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Impacts of touch massage on the experience of patients with chronic pain: A non-randomized cluster clinical trial

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ABSTRACT

Background: Chronic pain is a major public health problem. Non-pharmacological interventions are increasingly being used as a complement to chronic pain treatment and are strongly recommended. The aim of this study was to evaluate the impact of Touch massage (TM) on the experience of patients with chronic pain hospitalized in a rehabilitation ward.

Method: A non-randomized cluster clinical trial was conducted. Eighty-two participants were included in this study, 39 in the intervention group and 43 in the control group. Participants in both groups received 4 sessions of massage (TM or via a machine) over the course of 2 weeks. For both groups, Patients' Global Impression of Change (PGIC) in the perception of pain and secondary outcomes (pain intensity, anxiety/depression, patient-provider relationship) were measured at baseline and after the intervention.

Results: There was a small effect (Cohen's d = 0.42) of the intervention type on the score of the PGIC. Patients who received TM tended to perceive more change than participants who received machine massage. The type of intervention had no effect on the other key variables (pain intensity, anxiety/depression, or patient- provider relationship).

Conclusion: This study shows with a rigorous and pragmatic methodology that TM has a positive impact on the perception of pain relief in patients suffering from chronic pain. TM appears as a useful and well manageable therapy for these difficult to treat patients and somewhat better than machine delivered foot massage.

1. Introduction

Chronic pain prevalence varies from 19 % to 31 % in the general population across the world [1–3]. Chronic pain was defined in the ICD-11 as "persistent or recurrent pain lasting longer than 3 months" [4]. Overall, chronic pain is a major health issue around the world and has an important economical [5] and social impact [6]. Patients suffering from chronic pain often report sleep disturbance, impairment of physical and social functioning [1,3,7], depression or anxiety [1,3,8].

Massage is a commonly used treatment for chronic pain [1,9]. Massage therapy reduces pain across different conditions [10]. Besides, short-term improvement of pain and function in fibromyalgia [11], chronic low back pain [12,13], or chronic pain [14] have been documented. However, effects reported across studies are small which could be explained by the heterogeneity of interventions categorized as "massage therapy" [12,14].

Massage therapies vary significantly in goals, intention, and techniques [15], which makes comparison difficult. Regardless, small to

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moderate short-term effects on pain and function in patients with chronic pain are observed across different massage techniques.

Massage therapy contributes to reduction of depression and anxiety [11,16–19], increased well-being [18,19] and treatment satisfaction [17,20]. Overall, evidence is scarce. Consequently, further research on specific types of massages is warranted to better understand their effect on pain and functioning in patients with chronic pain.

The present study focuses on a specific massage intervention called Touch massage (TM) [21]. In recent years, this method had been taught to specialized nurses at a Swiss University Hospitals. Touch massage® has been 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" [21]. TM is characterized by the use of gentle touch and emphasizes the importance of touch in the therapeutic relationship [21]. Healthcare professionals' lack of time being often cited as a barrier to the implementation of massage interventions or other complementary therapies [22], TM is an interesting alternative which can have a beneficial effect on patient while requiring little time (15–45 min) [23].

Previous research on gentle Touch massage highlighted effects on the reduction of physiological stress responses, increase in pleasantness, reduction in self-reported anxiety, and positive subjective experience in patients and in healthy individuals [24–27]. Furthermore, touch plays an important role in social interactions [28], and massage therapy can strengthen patient-care provider relationship [29,30].

In line with the literature, previous findings in our research group showed a reduction of pain intensity, the enhancement of a feeling of proximity with care providers, and improvement of wellbeing in patients with chronic pain [23,31]. Those studies primarily focused on examining the firsthand experiences of patients and caregivers, using a qualitative methodology. They offer a valuable insight into the experience surrounding TM. However, the identification and possible recognition of the TM intervention as a relevant element in the management of patients suffering from chronic pain remains an open question. Our investigation adopted a quantitative approach to enhance our understanding of the effects of TM on individuals suffering from chronic pain.

This study aims to carry out a validation study of these results using a methodologically sound trial procedure. We hypothesized that TM has a positive impact on the patient's global impression of change (PGIC) in the perception of pain and its consequences after the intervention. Although pain intensity was not a primary outcome, we still considered it important to assess pain severity (intensity and interferences with daily activities) along with anxiety and depression, and quality of caregiver-patient interaction.

