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Impacts of Touch massage on the experience of patients with chronic pain: A protocol for a mixed method study

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ABSTRACT

Background: Chronic pain is a major public health problem. It affects the quality of life of many patients and their families and compromises physical and social functioning and psychological well-being. Non-pharmacological interventions are increasingly being used as a complement to chronic pain care. One of these interventions is Touch massage (TM) that can provide relaxation, comfort and well-being. In addition to its various physiological functions, TM can be used as a social communication tool.

Materials and methods: This is a cluster study with an exploratory qualitative part. Two groups will be considered: the experimental group will benefit from a TM delivered by trained members of care team and the control group will benefit from an intervention of the same duration with a foot massage device. At least 4 sessions will be delivered and spread over two weeks. Sample size calculation showed that 78 participants (39 per group) need to be included. As for the qualitative part, semi-structured interviews will be conducted to investigate the patients' perception of the intervention; focus groups will explore the satisfaction and general perception of the health care teams.

Expected results: Incorporating TM interventions into care planning could bring benefits in supporting patients suffering from chronic pain. TM is expected to increase the patients' feelings that their pain is seriously considered; physical and psychological support should help improve their sense of comfort and well-being and hence their quality of life. This practice might thus improve the caregiver-patient relationship with TM as a providing a new means of establishing communication through touch.

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1. Background

Chronic pain is a major public health problem that affects the lives of many patients and their families. About 20% of Europeans are affected by chronic pain, with osteoarthritis and rheumatoid arthritis in the foreground (42%) [1,2]. Among people with cancer, the overall prevalence of chronic pain is 28.2% according to a recent study [3]. Pain is defined as "an unpleasant sensory and emotional experience, associated with actual or potential tissue damage, or described in these terms" according to the International Association for the Study of Pain [4]. Pain persisting over three months is considered as chronic. Chronic pain affects the quality of life of patients and their families and compromises a person's physical and social functioning and impacts their psychological well-being [5]. In terms of employment and social relations, it can have a devastating impact. In addition, it is often accompanied by depression (21%) [1]. Suffering in not restricted to the body, but it affects the individual as a whole.

The subjective nature of pain makes its assessment complex. Pain perception is measured by self- or hetero-assessments using unidimensional or multidimensional scales taking into account clinical signs, sensory and emotional aspects of pain [6].

Non-pharmacological interventions are increasingly being used as a complement to chronic pain care [1]. Touch can bring relaxation, comfort and well-being [7,8]. In addition to its many physiological functions - mechanical action by stimulating cutaneous, muscular, nervous, endorphinic release and stimulation of the autonomic nervous system receptors [9] - the sense of touch can be used as a tool for social communication. The concept of physical contact in care pursues different intentions such as the promotion of physical, emotional, or psycho-spiritual comfort, as well as the realization of a social and sharing role for the caregiver [10,11].

Massage interventions might be beneficial on several levels. They may reduce pain-related sensations but also improve people's quality of life [12–15]. Clinically significant benefits of massage have been suggested in various chronic pain problems: back pain [16,17], neck pain [16], knee arthralgia [16–18], but also fibromyalgia, osteoarthritis, headaches, migraines or arthritis [15–18] and cancer [13,19].

In addition to reducing the pain sensation, people who have received massages describe a lasting improvement and further benefit on sleep quality(20), relaxation and sense of well-being. An increased sense of energy [21], a reduction in anxiety [13,22–24] and the experience of increased self-confidence have also been documented [23]. Stress decreases significantly with touch massage [14,25] insofar as biophysical factors such as stress hormones, blood pressure or other cardiac outcomes are reduced [24].

The effect of massage has also been documented on postoperative pain in patients who have undergone major surgery [26], such as after cardiac surgery [16]; similarly, in people hospitalized for burns, pain decreased significantly when a massage was combined with analyseic medications [15].

For people with cancer, therapeutic touch reduces symptoms such as nausea, fatigue pain and depression and increase the quality of life [24, 27–29].

With regard to the effects of energy massages, benefits are described in terms of reduced pain perception [20,25,30], depressive behaviors [20,25,30,31], stress [14], and of increased feelings of relaxation, well-being [30], and sleep quality [19,20].

Although the integration of massage interventions into the care planning points to a favorable economic impact on health organizations [24], several authors recommend that the documented positive effects of different touch therapies be interpreted with caution. This is due to methodological weaknesses or small sample sizes as well as to the lack of information to evaluate the conclusions and the possible generalization of the results [24,25,30,32,33]. In addition, it has been recommended to include qualitative studies of patients' lived experiences [29].

