

INVESTIGATION OF BEHAVIOUR BY DOGS PRIOR TO HUMAN EPILEPTIC SEIZURES AND POTENTIAL UNDERLYING MECHANISMS: EXPERIMENTAL PROTOCOL.

WP1 International inventory of seizure alert dogs:

- 1. Title of the study:** Investigation of behaviour by dogs prior to human epileptic seizures and potential underlying mechanisms. Part 1: International Inventory of Seizure Alert Dogs.

- 2. Introduction:**

We are a research group from Ghent University (Belgium) investigating whether and how some dogs seem able to detect imminent epileptic seizures.

If you would like to participate, please read this form carefully. If you have any questions, don't hesitate to contact us and we will be more than happy to give you more information about the study and how we use the data.

- 3. Study description**

Despite general public interest, the number of seizure alerting dogs across the world is still unknown, particularly the number of dogs who learnt to alert without any training. This international questionnaire aims to compile such a database of alerting and not alerting dogs. We will use it to study possible relationships between the type of seizure, prodromi, aura, etc. and the behaviour of the dog. We hope that this project will be able to provide information that will make it easier to train dogs to accurately predict seizures. Our final goal is to help epilepsy patients by adding predictability to their seizures.

In this stage of our research, we are trying to reach as many patients with epilepsy that own a dog as possible.

The survey is aimed to:

- A) People (18-year-old or older) who have been diagnosed with epilepsy
- B) Parents/legal representatives or children (younger than 18-year-old) with epilepsy
- C) Legal representatives of people with learning disabilities than have been diagnosed with epilepsy.

4. Risks and benefits of participating in the study

Participation in this study is completely voluntary.

There are no obvious direct risks for participating in this survey. Nevertheless, you don't need to answer any questions that make you uncomfortable.

While there will be no direct benefit to you, your participation is likely to help us find out more about how some dogs detect and react to seizures. We expect this to have a future impact on the training and acceptation of seizure alerting dogs as reliable aids for epileptic patients.

You will not be provided any economic incentive to take part in the research.

5. Confidentiality

The information you provide in this survey is for our research only and it will be kept private. We will not provide any information about your answers or contact details – should you decide to include them- to any third parties. The information recorded is confidential, your name will not be included in the analysis of the data. The information about you in our analysis will have a number on it instead of your name. Only the researchers will know what your number is and we will secure that information with a lock and key. If you decide to give us your email for further contact, it will only be accessed by the main researcher.

6. Sharing the Results

Nothing that you tell us by filling in the questionnaire will be shared with anybody outside the research team, and nothing will be attributed to you by name. Learning and outcomes from this study will be shared with service dogs trainers and epilepsy support groups. Each participant that so wishes will receive a summary of the results. We will publish some results (again, no information can be traced back to you) so that other interested people may learn from the research.

7. Privacy

This survey is being administered by the University of Ghent using a survey system provided by a third party, SurveyMonkey. Any personal information you submit as part of this survey will be stored and processed by SurveyMonkey on our behalf, in accordance with its Privacy Policy.

8. Ethical committee approval

This study was approved by the Ethical Committee of Ghent University Hospital. In no case should you consider the approval of the Commission for Medical Ethics as an incentive to participate in this study. In accordance with the Belgian law of December 8th, 1992 and the Belgian law of Augustus 22, 2002, we will protect your personal environment and you will be allowed access to the collected data. Any incorrect data can be adjusted on your demand.

Every research is conducted in accordance with the guidelines for good clinical practice (ICH/GCP) which are based on the declaration of Helsinki for protection of individuals who participate in clinical studies.

9. Injury due to participation in the study (only for participants in Belgium)

The researcher provides compensation and / or medical treatment in case of injury due to participation in the study. For this purpose, an insurance has been established with faultless liability in accordance with the Human Experiment Act of May 7, 2004. In this contingency, your information may be passed to the insurer.

10. Who to contact.

For more information or any comments you can contact the main researcher, drs Ana Martos, at this email address: ana.martos@ugent.be or using the following number +32 9-2647818 (Belgian number)

Ana Martos Martinez-Caja
E-mail: ana.martos@ugent.be

Phone: (+32) 09 264 78 18 (In English, Spanish and Italian)

Christel Moons
E-mail: christel.moons@ugent.be

Phone: Tel. (+32) 09 264 78 09 (In Dutch, French and English)

11. How to fill in the questionnaire?

This questionnaire has three main parts.

In the first part we will ask short questions about the seizures that you or someone in your family experiences. If you are a parent/guardian of an epileptic child or the legal representative of a person with a mental disability, please indicate so in the first page of the questionnaire.