A secondary aim was to explore the potential added value of a human-delivered massage.

2. Material and methods

2.1. Setting and design

The study was conducted in two units of the Division of General Medical Rehabilitation of the Geneva University Hospitals (Hôpitaux Universitaires de Genève, HUG), a 90-bed general medical rehabilitation ward comprising 5 units of 18 patients each. The units are similar in terms of care and population. The ward is part of a 1200-bed urban public and teaching hospital which is the major primary care hospital for the area and is devoted to general medical rehabilitation. Median and mean length of stay are 16 and 21 days, respectively during the study period (between October 2019 and June 2020). The study is designed as a non-randomized cluster clinical trial. The intervention (TM or control) was assigned to one of the two units/clusters. Patients were allocated to units following the usual general allocation rules of the ward. These rules are based on administrative and availability issues that are fully independent of the researchers' control. This study received the approval of the Cantonal Commission for Ethics and Human Research (2019–00848) and was pre-registered (ClinicalTrials.gov, NCT04295603) [32].

The cluster clinical trial has been selected for practical reasons; one treatment unit was formed and practiced the TM while the other used the approach with the Homedics HM MP RELEX 90 device. For reasons of service organization, it was difficult to train a mobile team in the technique and send them to the different units to perform the interventions. It should be noted that cluster clinical trials are widely used for public health interventions, including inter-institutional care practices. As budgetary and resource limitations had to be considered, we opted for this pragmatic methodology. The research was carried out with the clinical team because we wanted to allow for the implementation of the intervention.

We also aimed to explore the potential added value of a human-delivered massage. Therefore we chose a machine for the control group. Furthermore, it is easier to recruit participants by offering an intervention rather than just the usual care. Previous experiences showed that waitlist design is very difficult to organize without sufficient resources.

Power analysis was conducted with the following assumption: TM intervention increases the patient's perception of change (PGIC) by an average of 0.75 points in the experimental group as compared to the control condition; the standard deviation of the PGIC measured is 1.2 (internal data, Service of Clinical Pharmacology and Toxicology); The power is 80 % and the type I error risk is set at 5 % [33,34]. Based on those assumptions, the sample size estimated was $n = 39$ per group (total of $n = 78$).

2.2. Participants

The study population consisted of patients aged > 18 years, admitted in two units of the ward during a nine-month period. Patients were considered as eligible if they presented pain for more than 3 months, whatever their primary diagnosis. Pain syndromes were categorized as nociceptive, neuropathic, mixed or functional. Other inclusion criteria were: being fluent in French and having an expected hospital stay of $>$ 14 days. Patients were recruited for the purpose of the study within their first 72 h of stay by a trained investigator independent from the health care team. The health care team was informed of the aims of the study. We compared TM with a machine delivered massage, using a non-randomized cluster clinical trial design. As a result of this study design, neither the patients nor the nurses of the two wards could be blinded to the type of intervention. Exclusion criteria were: documented cognitive impairments, diagnosis of cancer interfering with foot massage (extremities metastases), major polyneuropathy, intake of therapeutics anticoagulants (IV) or important coagulation disorders, dermatological conditions interfering with foot massage, pregnancy, or having a pacemaker.

2.3. Interventions

The intervention in the treatment group (TG) was a 15 min massage technique TM [21] in the foot area. We decided to use foot massage for two main reasons: this technique was classically used by the nurses practicing TM and this allowed for between-group comparisons as the machine delivering the massage was adapted for use with the feet. The TM was administered to participants by trained care assistants and nurses in the care team, over the course of two weeks with four sessions for each participant according to the current practice at the hospital. The care team had been trained by a professional nurse expert in the domain of TM [32]. They all received two training sessions of two hours in which they were presented with theory and practiced in pairs. They also went through four sessions of supervision and debriefing (1.5 h each session). The details of the intervention can be found in the appendix of the research protocol [32].

