Therapist]

The time burden for potential trial participants might pose a particular challenge for those in employment.

I think it is going to be the other aspects of the trial that you'll find difficult to engage people on. I find that people who are... maybe people who are less able to commit time, so your working category of people. [Surgeon]

An enthusiasm for a variety of potential trial arms. Clinicians described an enthusiasm for particular research questions relating to thumb CMCJ OA. For example, some described their enthusiasm for a trial with an injection component, although there were different views about how best to do this.

I think an injection trial would be really interesting. It's just, as the question I asked you, I don't quite know what the best way of doing it is. [Surgeon]

Participants had varied preferences relating to an injection trial, both in terms of the number of intervention arms and choice of comparator to steroid injection. There was interest in both comparing steroid to a local anaesthetic or saline comparator, there was also enthusiasm for comparing a best practice package of care to this package with the additional of a steroid injection.

Discussion

This study presents six themes relating to the approach of clinicians to the management of thumb CMCJ OA. Overall, a flexible ladder approach starting with simple conservative interventions was favoured, within this the role of the steroid injection was highly malleable and surgery was generally seen as a last resort after all else had failed. This study also presents eight themes relating to the participants' views on clinical trial barriers and facilitators. Embracing uncertainty was felt to be vital, as was ensuring that the trial participants in all intervention arms felt they were getting treatment and not losing out by taking part.

The flexible ladder approach described by the clinicians in our study is an important finding. A study by Grant¹¹ described the wide variety of interventions but did not explore the approach to management by therapists. Our findings resonate with Jansen et al,⁹ who highlighted the importance of a 'package of care' in treating thumb CMCJ OA. Clinicians also described how the steroid injection should be delivered as part of a package of care and not in isolation. The 'ladder' approach is consistent with the clinical guidelines relating to hand OA, such as those developed by National Institute for Health and Care Excellence (NICE), European Alliance of

Associations for Rheumatology (EULAR), and the British Society for Surgery of the Hand (BSSH).^{18–20} Perhaps given the lack of high-quality evidence to guide practice, the ladder approach makes sense by reserving the more invasive and risky interventions for after all else has failed.²¹ This approach is also consistent with the cost-effectiveness of the NICE guideline development process, meaning that in the absence of high-quality evidence, less expensive interventions are generally preferred before considering the more invasive and expensive interventions.²²

Our interviews also demonstrated the highly malleable and adaptable role of the steroid injection as part of a package of care in people with CMCJ OA. Previous studies indicate the necessity of well controlled pain levels to enable or start exercises in this patient population.⁹ This is consistent with what we identified that earlier use of steroid injections would help people engage with exercises better by relieving the pain. Surgery being seen as a 'last resort' resonates with the BSSH guidance:²⁰ Moreover, it reflects the ladder approach with surgery being the most invasive option with risks and complications. This closely reflects what clinicians described relating to surgery in knee OA only when conservative treatments had failed.²³

Clinicians also provided insights on how the severity and impact of CMCJ OA influenced their treatment approach. The severity of symptoms and coping has previously been described by surgeons as relating to the decision regarding surgery in knee OA.²³ This is consistent with the way surgeons described the 'intrusiveness' of symptoms and 'misery' as ways to gauge whether to offer a particular intervention such as a steroid injection or surgery. The pandemic may have some influence on the management process, with perhaps patients and clinicians being more prone to engaging with the non-surgical interventions due to long waiting lists for surgery.

The collaborative and shared approach resonates "client-centred" nature of the decision making.¹¹ The perception that patient 'buy-in' and engagement were important factors previously described in relation to the management of knee OA.²⁴ Grant et al¹¹ concluded that therapists had a broader and more holistic scope of practice than the existing literature suggested. There is qualitative evidence demonstrating that people with knee OA preferred the shared collaborative approach to decision making over a more directive approach.²⁵ The NICE and EULAR guidelines both emphasize the importance of education, self-management, and shared decision-making in the management of hand OA.^{18,19} The holistic approach is not something that has been universally described relating to OA management. For example, Teo et al²⁶ noted that therapists often approach knee OA in a rather biomedical manner with little psychosocial consideration. The holistic nature of care is therefore something

which needs consideration in clinical trial designs, and in routine assessments and treatment decisions.

