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Article:
Lumley, E., O'Cathain, A., Ridsdale, K. et al. (2026) Views on outpatient paracentesis and GnRH antagonists for ovarian hyperstimulation syndrome: a qualitative study of patients and healthcare professionals. Health Technology Assessment. ISSN: 1366-5278

https://doi.org/10.3310/gjmm2923

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Research Article

Views on outpatient paracentesis and GnRH antagonists for ovarian hyperstimulation syndrome: a qualitative study of patients and healthcare professionals

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Published February 2026
DOI: 10.3310/GJMM2923

Abstract

Background: Ovarian hyperstimulation syndrome is a significant complication of fertility treatment, where the ovaries become enlarged if they are overstimulated, resulting in fluid leakage. Ovarian hyperstimulation syndrome can be classified as mild, moderate or severe. Symptoms vary dependent on severity but can include abdominal swelling, pain, nausea and vomiting, and shortness of breath. Treatment typically consists of monitoring initially, with active intervention if the condition progresses to a severe state, requiring hospitalisation. This study explored the acceptability and feasibility of outpatient paracentesis, and of gonadotropin-releasing hormone antagonists, as early interventions for ovarian hyperstimulation syndrome.

Methods: We conducted qualitative semi-structured interviews with healthcare professionals from fertility clinics (n = 8) and patients who had experienced ovarian hyperstimulation syndrome (n = 10) across six United Kingdom fertility clinics. Interviews explored views on the proposed treatment protocols, and potential barriers and facilitators to randomised controlled trials evaluating these treatments.

Results: Both healthcare professionals and patients were supportive of the proposed trials. Key findings included that healthcare professionals recommended clarity on patient eligibility, hospitalisation criteria and consent procedures. Patients expressed a desire to be given more detailed information about potential trials and had mixed opinions on self-monitoring. There were some concerns from both parties about treatment risks, particularly the paracentesis. Healthcare professionals noted a shift to more preventative practice due to the COVID-19 pandemic.

Conclusions: Outpatient paracentesis and gonadotropin-releasing hormone antagonists were perceived as promising interventions. Potential concerns and recommendations around both acceptability and feasibility were raised, which were used to refine the treatment protocols for the Shaping and Trialling Outpatient Protocols for Ovarian Hyperstimulation Syndrome trial.

This article should be referenced as follows:
Lumley E, O'Cathain A, Ridsdale K, Drabble S, White D, Pye C, *et al*. Views on outpatient paracentesis and GnRH antagonists for ovarian hyperstimulation syndrome: a qualitative study of patients and healthcare professionals [published online ahead of print February 25 2026]. *Health Technol Assess* 2026. https://doi.org/10.3310/GJMM2923

Funding: This article presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number NIHR128137.
A plain language summary of this research article is available on the NIHR Journals Library Website https://doi.org/10.3310/GJMM2923.

Introduction

Ovarian hyperstimulation syndrome (OHSS) is a significant short-term complication associated with pharmacological ovarian stimulation for assisted reproductive techniques.

Ovarian hyperstimulation syndrome develops in response to fertility drugs taken to stimulate the ovaries to increase the production of eggs. When there is overstimulation, the ovaries become enlarged and release chemicals into the bloodstream, resulting in fluid from blood vessels leaking out. OHSS results in extra fluid being released around the body, leaking into the abdomen and, in severe cases, around the heart and lungs.[1]

In the UK, the widely adopted Royal College of Obstetricians and Gynaecologists[1] classification categorises OHSS into mild, moderate, severe or critical. Mild OHSS is common and may be an expected side effect of ovarian stimulation with symptoms including abdominal swelling/bloating and nausea. Moderate OHSS cases involve increased fluid accumulation in the abdomen (ascites), increased ovarian size, abdominal distention and discomfort, vomiting and shortness of breath. In severe cases, fluid retention and dehydration can lead to changes in blood composition (haemoconcentration and hypoalbuminemia), while critical cases can result in respiratory distress, thrombosis, impaired renal and liver functions and, in rare instances, death.[2] OHSS can be further classified into early OHSS [typically caused by the ovarian stimulation drugs administered during treatment and usually manifests within 7 days after the final dose of human chorionic gonadotropin (hCG)], or late OHSS (usually occurs 10 days or more after hCG administration and is caused by endogenous hCG from the resulting pregnancy). Late OHSS is more likely to be severe than early OHSS.[3]

In the UK, treatment for OHSS is typically provided only after it has progressed to a severe state, requiring intensive inpatient treatment, which often includes paracentesis: the drainage of ascetic fluid, vaginally or through the abdomen, using a needle/syringe. Prior to this, patients are commonly monitored and provided with medication, such as antiemetics for nausea and analgesia for pain, and advice for rehydration to replace lost fluid. However, research suggests that patients can be managed safely in an outpatient setting, rather than an inpatient setting, which requires admission to hospital for one or more nights. Small-scale studies have suggested that carrying out paracentesis in the outpatient setting,[4–9] and administering gonadotropin-releasing hormone (GnRH) antagonist drugs[10–15] promptly upon the onset of OHSS, may avert the need for hospitalisation.