In the control group (CG), participants received a machine delivered foot massage of similar length (about 15 min), using the Homedics HM MP RELEX 90 device and its heat-free "shiatsu" program [32]. Similarly, the massages were administered over the course of two weeks with four sessions for each participant. TM involves a therapeutic relationship between patient and caregiver. Thus, the use of this device allowed us to administer a similar intervention while reducing the aspect of the therapeutic relationship between caregiver and patient.

2.4. Measures

2.4.1. Primary outcome

The **Patient Global Impression of Change (PGIC)** was used to measure the patient's perception about changes following treatment on limiting activities, symptoms, emotions and everything that affects the patient's quality of life in relation to pain [33]. Patients were asked to report their perception of change on 7-point scales ranging from 1 (no improvement or became worse) to 7 (very much improved) [34]. Significant associations were found between PGIC and improved pain [35, 36], pain interference in daily life or treatment efficacy [35].

2.4.2. Secondary outcomes

The **Brief Pain Inventory (BPI)** was used to assess pain severity and its impact on daily life activities on 9-items scales [37]. Four items assess pain intensity now, at its "worst", "least", and on average, using 10-points numerical scales (0 =no pain; 10 =strongest pain possible) [38]. The scale provides two main scores: pain severity (PS) and pain interference (PI).

The **Hospital Anxiety and Depression Scale (HADS)** [39] is composed of seven items measuring anxiety and seven items measuring depression on 4-point Likert scales (0 =never, 3 =very often). The 14-items scale provides a total score for anxiety and depression. Scores equal or greater than 11 are indicative of mood disorders (anxiety or depression, respectively). The scale has good internal consistency with a Cronbach $\alpha = .86–.88$ for patients with chronic and acute pain [40,41].

The **Nurse-Patient-Interaction Scale (NPIS)** was used to assess patients' perception of interaction with caregivers across 14 items [42] with 10-point Likert scales (1 =not at all, 10 =a lot). The questionnaire has good psychometric properties with a Cronbach alpha of 0.91 for construct validity and test-retest fidelity of 0.82.

Sociodemographic data were collected (age, gender, family situation, origin, level of education, and employment status). Information on diagnosis and treatment were collected from patients' and nursing medical files.

2.5. Procedure

Measurement took place when the participant was recruited (T0) and after the intervention (T1). After baseline measure at T0, sessions were scheduled by mutual agreement between participants and caregivers. The time interval between T0 and T1 was 2 weeks. Measures at T1 were done right after the last massage intervention for both TG and CG.

2.6. Data analysis

A per-protocol analysis was conducted.

Descriptive analysis was conducted for patients' medical and sociodemographic characteristic at baseline. Furthermore, characteristics of the two units (number of patients, number of caregivers, etc.) were reviewed for comparability.

A Welch t-test was first performed in order to assess the effect of the intervention on the PGIC. Then, exploratory t-tests were run to investigate the impact of the intervention on all other secondary outcomes (PI, PS, HADS and NPIS).

Exploratory multivariate regressions were then run to investigate the main effects of secondary outcomes together with their interaction with the intervention factor on the PGIC. First, we investigated the effects of the secondary outcomes measured at *baseline* and then the impact of the pre-post change in the secondary outcomes together with their interaction with the intervention factor on the PGIC.

Finally, we performed exploratory correlational analyses to investigate relationships between the secondary outcomes measured at baseline and their improvement scores between the measures pre and post intervention.

2.6.1. Effect size

The results are reported in terms of effect size and p-values. Effect sizes for Welch t-tests are expressed in Cohen's d [43] according to the rules of thumb setting that a d between 0.2 and 0.5 accounts for a small effect, a d between 0.5 and 0.8 for a medium effect and a d greater than 0.8 for a large effect. For multiple regressions, effect sizes are interpreted according to Field's rule of thumb [44] with an eta square lower than 0.01 considered as very small, between 0.01 and 0.06 as small, between 0.06 and 0.14 as medium and large if greater than 0.14.

3. Results

During the study period, a total of 130 patients were recruited. Of these, 107 agreed to participate in the study (attrition=23 %). Among the 107 patients, 25 participants did not complete measures at T1 (patients contracted COVID-19, had to be placed in strict isolation, returned home, asked to stop the massage, death, no consent form, or were transferred in another unit). The total number of participants is 82 including 39 from the treatment group (TG) and 43 from the control group (CG) (Fig. 1).

