

5th June 2024

Qualitative interview guide | Version 5_0

The BEYOND study - **B**urden of **rE**sidual **sY**mptoms and fluctuati**ON**s in **D**aily life

1 Introduction

The 1:1 web-enabled telephone interview should last approximately 45 minutes in length (not including scheduling time). The participant will be able to request a break at any point during the interview.

Text written in italics should be read as verbatim.

Text written in red is information specific to the interviewer and should not be read aloud.

All other questions can be asked in such a way as to ensure flow of conversation and to probe sufficiently into topics of interest.

1.1 Research objective:

While the burden of myasthenia gravis (MG) is relatively well-characterized, very little evidence exists to demonstrate the specific burden of fluctuations and residual symptoms on the day-to-day lives of patients.

Therefore, the specific aim of this primary research project is:

- > To describe, from a qualitative perspective, how fluctuations and residual symptoms, despite treatment, may affect a person's day to-day activities while living with generalised myasthenia gravis (gMG).

1.2 Pre-discussion requirements

Before beginning the discussion, please confirm the following (with reference to the form below):

- > The participant has expressed their informed consent to participate in the interview, and for their answers to be recorded.
- > The participant understands the extent to which their personal information will be collected, stored, and processed, and the justification for this to occur within this research.
- > The participant understands how the answers they give will be collected and stored, and for what purposes these answers will later be used.
- > The participant understands that any adverse events or technical complaints related to products of the Commissioning company (if mentioned) must be recorded and reported to regulatory authorities.
- > The participant understands their right to refuse to answer any question, and to withdraw from the interview at any point.

- Introduction:** Hello, my name is **[insert name]** and I am employed by [REDACTED]
[REDACTED] an independent research agency working with [REDACTED] within specific codes of conduct. I am contacting you as part of a health economic and outcomes research study we are conducting on behalf of a pharmaceutical company.
- Purpose:** The purpose of this interview is to describe how fluctuations and residual symptoms associated with myasthenia gravis (MG) may affect a person's day-to-day activities. Put simply, the goal of this interview is to hear from you how the ups and downs and lingering symptoms related to MG can impact patients' daily routines and tasks.
- The research is not intended to be promotional in any way. Any information presented is confidential and should be assumed to be hypothetical.
- Format:** The interview will take the form of a 45-minute, web-enabled, telephone interview and you will be compensated for your time with a remuneration of **[INSERT FAIR MARKET VALUE]**.
- Compliance:** The research will be conducted in accordance with all national laws protecting your personal data and with relevant guidelines, including but not limited to the European Society for Opinion and Market Research (ESOMAR), the European Pharmaceutical Market Research Association (EphMRA), the MRS (Market Research Society), and the BHBA (British Healthcare Business Intelligence Association), and all other relevant national codes of standards and ethics.
- [REDACTED] will act as the Data Protection Officer and Data Controller of any and all personal information processed in this study. Your personal data will be stored appropriately for a period of up to 10 years, in accordance with the study investigator's normal retention policy.
- Respondent rights:** Any information you provide us with will be treated as confidential and you will remain anonymous unless you consent otherwise. You have the right to refuse to answer a question or completely withdraw from the research at any time.
- Recording:** The interview will be audio recorded for analysis, pharmacovigilance, and quality control purposes. Any other use of the recording will be subject to your consent.
- Additional consents:** Do you consent to the following?
- Sharing of anonymized transcripts with the sponsoring company for analysis purposes.
 - Sharing of anonymized quotes with the sponsoring company for future scientific publications or social media posts – this is an optional consent, in case you may voluntarily, and anonymously, accept sharing any outstanding quotes from this interview.
- **Note to interviewer: Not all participants will consent to sharing quotes. This is not a criterion for discontinuation of the interview.**

**Adverse
event
reporting:**

We are required by our client to pass on details of adverse events/product complaints for any of the client's products, mentioned during the course of research interviews. This will be solely for drug safety to fulfil their obligation to the regulatory authorities.

If this happens, we will need to collect details and report the event, even if you have already reported this directly to the company or the regulatory authorities. You will be asked if you give permission for us to pass your contact details to the company's drug safety department for them to follow up. This will have no impact on the confidentiality and anonymity associated with the study itself.

Reminder:

Note to moderator: Remind respondent not to reveal personal details such as their name during the interview.

