Application form nWMO METC Máxima MC

With the help of the information provided on this application form, the METC Máxima MC determines whether the intended research is covered by the Medical-Scientific Research with Humans Act (WMO). No substantive review is carried out; the METC does not assess the study for relevance, quality and conformity with other applicable laws and regulations.

Send the fully completed and signed form (please in PDF format) by e-mail to the METC Máxima MC: metc@mmc.nl. Don't forget to send any attachments.

Please note that a *non-WMO declaration* is not a permission for the execution of the study. To do this, the institution must follow the appropriate procedures
(within MMC, the study is reported to the Committee on Local Feasibility Research).

1. Contact details

Removed due to privacy

2. General research

a. Title research: Experienced quality of an orthopaedic consultation prepared with digital history and prediction of diagnosis and treatment

b. acronym: N/a

c. Brief summary: During an outpatient consultation, the differential diagnosis and appropriate treatment are primarily determined on the basis of the history taking and confirmed with physical examination and any evaluation of medical imaging Results. The performing orthopaedic surgeon must perform these tasks within the short duration of a consultation and thus communicate it to the patient as clearly as possible. The experienced quality of the consultation by the patient depends on many factors such as the duration of the consultation, confidence in the orthopaedic surgeon, empathy of the orthopedic surgeon, communication, and the expectations of the patient (Waters et al., 2016).

For a patient, a consultation can be intimidating while they receive a lot of information in a short time. Research has shown that patients have difficulty remembering the information offered to them during consultations, and in particular medical information (Mcguire, 1996). In addition, about half of what patients remember appears to be inaccurate (Kessels, 2003). Another problem faced by patients is that the information presented during

a consultation is often poorly understood (Wills, 2009). Given the number of patients who need orthopaedic care, there is little to no possibility to extend the duration of the consultation with the orthopedic surgeon. However, according to orthopedists within St. Anna, the above factors have a negative impact on the ability to provide information to the patient and meet the patient's expectations. In addition, as mentioned earlier, the orthopaedic surgeon has the complicated task of determining the differential diagnosis and appropriate treatment within the short duration of a consultation based on the history and physical examination, and the results from here to the patient. According to orthopedists within St. Anna, the time pressure ensures that they cannot always prepare well for a consultation, which can compromise factors such as empathy and good communication.

In other words, the quality of an orthopaedic consultation can be improved. A previous study conducted within St. Anna hospital has examined whether patients' medical knowledge can be increased by offering personalized information to osteoarthritis patients before a consultation takes place (Timmers et al., 2018). This has shown that the provision of personalized information to osteoarthritis patients before the consultation takes place has a positive impact on both the real and the self-reported medical knowledge of the patient. It is expected that increasing medical knowledge will also increase the experienced quality of the clinical consultation by the patient because the expectations of the patient are more realistic and because the patient is better able to communicate with the orthopedic surgeon.

In addition to the study of Timmers et al. (2018) in which patients with a high risk of osteoarthritis of the knee were selected in advance, personalized information will be provided to patients in the current study by applying machine learning techniques based on the most likely diagnosis. These machine learning techniques can be used to predict diagnoses and treatments and these predictions allow personalized information to be offered to the patient via a mobile application. The models are created based on already implemented digital history taking questionnaires (usual care) which are filled in by patients before they visit the outpatient clinic. In addition to providing personalized information to patients, the digital history questionnaire and the predictions can be used to support the orthopedic surgeon. They can use the information to prepare the consultation and it is expected that the orthopaedic surgeon will be able to give a better consultation as a result.

In conclusion, the goal of St. Anna is to improve the patient-experienced quality of outpatient consultations. For this we use new machine learning techniques that we apply to an already existing working method, namely the taking of digital history questionnaires prior to the first consultation. With this we provide less general but more personalized information to patients and support the orthopedic surgeon.

d. Research objectives: With this study we want to investigate whether taking digital history questionnaires and providing personalized information to patients improves the experienced quality of an outpatient consultation.

e. Intended start date: 1-4-2021
f. Intended end date: 1-10-2021

g. In your opinion, the research concerns a medical-scientific study according to the definition of the CCMO ('Medical-scientificresearch is research that aims to answer a question in the field of disease and health *(etiology, pathogenesis, symptoms/symptoms, diagnosis,*

prevention, outcome or treatment of disease), by systematically collecting and studying data. The research aims to contribute to medical knowledge that also applies to populations outside the direct research population.')

☒ yes

☐ Doubt, because:To enter text, click here.

☐ No,because:

h. What kind of research is it?

- Data research *patient-related*
  - ☐ Retrospective data from status research/SPD
  - ☐ Retrospective research footage
  - ☐ Prospective data from status/EPD (also phase IV medicines)
  - ☒ Data from questionnaires, interviews
- Data research volunteer-related
  - ☐ Testing laboratory determinations
  - ☐ Testing equipment
  - ☐ Validate methods of research
- Data research non-personal
  - ☐ Quality research practice
  - ☐ Epidemiological studies
  - ☐ National registration systems
- Biobank research
  - ☐ Residual material
  - ☐ Material extra purchased in diagnostics
  - ☐ Material specially collected from patients or volunteers
  - ☐ Material made available by data subjects themselves (donor banks)
- Otherwise, namely: To enter text, click here.

