An internet based survey of migraine patients to study the impact of COVID-19 pandemic and lockdown in India on their disease activity and quality of life

Conducted by:

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THIS IS AN ACDEMIC SURVEY WITHOUT ANY COMMERCIAL INTEREST AND NOT SPONSORED BY ANY PRIVATE / PHARMACEUTICAL AGENCY
PARTICIPANT INFORMATION SHEET

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here.

PURPOSE OF THE RESEARCH STUDY: Migraine is a type of recurrent headache which is very common in general population and is highly disabling medical disease. It has been estimated that 1 in 4 individuals in India suffer from migraine. During the time COVID-19 pandemic and countrywide lockdown, it is possible that migraine patients are being impacted. This web based survey wants to study this impact and how this pandemic and lockdown affects the quality of life in person’s suffering from migraine. The survey consists of 5 sections consisting 50 questions and will roughly take 8-10 minutes of your time. Data collected in this survey will be totally anonymous (you can not be identified) and confidential. We will not be collecting any personal information and the responses given will not be shared with anyone. So, no-one will know who you are or what your answers were.

The data that will be generated will help us in identifying the impact of this pandemic on Indian migraine sufferers and how best they can be helped. Thank you for your participation and time.

WITHDRAWAL FROM STUDY: You are free to withdraw your consent and discontinue your participation at any time without prejudice.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS: Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

PRINCIPAL INVESTIGATOR (PI): Dr Debashish Chowdhury, Director-Professor of Neurology, GIPMER, New Delhi. You can contact PI by email: profdebashishchowdhury@gmail.com; mobile: 9718599306
INFORMED CONSENT FORM

I give informed consent to participate in the study: "An internet based survey of migraine patients to study the impact of COVID-19 pandemic and lockdown in India on their disease activity and quality of life".

I have read the information sheet provided and I give full consent for being enrolled in the above study and I reserve my rights to withdraw from the study whenever I wish without prejudice.

Kindly note that this survey is only for person above 18 years of age

| I don't agree | I agree |

If the person says I don’t agree a pop up window will be saying “We note that you are unable to participate in the survey. However, if circumstances change and you are willing to take the survey, please do revisit us. Thanks for your interest"

START SURVEY

| Enrolment number | Starts with 1 |
### Section 1
**These questions are to ascertain some general facts about you**

|   |   |   |
|---|---|---|
| 1 | What is your age? | Pop up appears: 18 years to 100 years |
| 2 | What is your gender | Male, Female, Other |
| 3 | What is your occupation | Student, Employed in Government, Employed in private sector, Self employed, Non employed, Retired |
| 4 | What is your marital status | Single, Married, Widower/widow, Divorced |
| 5 | In which part of India do you stay | Pop up appears listing all the states and UT of India |
| 6 | Do you stay in | Village, Small city, Metropolitan city |
| 7 | Are you an essential care worker for COVID-19 (doctor, nurse, paramedic, press, police, defence) | Yes, No |

### Section 2
**These questions are to ascertain that you suffer from MIGRAINE HEADACHES**

|   |   |   |
|---|---|---|
| 8 | Do you suffer from recurrent headaches? | Yes, No |
| 9 | Have you ever been diagnosed with migraine by a doctor? | Yes, No |
| 10 | Has a headache limited your activities for a day or more in preceding 3 months before the lockdown? | Yes, No |
| 11 | Do you have nausea (tendency to vomit) or vomit when you have headaches? | Yes, No |
| 12 | Does normal light or normal sound bother you during the headaches? | Yes, No |