3.1. Descriptive analyses

The final sample comprised 82 participants, including more females ($n = 59$ versus $n = 23$ males) (Table 1). In this sample, 69.5 % had children. The majority of the sample (62.2 %) were retired with a median age of 67 years (min=27 years-old and max=89 years-old). Moreover, 58.8 % of the sample reported leaving alone. Pain diagnosis was functional pain in 23.5 %, nociceptive in 11.8 %, neuropathic in 2 %, and mixed in 62.7 %. As many as 31 patients were not hospitalized with a pain-related diagnosis and pain was thus related to symptoms and complaints not directly related to the reason accounting for the present hospital stay. Both groups were comparable in terms of their sociodemographic and clinical characteristics. (Table 1).

Importantly, the majority of the sample (78 %) received four massages ($n = 64$), 8.5 % received three massages ($n = 7$), and only a little more than 10 % received only one ($n = 5$; 6.1 %) or two massages ($n = 6$; 7.3 %).

3.2. Intervention impact on PGIC

Welch t-test revealed an impact of the intervention on the PGIC with a *tendential* effect (p-value < 0.1) and a *small* effect size (Cohen's $d = 0.42$). The TM intervention increased the perception of change by an average of 0.71 points in the treatment group as compared to controls (4.29–3.58, see Table 2) with a standard deviation of PGIC measures corresponding to 1.64 for the control group and 1.77 for the treatment group. This effect is depicted in Fig. 2. Those results are aligned with the study's expectations (see Protocol, pp.8–9), where the TM intervention was expected to increase the PGIC by an average of 0.75 points compared to control group with intergroup standard deviation of 1.2. The main difference between the observed and the expected results therefore lies on the intragroup variability (sd= 1.64 and 1.77 against 1.2 expected) and not on the effect of intervention on the average PGIC score.

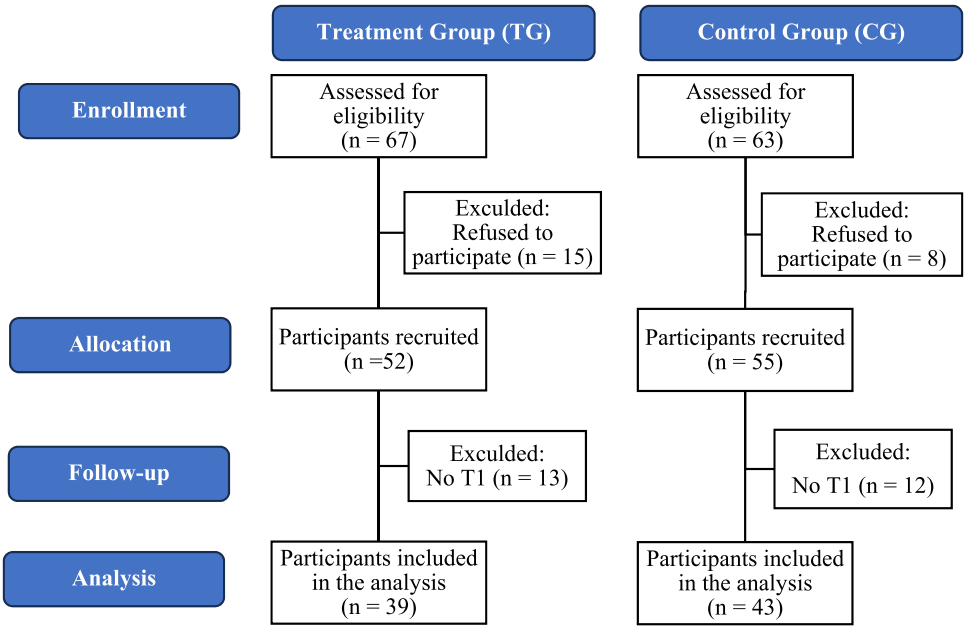

Fig. 1. Flow-chart of the inclusion in the study.

3.3. Intervention effect on the secondary outcomes

Exploratory Welch t-tests revealed that the intervention did not impact any other secondary outcome (see Table 3).