2 Discussion guide

2.1 Background [10 minutes]

The aims of this section are to:

- > **Introduce the objectives and background of the research.**
- > **Ease the respondent into the interview and open up a free-flowing dialogue.**

Throughout the interview, probe the respondent for rationale and reasoning where possible. Probes can be especially useful for less vocal participants to clarify their answers.

Thank you for agreeing to take part in this interview where we would like to hear from you on how lingering symptoms related to generalised myasthenia gravis, as well as their ups and downs, can impact your daily routines and tasks.

Throughout this interview we encourage you to speak freely and share your opinions with us. Please let us know if you require a short break at any point during the interview.

Before we begin, we would like to ask you about yourself and your experience with myasthenia gravis. Please note that you should avoid sharing any personally identifiable information at any point throughout this interview.

- 1) Tell me a bit about yourself:
 - a) What does an average week look like for you?
 - b) Who do you live with (alone, children, spouse/partner, other family, friends)?
 - c) When you have a free moment, what do you like to do for fun/enjoyment?
- 2) Please could you provide a brief overview of your experience with generalised myasthenia gravis (gMG) from initial diagnosis to now (following treatment)?
 - a) When did you first receive a diagnosis of generalised myasthenia gravis?

Note to interviewer: approximations are fine, but please try to categorise whether it has been <2, <5, or <10yrs.
 - b) What was your experience with receiving your diagnosis?

Probe on whether there were any delays in diagnosing or occurrences of misdiagnosis.
 - c) Has your doctor described your current myasthenia gravis (MG) as any of the following: mild generalised (MGFA class 2), moderate generalised (MGFA class 3), or severe generalised (MGFA class 4)?

Reassure the participant that it is ok if they do not know the grade of their disease.

Probe to understand if the participant has been categorised in different severity levels throughout the course of the disease.

Note to interviewer: Please thank the participant for their insights here and inform them that from this point forwards, we are interested specifically in the impact of residual and fluctuating symptoms, despite treatment, that impact their daily lives.

Please now share your screen and present slide two of the slide deck embedded below for the remainder of the interview:



Delphi panel in MG -
definitions for interview

Please note, for the purpose of this interview we will be using the following definitions:

Residual symptoms: Symptoms that occur despite treatment.

Fluctuating symptoms: Symptoms that occur despite treatment and vary in intensity, frequency, duration etc...

You have been included in this interview as you have indicated that you experience residual symptoms despite being on treatment for generalised myasthenia gravis. We will now ask you some questions to understand your symptoms and how they may change over time.

- 3) Please could you describe which symptoms of myasthenia gravis you continue to experience despite being on treatment?

Symptoms may include, but are not limited to, physical fatigue, difficulty breathing, trouble chewing and swallowing, slurred speech, drooping eyelids, double vision, difficulty walking, talking holding head up, raising arms...

- 4) When thinking about the residual symptoms that you experience with myasthenia gravis:

- a) When do these symptoms manifest during a typical day or a typical week?

Probe for how long these symptoms typically last.

- b) How and to what extent would you say each of these symptoms fluctuate?

Probe on differences between the frequency or intensity of symptoms.

Probe on differences in weekday versus weekend, holidays, or seasons.

- c) Do you believe any of your symptoms are linked to certain occurrences? If so, could you please describe how?

Probe on whether there are any triggers (such as high stress, weather changes, mood) that influence the frequency or intensity of symptoms.

- 5) Considering the symptoms you have noted in your previous answers, please can you rank the three most bothersome in terms of impact on your general life?

Note to interviewer: Please keep the symptoms mentioned in this section in mind throughout the remainder of the interview. It is important that we contextualise these symptoms in all aspects of the participant's life, hence these should be probed for throughout each of the sections, as appropriate according to the flow of conversation.

Additionally, please continuously probe on variations of answers based on whether the symptoms fluctuate.

2.2 Impacts of residual symptoms (despite therapy) on daily activities of patients with gMG. [10 minutes]

The aim of this section is to:

- > Understand the patient perspective on the various impacts of fluctuating or residual symptoms, despite treatment, on the day-to-day life of a person with generalised myasthenia gravis.**

For this research, we wish to learn more about how ongoing and changing symptoms, even with treatment, can impact a person's daily life when living with generalised myasthenia gravis.

- 6) In your experience;
- a) How and to what extent, do the residual symptoms of myasthenia gravis impact your daily activities?
 - b) How and to what extent do fluctuations of these symptoms impact your daily activities?
- 7) Please can you tell me about any aspects of self-care that are affected by the residual symptoms of myasthenia gravis you experience?