The Shaping and Trialling Outpatient Protocols for Ovarian Hyperstimulation Syndrome (STOP-OHSS) randomised controlled trials (RCTs) were, therefore, developed to establish the clinical and cost-effectiveness, safety and acceptability of paracentesis and GnRH antagonists in the outpatient setting, as an active management for patients with moderate or severe OHSS.[16] As GnRH antagonists could be dangerous to people who are potentially pregnant, and late OHSS is often caused by pregnancy, the project was designed to be split into two separate trials. Patients with late OHSS would only be randomised to either receive conservative management or outpatient paracentesis. Patients with early OHSS would be randomised to receive either conservative management (with increased monitoring contacts), outpatient paracentesis or daily injections of GnRH antagonists. All three of the treatment groups would also require self-monitoring at home.

As it is not common practice, managing patients in an outpatient setting may require a level of confidence and change in attitudes of healthcare professionals (HCPs). It may also require a cultural change for patients with OHSS. The acceptability of outpatient management compared to inpatient management is likely to vary largely between patients depending on geographical location and social circumstances. Where some patients may find admission to hospital more convenient, others may find this more disruptive and see a clear advantage of being managed in an outpatient setting. A change from no treatment to early treatment of moderate OHSS would require active engagement from patients.

This qualitative study was undertaken to explore the views of HCPs working at fertility clinics, and patients who had experienced OHSS, as part of feasibility work in preparation for the STOP-OHSS trial. Findings were then fed into a 'consensus exercise' to develop the clinical protocols for the delivery of paracentesis and GnRH antagonists in an outpatient setting. The aim of this study was to explore the acceptability and feasibility, to patients and HCPs, of early active intervention for moderate or

severe OHSS occurring at an early or late stage. Further findings from the qualitative interviews focusing on the experience of patients undergoing fertility treatment have been published separately.[17] Here we centre upon the acceptability and feasibility of the proposed study protocols.

Methods

Design

A qualitative approach was required to explore views and experiences in depth. A descriptive qualitative approach, using semi-structured interviews, was appropriate, as this was one of the first studies to focus on experiences of OHSS.[18,19] Participants included both HCPs and patients undergoing fertility treatment, hereafter referred to as 'patients'.

Sampling

All participants were purposively sampled from six UK fertility centres, including NHS and private clinics, both small and large centres, in order to reach a diverse sample.

We purposively selected patients who had experienced early or late, and moderate or severe OHSS that did, and did not, result in hospitalisation. We used a purposive sampling approach as OHSS presents in many different ways, and at different stages of fertility treatment; therefore, we wanted to include patients who could provide relevant insights into the complexity of OHSS, such as variation in symptoms, impact and treatment received.

For the HCPs, within each fertility centre, doctors and clinical nurses with experience of managing OHSS, and research nurses/midwives with experience of recruiting to and running fertility research trials, were all eligible to take part in the HCP interviews.

Recruitment

For the patients, the principal investigator was also asked to identify patients who had experienced OHSS in their centre in the past 18 months. Patients were eligible for interview if they were: aged over 18, able to read and understand English so they could give informed consent and participate in an interview conducted in English, and at least 1 month post OHSS when most acute symptoms were likely to have settled.

The site principal investigator gave HCPs an introductory letter documenting the research team contact details, and a participant information sheet (PIS) seeking permission to pass contact details to the research team. HCPs then contacted the researchers to ask any questions and indicate if they would like to take part, and to arrange an interview.

A HCP at each fertility centre identified patients who had experienced OHSS by using clinical records or outpatient visits. The HCPs approached the patients and offered them an introductory letter, a PIS and a response card with a freepost return envelope. Due to the difficulties recruiting patients via fertility centres caused by the COVID-19 pandemic, we also placed an online advertisement on the Facebook site of a fertility charity.

Data collection

For both HCPs and patients, we conducted qualitative semi-structured interviews virtually or by telephone during the first half of 2021. We did not undertake face-to-face interviews, as originally planned, due to the COVID-19 pandemic. Prior to the interviews, we sent packs containing information about the proposed RCT treatment protocols and asked participants to read through them, explaining that we would be discussing these in the interviews (see *Report Supplementary Material 1* and *Report Supplementary Material 2*).

We asked HCPs about: current experiences of managing and treating OHSS, including discussion of local protocols; their views on the current versions of our treatment protocols; and the potential barriers and facilitators to running the planned RCTs in their centre. We asked patients about: their experiences of OHSS and the treatment they received for it; their views on the plain English versions of the treatment protocols; their willingness to be randomised to the RCTs; and how to ensure that the RCTs were acceptable and feasible for them.