In recent years, specialized nurses from the mobile pain and

palliative care team at the University Hospitals of Geneva (*Hôpitaux Universitaires de Genève*, HUG) have been trained in the practice of Touch massage (TM)). TM is a concept first described by Sawatofsky (1986) as *Toucher massage*® and defined as: "A benevolent intention that takes shape through touch and the sequence of movements on all or part of the body, that allows relaxation, fitness, reassurance, communication or simply well-being, pleasant to receive and, what is more, to practice" [34].

Positive effects of TM have been collected from patients at the HUG [35]. The results obtained from these patients are in line with those in the literature, particularly with regard to reducing pain intensity, relieving various symptoms, feelings of proximity with care providers and valuing their role. However, it is important to carry out a validation study of these different results. To evaluate the effectiveness of such an intervention, a methodically appropriate and sound trial should be conducted. In addition, integrating a qualitative part with patients and caregivers would make the elements described as missing for a proper appraisal of such interventions. This may in turn allow for the identification and possible recognition of the TM intervention as a relevant element in the management of patients suffering from pain.

Within this framework, we devised a mixed method study protocol, which aims to measure and explore the benefits of TM in people suffering from chronic pain. In addition, it will explore the team's experience with this intervention in order to facilitate its possible future implementation.

2. Methods

2.1. Objectives

The main purpose of this study is to evaluate the impact of TM on the experience of patients with chronic pain hospitalized in a rehabilitation ward of internal medicine (Division of General Medical Rehabilitation, Beau-Séjour). We hypothesize that TM will have a positive impact on the global impression of change in the perception of pain.

The secondary objectives are to:

- 1. Measure the effects of TM on
 - a. the severity and impact of pain
 - b. anxiety/depression
 - c. caregiver-patient interaction
- 2. Explore the experiences of patients benefiting from TM
- 3. Explore perceptions, resistance, barriers and facilitators regarding the proposed interventions with the health care teams of the units.

2.2. Study design

This is a monocentric study designed as a non-randomized cluster trial with an exploratory qualitative part: the treatment (TM or control) is assigned to one of two care units and subjects are allocated to the care unit not according to a randomization process but based on the usual general allocation rules of the ward. Our design is a mixed method study. Each method (quantitative and qualitative) addresses a different research question and diverse hypotheses. The combined methodology will provide different types of data that inform one another and allow for a rich interpretation and deep understanding of the participant's experiences.

The quantitative part includes a pre-post design in the experimental and control group. The qualitative part includes semi-directed interviews with patients in the experimental group after the administration of the TM intervention and focus group with the health care teams in the units concerned.

The trial cluster has been selected for pragmatic reasons; one treatment unit will be trained and will practice the TM intervention while the other will use the Homedics HM MP RELEX 90 device. For reasons of service organization, it would be both difficult and impractical to train a

mobile team of nurses in the TM technique and send them to the different units to perform the interventions. It should be noted that cluster trials are types of clinical trials that are widely used for public health interventions, including inter-institutional care practices.

2.3. Patient population

The population is composed of patients suffering from chronic pain (co-morbidity reported in the file) hospitalized in two units of the Division of General Medical Rehabilitation, Beau-Séjour. The two units are similar in terms of care intake and populations cared for.

2.3.1. Inclusion criteria

- Patients >18 years-old (adults)
- Hospitalized for a minimum of two weeks
- Suffering from chronic pain for more than 3 months (pain syndromes were categorized as nociceptive (e.g. osteoarthritis), neuropathic (e.g. diabetic neuropathic pain), mixed or functional (e.g. fibromyalgia)
- Having sufficient command of French in reading, writing or speaking

2.3.2. Exclusion criteria

- Documented cognitive impairments,
- Diagnosis of cancer interfering with foot massage (extremities metastases)
- Major polyneuropathy
- Intake of therapeutics anticoagulants (IV) or important coagulation
- Dermatological conditions interfering with foot massage
- Pregnancy
- Having a pacemaker

2.4. Study intervention

The intervention for the Experimental Group (EG) includes a massage of about 15 min-time (according to the current HUG practice) on the foot area. At least four sessions will be delivered and spread over two weeks. The TM will be provided by the care team (care assistant, nurses) trained for the intervention (n = 15 out of 21 teams member) by a specialized nurse with extensive training massage and reflexology (Appendix 1). In order to be as close as possible to a standardized session, massage providers will benefit from an intervention guide (Appendix 2). Each massage provider benefited from 2 2-h training sessions and 4 supervision/debriefing sessions lasting 1.5 h. The training consisted of theoretical contributions, demonstration and experimentation of the technique in duo, followed by exchange and expressions of feelings.