Probe for hygiene (e.g., showering, brushing teeth, and styling hair).

- 8) Please can you tell me about aspects of nutrition that are affected by the residual symptoms of myasthenia gravis you experience?

Probe on eating habits (for example, as affected by potential issues with chewing/swallowing or time spent at a dinner table affected by muscle fatigue).

- 9) How and to what extent do the residual myasthenia gravis symptoms impact your sleep quality?

Prompt for examples such as quantity of sleep, ability to fall asleep, waking up in the night, or restless sleep.

10) How would you say the residual symptoms of myasthenia gravis affect your ability to carry out household activities such as:

a) Chores and/or housework?

Prompt for examples such as cleaning, tidying, cooking, doing laundry, etc...

b) Running minor errands?

Prompt for examples such as going to the shops

c) Tasks related to family/pets?

Prompt for caring for children (school runs, homework, bath time) and animals (dog-walking, feeding the pet).

Probe in all sub questions whether fluctuations of the symptoms affect the participant's answer in terms of ability to carry out household activities.

11) In your experience, what is the impact of residual myasthenia gravis symptoms on the amount/intensity of physical exercise you can do, in terms of:

a) Ability to play certain sports?

b) Going for a walk or run?

c) Going to the gym or working out at home?

Probe in all sub questions whether fluctuations of the symptoms affect the participant's answer (for example in terms of unpredictability making it difficult to be part of a team sport, to attend pre-booked gym classes...)

12) In your opinion;

a) How and to what extent do residual myasthenia gravis symptoms impact your choice of / participation in hobbies?

Potential hobbies might include arts and crafts, baking, gardening, playing video games, following sports, reading, using an iPad or other electronic device, watching TV/films, listening to music, etc...

b) Are some of your hobbies affected more by fluctuations in your symptoms? If so, how?

2.3 Impacts of residual symptoms (despite therapy) on the social life of patients with gMG. [5 minutes]

The aim of this section is to:

- > **Understand the patient perspective on the various impacts of fluctuating or residual symptoms, despite treatment, on the social life of a person with generalised myasthenia gravis.**

For this section of the interview, we wish to learn more about how ongoing and changing symptoms, even with treatment, can impact a person's social life when living with generalised myasthenia gravis.

13) In your experience;

- a) How and to what extent do the residual symptoms of myasthenia gravis impact your social life?
- b) How and to what extent do fluctuations of these symptoms impact your social life?

14) How and to what extent have the residual myasthenia gravis symptoms you experience impacted your relationships (such as friendships or family relationships)?

Probe for any feelings of isolation, that could lead to loneliness.

Probes for rationale: difficulty in making plans or having to make specific arrangements to accommodate symptoms, difficulties committing to activities, affected communication, challenges dining out (e.g., if impacted chewing or swallowing)?

15) How and to what extent have the residual myasthenia gravis symptoms you experience impacted your romantic and/or sexual life?

Probes for rationale: difficulty in making plans or having to make specific arrangements to accommodate symptoms, difficulties committing to activities, affected communication, challenges dining out (e.g., if impacted chewing or swallowing)?

Probe on feelings of perceived inadequacy/burdening of partner.

Probe whether fluctuations of the symptoms affect the participant's answer.

16) How and to what extent do you think the residual and/or fluctuating symptoms of myasthenia gravis impact your family, friends, or other caregiver(s)?

Probe on the amount of time family spends in a caregiving capacity (accompanying to medical appointments...)

17) To what extent do you try not to burden your caregiver because of your residual symptoms? How does this impact your life?

Probe on feelings of guilt relating to perceived burden to your caregiver.

18) What activities would you do more of if you had external help instead of relying on family?

2.4 Impacts of residual symptoms (despite therapy) on mental and personal wellbeing of patients with gMG. [5 minutes]

The aim of this section is to:

- > Understand the patient perspective on the various impacts of fluctuating or residual symptoms, despite treatment, on the mental and personal wellbeing of a person with generalised myasthenia gravis.**

For this section of the interview, we wish to learn more about how ongoing and changing symptoms, even with treatment, may impact a person's personal and mental wellbeing while living with generalised myasthenia gravis.

19) In your experience;

- a) How and to what extent do the residual symptoms of myasthenia gravis impact your mental and personal wellbeing?
- b) How and to what extent do fluctuations of these symptoms impact your mental and personal wellbeing?