The importance of embracing uncertainty has been widely reported and discussed in the literature.^{27,28} 'Equipose' is a state of equilibrium, while 'clinical equipose' refers to a state of genuine uncertainty regarding the effectiveness of different interventions. The belief in clinical equipose has been shown to be key to participants' consent to randomization.²⁹ A comprehensive review by Davies et al²⁷ found that the a priori preferences for treatment of both patients and clinicians, as well as the imbalanced presentation of interventions were important themes relating to recruitment problems in clinical trials. While Rooshenas et al²⁸ investigated how clinicians conveyed equipose in six clinical trials, finding that while clinicians intended to set their personal biases aside, equipose was omitted or compromised in 46% of the recorded appointments. Our finding, that embracing this uncertainty was felt to be key, is therefore consistent with the literature, and it points towards the important of adequately supporting and training staff to effectively communicate this uncertainty during future clinical trials.³⁰

Our study demonstrated that the being treated in all intervention arms of a clinical trial was an important theme. It has been widely shown that a pre-existing patient treatment preference is a common reason for not taking part in a clinical trial, while the perception of not getting treatment in a placebo arm is something that has been shown to harm recruitment.³¹ The presence of a placebo or no-treatment control has been shown to be a frequent barrier to recruitment in cancer trials.³² Work using the QuinteT recruitment intervention has demonstrated that failing to explore patient preference and difficulties explaining the trial intervention arms were frequent problems in surgical clinical trials.³³ This has important implications in terms of a trial in CMCJ OA in terms of designing trial interventions, adequately exploring patient preference, and explaining the treatment in each intervention arm.

The keenness of patients in taking part in clinical trials has been well described in the literature. A study by Welton et al³⁴ showed that an altruistic willingness to help and personal benefit were the most frequently stated reasons for taking part. Altruism has been widely reported as a facilitator to patients taking part in clinical trials.³⁵ Our study findings detailing the multiple patient motivators including personal benefit and helping others are consistent with this.

Participants demonstrated an interest in specific ideas including an injection trial and a joint arthroplasty trial. Given that both these interventions are widely used and there is a lack of high quality evidence to support their use, it is perhaps therefore unsurprising that these were trial ideas of interest to clinicians.^{36,37} Participants

preferred the idea of comparing joint arthroplasty to trapeziectomy rather than comparing surgery to a non-surgical intervention, and this appeared to be for a variety of reasons. As surgery was used as a 'last resort', it was felt that recruitment to a trial comparing surgery to a non-surgical intervention would be particularly tricky, while also participants largely felt that surgery was an effective intervention.

Strength and limitations. We used a qualitative design to explore the experiences and perceptions about clinicians' approach to management of CMCJ OA. Qualitative research findings offer an interpretation of data and, as such, the aim is not to be 'reliable' 'valid' or 'unbiased' in line with expectation of quantitative methodologies. The interpretive epistemological position of qualitative research is its strength. However, we took several measures to increase our confidence in the "trustworthiness" of the findings:³⁸ first, we recruited a diverse sample of key clinicians in thumb CMCJ OA care in terms of their professional background, work location and scope of practice within the UK healthcare system. This purposive sampling approach supports the 'transferability' or findings to other contexts.³⁸ Given the nature of qualitative research and the context in which interviews were conducted with those clinicians who volunteered, the study findings cannot be generalised to other contexts. It is likely that other clinicians, depending on their context, might have alternative or additional views. Second, to support the 'credibility' of our findings, we invested regular research time in 'team de-briefing' and PPI consultation in order to challenge and build on our interpretations.

In conclusion, the identified themes provide insight into the way clinicians approach the management of thumb CMCJ OA, which may be useful in designing clinical trials.



Take home message

- Clinicians favoured a flexible 'ladder' approach to managing thumb carpometacarpal joint (CMCJ) osteoarthritis starting with conservative treatment first and the role of steroid injections was highly malleable within this approach.
- Clinicians felt that it was important to manage thumb CMCJ in a shared, collaborative, and holistic manner.
- Surgery was seen very much as a last resort by clinicians, and it was consequently felt that recruitment to a trial comparing surgery to no surgery would be extremely difficult to recruit to.

Supplementary material



The CONSolidated criteria for REporting Qualitative research (COREQ) checklist.

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