The interviews were undertaken by two experienced female qualitative researchers. The researchers had no prior relationship with participants, and no previous experience of OHSS or of working in fertility services. Interviews were undertaken by telephone or online due to the COVID-19 pandemic, and recorded on an encrypted digital recorder. Reflexive notes were made during and after the interviews. HCP interviews lasted an average of 52 minutes (range 29–63). Fertility patient interviews lasted an average of 77 minutes (range 54–116).

Analysis

Data collection and analysis were iterative in that learning from the early interviews was fed back to the research team who were developing the treatment protocols.[20] After six interviews (three HCPs and three patients) from two centres, the qualitative researchers created a grid

of issues and their potential impact on the treatment protocols, RCT procedures, training for recruitment, or patient information. Then the wider team met to discuss the findings, actions that needed to be taken, and changes to be made to the proposed treatment protocols prior to the next set of interviews. Subsequently, another set of 12 interviews (5 HCPs and 7 patients) were undertaken, asking HCPs and patients to comment on the updated versions of the treatment protocols.

Interviews were transcribed verbatim and coded using NViVo 12™ (QSR International, Warrington, UK) [Lumivero. NVivo (Version 12). 2017. URL: www.lumivero.com] to ensure that all issues raised in the interviews had been considered by the team. All recordings were anonymised for identifiable information and erased after transcription.

A framework analysis[21] approach was selected, as there were specific research objectives, such as exploring the acceptability to patients and HCPs of the proposed treatment protocols, and exploring views about the proposed RCT and its feasibility. Framework analysis involved reading the transcripts to become familiar with the data, Sarah Drabble and Elizabeth Lumley then identified a coding frame of 'a priori' themes and subthemes (based on the research objectives and familiarisation with the data). Elizabeth Lumley, consulting with Alicia O'Cathain, applied this coding frame to each transcript in NVivo, added themes identified through inductive coding, which did not fit into the original framework, and then considered the content of the themes and relationships between them.

Ethical considerations

Ethical approval was granted from the Cambridge South NHS Research Ethics Committee on 29 June 2020 (20/EE/0123). All participants were given detailed information about the study purpose, what involvement would entail, and given the opportunity to ask questions about the study. Informed consent was obtained, either by an electronic consent form sent by e-mail, or by verbal consent recorded at the beginning of the interviews. Confidentiality was maintained by removal of identifying data from transcripts and through use of alphabetical and numerical identifiers unique to each participant to preserve anonymity.

Due to the subject matter of the interviews (OHSS developed during fertility treatment), the research team were conscious that the interviews could be upsetting for some fertility patient participants. In order to manage the potential for distress, we ensured that the interview topic guide (see *Report Supplementary Material 3*) was constructed with input from the study patient/public co-applicant and an experienced fertility research nurse. The topic guide, treatment protocols and the PISs were discussed, adapted and approved by a fertility patient and public involvement group. The PIS advised that patients could pause or stop the interview altogether if they became upset; this was also reiterated at the beginning of the interview. The two researchers that conducted the interviews are a nurse (Elizabeth Lumley) and chartered psychologist (Sarah Drabble) by background; both have extensive experience of interviewing, including covering sensitive topics and how to support interview participants. Throughout the interviews themselves, the researchers were alert to any signs of distress. Some patients did become emotional while being interviewed and were given the opportunity to pause or stop; no one felt the need to do so. As part of the research plan, the team had a process outlined to refer patients back to their fertility centre, or to signpost them to additional support, if it was felt to be necessary.

Findings

Participants

We sampled from six centres in England and Scotland, including four NHS and two private sites. We interviewed eight HCPs (four doctors and four nurses, seven worked in NHS centres and one was from a private clinic). We interviewed 10 patients: 8 who had experienced early OHSS, 1 late OHSS, and 1 patient who had experienced both early and late OHSS; 4 mild, 3 moderate, 1 moderate/severe and 2 severe OHSS; and 2 patients who had been hospitalised for OHSS. Interestingly, three patients reported that they had received one of the proposed RCT treatments (two outpatient paracentesis, and one GnRH antagonist). Patients were from a range of socioeconomic backgrounds, with representation from all English or Scottish deprivation quintiles: two from quintile 1, the most deprived quintile; one from quintile 2; three from quintile 3; three from quintile 4; and one from quintile 5. Nine patients self-identified as White British, while one described herself as British Asian, and the age range was between 28 and 39 years old, with an average age of 30.

Overall response to the proposed randomised controlled trials

Healthcare professionals overall were positive about the proposed RCTs, welcoming a study that addressed treatment for patients who developed OHSS despite preventative measures taken by centres. They recognised that not all cases of OHSS could be prevented and that a focus on treatment was important. HCPs in centres with patients living at a distance actively welcomed the RCTs. Currently, patients with severe OHSS could have

long travel times to reach centres for treatment, while experiencing difficult symptoms, and HCPs felt that this could be avoided using early management of symptoms.

