Information letter scientific research; Video glasses on the pain clinic

1. What is the purpose of the study?

A visit to the hospital for a medical procedure increases tension and emotion in many people. This is very understandable, which is why we are now investigating whether we can make your stay in the hospital more pleasant by using video glasses during the treatment.

How much fear / pain someone experiences during a nerve block differs per person. By using the video glasses, we hope to be able to provide you with sufficient distraction so that you will experience less fear and / or pain during the treatment.

2. Which product is being investigated?

The video glasses are a kind of glasses with headphones that allow you to watch and listen to a video during the treatment. We have several videos, you can decide for yourself what you want to watch.

3. How is the research carried out and what is the burden?

Participants will be assigned at random (by the computer) to one of the three research groups.

Group 1 standard treatment, with video glasses on during the treatment and a maximum of 5 minutes before the treatment to get used to the glasses and headphones.

Group 2 standard treatment, with video glasses on during the treatment but also 15 minutes before the treatment to completely unwind and relax.

Group 3 standard treatment, without using the video glasses (this is the current treatment currently being given in the hospital).

In order to measure the effect of the video glasses, we will ask you to fill in questionnaires at 3 times. These questionnaires are preferably taken digitally and are not linked to your medical file. You may therefore need to answer questions about things already known to your doctor. Furthermore, everyone's stress level is measured during treatment by measuring the heart rate and skin reaction with a device placed around your finger.

Measurement moment 1: after you have given consent to participate in this study, you will receive a questionnaire sent to your home by e-mail or on paper if you prefer.

The questions are about your personal situation (eg age, gender, whether or not to use medication), a pain score and a questionnaire about anxiety.

Measurement moment 2: on the day of your treatment in the hospital, after you have reported to the clinic, you will be in a separate room and will be asked again about pain and anxiety prior to the treatment.

Measurement moment 3: after the treatment you will be asked for the last time to give a pain score and answer the questions about anxiety. You will also be asked if you wore the glasses during the treatment; how you experienced using the glasses. After this you can go home.

The information you provide will be used to determine whether there are differences in perception between the groups with and without video glasses.

4. What is more or different than the regular treatment (s) you receive?

Regardless of the group in which you are divided, you will always receive the medical treatment that you have agreed with your doctor. Only participants in groups 1 and 2 wear video glasses before and during the treatment.

5. What side effects can you expect?

We do not expect you to experience any side effects from using the video glasses.

6. What are the possible advantages and disadvantages of participating in this study?

You do not directly benefit from participating in this study.

Possible disadvantage: You need a maximum of 10 minutes per measurement moment to answer the questions. The patients assigned to group II will sit up with the video glasses for an additional 15 minutes (before the start of the treatment).

7. If you do not want to participate or want to stop this study

You decide whether to participate in the study. Participation is voluntary and there is no financial compensation. If you decide not to participate, you do not need to do anything else.

Are you participating in the study? Then you can always change your mind. You may also stop during the study. You don't have to say why you are quitting. You must, however, report this immediately to the investigator or attending physician. You can always withdraw your consent to the processing of your data. The data already collected about you will then be destroyed.

8. What will happen to your data?

For this research it is necessary that your medical and personal data are collected and used. To be collected; email address (if available), gender, age (year of birth), location of pain treatment, previous pain treatments, previous surgery and whether or not you use medication for pain / anxiety / depression. Furthermore, a pain score, anxiety score, heart rate, stress score and your personal experience with the video glasses. The data is stored digitally in the Spaarnegasthuis. For the stored data, the privacy and information security is sufficient to comply with the obligations of the General Data Protection Regulation (AVG).

Each participant will receive a code that will be placed on your data. This is called pseudonimisation. Your name will then no longer be used.

Your data

All your data will remain confidential. Only the researchers know which code you have. The research data cannot be traced back to you when published in a (scientific) journal. If desired, you can indicate to the researcher whether you want to be informed of the results of the research.

By signing the consent form, you consent to the collection, storage and inspection of the medical and personal data you provide and directly measure.

The researcher will keep your data for 15 years. After that, the personal data will be destroyed.

You can ask the researcher for an electronic copy of data that you have provided or that have been measured directly at you. For more information about your rights in the processing of your personal data, please contact the researchers of this study E. Wisman or R. de Boer. Principal investigator R. de Boer is responsible for following the rules for the processing of your personal data. You can also contact M. Smit, Data Protection Officer of the SpaarneGasthuis. masmit@spaarnegasthuis.nl or 023-224 2181.

16-11-2020 – English translation of original Dutch document dated 05-06-2018
Translation – Karlijn van Stralen

If you are dissatisfied with how your privacy is handled, you can submit a complaint to the Spaarne Gasthuis complaints committee. The complaints committee can forward the complaint to the Data Protection Officer (see under the heading “Do you have any questions?”). You can also contact the Dutch Data Protection Authority yourself via https://autoriteitpersoonsgegevens.nl/

9. Are there extra costs / is there a reimbursement if you decide to participate in this study?

There is no financial compensation for participation in the study. You also do not have to incur any costs. To meet the additional parking costs that you may incur because of the extra time it takes to complete the questionnaire, you will receive an exit card from the hospital.

10. Which medical ethics review committee has approved this research?

The review committee of the medical ethics review committee (METc) of the VUmc in Amsterdam has assessed that this research is not covered by the Medical Scientific Act research involving humans (WMO). And the Advisory Committee on Local Feasibility (ACLU) of the Spaarne Gasthuis has given permission to carry out this research feed.

11. What now?

If you decide to participate, we request that you give the signed consent to your doctor. If you do not want to participate, we ask you to indicate why you do not want to participate, but it is not mandatory.

Do you have any questions?

If you have any questions, please contact mrs. E. Wisman, the study coordinator . You can email her: ewisman@spaarnegasthuis.nl or call the Pijnpoli +31 23 224 01 90 Opening hours: 8:00 AM - 4:30 PM, after which you will be called back if necessary.

Would you like independent advice about participating in this study? Then you can with an independent doctor: mr. H.W.J. Rockx, rehabilitation doctor. Rehabilitation clinic: +31 23 224 00 85 Opening hours: 8:00 am - 4:30 pm

If you have any complaints about this investigation, please report this to the coordinator of the research; ewisman@spaarnegasthuis.nl or else to the complaints committee of the SpaarneGasthuis. The complaints officer is impartial and has a duty of confidentiality. You can reach the complaints coordinator on telephone number +31 23 224 2130. More information about this can be found at https://spaarnegasthuis.nl/patientenvoorlichting/klachten.

Thank you for your attention.

Consent form

Is wearing video goggles during nerve block placement an effective aid in reducing pain and / or anxiety?

- I have read the information letter. I could also ask questions. My questions have been sufficiently answered. I had enough time to decide whether to participate.

- I know that participation is voluntary. I also know that I can decide at any time not to participate or to stop the study. I don't have to give a reason for that.

- I consent to the collection and use of my data in the manner and for the purposes stated in the information letter.

- I give permission to keep my data for another 15 years after this research.

- I give permission to use my email address (which is known at the hospital)) to receive the questionnaire.

- I want to be kept informed of the results of this investigation. Yes No*

- I want to participate in this investigation.

Name of subject:

Signature: Date: __ / __ / __

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I hereby declare that I have fully informed this subject about the said study. If information becomes known during the study that could influence the subject's consent, I will inform him / her in good time.

Name researcher (or his representative):

Signature:

Date: __ / __ / __

* Strike out what does not apply

Additional information is provided by (if applicable):

Name: Position:

Signature: