



Measuring patient reported outcomes of acupuncture treatment on pain patients' health status



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1. Introduction

Pain is an unpleasant and emotional experience [1] that influences quality of life, daily functioning, and work status [2]. Pain is very common in the Netherlands, where one of every five adults has chronic pain [3]. Sensation, perception, and behaviour affect pain and should be considered when diagnosing and treating each individual patient [4]. Many studies have shown that acupuncture is an effective method and reasonable referral option for the management of pain [5,6]. However, testing acupuncture treatment in a satisfactory way in randomized controlled trials (RCTs) with standardized treatment protocols is very difficult [7–10]. Blinding or controlling with the correct intervention seems particularly complicated in practice [11–13], partly due to the holistic healthcare model of acupuncture, which examines the whole person rather than the illness alone [14]. The World Health Organization (WHO) is currently calling for member states to increase regulation and integration of complementary medicine in healthcare [15]. Therefore, it is important to identify different ways to study the personalized, non-reductionist approach to diagnosis and treatment in holistic healthcare [11,16].

Acupuncture is the most popular form of complementary medicine in the Netherlands [17] and it is expected that its popularity will continue to rise in the future [18]. However, little is known in the Netherlands about pain patients' perspectives of their health status following acupuncture treatment. Therefore, rather than the isolated effects of acupuncture, this study investigates patient-reported outcome measures (PROMs) of complete acupuncture treatment in practice. This approach is in line with the ICF model (International Classification of Functioning, Disability and Health) used by the WHO, which states that the patient's perspective of health and desired health benefits, rather than the medical diagnosis, should be central [19]. The Netherlands has adapted this new approach to healthcare, in which healthcare and prevention are more coordinated [20].

This observational multicentre case series study aims to demonstrate the perceived value of acupuncture treatment regarding pain patients' health status. Do pain patients experience an improvement in health status following acupuncture treatment? Health status in this study is determined by level of pain, limitations to daily functioning as a result of pain, and subjective wellbeing. The secondary aim of this study is to determine which aspects of acupuncture treatment can be associated with changes in pain patients' health status.

2. Materials and methods

The present study is registered in the Dutch Trial Registry as number 4787. Prior to the commencement of the study, the attending acupuncturists were trained in the use of the patient-reported online questionnaire 'MYMOP2-online' (Appendix 1).

2.1. Measurement instrument

The MYMOP2-online questionnaire was adapted from the MYMOP2, which is a problem-specific questionnaire developed for research into complementary healthcare, and useful for a wide variety of health problems [21]. It is a short list, simple and quick for the patient to complete during a consultation; therefore, it is particularly well-suited for use in acupuncture practice. The MYMOP2-online asks for one or two specific pain complaints for

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which the patient seeks treatment, a description of the limitations to daily functioning, and a subjective opinion of their wellbeing during the previous week. Another question concerned the use of analgesic medication and whether patients thought it important to reduce or avoid medication. The location of pain, limitations to daily functioning, subjective wellbeing, and type of analgesic medication used were reported by the patient in the first questionnaire (T0; prior to the initial consultation) and were reprinted in the follow-up lists (T1, after four weeks; and T2, after 16 weeks); however, the scores for these items were erased to avoid influencing the new scores. The MYMOP2-online scores were stored in a database that was inaccessible to the acupuncturist. The questionnaire included a seven-point scale, from zero to six. A score of six denoted 'as bad as it could be,' and a score of zero denoted 'as good as it could be.' Additionally, the acupuncturist was asked to document data, including date, duration, theoretical base, and modality of acupuncture treatment from each treatment, in a database. MYMOP2 has been found to be valid and sensitive to change for evaluations in different clinical settings, including the acupuncture setting [22,23]. For the present study, the Dutch-translated version of MYMOP2 was used (Kortekaas, Kwee, & Winkelmeijer: Translation MYMOP instruction and forms. Unpublished material, 2013).

2.2. Design

Research took place in independent acupuncture practices. Computers, necessary for completing the questionnaire, were available in the practices. Newly-registered patients were invited to participate in the study in the order of arrival. During the initial consultation, patients received information from the acupuncturist regarding the goal of the study, and detailed instructions on how to complete the MYMOP2-online questionnaire. The patient received a closed envelope from the acupuncturist containing the login codes required to access the MYMOP2-online questionnaire. Prior to completing the questionnaire, informed consent was requested online for use of patient personal clinical data for this study. Patients completed the follow-up questionnaire T1 after four weeks and T2 after 16 weeks via a link in an automatically-generated email sent to them. In order to prevent missing data from uncompleted questionnaires, reminder emails were sent one week after the first email and, if necessary, again after two weeks.

2.3. Participants

All members (853) of the Dutch Acupuncture Association (NVA) were invited by email to participate in this observational multi-centre case series study. Twenty-six acupuncturists voluntarily agreed to participate. Eight acupuncturists withdrew before the commencement of the study, largely stating the extra workload involved. Eighteen acupuncturists (50% female, aged 40–65 years) with a minimum of two and a maximum of over 30 years' clinical acupuncture experience enrolled 110 pain patients in order of consultation. The acupuncturists, like all members of the NVA, were educated as physical therapists (11) or in another (para) medical profession (7), and trained in traditional Chinese medicine (TCM)-acupuncture. The inclusion criteria for the acupuncturists were: be a member of the NVA, practice in the Netherlands, have at least two years of clinical acupuncture experience, that the practice houses a computer, and be a Dutch speaker.

The recruitment of pain patients took place in Dutch acupuncture practices between September 2014 and February 2015. The inclusion criteria for patients were: new patients with pain longer than seven days in duration, not being treated with acupuncture elsewhere, older than 15 years, and able to complete a Dutch online

questionnaire. For personal reasons, 17 patients refused to participate in the study. Participants were allowed to resign from the study at any time, without consequences.

2.4. Intervention

The intervention consisted of routine acupuncture treatment. A deliberate choice was made not to assign patients to an intervention or control group, since patients had independently chosen to seek acupuncture treatment. Likewise, blinding the acupuncture treatment was not an option, as the personalized holistic approach, a defining characteristic of TCM, would be lost through treatment standardization. Acupuncture, based on the principles of TCM, includes treatment with needles supplemented with moxa, massage (tuina/guasha), cupping, electro-stimulation, instructions/lifestyle advice, etc. Several theoretical backgrounds underlie acupuncture treatment. The acupuncturists were mindful to act as if no study was taking place; therefore, nothing was changed as a result of the study. The acupuncturists choose from amongst 'Zangfu,' 'Five Element,' 'Dr. Tan's Balance Method,' 'Stems and Branches,' 'Ashi points,' 'Ear acupuncture,' and others. Acupuncture treatments were performed according to the rules of the NVA, which provide guidelines for quality, hygiene, and sterility in acupuncture practices. The rules of conduct and ethics were also adhered to.

2.5. Outcome measurements

The primary outcome measure was the results from the MYMOP2-online, which was completed by the patients at three given times (T0, T1, T2). The questionnaire included PROMs on pain, limitations to daily functioning, subjective wellbeing, and the use of analgesics. The secondary outcome measure was the acupuncturists' database, which included data regarding the number, duration, theory, and modality of acupuncture treatment.

2.6. Data collection and analysis

Data were collected in SPSS v21 for the purpose of performing statistical analyses. Open questions regarding 'pain location' were coded by two independent coders, and an agreement was reached in 90.6% of cases. After discussing the differences, an agreement was reached in 100% of cases. The demographics (age, sex) of the research population, duration of existing pain at the commencement of acupuncture treatment, and pain location were described. Mean and standard deviation (SD) of the MYMOP2-online items (symptom 1, symptom 2, daily functioning, and wellbeing) at T0, T1, and T2 were calculated. The health status of each patient was calculated as the sum of the mean of all completed items. Mean difference scores between T0 and T1 and between T1 and T2 of each item were calculated. The relative percentage in mean change was also calculated between the three time points. The outcomes of patients with complete data and patients with missing follow-up data were compared. Repeated measures ANOVA tests were performed to determine significant differences in mean change scores in patients who completed the questionnaire at all three time points. Questions regarding medication were not counted as a measure of health status, but were described separately. For example, '50% of the patients thought reducing medication is important.' To assess whether the PROMs were associated with patient demographics and treatment data (number, duration, theory, and modality), repeated measures ANOVA tests were performed.

2.7. Missing data

The total set of three MYMOP2-online questionnaires (T0, T1,

and T2) was completed by 68 patients. Forty-two patients did not complete one or more questionnaires. It appeared that at baseline patients with complete data had more pain and limitations to daily functioning compared to patients with missing follow-up data. Missing values were replaced according to the last observation carried forward (LOCF) method. All analyses were performed with and without the replacement of missing data. The differences between the follow-up measurements decreased slightly, which was compensated by the larger number of observations. In general, the replacement did not affect the results. For this reason, and because the imputation introduces extra bias to the means, only the original data were reported.

3. Results

3.1. Participants

During the initial consultation, participants (N = 110) provided informed consent and completed the first MYMOP2-online questionnaire (T0). The indicated duration of pain before the commencement of acupuncture treatment varied from one week to more than five years. Eighty percent of participants suffered from chronic pain (>3 months' duration). Participants sought acupuncture for a variety of pain problems, ranging from musculoskeletal pain in the lower extremities/hips, back, neck, upper extremities/shoulders, and head/face, to internal pain in the stomach, intestines, bladder, or due to menstruation. Patient characteristics are presented in Table 1.