*To proceed further with the questions:*

1. Answer to question 8 must be **yes**. **If no, the survey shall not proceed further.**
2. If Answer to question 9 is **yes**, then proceed to **Question 13**
3. If Answer to question 9 is **no**, then at least **two answers of questions 10,11,12** must be **Yes to proceed to question 13**
4. If these condition are not fulfilled, the participant is taken to **question no 48** (note: before that a pop up appears which says that “Thanks for your participation. Since you are not suffering from recurrent headaches or your headaches do not conform to migraine, we shall not proceed further with the survey. However, kindly answer **ONE more questions** about your present quality of life so that we can compare it with migraine patients”. **AFTER THIS FOR THIS PARTICIPANT THE SURVEY ENDS AND HE IS SHOWN THE LAST PAGE OF “THANK YOU”**)

| Section 3 | These questions are to ascertain the magnitude of your migraine problem BEFORE THE COVID-19 PANDEMIC AND LOCKDOWN |
|-----------|----------------------------------------------------------------------------------------------------------|
| 13        | How many migraine days did you usually suffer in a month (BEFORE THE LOCKDOWN)? Pop up appears: 1 day to 30 days |
| 14        | How much duration of migraine headache attack used to last if you did not take any medicines to relieve your acute headaches? Pop up appears: First option would be: I always take medicines. Then start with less than 4 hours, 4 hours to 72 hours. Last option would be more than 72 hours |
| 15        | Do you use medicines to get relief of your acute headaches? Yes No If no, take the participant to question no 19 |
| 16        | How much duration of migraine headache used to last if you took medicines to relieve your acute headaches Pop up appears: 0.5 hours to 72 |
| 17        | What has been the usual severity of your headache pain Mild Moderate Severe |
| 18        | Can you name your acute medicine? Please type the medicines name I don’t remember |
| 19        | Do you use any of the following home remedies to treat your acute attacks (you can fill more than 1 choices) Sleeping Tying a band Applying balm Take tea or coffee Induce vomiting |
| 20        | Do you use any preventive (regular medicines) medicine to decrease your headache frequency Yes No If no, take the participant to question no 22 |
| 21        | If yes, can you name the regular medicine? Please type the medicines name I don’t remember |