> *Definitely, I think it was daunting the first time I read [the proposed trial information]. I thought 'woah' (participant laughs) You know I'm thinking of patients that we've set up and being in for a while but then what you said before about getting them a stage earlier and getting it when it's more moderate than severe. If the protocol's all in place to do that and it can be managed like that then I do think it would benefit the patient.*
>
> *NHS-based clinical nurse specialist*

Patients in the sample actively welcomed the RCTs, describing how they would rather be at home than admitted to hospital, particularly if they lived a long distance from the hospital. Only one patient we interviewed, who had developed complications from OHSS, favoured less intervention than offered in the proposed RCTs. Otherwise, patients were positive about the RCTs and saw a need to improve current treatments, which they described as 'a wait-and-see approach' with few active treatment options.

> *No, I think it's really good. Like I say you aren't going to learn about something without trying things, are you? And like you say, I think trying to catch it earlier, and then it's easier to manage is ultimately far better for yourself […] not getting poorly and things like that, but equally for the NHS you know it's going to be less costly, less risky.*
>
> *Patient 05 – early, severe OHSS*

> *To perhaps have something that can reduce the severity of it all or early action I do think's really good as opposed to it just being 'you might get it, you might not and if you do, we'll just have to wait and see'. The idea of being able to get on top of it straightaway and perhaps prevent it from becoming severe I do think's a good idea.*
>
> *Patient 18 – early, mild OHSS*

Contextual issues affecting ovarian hyperstimulation syndrome management: the focus on ovarian hyperstimulation syndrome prevention, variation in definitions, and ovarian hyperstimulation syndrome in the wider in vitro fertilisation cycle

Both HCPs and patients discussed issues that were not directly relevant to OHSS management but had the potential to impact on OHSS management and the RCTs.

First, the study took place during the COVID-19 pandemic, and HCPs described changes to how centres approached OHSS during this time, with a move to prevention and more conservative management of OHSS to minimise the need for hospitalisation and risk of infection. HCPs discussed the use of 'long protocols' using antagonist triggers, 'short protocols' with antagonist triggers, HCG levels, estradiol measures, consultant involvement in diagnosis, assessment of symptoms on egg collection, and 'freeze-all' cycles. In a normal in vitro fertilisation (IVF) cycle, an embryo is transferred to the womb a few days after egg collection. However, in a 'freeze-all' cycle, the embryo is frozen until OHSS symptoms have resolved, and the patient has had a menstrual cycle (either naturally or medically induced); the embryo is then thawed and transferred to the womb. HCPs welcomed the focus of the proposed RCTs on treatment as a positive step for those patients who did not respond to, or who had missed, preventative actions.

These COVID-19-related changes were not welcomed by all patients interviewed. Some of the patients found that freezing embryos led to delays in their fertility journey. Others stated that they were not aware that there was a chance of having a freeze-all cycle, leading them to feel under informed and not part of a shared decision-making process.

Second, HCPs identified variation in how well colleagues understand mild versus moderate OHSS. One doctor described how junior staff often wrongly asked for scans of ovary size to diagnose OHSS. Therefore, HCPs wanted clear guidelines on when patients would be eligible for the RCTs, that is, what should be classed as moderate OHSS and when treatments should occur.

Patients discussed a further contextual issue. They described the heavy emotional impact of fertility treatment, where they were willing to do whatever they could to have a baby. To enable them to make an informed choice about taking part in the RCTs, they wanted the RCTs and any treatments to be explained in terms of their wider IVF cycle so that they understood how their cycle would be affected. They wanted to know about the potential for any effect on the number of eggs and embryos, potential for delays to embryo transfer, cost implications (as one patient at a private centre reported having to pay extra for a frozen embryo transfer), risks to current or future cycles, and any potential impact in relation to pregnancy.

Outpatient paracentesis treatment protocol: need to make it feasible in centres and patients need reassurance about risks

Healthcare professionals in one fertility centre described how they were already doing outpatient paracentesis because patients often lived many hours travel from the centre. They were confident that this procedure was of

benefit to patients and was feasible to deliver. These HCPs supported the need for the RCTs because they wanted an evidence base for their current practice. These HCPs also confirmed that they would be willing to stop doing paracentesis as an outpatient procedure for the duration of the RCTs to avoid contamination to the 'treatment as usual' arm.

Healthcare professionals in other centres questioned whether the risks of treating moderate OHSS outweighed the benefits, and whether treatment would be necessary if symptoms were not severe, because they believed that the symptoms could resolve if left untreated. They wanted evidence, clinical justification and reassurance about this proposed intervention. One HCP suggested that earlier treatment with outpatient paracentesis would need to be explained well because it could seem frightening to some patients.