The Control Group (CG) will benefit from an intervention of identical duration. The treatment consists of a foot massage with a Homedics HM MP RELEX 90 device, a heat-free "shiatsu" program, which lasts about 15 min. The use of the Homedics device is no more a common treatment than the practice of TM, in the Division of General Medical Rehabilitation. TM involves a therapeutic relationship between caregiver and patient. We thus needed a comparator that would allow us to keep the aspect of the massage while decreasing the aspect of the therapeutic relationship and therefore offer us an adequate comparator.

2.7. Sample size

For the power calculation, based on the primary outcome, i.e. the score on the PGIC (Patient Global Impression of Change [36,37]), the following assumptions are used:

1) Active processing increases the perception of change (PGIC) by an average of 0.75 points in the experimental group as compared to the control condition

- 2) The standard deviation of the PGIC measured is 1.2 (internal data, Service of Clinical Pharmacology and Toxicology)
- 3) The power is 80% and the type I error risk is set at 5%.

Based on these data, the necessary sample size is $n=39\ \text{per}$ group (unit).

3. Study procedures

3.1. Recruitment, screening and informed consent procedure

Considering that both the intervention and control units have 18 beds (365 patients/year in 2017 per unit) and with an expected prevalence of 20% of chronic pain, a recruitment of approximately seven patients per unit and per month is possible. Thus, a recruitment period of seven to eight months is scheduled to include the 78 participants needed. The duration of the overall study will be 18 months. The recruitment period will extended from October 2019 to December 2020.

General information regarding the study will be provided by the investigators to the collaborators of the relevant units. After approval of the study protocol by the Cantonal Commission for Ethics and Human Research in Geneva (CCER), the recruitment will take place in the two units and will be carried out by a research collaborator and the healthcare providers of the units (Appendix 3).

All of the recruited participants will complete baseline measures (before the intervention, i.e. T0). The meetings for the intervention will then be scheduled by mutual agreement between the patient and the person who will deliver the intervention.

3.2. Ethical considerations

All subjects will be informed of the goals and design of the study and assured of confidentiality before formally agreeing to participate. The formal consent of a participant, using the approved consent form, will be obtained before the participant is included in the study and submitted to any study procedure. Data will be de-identified to ensure confidentiality. Authors will be careful to conform to the ethical standards promoted in the Declaration of Helsinki. Institutional review board (CCER) was obtained before subject enrollment.

3.3. Outcome measures

Measurements will be taken at T0 and T1 by a research nurse. The time interval between T0 and T1 is two weeks (which corresponds to the timeframe right after the end of the four massage sessions for both the EG and CG groups). Sociodemographic, health and data from the questionnaires will be collected by the research nurse at T0 and T1.

3.4. Primary and secondary endpoints

The main outcome is the:

Change: The Patient Global Impression of Change (PGIC) measures the patient's feelings about the change following treatment on limiting activities, symptoms, emotions and everything that affects the patient's quality of life in relation to pain [36]. (Patients are asked to give an assessment on 7-point scales ranging from 0 (no change or become worse) to 7 (much better, a considerable improvement that makes all the difference) [37]. The instrument has been used in other studies following multi-disciplinary pain management interventions. Significant associations were found between PGIC and improved pain [38–40], physical activity and mood in patients with chronic pain [38]. However, the authors recommend that the evolution of pain specific to one domain to be evaluated in parallel with another measurement scale. Completing the PGIC takes a maximum of 5 min.

The secondary outcomes are:

Pain: The Brief Pain Inventory (BPI) assesses the severity of pain and the impact on activities. The scale contains nine items: four of which have a numerical assessment scale for pain severity ranging from 0 to $10~(0=\mathrm{no}~\mathrm{pain}~\mathrm{and}~10$ representing the strongest possible). The impact of pain is assessed on general activity activities, mood, walking ability, work, relationships, sleep, and taste for life ($0=\mathrm{does}~\mathrm{not}$ interfere, $10=\mathrm{gene}~\mathrm{completely}$). The scale provides two main scores: a severity score and a pain repercussions score. The instrument has been translated into a dozen of languages and is widely used in research and clinical settings [41]. It takes about 5 min to complete the questionnaire [42].

