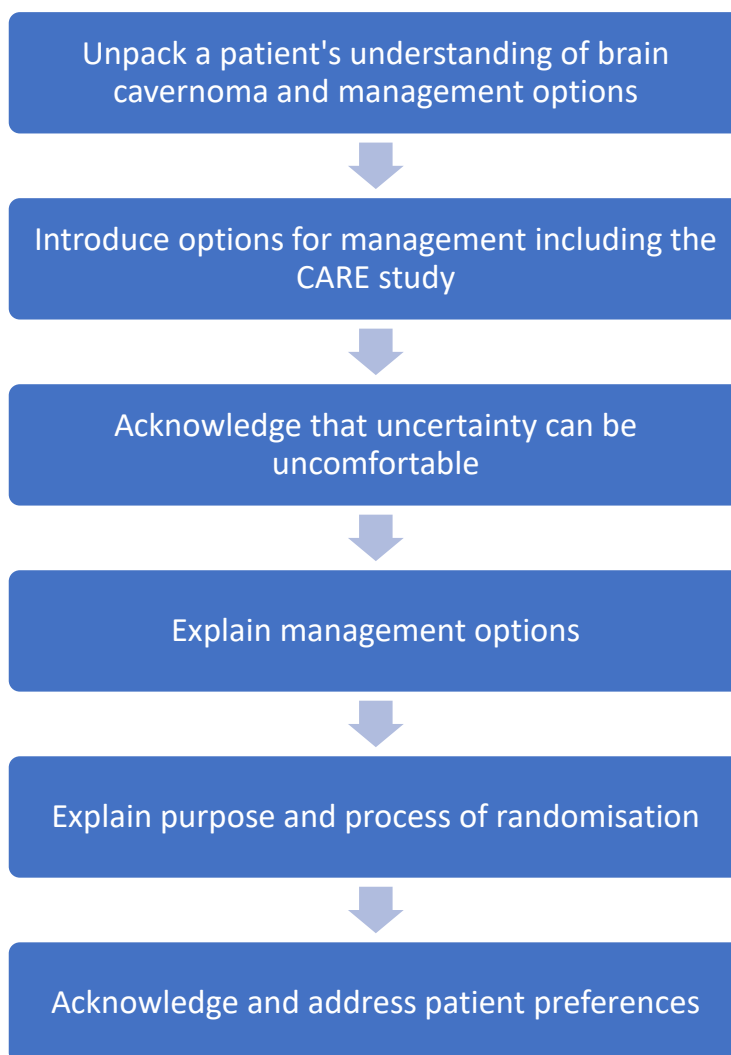




Tips and Guidance: Recruiting to CARE

Structuring your conversations about CARE

- You will have established patterns of how you communicate potential treatment options with patients.
- This guidance is not intended to override these skills, instead to offer a structure which may help to explain research to patients in general and help with CARE specifically.



Unpacking a patient's understanding of brain cavernoma and management options

- It can be helpful to understand what pre-conceptions the patient has about their prognosis and treatment options.
- Some patients may have beliefs about their suitability for certain treatments, or misconceptions about what is available to them.
- Understanding these early can help tailor the discussions you have with patients about CARE.

Introduce options for management including the CARE study

"The decision we're trying to make is whether we use surgery to treat the cavernoma that has caused your symptoms, or whether we decide not to use surgery. There is uncertainty about which of these is best for you. The CARE study is a clinical trial and if you take part, you will have an equal opportunity of being allocated to either treatment including surgery or treatment without surgery."

- Briefly explain that the CARE study is comparing treatment including surgery and treatment without surgery for their cavernoma, because there is uncertainty about which of these options is best amongst the community of doctors and surgeons.
- The study is UK government-funded, with sites across the UK/Republic of Ireland and supported by Cavernoma Alliance UK.

Acknowledge that uncertainty can be uncomfortable

- A team of doctors (the MDT) has discussed their case and agreed that either treatment including surgery or treatment without surgery are equally suitable options for them.
- Being uncertain can leave patients, families and you feeling uncomfortable and looking for a way out of the dilemma of what to do.

"I get the impression you are a bit like me, that you're not sure either and that's why it is so difficult. And my advice in this setting is to enter the trial, as it does take some of that responsibility for making the decision away from us, because the trial itself deals with the uncertainty. Does that make sense?"

- Participation in the study can provide a clear direction and way to manage this discomfort.
- Briefly note that there are benefits and risks to both treatment with surgery and treatment without surgery, which you will cover.

"The conclusion from the multidisciplinary team meeting is that both treatment with surgery and treatment without surgery are equally good, for somebody like you. They both have advantages. And they both have downsides."

Explain management options

- If the patient has already indicated a preference for either treatment with surgery or treatment without surgery, **explain the non-preferred option first.**
- When describing the treatment options, present the **benefits** of treatment **before** discussing the **risks.**
- Use the table provided in the **CARE Supplementary Patient Information Leaflet** to guide your discussions about the treatment options.
- Balance of risks: the upfront risks of surgery are similar to the long-term risks for treatment without surgery. The key message is that these risks balance each other out.

“The idea of doing surgery is very much to see if we can reduce your risk of having a bleed (or epileptic seizure) in the future, so to improve your quality of life in the future. The idea of treatment without surgery is to manage any symptoms now or in future.”