3.4. Secondary scores and intervention effects on PGIC

3.4.1. Secondary scores at baseline

3.4.1.1. NPIS at baseline. Multiple regressions analyses revealed that the NPIS score measured at baseline and the intervention factor interacted significantly for predicting the PGIC score with a medium effect size (p-value <0.05, eta squared = 0.07). The simple intervention effect remained tendential with a small effect size within this analysis (p-value < 0.1 and eta squared = 0.05, see Table 4).

3.4.1.2. PS at baseline. Multiple regression revealed that the PS score at baseline interacted tendentially with the intervention factor for predicting the PGIC with a small effect size (p-value <0.1, eta squared = 0.05, see Supplement - Table S1). Within this analysis also, the main effect of the intervention remained tendential with a small effect size (p < 0.1 and eta square =0.05, see Supplement - Table S1) and, the main effect of PS was not statistically significant.

For PI and HADS scores at baseline, multivariate regressions did not reveal any significant or tendential effect. Note that the intervention effect remained tendential with a small effect size within those analyses too (See supplement - Tables S1 & S2).

3.4.2. Secondary scores improvement

3.4.2.1. PS improvement. Multivariate analyses revealed that the PS improvement (before and after the intervention) predicted significantly the PGIC score with a medium effect size (p-value <0.05, eta squared = 0.07, see supplement - Table S3). Again, the simple intervention effect remained tendential with a small effect size (p-value < 0.1 and eta squared = 0.05) and the interaction effect is not significant. The Pearson correlation between those two variables displayed a medium-size effect and is significant ($r = 0.28$ with $p < 0.05$). For PI, HADS and NPIS scores improvement, multivariate regressions did not reveal any significant or tendential effect. The intervention effect remained tendential with a small effect size within all those analyses (See supplement - Tables S3, S4 & S5).

3.5. Exploratory correlational analysis

Finally, we performed an exploratory correlational analysis to investigate relationships between the secondary outcomes measured at baseline and their improvement scores between the measures pre- and post-intervention. The results showed that depression scores correlated positively with pain scores and NPIS. More precisely, depression measured at baseline correlated positively with the PI measured at baseline with a very large effect size ($r = 0.53$, $p < 0.001$). Moreover, the improvement score in the depression scale between pre-and post-intervention correlated positively with the PI improvement with a very large effect size also ($r = 0.46$, $p < 0.001$). NPIS measured at baseline correlated positively with the PS score improvement with a large effect size ($r = 0.37$, $p < 0.001$). The NPIS improvement between pre-and post-intervention correlated first with the PS improvement with a very large effect size ($r = 0.41$, $p < 0.001$), with the PI improvement with a medium effect size ($r = 0.26$, $p < 0.05$) and with the depression score improvement with a large effect size ($r = 0.32$, $p < 0.01$) (see supplement – Fig. S1).

4. Discussion

To the best of our knowledge, this is the first study using a non-randomized cluster clinical trial to study TM in patients with chronic pain. The results showed a tendential effect of the intervention on the Patient Global Impression of Change (PGIC) (p-value < 0.1). This result is in line with the research protocol and the tendential small effect (instead of significant medium effect expected) can be explained by the intergroup variability, and the small size of our sample. The intervention thus has an effect which can be qualified as “small” according to Cohen which appears at the limit of statistical significance. Although this does not allow to conclude in a definite way on the efficacy of TM it brings confidence on a positive impact of the intervention for the treatment of chronic pain. As the exploratory t-tests showed that the intervention did not impact any other variable of interest, the effect of the intervention appears therefore to be specific to the PGIC measure.

Exploratory multiple regressions analyses showed first that the

Table 1
Socio-demographic data and clinical data.