Anxiety: The HADS (Hospital Anxiety and Depression Scale) [43] is composed of seven items measuring anxiety, and seven items concerning depression. This 4-point Likert scale (0= never, 3= really very often) provides a total score for anxiety and depression. A score greater than or equal to 11 indicates that the person is suffering from anxiety or depression. Administration takes a maximum of 10 min. Interaction: The Nurse-Patient-Interaction Scale (NPIS) questionnaire developed by Haugan in 2012 will be used to assess the patient's perception of interaction with caregivers across 14 items [44] with a 10-point Likert scale (1= not at all and 10= a lot). The questionnaire has good psychometric properties, including construct validity with a Cronbach alpha of 0.91 and a test-retest fidelity of 0.82. Administration takes a maximum of 5 min.

Sociodemographic data will provide information on age, gender, family situation, origin, level of education and employment status. The medical data will be taken from the nursing and medical files and will provide information on diagnosis and treatment.

3.5. Qualitative part

As for the nested qualitative part of the study, semi-structured interviews will be conducted and recorded with patients in the experimental group after the administration of the TM intervention (n = approximately 15 patients) and will investigate the patients' perception of the intervention. An interview guide will be developed with a multidisciplinary team (two nurses specialized in the practice of TM and two skilled in the treatment of pain and in palliative care, two MDs specialized in internal medicine, and a psychologist) and tested with a patient to ensure its relevance. The guide will include the following topics: recall of TM, general appreciation of the sessions, perceived facilitators and barriers to the experience of TM, and possible benefits of the intervention for other patients (Appendix 4). Participants will first be asked to share their experience of the TM and then prompts will used to encourage them to develop their experience following the interview guide. The recording will be transcribed verbatim. A thematic analysis based on an inductive approach will be carried out by two members of the research team, initially allowing individual and independent coding. After comparison and agreement on the codes, the themes will be identified.

Focus groups will explore the satisfaction and general perception of the multidisciplinary health care teams in the units concerned (at least five participants, including nurses, assistant nurses, physical therapists and physicians). A written informed consent will be required. The focus group will allow to assess the impact on general care, the experience, the positive effects, the negative effects and the impact on the development and planning of care. The focus groups simultaneously generate data for three levels of analysis: the individual, the group and the interactions between participants that reveal the degree of consensus or sense of cohesion [44]. The interview will be audio-recorded, and the recording will be transcribed verbatim.

3.6. Confidentiality and coding

Trial and participant data will be handled with utmost discretion and will be accessible only to authorized personnel who need the data to complete their assigned tasks within the scope of the study. On every specific document, participants are only identified by a unique participant number.

Data generation, transmission, storage and analysis of health-related personal data within this project will strictly follow the current Swiss legal requirements for data protection and will be performed according to the Ordinance on Human Research (OHR), Art. 5. Direct access to source documents will be permitted for purposes of audits or inspections.

All information collected will be coded through a study participation number (the participant's name will not appear) and stored in a computer database to which only the research team will have access. The information collected will be treated anonymously and confidentially. To ensure these principles, the identity of the participant will be coded by means of a reference number for which only the investigators will have the correspondence key.

4. Analysis

4.1. Statistical analysis plan

Descriptive analyses of the sample for the main medical and sociodemographic characteristics at baseline will be performed. Similarly, the characteristics of the two units (number of caregivers, number of usual patients, etc.) will be described to ensure comparability between the two care units. Inferential analyses, using the Student t-test (if parametric) or Wilcoxon test (if non-parametric) will be performed to assess possible differences between the two groups after the intervention on the primary outcome. In case of statistically significant differences, other variables (patient characteristics and unit characteristics) will then be introduced in multivariate analyses to evaluate the effect of the intervention while controlling for these co-variables.

For secondary outcomes, a descriptive analysis will be performed and reported by intervention group and by measurement time point. Inferential analyses will then be performed using a Student t-test (if parametric) or Wilcoxon test (if non-parametric) to evaluate the effects of the intervention. No correction is planned for multiple testing. The data collected will be processed with the SPSS Software version 22.

The number of missing data will be reported for each outcome. Imputation techniques will be applied if there are more than 10% of missing data in a sensitivity analysis. A scale in which less than half of the items are completed will be treated as a missing. Drop-outs will be kept in the analysis until the point of drop-out.

As patients are in-patients, procedures are not associated with particular side effects and follow-up is short, it is not expected to have a high drop-out rate, if any. Moreover, the assumption on the magnitude of the intervention effect is rather conservative and is robust enough to resist a 5% drop-out rate.