Healthcare professionals also had initial concerns about the feasibility of performing outpatient paracentesis in relation to both their confidence to do this, and the practicalities of performing the procedure within their local facilities. They discussed the need for additional facilities such as a sluice, stocked storeroom, dressing packs, clinical waste bins, private rooms, a specific staff member to monitor paracentesis before and after treatment, intravenous infusion pumps, stands, fluid and adequate pain relief. After raising these concerns in the interviews, HCPs reflected that these issues could be addressed if centres in the RCTs were supported by researchers to develop feasible processes for delivery of, and training in, outpatient paracentesis.

> *I've got experience in both [...] But I would not be happy to do a transabdominal paracentesis in a stand-alone clinic like mine. But I would do trans-vaginal aspiration in a clinic like mine if it was early onset OHSS. I'm not so sure about late onset OHSS whether I would do it or not because when they are already pregnant and they have OHSS their risk of thrombosis will be higher. So I would just worry a little bit about doing that in the clinic I think but we need to understand that a bit more I think. I need to discuss this with colleagues. We can have a discussion what are the pros and cons.*
>
> *Private centre consultant*

> *We are very much an outpatient clinic and I don't know if we would be the area to do this. But you might be able to do them in gynae outpatients just round the corner. It's having all the bits and bobs you know bits of tape, bits of dressing. We're not really equipped for suddenly doing a little minor procedure on the wards really. You want a fully stocked store room really that's got sutures and pots and sterile cotton wool. [...] we have some of the things you need but quite simply we don't have a sluice we could put all the fluid.*
>
> *NHS-based nurse*

Paracentesis was perceived as riskier and more invasive than GnRH antagonists by both the HCPs and patients we interviewed. Patients expressed a range of views about paracentesis. Some patients in the sample found it acceptable, whereas others did not like the idea of a procedure involving a big needle unless it was necessary.

Some patients also expressed concerns about having this procedure for late OHSS when they might be pregnant and discussed the need to consider the risks involved to themselves and the fetus in relation to the severity of OHSS symptoms.

> *I think if you've gone through that much to get pregnant. I think then any procedure that's vaguely in that region, you're going to be quite anxious about. But equally, if you're struggling with it and you're very unwell, then you've got to have some kind of treatment for it, regardless of - it's not something that's going to go away on its own is it?*
>
> *Patient 03 – late, mild OHSS*

> *I think you'd probably want to know 'ok is this going to increase my risk of miscarriage or ectopic pregnancy?' I think that would probably be just the main thing for me.*
>
> *Patient 08 – early, moderate OHSS*

Gonadotropin-releasing hormone antagonist treatment protocol: acceptable as already used in fertility treatment, though some patient concern about risks

Healthcare professionals, in both private and NHS settings, described how the GnRH antagonist proposed in the RCT was acceptable because the drug was already used in other parts of fertility care and so was perceived as less risky and invasive than outpatient paracentesis. Several HCPs described how they employed a proactive preventative approach to OHSS by using GnRH agonist triggers, in addition to 'freeze-all' cycles, with patients who they perceived to be at risk of developing OHSS. One HCP and one patient described the different drugs used, but it was not clear to the interviewer if these were used for OHSS prevention or OHSS treatment. One HCP discussed using a GnRH antagonist as a treatment for early OHSS and indicated that they would not be prepared to stop

using the GnRH antagonist to participate in the RCT, as they believed that using the drug was effective.

> *My […] issue is that, would I be happy to leave somebody in the [control] arm and then to have ascites when I know that if I intervened early (by giving GnRH antagonist as treatment) it would not happen.*
>
> *Private centre consultant*

The patients we interviewed expressed different opinions about GnRH antagonists. The majority of patients in the sample preferred treatment with GnRH antagonists to paracentesis because it was perceived to be less invasive, and there were many references to the familiarity of injecting themselves as part of their fertility treatment.

> *I don't find injections traumatic at all, you just stick a needle in and there you go [laughs]. […] An injection just feels like something routine that I'd have done.*
>
> *Patient 02 – early, moderate OHSS*

However, two patients expressed concerns about the potential for drug side effects. Indeed, one patient said she would not participate in the RCT because of fears around side effects and because she was already taking a number of drugs in relation to her fertility treatment.

> *I think personally if it was me, I wouldn't want to have the injections. That's probably personal to me. I'm quite fussy about injecting myself and just taking medication in general.*
>
> *Patient 16 – early and late, moderate and severe OHSS*

Self-monitoring: some challenges but a welcome addition to treatment

Healthcare professionals stressed the importance of the availability of the right equipment for patients to monitor their symptoms and expressed concerns over the reliability of measuring urine input/output. They suggested alternatives such as measuring ketones using urine dipsticks. One HCP thought that diarrhoea should be added to the symptom list in the treatment protocol. HCPs stressed the importance of having research nurses available to undertake the telephone calls to collect these self-monitoring data from patients. HCPs in private centres asked for support from the RCT team because they do not have research nurses. HCPs stressed the importance of clear information and proformas to aid data collection.