The health status score was calculated using the mean of all the completed items: symptom 1, symptom 2, daily functioning, and wellbeing. A MYMOP2-online score of six denotes 'as bad as it could be,' and a score of zero denotes 'as good as it could be.' At baseline (T0), no significant differences were found in health status score between the age and sex groups. Patients with internal pain reported a significantly poorer health status compared to patients with neck pain ($p < 0.01$), upper extremity/shoulder pain ($p < 0.01$), and head/facial pain ($p < 0.05$). These differences were not observed at T1 and T2.

Before attending the acupuncture practice, 35.5% of patients used medication to treat their pain. Of these patients, 79.5% thought it was very important to reduce their use of medication.

Table 1
Patient characteristics. Frequency (%) N = 110.

Patient characteristics	Frequency (%) N = 110
Gender	
Male (%)	32 (29.1)
Female (%)	78 (70.9)
Age (years)	
<20 (%)	3 (2.7)
20–39.9 (%)	29 (26.4)
40–59.9 (%)	54 (49.1)
>60 (%)	24 (21.8)
Median (range)	47.6 (15.4–82.9)
Duration of pain symptoms	
1–4 weeks (%)	11 (10.0)
4–13 weeks (%)	11 (10.0)
3–12 months (%)	28 (25.5)
1–5 years (%)	29 (26.4)
>5 years (%)	31 (28.2)
Pain location	
Lower extremity/hip (%)	18 (16.4)
Back (%)	27 (24.5)
Neck (%)	10 (9.1)
Upper extremity/shoulder (%)	26 (23.6)
Head/face (%)	17 (15.5)
Internal (%)	12 (10.9)

After four weeks (T1), the number of analgesia users was 15.8%, a decrease of 44.5%. Of the T0 non-medication users, 62.0% thought it very important to avoid using analgesic medication. Patients who used medication at the commencement of acupuncture treatment reported a significantly higher pain score (S1) at T0 ($p < 0.05$) and at T1 ($p < 0.01$) than those who did not use medication. These differences were not observed at T2.

3.2. MYMOP2-online mean scores

Patients who did not complete all three questionnaires were excluded from the analyses. Repeated measures ANOVA tests were conducted to compare differences in the means of all MYMOP2-online items: symptom 1, symptom 2, limitations to daily functioning, wellbeing, and health status before (T0), during (T1), and after (T2) acupuncture treatment (Table 2 ($p < 0.01$)).

Fig. 1 clarifies where the differences in the means of all the MYMOP2-online items, with 95% confidence intervals (CIs) at three time points (T0, T1, and T2), were observed.

The mean baseline MYMOP2-online score for pain (S1) was 4.15 (SD: 1.11). At T1, the score was 2.54 (SD: 1.65), and at T2 it was 2.31 (SD: 1.67). The total health status score at T0 in the study population was 3.82 (SD: 1.01), at T1 2.52 (SD: 1.44), and at T2 it was 2.31 (SD: 1.41). The non-overlapping confidence intervals showed significant differences between the means from T0 and T1, and between T0 and T2, but not between T1 and T2.

In addition, the percentage change of all items was calculated. After four weeks (T0-T1), pain patients reported a 38.8% decrease in primary pain, a 38.4% decrease in secondary pain, a 33.2% decrease in limitations to daily functioning, a 24.2% improvement in wellbeing and a 34.0% improvement in health status. Health improvements persisted over the long term. From the start of acupuncture treatment until 16 weeks later (T0-T2), patient-reported improvements were 44.4% for primary pain, 55.0% for secondary pain, 42.9% for limitations to daily functioning, 33.7% for wellbeing and 39.5% for total health status.

Fig. 2 shows the mean differences (95% CI) in pain (S1) at T0, T1, and T2 according to the duration of the existing pain before patients commenced acupuncture treatment. The CIs in Fig. 2 show a trend in mean differences in all groups between T0, T1 and T2; longer-term pain demonstrated smaller differences in means after acupuncture treatment. However, repeated measures ANOVA (N = 68) tests did not show statistically significant interactions between patient pain duration prior to the commencement of acupuncture treatment and the improvement in the means for symptom 1 (N = 68; Wilks' Lambda = 0.803, F (8,124) = 1.795, $p = 0.084$).

3.3. Acupuncture treatment characteristics

The acupuncturists attempted to perform treatments as though no study was taking place. Acupuncture involves a holistic approach that takes the whole person into consideration, rather than the illness alone. Therefore, it is possible that patients with

Table 2
Repeated measures ANOVA of MYMOP2-online items (N = 68).

Wilks' Lambda	Value	F	Df (error)	Sig.
Symptom 1	0.501	32.911	2(66)	<0.001**
Symptom 2	0.486	7.947	2(15)	<0.004*
Daily functioning	0.539	16.271	2(38)	<0.001**
Wellbeing	0.855	5.599	2(66)	<0.006*
Health status	0.528	29.495	2(66)	<0.001**

* $p < 0.01$ ** $p < 0.001$.