4.2. Qualitative part

Interviews will be tape-recorded and transcribed. The MaxQDA version12 software will be used to manage and analyse the qualitative data collected. We will perform a thematic content analysis of the interviews [45]. The qualitative analysis will start with individual readings by three researchers (two nurses and one psychologist [GR, CT, CC]). The analysis will last throughout the data collection and the encoding process using the constant comparative method, which consists of analysing the interviews by comparing one response to earlier reported responses [46]. This analysis will then be used to establish analytical categories that will serve as a basis for the final grid aimed at analyzing the transcripts. Using participant-generated data via the

interviews and verifying their interpretation using triangulation between the three researchers will provide access to their reliability [47]. In accordance with the stated objectives, the analyses will focus on the identification of key elements of the experience of TM. Emergent data will be corroborated with existing theories and compared to previous research data to assess their degree of conformity.

4.3. Bias

As patients will be referred to one of the units according to administrative criteria, it will be necessary to ensure that these criteria do not influence the outcome of the study and to document this process. It will also be necessary to ensure that the risk of differences between the two groups on variables that may confuse the effect of the intervention is minimized. This must therefore be distinctly explored, in particular by presenting socio-demographic and clinical variables with a baseline between group assessment. Analyses of covariance taking into account major covariates will also be implemented.

Another issue that must be taken into consideration is that the study being a cluster trial, the treatment is assigned not to a subject but to a care unit. We are aware that the cluster effect, i.e. the presence of confounding factors, particularly with regard to training, the experience of health care teams, number of caregivers, workload, etc., could create differences between the two units and thus increase or reduce the effect of the treatment we are trying to highlight. For this reason, it will be important to describe the characteristics of the two units participating in the study to ensure that the two experimental settings are indeed very similar. This is also why we propose to carry out post-hoc exploratory analyses to adjust the analyses in relation to these possible confounding factors that we might be identified. We recognize that the design of the study has some limitations, but it is a compromise between methodological optimization and the realization of a pragmatic study with the operating constraints of clinical services.

5. Expected clinical benefits

Managing chronic pain is and remains a major challenge, in particular because of an increasing number of people dealing with comorbidity and polymedication. Therefore, it is essential to find new ways to heal chronic pain, in addition to pharmacological interventions.

TM is already known to bring benefits on chronic pain and to improve the patient's quality of life. Benefits have also been shown on the relation between the patient and the care provider, who can both feel complicity and gratitude after giving/receiving a TM.

Positive effects of TM could be collected from patients at HUG [35]. The results obtained from this observational survey are in line with those in the literature, particularly with regard to reducing pain intensity, relieving various symptoms, feelings of proximity with careers and valuing their role.

This study is innovative in its design, trying to validate these different results. Additionally, integrating a qualitative part with patients and care providers would make elements regarding patients' lived experience available in order to identify and recognize the TM intervention as a relevant element in the management of patients suffering from pain.

The expected results, at the end of the proposed project, should bring a certain number of benefits for researchers/clinicians, for practice, but also and above all, for patients. More specifically:

For practice: Including TM interventions in care planning could provide a useful and manageable tool in the care of patients suffering from chronic pain. TM may help patients feeling the expression of their pain is considered. As TM tackles both the physical and the psychological dimensions, it may in turn help to improve their sense of comfort and well-being and thus their quality of life. Through this

practice, the caregiver-patient relationship may be improved. A new means of communication would be considered and implemented through touch. This care would allow the caregiver to feel less helpless in the face of pain, to have new resources, to experience a sense of beneficence and comfort. This person-centered care may also contribute to the quality of care.

For research: This type of research aims at demonstrating the effectiveness of the TM intervention by following a rigorous methodology, often considered insufficient in previous research. A sample size of 78 patients will provide a more representative picture and complement current knowledge on the possible consideration of this non-pharmacological intervention as a reliable treatment option. In addition, qualitative interviews will collect patients' experiences and perceptions and caregivers' experiences that will help to develop a general understanding of the phenomenon being studied and determine the feasibility and acceptability of this intervention in care planning. If conclusive, these results will support the development of recommendations for good practices taking into account the context of care. The results will be disseminated through scientific communications and publications for clinicians; through professional publications for care providers and presented to health professionals involved in the management of patients suffering from chronic pain in Bachelor courses.

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Ethical approval

This study protocol has been approved by the Cantonal Commission for Ethics and Human Research (reference no. 2019–00848) on 9 July, 2019.