Baseline characteristic N	Control group 43	Treatment group 39	Full sample 82
Gender, *n (%)*			
Man	14 (32,6)	9 (23,1)	23 (28,0)
Woman	29 (67,4)	30 (76,9)	59 (72,0)
Age, *M (SD)*	68,8 (±14.3)	66.5 (±10)	67.7 (±12.4)
Children *n (%)*			
No	13 (30,2)	12 (30,8)	25 (30,5)
Yes	30 (69,8)	27 (69,2)	57 (69,5)
Number of children, *n (%)*			
1	6 (20)	8 (29,6)	14 (24,6)
2	15 (50)	12 (44,4)	27 (47,4)
3	5 (16,7)	5 (18,5)	10 (17,5)
4	3 (10)	1 (3,7)	4 (7)
5	0 (0)	1 (3,7)	1 (1,8)
Missing	1 (3,3)	0 (0)	1 (1,8)
Level of education, *n (%)*			
Mandatory school	13 (30,2)	8 (20,5)	21 (25,6)
Apprenticeship	13 (30,2)	8 (20,5)	21 (25,6)
High-School	2 (4,7)	4 (10,3)	6 (7,3)
University	10 (23,3)	12 (30,8)	22 (26,8)
Other	4 (9,3)	6 (15,4)	10 (12,2)
Missing	1 (2,3)	1 (2,6)	2 (2,4)
Professional situation, *n (%)*			
Full-time	5 (11,6)	2 (5,1)	7 (8,5)
Part-time	2 (4,7)	1 (2,6)	3 (3,7)
No activity	2 (4,7)	3 (7,7)	5 (6,1)
Unemployment	2 (4,7)	0 (0)	2 (2,4)
Disability	5 (11,6)	9 (23,1)	14 (17,1)
Retirement	27 (62,8)	24 (61,5)	51 (62,2)
Living alone, *n (%)*			
No	18 (41,9)	15 (38,5)	33 (40,2)
Yes	23 (53,5)	24 (61,5)	47 (57,3)
Missing	2 (4,7)	0 (0)	2 (2,4)
Pain duration, *n (%)*			
3–6 month	17 (39,5)	12 (30,8)	29 (35,4)
7–12 month	5 (11,6)	6 (15,4)	11 (13,4)
13–23 month	0 (0)	5 (12,8)	5 (6,1)
2–5 years	6 (14)	7 (17,9)	13 (15,9)
6–10 years	1 (2,3)	2 (5,1)	3 (3,7)
> 10 years	1 (2,3)	2 (5,1)	3 (3,7)
Missing	13 (30,2)	5 (12,8)	18 (22)
Pain diagnosis, *n (%)*			
Nociceptive	2 (4,7)	4 (10,3)	6 (7,3)
Neuropathic	0 (0)	1 (2,6)	1 (1,2)
Functional	6 (14)	6 (15,4)	12 (14,6)
Mixed	14 (32,6)	18 (46,2)	32 (39,0)
Not the reason of the stay	21 (48,8)	10 (25,6)	31 (37,8)
HADS, *M (SD)*			
Anxiety	7.67 (±4.75)	8.24 (±4.67)	
Depression	6.23 (±3.72)	6.45 (±4.07)	
NPIS, *M (SD)*	7.92 (±1.76)	7.6 (±1.93)	

HADS: Hospital Anxiety and Depression Scale; NPIS: Nurse patient Interaction Scale

Table 2
Summary Statistics of Primary and Secondary Outcomes by Treatment group.

	Control Group			Treatment group		
	n	Mean	SD	n	Mean	SD
PGIC	38	3.58	1.64	34	4.29	1.77
PI	43	0.147	0.376	39	0.124	0.529
PS	43	1.392	2.551	39	0.889	2.292
HADS	43	0.116	0.459	39	0.197	0.554
NPIS	43	1.345	3.321	39	0.368	3.381

PGIC: Patient Global Impression of Change; PI: Pain Intensity; PS: Pain Severity; HADS: Hospital Anxiety and Depression Scale; NPIS: Nurse-Patient-Interaction Scale. With the exception of PGIC score, all secondary outcomes were measured at baseline (T0) and at T1. Thus, scores displayed in this table are the difference between scores at T0 and at T1 (T1-T0). For PGIC, 5 missing data for CG and 5 for TG were reported.

Nurse-Patient-Interaction Scale (NPIS) score measured at baseline significantly interacted with the intervention factor for predicting the PGIC score (p-value < 0.05). This interaction effect revealed that the higher the NPIS at baseline, the greater the PGIC after the intervention, but this *only for the control group* (see supplement – Fig. S2). This result is important as it highlights that the intervention effect is underpinned by an effect of the relationship with the nurse. When the intervention is performed by a nurse (i.e. for the treatment group), the effect of the NPIS score measured at baseline on the PGIC disappears. This means that the part of the variability in the PGIC score due to the relationship with the nurse is caught by the intervention factor when the intervention is performed by a nurse and remains visible when the intervention is performed by a machine. The PGIC score is globally higher for the intervention than for the control group, whatever the NPIS score at baseline. It is of note that the NPIS scores at baseline did significantly differ between groups.

