

Title: Patient perspectives and experiences of preventive treatments and self-injectable devices for migraine: a focus group study

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Online Resource 2: Focus group discussion guide

Below is an outline of a semi-structured discussion script. It is to be used as a guide only. The actual areas of conversation are fluid and may be discussed at moments different from the order appearing below. The interview will be approximately 90 minutes, with breaks as needed. The interviewer may adapt the guide to cover the topics in the amount of time allotted for the session, or to best elicit themes from the participants.

Participants should have been consented prior to the focus group discussion using an online consent form. Participants should have also completed a web-based survey prior to the discussion containing sociodemographic and clinical questions.

Participants were asked to bring a valid ID and medication (e.g., prescription, medication), if available. Bringing medication(s) is encouraged but not mandated. **Please review both ID and medication, if available, and record this into the appropriate Excel tracker.** This includes: participant ID and treatment name(s).

Please ensure that confirmation of consent is recorded at the beginning of the audio-recording and prior to the start of any questions.

At the start of the session, the study background and group rules will be explained, and then introductions will begin.

Introduction to Study and Focus Group (10 min)

Thank you for agreeing to participate in this online group discussion. My name is [NAME], and I will be your moderator for the discussion. I am a [JOB TITLE] from Evidera/Global Perspectives and based in [CITY]. This is my colleague [NAME], who also works at Evidera/Global Perspectives; they will be the co-moderator during this focus group. They will be taking notes and assisting when needed.

The purpose of this study is to obtain an understanding from you about your experiences with migraine and your experiences and satisfaction with treatments that you have used or are currently using to prevent a migraine. Everyone who is participating in this focus group has a diagnosis of migraine. Evidera, the company I represent, is conducting the research on behalf of a pharmaceutical company. The pharmaceutical company is interested in understanding patients' preferences for treatment that prevent migraines.

Let me tell you a little about what we are going to be doing. I will start by asking some general questions about your experiences with preventive treatments for migraine. Then we will also look at five different medical injectable devices. I will then ask some questions about your views about the medical devices. We will conclude with a rating exercise to understand each of your personal perspectives about the characteristics of preventive medical treatments for migraine.

Our session today is expected to take about 90 minutes (1.5 hours), and I would like to ask for your full participation for the duration of this time. This session will be audio-recorded.

Before we begin, let me suggest some things that will make our discussion more productive.

- My role here is to guide the conversation, ask questions and to listen. I will move from one topic to the next, as needed, to ensure we finish in time. For some topics I will go around and ask each of you questions. For that purpose, we will use the following order for taking turns [explain in what order], to help identify who has said what in the audio. For some questions, we will use a polling system accessible with your mobile phone with internet access. If you do not have one with you, the moderators can record your answers using extra devices we have with us [Co-moderator: provide instruction to polling].
- During the focus group we will be on a first-name basis, but in later reports, no names will be attached to any comments. Your name will be kept confidential. We have placed name cards on the table in front of you just to help us remember each other's names during the course of the group session. Any personal information mentioned in the discussion will be removed from the transcript.
- I am not a medical doctor, so I am not qualified to give out medical advice. I would also like for you to be as open and honest as possible, there are no right or wrong answers at all during our discussions today, we are interested in your opinions.
- We are planning on taking a break at about (TBD), but please feel free to get up whenever you need to. During the break, you can ask me any questions you might have.

Any questions so far?

Before we get started, I would like to provide some ground rules for the discussion today:

Discussion Group Rules

- Please set any cell/mobile phones on silent mode if you have not done so already. We will however be using these later in the focus group.
- Please all participate in the discussions; if I do not hear from someone, I will likely call on you.
- We are audio-recording the session, so please speak clearly, and only one at a time

- Since it's an audio-recording, it will not pick up things like gestures and head nods. Please do your best to say these things out loud, so they are captured in the transcripts.
- Also, during part of our discussion we'll be reviewing several devices. For ease we have labeled these a, b c etc. Please do your best to say the letter when you are talking about one specifically, so we know when one is being discussed in the audio.
- We'll help to remind you about this as well.
- Please be respectful to everyone's opinion and listen, even if you disagree or have had a different experience.
- Just as a reminder, when we use the term "preventive treatments" we mean a medication that you take regularly to prevent or reduce the frequency, severity or duration of your headaches. We are NOT discussing treatments or medications you use to treat or relieve a headache attack or that you use when you feel a headache coming on.

Any questions before we begin?

(Answer any questions and begin discussion)

Now, let's get started and I will turn on my recorders...

Begin: This is Study EVM-24997-00. today is [Date] and I'm here with focus group (focus group #).

Before we begin, do I have everyone's permission to audio record this interview? (wait to hear yes from each participant)

And can you all confirm that you have signed the online consent form? (wait to hear yes)

Great, let's begin.