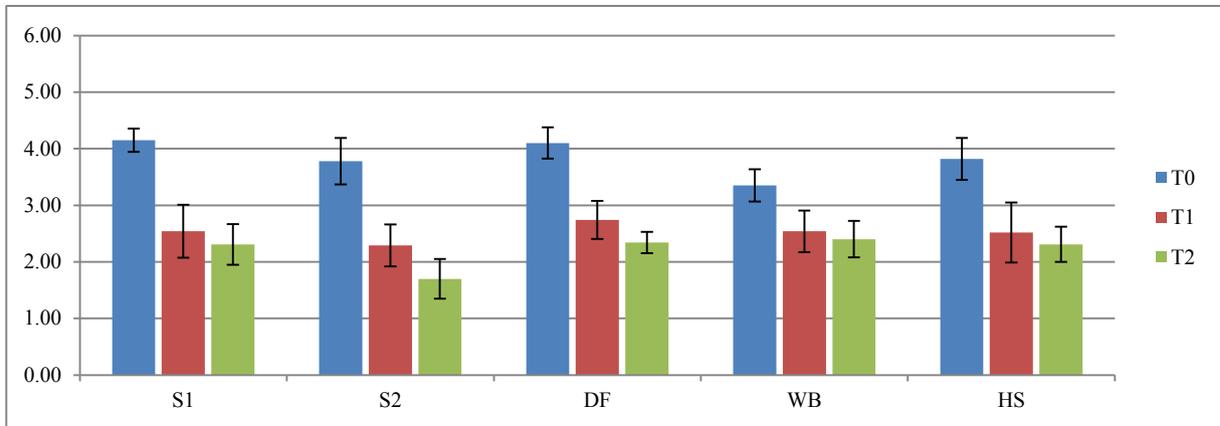


Fig. 1. MYMOP2-online mean scores. Six represents “as bad as it could be,” and 0 “as good as it could be.” T0 = baseline (N = 110), T1 = at four weeks (N = 76), T2 = at 16 weeks (N = 80). S1 = symptom 1, S2 = symptom 2, DF = limitations in daily functioning, WB = wellbeing, and HS = health status.

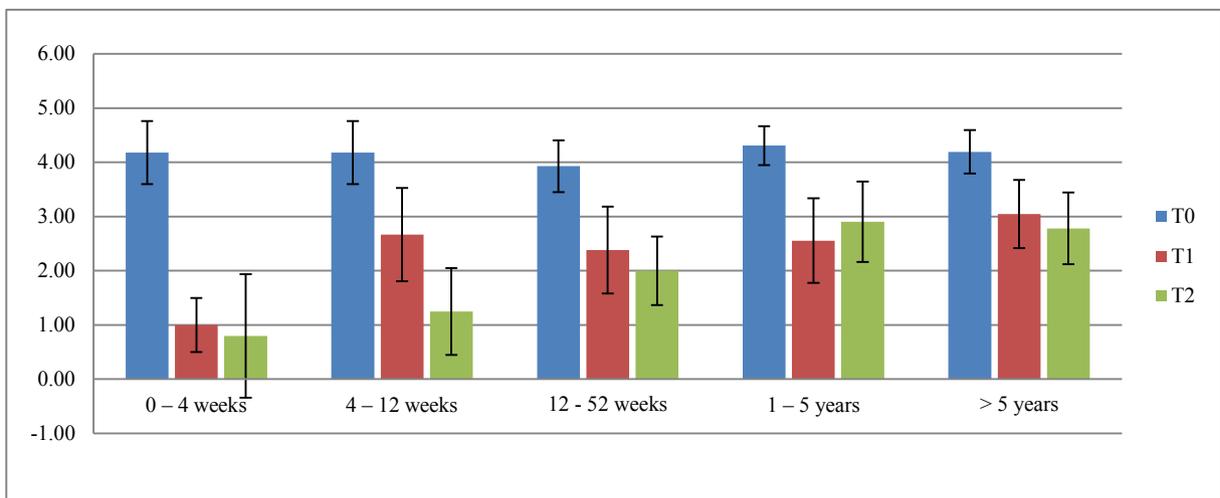


Fig. 2. Mean scores of symptom 1 (S1) in relation to the duration of pain at the start of acupuncture treatment. Six represents “as bad as it could be,” and 0 represents “as good as it could be.” T0 = baseline (N = 110), T1 = at four weeks (N = 76), T2 = at 16 weeks (N = 80).

individually differing energetic conditions, can receive different acupuncture treatments. Thus, there are neither protocols nor universally-prescribed treatments; rather, each individual acupuncturist determines, in mutual agreement with the patient, what the desired goals are and which treatment is the most appropriate at this time for the patient.