Patients actively welcomed self-monitoring as a benefit of being in the RCTs. They described it as reassuring, giving them a sense of control over their treatment, offering more support than currently offered, making treatment feel more proactive, and an active intervention in its own right. As one patient said: '*I would've loved it*'.

> *I think even just introducing something like the self-monitoring, just makes people feel a bit like something's happening and there's a bit more control and monitoring over it, which is quite reassuring after having gone through all the challenges of IVF. If you develop symptoms then not a lot happens, it feels a bit like 'oh this is at odds with what you've been through really.*
>
> *Patient 03 – late, mild OHSS*

However, some patients expressed concerns and challenges around self-monitoring. Some worried that it might engender anxiety, and doing it in practice might prove difficult – for example, monitoring urine output at work would risk revealing that the patient was undergoing IVF treatment when they had not shared this with their workplace. Phone calls and texts were patients' preferred contact options as these were more regularly checked; one patient had previously missed an important e-mail from her clinic.

Criteria for hospitalisation

Healthcare professionals in the sample believed that hospitalisation should occur if OHSS symptoms became unmanageable. They wanted clear criteria about when to hospitalise patients in the RCTs. Some HCPs expressed concerns about patients with more severe symptoms being managed as outpatients rather than as inpatients. One HCP queried whether hospitalisation should be based on clinical judgement alone. The treatment protocol we presented during interviews stated that hospitalisation would be discussed at the symptom deterioration visit, but it was unclear to some HCPs how this would work.

Patients described how they would rather stay at home unless symptoms such as shortness of breath became frightening, or pain was unmanageable. Patients who had experienced more severe OHSS symptoms felt that there was a point at which they felt unsafe and should be hospitalised.

> *When I was starting to feel quite short of breath, I think that's when I did probably feel better being in hospital. I think you can deal with pain, discomfort those types of things to a certain degree but I think when you feel that you've got all that and you're struggling to breathe as well, I think that's when it goes from being uncomfortable to feeling unsafe with it.*
>
> *Patient 05 – early, severe OHSS*

Randomised controlled trial procedures

Identifying and approaching patients with ovarian hyperstimulation syndrome

As described above, HCPs described an increasing emphasis on prevention of OHSS during the pandemic. They perceived that there were fewer cases of early OHSS and less severe cases of OHSS during this time in comparison to pre pandemic, therefore expressed some concern regarding recruitment of participants.

Patients in the sample said that they wanted to hear about the study from a nurse or doctor in the clinic before being approached by research nurses. Some patients wanted to be approached by nurses because they were perceived as more caring, and patients had developed a greater rapport with them over time. Other patients preferred doctors to make the approach because they would have more confidence in the information given.

There was no agreement about the right time to recruit, with some patients favouring recruitment at the start of the IVF process, while others favoured the start of OHSS treatment. Patients asked that any approach be made with sensitivity because patients attend clinics for different reasons, for example, for confirmation or not of pregnancy, or due to experiencing a miscarriage. Some participants felt that patients and their partners who had had many cycles of unsuccessful fertility treatment might not be receptive to an approach to join the RCT.

Patients saw visits to a fertility centre as part of their treatment pathway and were not concerned about extra clinic visits related to the RCT, as long as there was a degree of flexibility about when they occurred. This contrasted with the views of some HCPs who were concerned about parking, travel costs and distance from the clinic as barriers to participation.

Information, consent and randomisation

Healthcare professionals wanted clarification about who would take consent. Patients in the sample liked the flow diagrams (*see Report Supplementary Material 1* and *Report Supplementary Material 2*) presented within the treatment protocol information in preparation for the qualitative interview study. They described them as clear and easy to understand. One patient suggested having a trial-specific website with videos and links to information, in addition to printed leaflets for patients to refer to, to offer a dyslexia-friendly information resource.

Healthcare professionals had no concerns about randomisation in principle. Most of the patients in the sample said they would be willing to be randomised, but some stated preferences for different arms of the early OHSS RCT. A few patients felt that their preference for one treatment over another would stop them participating in the RCT. Patients in the sample found randomisation to usual care acceptable because they felt that it would provide better care than they currently received due to the self-monitoring of symptoms required in all arms of the RCTs.

Randomised controlled trial outcome measures

During the interview, we asked for views on outcome measures for use in the RCTs. One HCP believed that it could be difficult to identify change in the proposed primary outcome of OHSS-related hospitalisation, so suggested that a secondary outcome around self-management of symptoms may be useful to include. Another HCP believed that as cases of renal failure and deep vein thrombosis were now relatively uncommon, it would not be appropriate to include reduction of cases of either of these as an outcome measure.

In terms of tests used to ascertain presence of OHSS, and grade severity level, two HCPs suggested that a liver function test, that also measures blood albumin level, should be included in the baseline blood tests. HCPs also suggested that due to the subjective nature of many OHSS symptoms, aspects of symptom relief, including pain, shortness of breath and quality-of-life changes, could be appropriately assessed using questionnaires. HCPs perceived that other clinical outcome measures, such as improved renal function and reduction of ascites, should be assessed using measures of urine output, blood tests (urea and electrolytes) and ultrasound scans.