In the same line, exploratory multiple regressions analyses showed that the Pain Severity (PS) score measured at baseline tendentially interacted with the intervention factor for predicting the PGIC score (p-value < 0.1). This interaction effect revealed that the higher the PS score at baseline, the greater the PGIC after the intervention, but *only for the control group* (see supplement – Fig. S3). The PS at baseline hence matters for predicting the PGIC after the intervention (the higher the PS, the higher the PGIC) but *only* if the massages are performed with a machine; if performed by a nurse, the effect of PS at baseline disappears and the PGIC is overall higher than the PGIC measured in the control group.

Taken together, these results highlight the consistency of the phenomenon for nurse-patient interaction and for pain severity. This consistency supports the hypothesis that the results of a TM performed by the nurse are not random but rather point to a real effect of the intervention which abrogates the confounding effects due to NPIS and PS at baseline. These observations hence reinforce the confidence that one can draw from the results observed with the primary endpoint.

Among secondary outcomes anxiety and depression were considered. No specific effect on these variables was observed. However, it should be noted that patients in both groups had low scores (mean scores largely below 11) for both anxiety and depression at baseline (Table 1) indicating the absence of both mood problems.

These results are in line with those of the literature indicating that massage therapy contributes to increased well-being [18,19] and treatment satisfaction [17,20]. However, we did not select a specific type of pain, be it neurogenic, nociceptive or neuroplastic, as we were mainly interested in the patients' subjective perception of pain. We were all the more interested in this dimension that Touch massage typically belongs to integrative care. We none the less analyzed the results according to the patient's type of pain, but the results showed no significant differences ($F(3, 35) = 2.599$; $p = 0.068$). Further, the description of the patient population also showed that the nature of pain was also very similar in both groups (see Table 1).

Furthermore, participants in the TM group tended to perceive more global change in the impact of pain on quality of life than participants who received massage from the machine. Therefore, TM is a promising intervention in the context of chronic pain which knows to significantly impair patients' quality of life [1,3,7]. It is worth mentioning that we decided on twice fifteen minutes of massage per week for pragmatic reasons but according to the setting and the type of pain, the literature shows that other doses can be beneficial. This is particularly the case for cancer pain [45]. Our results thus support the conclusion that through gentle touch, massage therapy can strengthen patient-care provider relationship [24,29,30].

This study has limitations that need to be acknowledged. Although a power calculation was performed before starting the study, the sample size ended up being too small to conduct subgroup analyses that may have allowed us to refine our results. As a consequence, the impact of variables such as the pain duration, location or its nature could not be investigated any further. It could be argued that the effect of foot

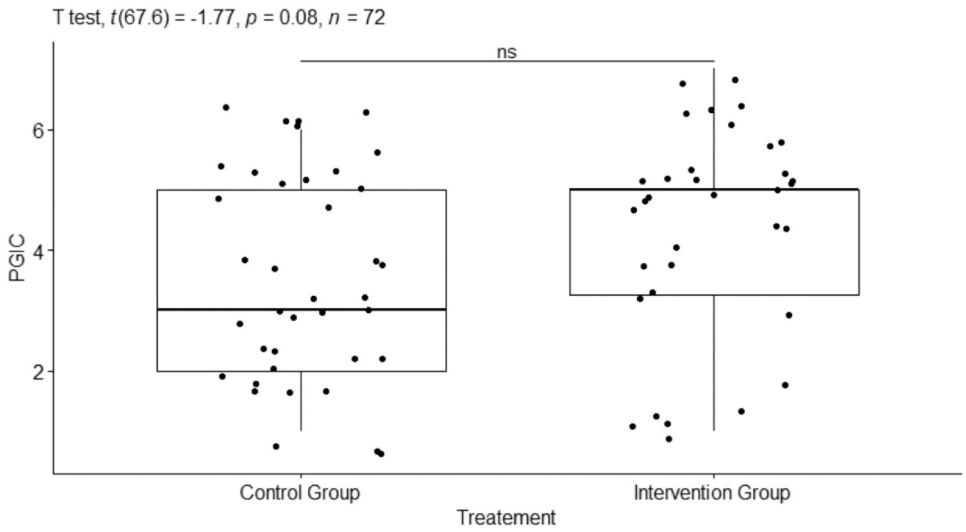

Fig. 2. Distribution of PGIC across control and treatment group.