Probe for feelings of anxiety or frustration.

Probe on impact of participant's self-esteem (if the symptoms impact looks, speech for example).

20) How and to what extent do you feel your independence is impacted by residual symptoms?

Probe for impact on ability to make plans alone, travel, self-care, etc.

21) How and to what extent do the residual symptoms you experience impact your financial situation?

Probe for any costly steps (such as additional transport, or extra support) the participant deals with in their day-to-day lives to compensate for, or alleviate these symptoms?

Probe for the impact on their job stability (e.g., number of days or hours the participant can work)

Probe for the impact on financial decisions such as housing.

22) Do any of your answers to this section on wellbeing vary when considering fluctuations of the residual symptoms? If so, how?

2.5 Impacts of residual symptoms (despite therapy) on work and education in patients with gMG. [5 minutes]

The aim of this section is to:

- > **Understand the patient perspective on the various impacts of fluctuating or residual symptoms, despite treatment, on the work and education of a person with generalised myasthenia gravis.**

For this section of the interview, we wish to learn more about how ongoing and changing symptoms, even with treatment, may impact a person's work and/or education while living with generalised myasthenia gravis.

Note to interviewer: please only ask specific questions in this section if applicable to the participant's situation.

23) In your experience;

- a) How and to what extent do the residual symptoms of myasthenia gravis impact on your work and/or education?
- b) How and to what extent do the fluctuations of these symptoms specifically impact your work and/or education?

Probe on ability to study for long periods of time, impacted memorisation, adhering to deadlines, etc. Probe on impact of ocular fatigue symptoms and associated reading challenges.

24) Have you experienced any challenges with learning job roles or career-related skills as a result of the residual symptoms of myasthenia gravis?

Probe for impact on travel, communication, focus on tasks, adhering to deadlines, etc. Any specific symptoms such as those related to neck weakness and/or ocular fatigue and associated reading challenges.

25) Have you experienced challenges with commuting (e.g., driving, cycling, public transport) to work as a result of the residual symptoms of myasthenia gravis?

26) Have you experienced any challenges with learning new skills outside of work as a result of the of the residual symptoms of myasthenia gravis?

Probe for skills such as home improvement, hobbies, etc. Probe on impact of ocular symptoms and effect of neck weakness.

27) Do any of your answers to this section on career vary when considering fluctuations of the residual symptoms? If so, how?

2.6 Impacts of residual symptoms (despite therapy) on planning for the future for patients with gMG. [5 minutes]

The aim of this section is to:

- > Understand the patient perspective on the various impacts of fluctuating or residual symptoms, despite treatment, on the long-term plans of a person with generalised myasthenia gravis.**

For this section of the interview, we wish to learn more about how ongoing and changing symptoms, even with treatment, may impact a person's long-term plans and life goals while living with generalised myasthenia gravis.

28) In your experience, how and to what extent do your residual symptoms of myasthenia gravis impact your long-term plans?

29) How and to what extent have the residual myasthenia gravis symptoms you experience impacted your plans for a family?

Probe for impact on marriage, number of children, concerns over pregnancy, parenting, impact on their partner(s).

30) How and to what extent have the residual myasthenia gravis symptoms influenced your long-term career goals?

Probe for both choice of career and continuation/promotions within the job.

31) In your opinion, does having generalised myasthenia gravis have long-term impacts on any of your other life goals?

Probe for perceived challenges with these goals being more difficult to achieve or envision.

32) Do any of your answers to this section on long-term impacts vary when considering fluctuations of the residual symptoms? If so, how?

2.7 Conclusion [5 mins]

This section can be used to summarize any key points made earlier in the discussion, and to identify any final comments the respondent would like to be captured.

For this section of the interview, we wish to capture any final thoughts or questions you may have to conclude the interview.

33) Considering the ways you are affected by symptoms of myasthenia gravis despite treatment, please can you rank on a scale from 0-10 how you would feel if you were to continue experiencing the same residual symptoms and fluctuations for the next months (0: utterly unhappy and depressed; 10: extremely happy and satisfied)?

34) Is there anything else we have not covered today that you would like to add regarding impacts on your daily life with generalised myasthenia gravis, despite being on treatment?

35) Are you happy to be contacted again if further clarification on your responses is required?

Thank the participant for their participation.

Finally, on behalf of myself and of the research team, I would like to thank you for taking part in this interview and sharing your experiences with generalised myasthenia gravis.