Part 1: Treatment Experience and Expectations (30 min)

Please introduce yourselves, using your name and answer these two questions. (*Important for the transcriber to hear which voice is which participant*). I will ask you to do this in the order *[insert order]*.

1. When were you diagnosed with migraine?
 - a. What symptoms did you have at the time of your diagnosis?
2. What treatments have you used to prevent your migraines? Which of these are you currently taking? We are interested in your thoughts and impressions on preventive treatments for migraine.

Co-moderator to note which preventive treatments for migraine the participant is currently taking and which treatments they have taken in the past, but now no longer take.

What do you expect from a treatment that prevents migraine?

If not mention probe on each of the following

- a. Efficacy
 - i. Change in frequency, intensity of migraine, impact on specific symptoms
 - ii. How they feel a preventive treatment would impact their functioning
 1. Physical, social and emotional
 - iii. Any others

- b. Tolerability

What potential side effects of preventive treatments for migraine concern you?

Prompt: List of adverse-effects to probe on:

- i. Cognitive difficulties such as ability to concentrate and memory problems
 - ii. Changes in weight, particularly weight gain
 - iii. Injection site pain or stiffness (only if participants have experience with CGRP mAbs or botox)
 - iv. Other injection site reaction including rash, itchy skin (pruritus), swelling (only if participants have experience with CGRP mAbs or botox)
 - v. Nausea
 - vi. Stomach discomfort
 - vii. Constipation
- c. Convenience

What other aspects of a preventive migraine treatments are important for you?

Prompts:

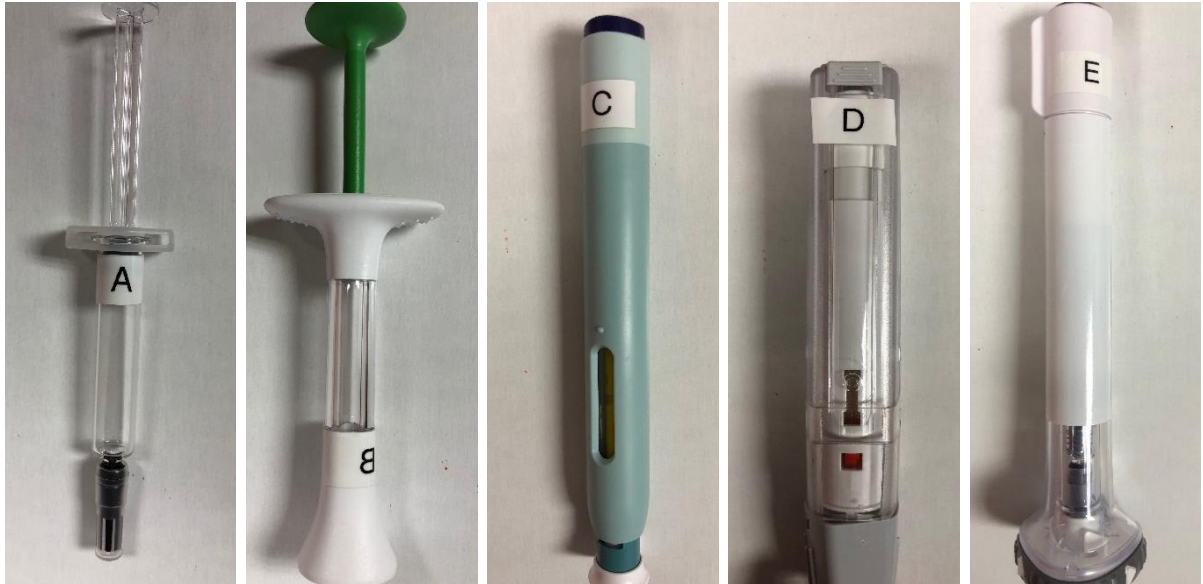
- i. How often you have to take the treatment,
- ii. Where you receive/take the treatment,
- iii. How portable the treatment is

Moderator/co-moderator to note-down specific characteristics that participants mention for use in the final rating exercise

4. Would you be willing to take a preventive migraine medication, that you would need to inject monthly?

Part 2: Review of Medical Devices (40 min)

[MODERATORS and COMODERAORS: Make sure devices are reset as below prior to demonstration]



Now let's look at the five demonstration medical devices.

You may already be familiar with a medical device like this, but there may be some differences, so please pay attention as I provide you the instructions on how to use these medical injectable devices.

The injection is usually administered once a month and you can often do this yourself at home, or a health professional may help you. The devices we have for discussion today are being identified by 'letters of the alphabet A – E' for their name.

There are two examples of each to help you test how to use the device on yourself.