The second part is about your dog. We will ask whether your dog is an assistance dog or a companion dog and whether it has ever “alerted” (that is, shows a behaviour change that you have associated with an imminent seizure) in any way before a seizure. If your dog has never alerted, don’t worry, we will still need your help with the next part of the questionnaire.

The third part will help us to know more about the kind of relationship that you and your dog have.

Please note that there are no right or wrong answers to any of these questions. We want to learn about you and your dog.

The questionnaire can be completed in 20-45 minutes, depending on the number of dogs.

Each set of questions has instructions on how to answer them. You can decide not to answer most of the questions by selecting the “I prefer not to say” option or by leaving the question blank. Some questions may require an answer to continue but you can stop and leave the questionnaire at any point.

It is possible to leave the questionnaire and return later. Your answers will be saved and you will be able to continue from the point where you left it automatically. Once you submit the questionnaire it will not be possible to change your answers

INFORMED CONSENT FOR EPILEPSY PATIENTS

Please confirm that you agree with the following statements

I have read the previous information, or it has been read to me. I have had the opportunity to contact the researchers to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study. []

I understand that this study has been approved by the Ethical Committee from Ghent University. This approval is not the only reason I have agreed to participate in the study. []

I declare that I have been informed about the study in a comprehensible way. []

I am aware that for the participation in this study, no additional costs are incurred and that there is no financial benefit attached to it. []

I can remove myself from the questionnaire at any time. I am aware that the answers of this survey are confidential and the data will be anonymised for analysis. I realize that anonymous data cannot be removed from the analysis. []

The refusal of further participation in the study will not have any effect on the rest of my treatment and my relationship with my dog's trainer or my doctors.

Name of the participant: _____

INFORMED CONSENT FOR MINORS BETWEEN 12 AND 18.

Please ask your child to read and sign this text to show his/her consent to the participation in this survey

Hello! My name is Ana Martos, I am a researcher from Ghent University. My job is to study how dogs can help people that have epilepsy. I am interested in how we can train more dogs to tell their owners when they are going to have a seizure, so they have time to prepare.

I am asking people with epilepsy that live with a dog to answer some questions. It would be great if you and your dog could help me. If you want to participate in the study, you can indicate it below. I will then ask your parents or guardian to answer some questions about your seizures and about your dog but it would be even better if you help them answer. I will use this information to learn about why some dogs are able to sense the seizures before they start.

I will also ask your parents or guardian if they agree to answer the questions but they don't have to participate in this research if you don't want to. It's up to you. If you decide not to be in the research, it's okay and nothing will change with your doctors or dog trainers.

I won't tell other people that you are in this research and I won't share information about you to anyone who does not work in the research study. If you want, once we finish, we will send you an email with the results written. Afterwards, we will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do. We won't use neither your name your parent's or guardian's.

For any questions, you can contact me in the following email address: ana.martos@ugent.be and I will be happy to clarify any doubts that you may have.

- A. I have read and understood the previous information about the study and I am ok with my parent/guardian answering some questions about my seizures and about our dog []
- B. I don't agree to take part in the research []

Name of the minor: _____

INFORMED CONSENT FOR PARENTS/GUARDIANS

Please confirm that you agree with the following statements

I have read the previous information, or it has been read to me. I have had the opportunity to contact the researchers to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study. []

I understand that this study has been approved by the Ethical Committee from Ghent University. This approval is not the only reason I have agreed to participate in the study. []

I declare that I have been informed about the study in a comprehensible way. []

I am aware that for the participation in this study, no additional costs are incurred and that there is no financial benefit attached to it. []

I can remove myself from the questionnaire at any time. I am aware that the answers of this survey are confidential and the data will be anonymised for analysis. I realize that anonymous data cannot be removed from the analysis. []

The refusal of further participation in the study will not have any effect on the rest of my treatment and my relationship with my dog's trainer or my child's doctors. []

Name of the participant: _____

INFORMED CONSENT FOR LEGAL REPRESENTATIVES

Please confirm that you agree with the following statements

I have read the previous information, or it has been read to me. I have had the opportunity to contact the researchers to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study. []

I understand that this study has been approved by the Ethical Committee from Ghent University. This approval is not the only reason I have agreed to participate in the study. []

I declare that I have been informed about the study in a comprehensible way. []

I am aware that for the participation in this study, no additional costs are incurred and that there is no financial benefit attached to it. []

I can remove myself from the questionnaire at any time. I am aware that the answers of this survey are confidential and the data will be anonymised for analysis. I realize that anonymous data cannot be removed from the analysis. []

The refusal of further participation in the study will not have any effect on the rest of the dependent's treatment and my relationship with my dog's trainer or doctors.

Name of the participant: _____