Fig. 3 shows the wide variety of acupuncture treatment characteristics that appeared in the present study. Treatments were documented by the acupuncturists for 107 patients. Reports for three patients were missing.

Patients received a mean of 3.6 acupuncture treatments in the first four weeks (T0–T1) and 5.8 treatments in the total 16-week period (T0–T2). Most treatments (52.7%) had duration of between 30 and 45 min (Fig. 3a). The theoretical background of the acupuncture treatments (Fig. 3b) used in this study are based on ‘Zangfu’ (65.4%), ‘Five Elements’ (34.6%), ‘Dr. Tan’s Balance Method’ (40.2%), ‘Stems and Branches’ (13.1%), ‘Ashi points’ (54.2%), ‘ear acupuncture’ (27.1%), and others (15.9%). The modality of acupuncture treatment (Fig. 3c) consisted for 100% of needles. Additionally, supporting treatments consisted of ‘moxa’ (27.1%), ‘massage’ (tuina/guasha) (6.5%), ‘cupping’ (17.8%), ‘electro-stimulation’ (15.0%), ‘instructions/lifestyle advice’ (61.7%) and others (26.2%).

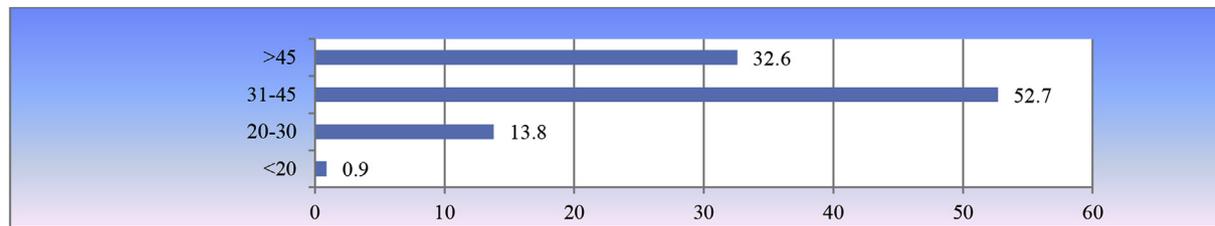
Fig. 4 shows the improvements in health status mean scores in

relation to the theoretical background (Fig. 4a) and modality (Fig. 4b) used for the treatment.

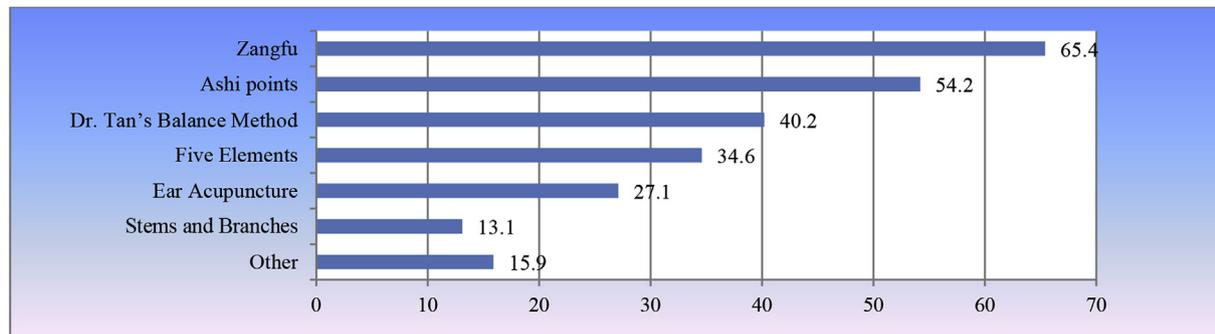
Acupuncture treatment in the present study reflected common clinical practice; therefore, more than one theoretical background and/or modality can be used during a single treatment. ANOVA repeated measures tests could not reveal a specific association between changes in health status mean scores and theoretical background or modality of treatment.

As reported by 88.2% of the acupuncturists, ‘lifestyle advice/instructions’ were an integral part of the acupuncture treatment. ‘Lifestyle advice/instructions’ were provided in 61.7% of the acupuncture treatments, and included the following options: ‘relaxation/breathing exercises’ (23.5%), ‘motion exercises’ (41.2%), ‘helping the patient to understand their own condition’ (35.3%), ‘facilitating a patient’s own contribution to recovery by giving advice about relaxation/movement/diet/lifestyle in relation to TCM diagnoses’ (64.7%), and ‘yoga/qigong/tai chi’ (17.6%). Some acupuncturists (17.6%) reported none of these options, claiming that ‘I think it is self-evident: facilitating the patient is a natural part of the acupuncture treatment that I provide’; therefore, they did not report this as an extra treatment option.