Table 3
Welch t-tests Results.

Dependant Variable	*t* (df)	*p*-value	Cohen's d
PGIC	1.77 (67.6)	0.081	0.42
PI	0.23 (67.85)	0.822	0.05
PS	0.94 (79.99)	0.350	0.20
HADS	0.72 (74)	0.475	0.16
NPIS	1.32 (78.92)	0.192	0.29

Effect of the intervention on the primary and secondary outcomes. PGIC: Patient Global Impression of Change; PI: Pain Intensity; PS: Pain Severity; HADS: Hospital Anxiety and Depression Scale; NPIS: Nurse-Patient-Interaction Scale.

Table 4
Multiple Regressions of NPIS score measured at baseline.

	Df	Sum Sq	Mean Sq	F value	Pr (>F)	Partial Eta Square
Intervention	1	9.178	9.178	3.428	0.068	0.048
NPIS baseline	1	6.734	6.734	2.515	0.117	0.036
Intervention x NPIS baseline	1	13.516	13.516	5.048	0.028	0.069
Residuals	68	182.072	2.678	NA	NA	

NPIS: Nurse-Patient-Interaction Scale. Effects of NPIS score measured at baseline and intervention on the PGIC.

massage may vary according to these variables. It may also be a point for future research to investigate the importance of the location of the body part that is massaged on the patient's pain experience. The study has been severely hampered by the SARS-Covid2 outbreak, insofar as patients had to be transferred to specific units devoted to the treatment of the disease, but the outbreak also significantly affected the burden of care on the health care teams. This made not only the recruitment for the study more difficult, but it also considerably restrained the time availability of the providers trained to perform the massages who became involved in more urgent day to day care obligations.

While our methodological approach does not present with the well-known strengths of RCTs, it has a clear interest when it comes to conduct a study in real-life settings, where a pragmatic approach may be required. Our clinical cluster trial design has clear weaknesses and our results would merit further confirmation which could be obtained only via a proper RCT. However, we still consider that our findings point to important aspects when it comes to consider the benefits of a technique such as Touch massage. The reliability of the data lies with the use of a sound and adequate methodological design in spite of its weaknesses, and the collection of data using validated questionnaires.

5. Conclusion

This study shows with a rigorous and pragmatic methodology that TM has a positive impact on the perception of pain relief in patients suffering from chronic pain. TM appears as a well manageable and promising therapy for these patients who are often very difficult to treat because of the nature of pain, its chronicity and its impact on the patient's life. Enlarging the sample size would increase the significance level of the findings and thus provide the conditions necessary to confirm the benefits of TM.

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Ethical statement

This study received the approval of the Cantonal Commission for Ethics and Human Research (2019–00848) on 09 July, 2019. Written and oral consent form was obtained.

CRediT authorship contribution statement

DA ROCHA RODRIGUES. Gora: Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Funding acquisition, Project administration, data curation, Investigation, **BOLLONDI. Catherine**, Conceptualization, Investigation, Supervision, Funding acquisition, **BOEGLI. Monique**, Conceptualization, Supervision, Investigation, Massage training, **CURTIN. François**, Methodology, Formal analysis supervision, Software, Writing – review & editing, **ANEX. Adrien**, Writing – original draft, Writing – review & editing, literature review, Data curation, **CEKIC. Sezen**, Formal analysis, Writing, **LUTHY. Christophe**, Resources, Writing – review & editing, Supervision, **DESMEULES. Jules**, Conceptualization, Methodology, Validation, Project administration, **CEDRASCHI. Christine**, Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Supervision, Project administration.

Declaration of Competing Interest

The authors have no conflicts of interest to declare. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.aimed.2023.09.004.

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