- The devices have had the needles removed and are safe to try out.
 - We will assume that the size of the needles will be identical across the different devices.
- All of them have also had the medicine removed. Therefore,
 - you will not be able to click them as you would if they still had the medicine in them.
 - For the medical devices that have a lock/unlock component (medical device C, D, and E), they will be unlocked as if it is already used for injection in the demonstration.
- All devices can be injected into either the thigh or abdomen. We will be demonstration in the abdomen.

Note to moderator:

- *Each focus group will see 5 medical device types. The order of the medical devices is introduced differs by focus group (e.g., FG1: ABCDE, FG2: CDEAB; FG3: EDCBA).*
- *As each device is being demonstrated, co-moderator to wipe down each with alcohol wipes, and handout two examples for participants to try.*
- *As necessary, if a topic is raised about efficacy that may differ by device during Part 2 discussion, state the assumption that all the devices have the same efficacy and safety profile.*

[PROVIDE FOR STEP BY STEP INSTRUCTIONS ON USING THE MEDICAL DEVICE/DEMONSTRATION]

[MODERATOR: BEGIN DEMONSTRATION; COMODERATOR: READ THE SCRIPT]

The green text below are instructions to make the demonstration activity consistent across 9 FGs.

Medical device A

- Here is the medical device A, (clear pre-filled manual syringe). This is a pre-filled syringe.
- Pick the syringe with one hand, pull the needle cap straight off with your other hand.
 - Do not twist the cap.
 - The needle will be visible.
- Using your free hand gently pinch the skin of the stomach, insert the needle at **45- to 90-degree** angle.
- When the needle is all the way into your skin, use your **thumb** to push the plunger all the way down as far as it will go to inject the medicine.
- To know the dose is complete you must look at the syringe to check the plunger is fully down and there is no medicine left.
- After you have injected the medicine, pull the needle straight out, it does not auto retract.
- *[Moderator instructions: hand the devices out to the group; allow a few minutes to look at the device]*

Medical device B

- This is the medical device B (green and white pre-filled syringe). This is also a pre-filled syringe.
- Firstly, you pull the cap off the syringe.
 - Then pinch the skin of the stomach.
 - The needle will be visible and should be inserted at a **45- to 90-degree angle**.
- When the needle is fully inserted, use your **thumb** to push the plunger down. This needs to be pushed slowly all the way down, as far as it will go, to inject all the medicine.
- To know the dose is complete you must look at the syringe to check the plunger is fully down and there is no medicine left.
- When this is complete, you pull the needle straight out, it does not auto retract.”
- *[Moderator instructions: hand the devices out to the group; allow a few minutes to look at the device]*

Medical device C

- This is the medical device C (blue autoinjector).
- Firstly, you pull the white cap off the syringe.
 - Then pinch the skin of the stomach.
 - The needle will not be visible.
- Place the autoinjector on your skin at **90 degrees**.
- You need to push the medical device down into the skin,
 - wait until the autoinjector stops moving, the shield would push back,
 - so the main body is flat against your skin
- When you are ready to inject, press the purple button on the end—you will hear the **1st click**.
 - You need to continue pushing down on your skin, but do not need to hold the start button because once you press the button, the medical device will automatically inject the medicine.
 - *[Moderator instructions: this will not be possible in the fired devices to see, the shield is fixed outside of the main body]*
- After about **15 seconds** you will hear a **2nd click**, but you must remember to release the button after initially pushing to hear this 2nd click.
 - *[Moderator instructions: say 1, 2, 3, ..., 15 to count for 15 seconds]*
 - This **2nd click** happens just before the full dose of medicine is injected.
 - *[Moderator instructions: device will not click since it is already fired]*

- In addition to the click, if the device's window is facing you, you will be able to see it turn yellow.
- *[Moderator instructions: point to window. In demonstration device it will be red because it's fired]*
- When this is complete, you pull the needle straight out, it does not auto retract.
 - This device has a **needle shield** that travels downward and covers the needle post-injection.
 - *In demonstration device the shield is down because it's been fired. The needle will be covered by the shield]*
- *[Moderator instructions: hand the devices out to the group; allow a few minutes to look at the device]*

Medical device D

- For this medical device D, first, you twist off the cap numbered 1, then you remove the end numbered 2 to unlock this device.
- Place the medical device on your stomach and push down firmly into your skin, you will hear a **loud click**.
 - *[Moderator instructions: device will not click since it is already fired]*
- Hold the medical device there for **three seconds**.
 - *[Moderator instructions: say 1, 2, 3 to count for 3 seconds]*
- When the dose is complete the window will be coloured red.
 - *[Moderator instructions: point to window. In demonstration device it will be red because it's fired]*
- The needle does not auto retract, and you need to pull the needle straight out.”
 - This device has a **needle shield** that travels downward and covers the needle post-injection.
 - *In demonstration device the shield is down because it's been fired. The needle will be covered by the shield]*
- *[Moderator instructions: hand the devices out to the group; allow a few minutes to look at the device.]*