3. *Subjects / participants*

a. Are the subjects themselves involved in this study?

☒ yes

☐No, the subject does not have to do anything himself, for example retrospective dossier research)

b. Are individuals subjected to acts or are they subjected to rules of conduct (including taking questionnaires/interviews, please add them as an attachment)?

☐ No, because: To enter text, click here.

☒Yes, namely the following actions/rules of conduct that are not done in the context of the standard treatment (indicate what the actions/rules of conduct best and how much time the participants spend with this in the total study): This is a patient-related data research that matches the 'usual care' process. In St. Anna's, the usual care around the first consultation is that patients fill in a digital history and that they prepare for the first consultation with the help of an app. This study extends this with questionnaires related to the actual and self-reported medical knowledge of the patient. It is estimated that the patient spends a total of

15 minutes on this. The general preparatory information shall be replaced by personalised information in the intervention group. In addition, a questionnaire about the experienced quality regarding the consultation is taken 1 day after the consultation. It is estimated that the patient spends 5 minutes on this.

c. What's blood taken before this test?
☒ no
☐ Yes, from an existing line or planned vena puncture (indicate how often and how many milliliters):
☐ Yes, from an extra prick action: times milliliters (indicate how often and how many milliliters):

d. What are the characteristics of the research population (disease picture, target group, inclusion / exclusion criteria, type of condition, etc.)?

Patients over 18 years of age with complaints to the knee. In addition, they must speak Dutch, be in possession of a e-mail address, own a smartphone or tablet, and want to participate in the study.

e. What is the age of the target group?
☐ Children under 12 years
☐ Children between 12 and 15 years
☐ Young people between the age of 16 and 18
☒ Adults 18 years and older

f. Are all subjects capable of will?
☒ yes
☐ No, because:

g. How many subjects are included in the overall study? For estimating/calculating the required sample Size we assume a two-sample one-sided proportion hypothesis in which we compare whether the proportion of subjects in the experimental group who have all quality-related questions with answering well, very well or excellently is significantly greater than the proportion of subjects in the control group that all quality-related questions with good, very good or excellent answer. Based on pilot data (n=322) is the current proportion patients who are all quality-related questions with good, very good or excellent answer 45%. We estimate that this proportion is increased by 20% in the intervention group. With a sampling ratio of 1, the minimum sample size is equal to 204. Based on an estimated 10% drop-out rate, we arrive at a sample size of 230 patients.

4. Recruitment / consent

a. Is *informed consent* requested from the participants?
☒ Yes, see the attachment for the information letter and the corresponding consent form
☐ No*, because:
**without the participant's consent, scientific research or research in the field of public health can be carried out if 1) asking for consent is not reasonably possible or can be required and that there are guarantees that the patient's privacy is not harmed EN 2) that the study serves a public interest AND 3)*

that the examination cannot be carried out without the patient concerned AND 4) than the patient has not objected. In all other cases, participants must be asked for permission.

b. Briefly describe how the recruitment is going (how and by whom the participant is informed about the research and who asks the participant for permission to participate in the study):

Eligible patients will be asked to participate in this research after they have made an appointment for an outpatient consultation. The suitability of patients will be assessed during the patient's first contact with the hospital for planning a clinical consultation. Patients who are interested will receive an email with all the necessary information about the study for informed Consent. Patients will have a period of two days to process this information. When patients have questions, they can contact the lead or co-investigator. Patients who no longer have questions can indicate their preference in an online consent form. This form will also emphasize that the patient's data will be kept confidential and secure.

5. Medical Device

a. Is it an examination with a medical device?
☒ No (continue with part 6)
☐ Yes, the medical device has a CE marking and is used in this study for the intended use for which the CE marking was issued (continue with question 6)
☐ Yes, the medical device has a CE marking but is **NOT** used in this study for the intended use for which the CE marking has been issued
☐ Yes, the medical device does not (yet) have a CE marking

b. My research must be reported to the Health and Youth Inspectorate (IGJ).
☐ Yes, so I ask the METC Máxima MC to give a positive opinion.
☒ no

6. Additional information

a. Here you can provide additional information that may be important for the METC to assess the study: Because there is only a slight burden for the patient and little to no risk for the patient when participating in this study, we ask the METC to exempt this study from the WMO obligation and that there should be no additional insurance necessary for carrying out this examination.

7. Checklist and signature

a. The following Annexes* have been added to this application:
☒ The protocol of the intended study with version/date
☐ The subject information plus the consent form
☐ Questionnaires, diaries, interview schedule, topic list, etc., namely:

** These annexes are not assessed in substance.*

b. This application form has been completed carefully and truthfully.

Applicant name: Tristan Warren

date: 14-12-2020

Signature submitter:

Removed due to privacy

Send your request to metc@mmc.nl