Clinical trial registry protocol

ClinicalTrials.gov, NCT04295603, Registered on 4 March, 2020.

Author statement

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Declaration of competing interest

Authors declare no conflict of interests.

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Appendix 1. Massage's training background of the instructor

The nurse in charge of training the care providers in dispensing TouchMassage has a solid background, both in term of degrees and of experience. She is a specialized nurse and has participated in numerous trainings related to complementary approaches and particularly with regard to massage. Concerning TM, she is certified from the Joël Savatofsky institute where she followed several trainings, since 2005. She also gained a certification in healing touch (2016, 2018).

Additionally, she has been long certified in reflexology, in comfort massages and massages in a context of palliative care, in circulatory massages of the legs (2019) and in masso-relaxation (since 2000 and onward).

Appendix 2. Foot massage guide

The Touch massage (TM) session lasts about 15 min. The massaged area of the body will be the feet. The massage is performed with sweet almond oil according to the recommendations of the HUG. The agreement of the doctor in charge of the patient is required. The caretaker ensures that the patient is comfortably positioned. As far as possible, he or she will try to promote a calm environment (soft light, little noise, soft and calm voice).

The treatment follows the following pattern: light pressure to coat the massaged part of the body with oil and warm it up (oiling must be quick), then the pressure is applied more deeply during the treatment. Finally, to prepare for the end of the massage, a lighter pressure is applied followed by a light touch The massaged part is covered with a cloth and pressure is applied with both hands, using the weight of the body. The caregiver stays with the person for a few minutes, giving him/her time to "integrate" the sensations perceived. The following principles are respected during the treatment:

- Preparation of the caregiver: feet firmly anchored to the ground, shoulders relaxed, a few deep and ample breaths.
- The contact: soft and progressive. Then during the treatment, the hand never leaves contact with the body.
- The hands: warm them before the treatment so that the person does not braid at the first contact. Both flexible and firm, they follow the slightest contours of the foot, recognizing the sensitive areas where pressure should be avoided and the fleshier parts to be massaged more deeply.
- The massage gestures: rounded and enveloping, they reinforce the feeling of security.
- Speed: the movements are performed slowly and precisely (the slower the movements, the more relaxing the massage).
- Beware: during the massage, be constantly attentive to the person's verbal and non-verbal expressions, to the "feeling" of our presence, of our hands and readjust the gestures or stop the massage if necessary.
- The posture of the caregiver: with a straight back, relaxed shoulders, the caregiver uses movement, the weight of his or her own body during the maneuvers and swaying to squeeze but gently and smoothly.

Appendix 3. Informed consent details

Patients eligible according to the inclusion criteria will be identified and approached by the care teams under the supervision of the co-investigator. The research nurse will explain the study to the patients and hand out the information and consent materials. The investigators will explain to each participant the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant will be informed that the participation in the study is voluntary and that he or she may withdraw from the study at any time and that withdrawal of consent will not affect his or her subsequent medical assistance and treatment. The participant will be informed that his or her medical records may be examined by authorised individuals other than their treating physician.

All participants will be given an information sheet and a consent form describing the study and providing sufficient information for the participant to give an informed decision about their participation in the study. A minimum of 24 h will be given to the participant to decide whether or not to participate.

The formal consent of a participant, using the approved consent form, will be obtained before the participant is included in the study and submitted to any study procedure. The consent form will be signed and dated by the investigator at the time of patient signature. A copy of the signed informed consent will be given to the study participant. The consent form will be retained as part of the study records.

Appendix 4. Interview guide

First question.

You have experienced two sessions of TouchMassage that have been delivered by a specialized nurse. Could you tell me about your experience of these sessions of TouchMassage sessions? How were these sessions for you? We would like to know about how you felt during these sessions.

Themes	Probes
1. Recall of TouchMassage	Do you think you benefited from TouchMassage ? Do you have any specific memory of TouchMassage sessions?
2.General appreciation of TM	What did you like or dislike in the sessions with the nurse?
	What did you feel? Did you experience specific emotions during these sessions? If so, can you describe them?
3. Facilitators in the experience of TM	Could you identify elements during the sessions that facilitated these sessions for you? That helped you benefit from them?
	Are there elements that you would describe as favorable, facilitating the experience of TouchMassage?
4. Barriers to the experience of TM	On the opposite, were there elements during the sessions that hindered these sessions for you? That prevented you benefiting from them?
5. Benefits for others	Would you recommend such sessions of TouchMassage to other patients? What would you tell them?

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