Medical device E

- Here is the medical device E.
- First twist off the base cap.
 - You do not need to pinch the skin on your stomach and
 - do not need to apply pressure to the skin.
- Place the clear base flat and firmly against your stomach.
- At the end of the pen there is an image of a grey locked padlock and a green unlocked padlock.
 - To unlock the device, twist the top “**lock ring**” to the green unlocked padlock position.
- You do not need to hold the device on your skin with pressure.
 - Press and hold the button, listening for a **click**.
 - Continue holding the pen against your skin, after about **10 seconds** you will hear a second click, which means the full dose has been delivered.
 - *[Moderator instructions: say 1, 2, 3, ..., 10 to count for 10 seconds]*
- You can view this device at **any angle** to view how much has been injected and confirm the dose completion.
 - *[Moderator instructions: point to window]*

- The needle **auto retracts**, so you do not need to pull it out, and you will not see the needle after the dose is complete.”
- *[Moderator instructions: hand the devices out to the group; allow a few minutes to look at the device.]*

[Ask the below and document spontaneous answers. Follow up with the probes listed below if they are not discussed spontaneously]

[AFTER INTRODUCING THE MEDICAL DEVICES, PARTICIPANTS WILL BE GIVEN TIME TO TRY ALL MEDICAL DEVICES.]

3. Of the five medical devices we have looked at which do you like most? Why did you select <X> as the medical device you liked most?
 - Which aspects of this medical device cause you to like it the most?
 - Which aspects do you not like about this medical device?
4. Of the five medical devices we have looked at which do you like the least/disliked the most? Why did you select <X> as the medical device you liked the least/ disliked the most?
 - Which aspects of this medical device cause you to dislike it the most?
 - Which aspects did you like about this medical device?
5. If the Device D took 10 seconds to inject, not 3 seconds and required pinching the skin, would it possibly change your mind?

[Please probe on the below, if not already discussed]:

- Convenience to **remove or open the needle shield/cover**
- **Weight** of the medical device
- **Size** of the medical device
 - Volume of the medical device
- **Portability** of the medical device when traveling
- **Storage and disposal**
- Convenience to **hold the medical device in your hand**, during the mock injection
 - Size or shape of the flange/finger rests
 - Size or shape of the plunger
- **How stable the device felt against your skin**, during the mock injection
- **Knowing that you are administering the correct dose**
- **Confidence** in knowing the device was ready to inject
- **Ease or difficulty to know** that your dose is complete
 - Size or type of window
 - Clicking sound
- Ability to inject **without the help** of a caregiver
- Having to pinch the skin before injecting
- Needle not visible due to auto retraction
- **How long it takes** to inject the substance
- **Frequency** of administration
 - **How often** would you be willing to use your most preferred medical device

- **How often** would you be willing to use your least preferred medical device

Part 3: Rating Exercise (10 min)

If sufficient time is left, moderators can carry out part 3.

Now, I will show you a list of treatment aspects that we have discussed in the previous part and ask you to rate each of the aspects by importance to you, when considering a preventive treatment for migraine. We will show you the collected responses on the screen to discuss further.

If you do not have a phone, you can raise your hand for assistance.

The moderators will provide a web address on which participants can send their responses and instructions on how to respond. For those who do not have a phone with internet access, the second moderator will approach the participants with extra phones.

Note for moderator: These aspects could include (but are not limited to) reduction in monthly headache days, injection site reaction, injection site pain, dose confirmation and injection time but may be updated with data collected through the previous rounds.

Respond at PollEv.com/jaeins218

Please rank the following characteristics (from most important to least important).

Attribute 1	
Attribute 2	
Attribute 3	
Attribute 4	
Attribute 5	
Attribute 6	
Attribute 7	

Answers to this poll are anonymous

- Discuss the characteristic rated the highest
 - Can you tell me what you were thinking about when you rated this characteristic?
- Discuss the characteristic rated the lowest
 - Can you tell me what you were thinking about when you rated this characteristic?

Part 4: Closing

1. Would you be willing to use any of the medical devices we reviewed today?
2. Is there anything else related to these medical devices, that you think is important, that was not covered in our discussion?
3. Do you have any other final thoughts or questions?

I will now turn off the recorder. Thank you for participating in our study today. Your input has been very helpful.

You will receive the \$150/£75/€80 remuneration from Global Perspectives within the next two weeks.

Thank you again!

Note for moderator: Please wipe all the devices (3 sets of 5 devices) for sanitary purpose between focus groups.