a. Duration of acupuncture treatment



b. Theoretical background



c. Modality

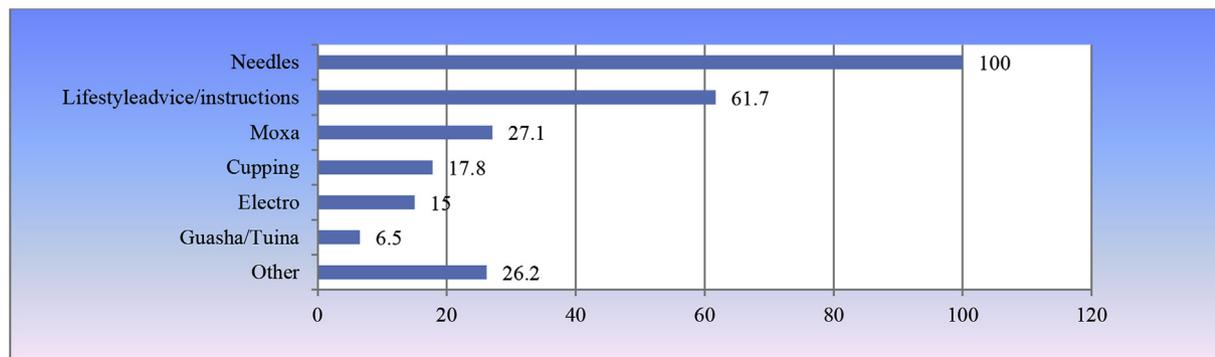


Fig. 3. Characteristics of acupuncture treatment per patient (N = 107). (a) Duration of acupuncture treatment (min). (b) Theoretical background (*more than one option allowed*). Frequency (%). (c) Modality (*more than one option allowed*). Frequency (%).

4. Discussion

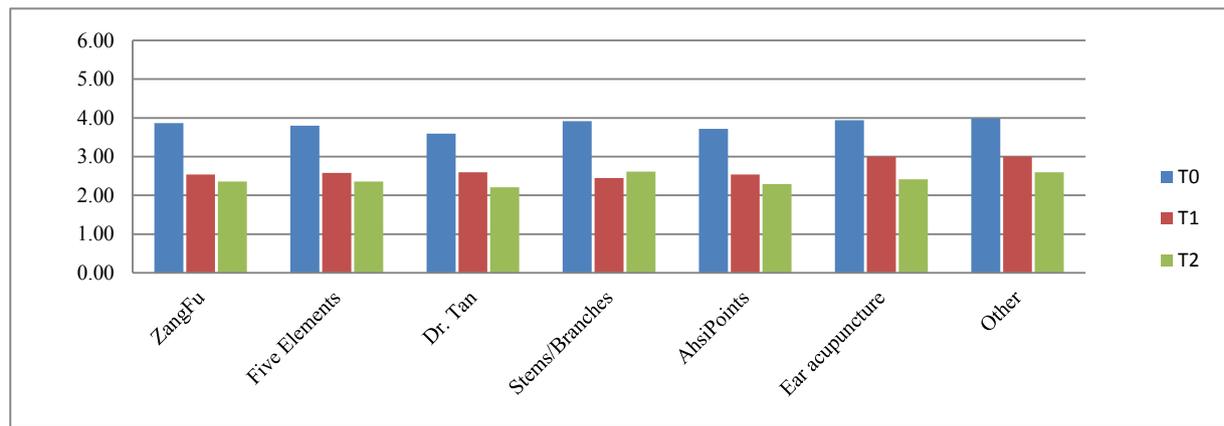
Conducting pragmatic research was one of the aims of the present study. Pragmatic trials are designed to evaluate the effectiveness of interventions in real-life routine practice conditions [24]. As patient perspectives of changes in health status were the focus of the current study, a deliberate choice was made not to randomize and not to compromise the holistic model of acupuncture treatment; therefore, each individual received a personal approach to her/his pain. The holistic model of acupuncture assumes that health is more than the absence of illness. Therefore, all aspects that form the pain patient's health status, rather than pain alone, were investigated.

The improvements observed in pain, limitations to daily functioning, subjective wellbeing, and total health status were statistically significant after four weeks of acupuncture treatment. Improvements persisted over the long term, measured here at 16 weeks.

The clinically minimal important difference for a change score, using a seven-point scale, is between 0.5 and 1.0. Therefore, any change less than 0.5 does not represent a change of importance to the patient, and any change above likely does [25]. The improvements observed here, of 1.61 (38.8%) in pain and 1.30 (34.0%) in total health status after four weeks, can therefore be considered clinically meaningful for both acute and chronic pain patients. Chronic pain patients, who sometimes suffer for years, often consider many different treatment options before turning to acupuncture. In many cases, the chronic pain patients in this study reported being told to 'learn to live with it.' The health benefits observed here that were gained from acupuncture are particularly valuable for this group.