Both HCPs and patients in the sample found the short EuroQol-5 Dimensions, five-level version,[22] consisting of five questions, acceptable. Patients preferred text messages or telephone calls to collect the data, with telephone calls scheduled around work commitments.

Discussion

Summary of findings

The qualitative interviews identified support for the RCTs from both HCPs working in fertility clinics, and from patients, and provided learnings for design of the treatment protocols and the RCT procedures.

Healthcare professionals noted a shift to a more cautious and preventative approach to OHSS, to prevent the need

for hospitalisation during COVID-19. They recommended clearer guidelines on patient eligibility, particularly in distinguishing between moderate and severe OHSS. Additionally, they requested detailed criteria for hospitalisation and consent procedures.

Patients expressed a desire to receive more comprehensive information about potential trials, especially in relation to their overall fertility journey. Opinions on self-monitoring symptoms were mixed; some patients found it empowering, while others considered it impractical. Generally, patients supported the idea of avoiding hospitalisation unless their symptoms were alarming.

Both HCPs and patients raised concerns about treatment risks, particularly regarding paracentesis. Some HCPs also questioned the feasibility of certain procedures. These issues could potentially be addressed through additional training and support from the study team.

Context of other research

There is very little research about the feasibility of using GnRH antagonists or outpatient paracentesis for early management of OHSS. There is also very little other research about patients' experiences of OHSS and treatment for it. A qualitative study in Taiwan identified that patients being hospitalised for OHSS can cause additional family stress.[23] Our findings supported this study in that patients wanted to avoid hospitalisation unless it was really needed.

Strengths and limitations

This is one of first studies to explore HCP and patients' experiences of the management of OHSS. Identifying support for, and concerns about, the proposed treatments and RCTs offered the opportunity to address concerns when refining treatment protocols and RCT procedures.

Due to the COVID-19 pandemic, recruitment to the study was challenging. Some centres closed during the pandemic, and research permissions processes were prioritised for COVID-19-related studies. We recruited fewer participants than planned (18 compared to the intended 24–31). Despite this, we felt that data saturation was reached, as no new findings were identified during later interviews.

Despite informing participants that the research team were independent from clinical care, and that feedback from interviews would be anonymous, the researchers acknowledge that participants may have felt inclined to give positive feedback regarding the protocols if they considered the research team to be affiliated with the trial team.

This study was undertaken in the UK, where access to fertility and cost of fertility treatment differs dependant on where those accessing it live. For a small number of people in some areas, NHS-funded fertility treatment may be free; however, the qualifying criteria for funded fertility treatment does vary. Some private healthcare centres and patients were included; however, we acknowledge that the findings may not be internationally transferable where healthcare systems, and fertility services, differ.

Equality, diversity and inclusion

The researchers ensured that the topic guides, treatment protocols and PISs used understandable and sensitive language and terminology to make the research inclusive. These were developed with assistance from an experienced fertility research nurse, patients and separate Reproductive Health Research Public Advisory Panel.

Participants were diverse in terms of type (early or late) and stage of OHSS (mild, moderate, severe) in patients, and different professions and settings for HCPs. However, our sample was biased towards patients with early OHSS despite multiple actions taken to recruit patients with late OHSS. Unfortunately, only one fertility patient was from an ethnic minority community; therefore, the views expressed here may not be generalisable to all populations.

As far as we are aware, the researchers spoke with only patients who were female from birth, and who identified as women; however, this was not part of the inclusion/exclusion criteria. We did not seek to exclude gender diverse patients, however; with hindsight, we recognise that the language used in the study materials may not have been inclusive.

Implications and recommendations

The findings were fed back to the research team during data collection. Team members were able to consider changes to the treatment protocols, the proposed RCT procedures and RCT design, at a structured Consensus Development Panel attended by five doctors and five nurses. These changes were incorporated into the finalised STOP-OHSS trial protocol, which has since been published.[16] The findings also influenced development of a survey to assess how clinical practices have changed due to the COVID-19 pandemic.

Due to the value of this work, we recommend that future studies on new interventions should conduct similar qualitative preliminary work before confirming their treatment protocols. Other future qualitative work on OHSS management could investigate the views of participants from different backgrounds or minorities.

This article should be referenced as follows:
Lumley E, O'Cathain A, Ridsdale K, Drabble S, White D, Pye C, *et al*. Views on outpatient paracentesis and GnRH antagonists for ovarian hyperstimulation syndrome: a qualitative study of patients and healthcare professionals [published online ahead of print February 25 2026]. *Health Technol Assess* 2026. https://doi.org/10.3310/GJMM2923

Conclusion

In this study, outpatient paracentesis and GnRH antagonists as early treatments for OHSS were mostly found to be acceptable and feasible to patients and HCPs. Several issues were identified which were used to improve the design of the STOP-OHSS trial, and which could impact the delivery of these treatments and the design of future RCTs evaluating them.