| Section 4 | These questions are regarding the impact of COVID-19 pandemic and lockdown on your migraine headaches |
|   | Question                                                                                      |   |
|---|----------------------------------------------------------------------------------------------|---|
|22 | When did you first learn about the COVID19 pandemic?                                          |   |
|   | January 2020                                                                                 |   |
|   | February 2020                                                                                |   |
|   | March 2020                                                                                   |   |
|23 | Has your migraine worsened after the lockdown?                                                |   |
|   | Yes                                                                                          |   |
|   | No                                                                                           |   |
|   | Not sure                                                                                     |   |
|   | **If no, the participant is taken to question no 31**                                        |   |
|24 | Have your headaches become more frequent in terms of attack frequency after the lockdown?    |   |
|   | (say, earlier you used to have 3 attacks per month and now it has become 6 per month)        |   |
|   | Yes                                                                                          |   |
|   | No                                                                                           |   |
|25 | Have your headaches become more frequent in terms of headache days per month after the lockdown? (say, earlier you used to have 3 days of same headache per month and now it has become 6 days per month) |   |
|   | Yes                                                                                          |   |
|   | No                                                                                           |   |
|26 | Have headache attack duration become more after the lockdown? Have headache attack duration become more after the lockdown? (say, earlier you used to have headache attack for 3 hours and now it has become 6 hours) |   |
|   | Yes                                                                                          |   |
|   | No                                                                                           |   |
|27 | Have your headaches become more severe after the lockdown? Have your headaches become more severe after the lockdown? (say, earlier you used to have mild or moderate attacks but now they have become severe) |   |
|   | Yes                                                                                          |   |
|   | No                                                                                           |   |
|28 | Overall how much worsening in your headaches occurred after the lockdown as compared to pre-lockdown? (this is a rough estimate, not exact) |   |
|   | 25%                                                                                          |   |
|   | 50%                                                                                          |   |
|   | 75%                                                                                          |   |
|   | 100%                                                                                         |   |
|   | Not sure                                                                                     |   |
|29 | Do you feel the worsening of your headaches is related to lockdown?                          |   |
|   | Yes                                                                                          |   |
|   | No                                                                                           |   |
|   | Not sure                                                                                     |   |
|30 | What do you think is/are the most likely reason(s) for worsening of your migraine (you can fill more than 1 choice) |   |
|   | Anxiety because of COVID19 pandemic and spread of infection                                  |   |
|   | Inability to go out for relaxation                                                           |   |
|   | Inability to access healthcare (doctors, hospitals etc)                                     |   |
|   | No able to get                                                                               |   |
|   |   |   |
|---|---|---|
|   | acute /preventive medication because of lockdown* |   |
|   | Increased household work |   |
|   | Financial worries/ fear of loss of job/ less salary |   |
| 31 | Did you have headache yesterday? | Yes |
|    | No |   |
|    | If answer is no, the participant is taken to question no 36 |   |
| 32 | If yes, was it the same type of headache that you usually have? | Yes |
|    | No |   |
| 33 | Did you take acute medicines yesterday to get relief of your acute headaches? | Yes |
|    | No |   |
| 34 | How long did it last? | Less than 4hours |
|    | 4-12 hours |   |
|    | 12-24 hours |   |
| 35 | How severe was it? | Mild |
|    | Moderate |   |
|    | Severe |   |
| **Section 5** | These questions are regarding the impact of COID -19 pandemic and lockdown regarding your access to health care |   |
| 36 | Were you able to access your doctor for your headache? | Yes |
|    | No |   |
|    | If no, the participant is taken to question no 39 |   |
| 37 | If yes – how did you get access to your doctor? (you can fill more than 1 choices) | Personal Visit |
|    | | Telephonically (landline or |
|   |   |   |
|---|---|---|
|   | If the consultation was provided by means other than personal visit, were you satisfied? | Yes  
No |
| 38 |   |   |
|   | What were the reasons for not able to access your doctor? | Doctor was not contactable  
Clinic was closed  
Doctor was contactable but he was not providing consultation without personal visit  
Did not go because transport was not available because of lockdown  
Did not go because I was afraid of COVID patients at clinic/hospital |
| 39 |   |   |
|   | Were you able to get your preventive and medications for acute relief of migraine during the lockdown? | Yes – always  
Sometimes with difficulty  
No |
| 40 |   |   |
| If no, go to Q42 |   |   |
| 41 | If yes or sometimes with difficulty, how difficult was it for you to get treatment for your unresponsive severe headache? | Very difficult  
Somewhat difficult |
| Question | Description | Options |
|----------|-------------|---------|
| 42       | If you were not able to get medication what did you do for relief of headaches (you can fill more than 1 choices) | Take rest and sleep it over, Used balm/oil, Used other household remedies |
| 43       | During the lockdown period did you have a severe headache that did not resolve with your usual medication and lasted for days? | Yes, No |
| 44       | If yes how difficult was it for you to get rescue treatment for your unresponsive severe headache? | Very difficult, Somewhat difficult, Not difficult |
| 45       | During such an unresponsive severe headache were you able to contact/consult your doctor? | Yes, No |
| 46       | Were you satisfied with the consultation provided by the doctor for your unresponsive headache? | Yes, No |
| 47       | If you were not able to contact/reach doctor during a severe headache – what was the most likely reason? (you can fill more than 1 choices) | Doctor was not available/ contactable / Physician’s clinic was closed, The usual hospital was converted to a dedicated COVID 19 facility and was not accepting non – COVID patients, Not able to reach hospital/clinic because of lack of transport, Was afraid of going to hospital because of the fear of contacting COVID19 |
| 48 | What is the quality of your life during the past month? (Are you happy, full of energy, feel healthy, having good relations with other members of your family and feel financially secure for the past 1 month?) | Very good | Good | Average | Bad | Very bad |
| 49 | Do you think your headaches affected your quality of life during past 1 month? | Very likely | Likely | Not sure | Unlikely |
| 50 | Finally, I want to ask you a hypothetical question. Suppose, there is a treatment available which can make your headaches go away during this period of lockdown. How much you are ready to spend for this treatment? | Rs 100/- max per month | Rs 500/- max per month | Rs 1000/- max per month | Rs 10,000/- max per month | Rs 30000/- max per month | If more than this, write the actual value here |
Thanks you very much for your time and participation.

Your inputs shall be invaluable in understanding the impact of COVID-19 pandemic and lockdown on migraine patients in India.