The results of this study are in line with results from a systematic review of 12 randomized controlled trials of knee osteoarthritis, which showed that acupuncture significantly reduces pain intensity and improves functional mobility and quality of life.

a. Theoretical background



b. Modality

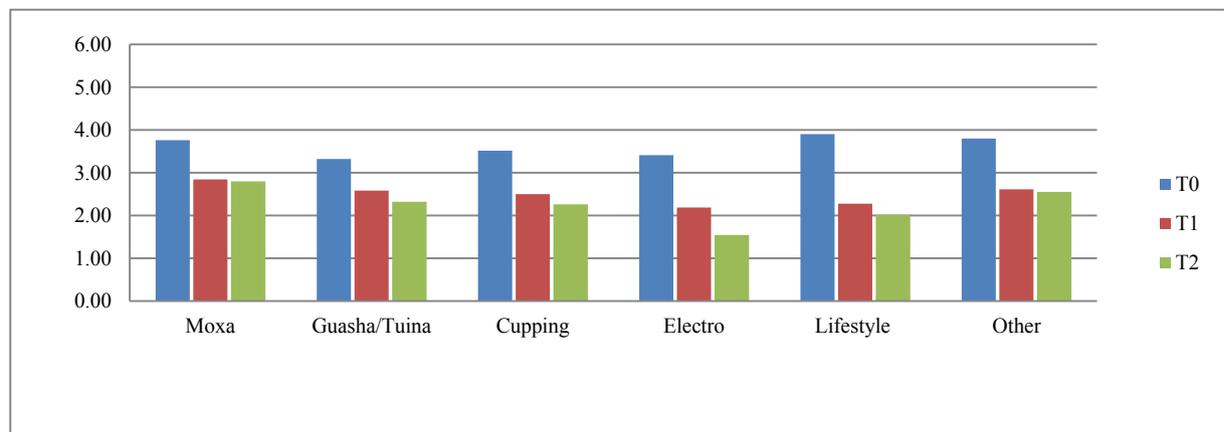


Fig. 4. Health status mean scores in relation to acupuncture treatment characteristics. (a) Theoretical background. (b) Modality; six represents “as bad as it could be.” and 0 represents “as good as it could be.” T0 = baseline, T1 = at four weeks, T2 = at 16 weeks (N = 107).

Greater reduction in pain was found when the treatment duration was more than four weeks [26]. Also, an overview of 16 systematic reviews of low back pain showed short-term improvements in pain and function using acupuncture [27]. Other ‘positive effects’ of acupuncture treatment of pain have been found for migraine prophylaxis, headache, and post-operative pain [28].

On average, 5.8 treatments were applied; therefore, patients likely did not receive treatment for the entire course of the present study. The reason for this was not investigated. In the Netherlands, acupuncture treatment is not completely covered by basic health insurance; patients who are considering acupuncture treatment are required to purchase extra insurance to receive (partial) compensation. Therefore, long-term treatment may not be feasible for many patients. Nevertheless, the health benefits gained from acupuncture persist over the long term.

Many patients indicated that it was important to avoid or reduce the use of analgesic medications. Over the course of the present study, the amount of analgesic medications taken by patients decreased considerably. During acupuncture treatments, patients may become more aware of their self-healing abilities and potential to contribute to their own recovery; in this way, they may become less dependent on analgesic medication. Another possibility is that patients often seek help from an acupuncturist on their own initiative, indicating that they may have an interest in holistic

health modalities and are therefore more critical and cautious of the use of medication. The reduction of medication observed here is in line with the results of a large literature review, which identified five pain conditions in which acupuncture may be used to reduce reliance on pharmacological and surgical analgesic options [28].

Needles are the best-known acupuncture medium and were used for all patients in this study. However, the wide range of theory and modality options considered in this practical study shows that acupuncture is a very complex and multimodal intervention. It was not possible to assign the improvements in health status to one theory or modality. Further research is necessary to investigate the connection between specific theories and modalities and improved patient-reported outcomes. In practice, this type of research will be very difficult, because a TCM consultation depends on the personal needs and conditions of the patient. Therefore, a choice was made in this pragmatic study to use the patient’s perspective as the best method to assess the effectiveness of acupuncture treatment on the patient’s health status, regardless of the theory or modality used.

The many types of acupuncture treatment considered in the present study showed that there is more than just the use of needles at play in acupuncture therapy. The acupuncturists attempted to help the patient to understand her/his complaints and condition/s from a holistic approach by providing lifestyle advice and exercises

for a longer-term effect. Other studies have confirmed that promoting individualised self-care instructions and lifestyle advice is an integral part of acupuncture treatment [29], and that it is important to involve the patient in her/his own recovery to facilitate a longer-lasting effect [30]. This was also confirmed by a recent systematic review on patient-practitioner communication, which showed a small effect of acupuncturist behaviour on pain outcomes [31]. The patient's beliefs [32] and positive suggestions from the acupuncturists had an effect both on pain reduction and on satisfaction [33].