Additional information

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Acknowledgements

We express our thanks to Anya Sizer and Kate Brian from Fertility Network UK for their assistance with developing the treatment protocols and attending the trial management group meetings. We also acknowledge the support of the Reproductive Health Research Public Advisory Panel at The Jessop Wing at Sheffield Teaching Hospitals. In addition, we thank the independent Trial Steering Committee, Andrew Horne (Chair), Babak Choordari-Oskooei, Sebastian Hinde, and Ippokratis Sarris, and the independent Data Monitoring and Ethics Committee, Jane Daniels (Chair), Professor James Wason, Raef Faris, and Howard Thom.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Ethical approval was obtained from the Cambridge South NHS Research Ethics Committee on 29 June 2020 (20/EE/0123).

Information governance statement

The University of Sheffield is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Sheffield is the Data Processor; University College London is the Data Controller, and we process personal data in accordance with their instructions. You can find out more about how we handle personal data, including how to exercise your individual rights, and the contact details for University College London's Data Protection Officer here: www.ucl.ac.uk/data-protection/data-protection-0.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJMM2923.

Primary conflicts of interest: Ying Cheong has received Speakers' fees from Ferring, Merck, and Nordic Pharma. Raj Mathur has received payment for Medicolegal expert opinion for

cases in their field of expertise. Andrew Drakeley has received payment for speaking at Ferring, occasional medical reports, support for attending Ferring and IBSA, and Consulting fees for TMRW life science and Cambridge clinical laboratories.

Department of Health and Social Care disclaimer

This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by the interviewees in this publication are those of the interviewees and do not necessarily reflect those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health Technology Assessment programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Publications

Lumley E, O'Cathain A, Drabble S, Pye C, Brian K, Metwally M. Managing ovarian hyperstimulation syndrome: a qualitative interview study with women and healthcare professionals. *J Clin Nurs* 2023;**32**:6599-610. https://doi.org/10.1111/jocn.16701

Pye C, Tinkler L, Metwally M. Clinical research nurse and midwife as an integral member of the Trial Management Group (TMG): much more than a resource to manage and recruit patients. *BMJ Lead* 2023;**7**:152-5. https://doi.org/10.1136/leader-2022-000641

Metwally M, Ridsdale K, Pye C, Dimairo M, Barr A, Cheong Y, *et al*. Outpatient paracentesis for ovarian hyperstimulation syndrome: STOP-OHSS feasibility study and RCT synopsis. *Health Technol Assess* 2026; in press.

The following was still under review when this synopsis was published. The following preprint version is available for the reader; please be aware this may not have been peer reviewed:

Metwally M, Ridsdale K, Dimairo M, Pye C, Cheong Y, Desoya L, *et al*. Ovarian Hyperstimulation Syndrome: The STOP-OHSS RCT of outpatient paracentesis and survey on preventive practices. *medRxiv* 2026. https://doi.org/10.1101/2025.07.18.25331764

Trial registration

This trial is registered as ISRCTN71978064.

Funding

This article presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number NIHR128137.

This article reports on one component of research award *STOP-OHSS (Shaping and Trialling Outpatient Protocols for Ovarian HyperStimulation Syndrome): A randomised controlled trial to assess the clinical and cost-effectiveness of active outpatient management of Ovarian HyperStimulation Syndrome*. For more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/NIHR128137).

About this article

The contractual start date for this research was in December 2019. This article began editorial review in December 2024 and was accepted for publication in September 2025. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and publisher have tried to ensure the accuracy of the authors' article and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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List of supplementary material

Report Supplementary Material 1
Planned RCT treatment protocols given to patients before the interviews for their review

Report Supplementary Material 2
Planned RCT treatment protocols given to HCPs before the interviews for their review

Report Supplementary Material 3
Patient and HCP topic guide

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GJMM2923).

Supplementary material has been provided by the authors to support the article, and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors, and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

GnRH	gonadotropin-releasing hormone
hCG	human chorionic gonadotropin
HCP	healthcare professional
IVF	in vitro fertilisation
OHSS	ovarian hyperstimulation syndrome
PIS	participant information sheet
RCT	randomised controlled trial
STOP-OHSS	Shaping and Trialling Outpatient Protocols for Ovarian Hyperstimulation Syndrome

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This article should be referenced as follows:
Lumley E, O'Cathain A, Ridsdale K, Drabble S, White D, Pye C, *et al*. Views on outpatient paracentesis and GnRH antagonists for ovarian hyperstimulation syndrome: a qualitative study of patients and healthcare professionals [published online ahead of print February 25 2026]. *Health Technol Assess* 2026. https://doi.org/10.3310/GJMM2923