Explain neurosurgery or stereotactic radiosurgery (SRS) as appropriate to the individual patient.

- If possible, be clear prior to the consultation whether you would recommend (1) neurosurgery, (2) SRS, or (3) either neurosurgery or SRS for the individual patient.
- Highlight that neurosurgery/SRS are intended to reduce the future risk of a bleed (or seizure or FND if applicable).
- The risks of neurosurgery/SRS are similar to the risk of a serious bleed if the cavernoma is not treated with neurosurgery/SRS
- We aren't certain whether treatment including surgery or treatment without surgery is better, but:
 - neurosurgery techniques are well-established and the surgeon operating will have plenty of experience performing this type of surgery.
 - SRS techniques have been used for several decades and evidence indicates a balance between the risks of leaving the cavernoma and the risks of having SRS.
- For more information on the process of referring patients for SRS in CARE see [here](#).

Explain medical management

- The benefit of medical management is that any of the risks of neurosurgery/SRS are avoided
- However, this means that there is a continued risk of a bleed – and we cannot say for sure what the impact of a future bleed might be, or how likely it is to occur.

Explain purpose and process of randomisation

- When describing randomisation, it is important to explain both the **purpose** and **process** of randomisation.
- The **purpose** of randomisation is to **create comparable groups** which enables us to make a **fair comparison** between the two groups in the CARE pilot trial.
- Treatment is allocated at random rather than chosen, to avoid bias from the doctor or patient selecting a treatment.
- When describing the **process** of randomisation, it is helpful to avoid explaining it in a way which gives the impression the computer has 'agency' to make a decision about which treatment is best for the patient. Be aware that some patients perceive analogies such as '*tossing a coin*' or '*shaking a dice*' to be a flippant way to determine such a potentially life changing decision.
- The **process** can be described as a way of **providing an equal opportunity** to access either treatment option.
- **Randomisation** can be **framed positively**: to provide a **way out of the dilemma** left by the **uncertainty** as to which treatment option is best.

"We use randomisation when we don't know which treatment is best for the patient. It helps us to create equal groups of patients, without introducing bias"

"You will have an equal opportunity of being allocated to either treatment including surgery or treatment without surgery"

Acknowledge and address patient preferences

- Patient preferences may be weaker than you think.
- Preferences are often based on a lack of knowledge or misunderstandings (e.g. unfounded fears of surgery, or perception that treatment without surgery is the 'easy option').
- Gently exploring patients' preferences is part of the process of ensuring they are fully informed about their options.

Acknowledging preferences

- Using the expression "*Ok, but*" is a helpful way of acknowledging that you have listened to the patient's preference but will balance these preferences with the reasons behind offering alternative options.

- Opening up the conversation can help to unpack the reasons behind preferences.

Addressing preferences

Patient: "I want treatment without surgery because I just want to carry on as I am."

Recruiter: "OK, I understand why you might say that. **But** can I just check that you realise that for your cavernoma, surgery might be a very good option. Can I just check what your feelings are about surgery?"

- Exploring reasons underpinning patient preferences is an important part of making sure patients are making informed decisions.
- Patients may have general preferences, such as wishing to avoid surgery, without a full understanding of what surgery would entail.

Patient: "Well, I've had a lot of thoughts about the study and I'm **not altogether sure** but **I think** I want to go for treatment without surgery"

Recruiter: "Ok. You'd rather have treatment without surgery? So could you help me understand why that is?"

Patient: "Er, not really because, er I don't really know enough about it to be able to, er, give you a serious reason. I just always prefer to avoid surgery if I can."

Recruiter: "OK, that's fine. Perhaps we could discuss what concerns you have about surgery?"

Check willingness to accept randomly allocated arm

- Patients may have some degree of preference and still be willing to join CARE. This could stem from altruistic tendencies (wanting to help others with cavernomas) or a desire to access the increased follow-up and monitoring in CARE.
- It is key to 'check in' with patients prior to proceeding to randomisation that, despite these preferences, they would be willing to accept either of the arms within CARE if allocated. We suggest avoiding asking them if they have a preference: if they have a mild preference they will likely respond 'yes'. Instead explore whether they feel able to accept either arm:

"Can I check that if you go forward with randomisation, you would be comfortable accepting allocation to either treatment including surgery or treatment without surgery?"

Acknowledge benefits of participation

- You can acknowledge the benefits of taking part in a study like the CARE study, which include direct access to the clinical and research team and a 6-month follow up scan.

“I guess the other thing to say about clinical trials is that you usually get good information when you’re involved in clinical trials, you usually get good monitoring and access to the research nurses here, to support you and so on. So, there are advantages of being in studies in that there is support and people that you can ask questions to as things go on.”

This information has been put together based on comments and experiences of your colleagues and is a work in progress. If you have comments or questions about this information or that arise as you discuss CARE with patients, we would like to hear them:

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Links to ‘CARE Chats’ that might help answer frequently asked questions
CARE Chat – How to complete screening logs
CARE Chat – Screen-as-you-go
CARE Chat – Logistics of recruitment
CARE Chat – Approaching patients diagnosed long ago & treated without surgery
CARE Chat – Tips for conversations about the CARE study
CARE Chat – Latest top tips for recruitment conversations
CARE Chat – Audio-recordings
CARE Chat – Describing randomisation
CARE Chat – When to randomise
CARE Chat - SRS