4.1. Strengths

Instead of comparing an experimental intervention under controlled conditions, the aim of the present study was to document how and with which outcome acupuncture is provided in routine practice for pain patients in the Netherlands. The minimal interference exerted here in routine acupuncture practice ensures that the findings reflect current practice in the Netherlands. A further strength of the present study was the use of the MYMOP2-online questionnaire, which is short, simple, and easy to complete. The MYMOP2 shows a better response rate than the SF-36 health survey [34]. The patient completed the questionnaire in a shielded environment without any involvement by the acupuncturist, which maintained answer purity. In addition, this instrument was deliberately chosen because of its ability to clarify the scores of the questions in the follow-up lists. Patients were not required to remember their pain at the time of relief; they were rather asked to assess their level of pain during the previous week. A comparison of their own, previously-reported (T0, T1) scores was impossible; therefore, the new scores were rendered as purely as possible.

4.2. Limitations

The main limitation of the present study was the absence of a control group. Therefore, it is possible that the results observed for acupuncture treatment were due to placebo effects or spontaneous remission. However, pure placebo effects tend to be small and decrease after multiple treatments [35], which is in contrast to our long-term results. Moreover, the statistically significant results of the present study are in line with the results of a randomized controlled trial (RCT) of low back pain, in which acupuncture treatment was significantly beneficial for a participating group compared to a waiting list control group [36].

Of the 110 pain patients included in the study, 68 completed the total set of three questionnaires. Reminder emails did not always lead to the required response. As a result, there were missing data that had to be dealt with by making assumptions about underlying missing data mechanisms. Since there were no indications that the imputed LOCF data provided a better estimate of the impact, our calculations should provide valid data.

The results may have been biased by patient selection. The acupuncturists sometimes forgot to ask patients to participate in the study. Acupuncturists may not have turned their full attention to the study, as they did not receive any additional financial compensation for participating. Likewise, it is possible that patients who agreed to participate and who completed all questionnaires had more positive expectations of treatment results. Despite these limitations, we believe the results of the present study are statistically and clinically meaningful.

4.3. Recommendations

To strengthen the results using the patients' perspectives, future studies should compare two groups. This may be difficult in practice as patients attend the acupuncture practice on their own

initiative and are willing to assume the costs involved due to the possibility of receiving help. It is unlikely that patients would be satisfied being placed into a 'non-treatment' group, or that they would be willing to pay for it. Therefore, we suggest comparing two randomized groups. One group of patients should receive personalized acupuncture treatment with the full attention and presence of the acupuncturist. The acupuncturist should accurately describe and choose a treatment from the wide variety of treatment options. The second group should receive acupuncture treatment in which the acupuncturist leaves the treatment room immediately after applying the needles. Communication between patient and acupuncturist in this group should not form part of the treatment, except for during the initial consultation, during which the tailored treatment plan is decided. Furthermore, treatment modality options other than needles should not be chosen. In this setting, the effect of needles only could be compared to the effect of the full range of acupuncture treatment. Finally, it would be interesting to investigate whether the improvement in daily functioning reported by the patient leads to reduced work absences. Statistics regarding absenteeism can easily be retrieved from large companies.

4.4. Implications for nursing

The present study provides a solid foundation for the examination of the PROMs of health status following acupuncture treatment. The results provide physicians and nurse practitioners with further insight into the holistic healthcare model of acupuncture. These practitioners should in turn provide information to patients regarding the possibilities that acupuncture treatment can offer in the management of pain. When conventional treatments are ineffective, unacceptable to the patient, or have intolerable side effects, acupuncture may be considered as a referral option for the treatment of pain. The results reported here are invaluable for pain patients, who are responsible for taking care of their own well-being. The results of the present study may also be useful in the preparation of Dutch guidelines on pain.

5. Conclusions

In conclusion, the results of the present study show that the pain patients who self-selected acupuncture and chose to complete all three questionnaires experienced a statistically-significant and clinically-relevant improvement in health status after four weeks of acupuncture treatment. This improvement persisted after 16 weeks. However, due to the absence of a control group, the extent to which the improvements were a result of the different aspects of acupuncture treatment remains unclear. This observational study demonstrates the overall effectiveness of routine acupuncture treatment without compromising the patient-centred and holistic approach of acupuncture to diagnosis and treatment. In short, the positive results observed here support the effectiveness of acupuncture in routine practice as perceived by the pain patient; support their consideration as a reasonable treatment option for pain.

Compliance with ethical standards

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical approval

Full ethical approval by a research ethics committee for this study protocol was not mandatory; however, this study was registered in the Dutch Trial Registry under number 4787.

Informed consent

Informed consent was required to be provided online from all individual participants included in the study prior to completion of the initial questionnaire.

Acknowledgments

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ctcp.2017.06.005>.

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