

An Acupuncture Protocol for the Treatment of Erectile Dysfunction: A Delphi Process

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Keywords

Acupuncture · Erectile dysfunction · Treatment protocol · Delphi process · Traditional Chinese medicine · Expert consensus · Best practice

Abstract

Introduction: Erectile dysfunction (ED) is a widespread disorder, and the worldwide incidence is rapidly increasing. Acupuncture, an intervention out of the spectrum of traditional Chinese medicine (TCM), has a long tradition as treatment for ED. Nonetheless, a best-practice treatment protocol is currently missing. A recent systematic review and meta-analysis confirmed a huge diversity of acupuncture treatments for ED and concluded that there is an urgent need to standardise acupuncture treatment for ED. Consequently, the authors conducted a Delphi process with the aim to achieve an expert consensus as a basis for the development of a best-practice protocol. **Methods:** The Delphi process consisted of four rounds of questionnaires with closed and open-ended questions. Eleven acupuncture experts participated. The therapeutic aim was defined as "to achieve an erection sufficient for sexual satisfaction." **Results:** Consensus was achieved on 24 acupoints corresponding to 12 TCM syndromes. The syndromes were KI Yang xu, KI Yin xu, KI Qi xu, Ki and HT not harmonised, LR Qi Stagnation, LR Qi stagnation and Heat, Liver Blood xu, Liver Blood xu and Liver Qi stagnation, Damp-heat sinking to the lower Jiao5, HT and GB Qi xu, SP xu and HT Blood xu, Yin xu. The suggested optimal dose was between 11 and 15

treatments given once or twice a week. **Conclusion:** An expert consensus-based, semi-standardised best-practice treatment protocol for the treatment of ED was developed. Moreover, the Delphi process also revealed inconsistencies as to which signs and symptoms constitute a TCM syndrome. Further Delphi studies including a broader range of experts from various acupuncture traditions are needed to establish further agreement. Nonetheless, the best-practice protocol introduced in this study provides a first point of departure for the implementation of a more standardised treatment approach. Moreover, since a recent meta-analysis concluded that more high-quality clinical studies on the topic are needed, this study provides a first standardised acupuncture treatment protocol for ED.

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Plain Language Summary

As many as 322 million men may be afflicted by erectile dysfunction (ED) (impotence) by 2025. The health consequences are substantial with an increased risk of cardiovascular diseases and higher mortality in addition to reduced quality of life. Acupuncture may be a potential treatment option with a low side-effect profile; however, a standardised treatment protocol has been lacking for the use in the clinic and in clinical trials. This study aimed to develop a best-practice acupuncture treatment protocol for the treatment of ED. Eleven acupuncture experts have by the

means of a Delphi process reached tool consensus on a diagnostic and a treatment protocol for men suffering from ED. This is the first attempt in modern times and in the West to provide clinical acupuncturists and researchers with a treatment protocol for this common health issue.

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Akupunkturprotokoll für die Behandlung der erektilen Dysfunktion – Ein Delphi-Verfahren

Schlüsselwörter

Akupunktur · Erektile Dysfunktion · Behandlungsprotokoll · Delphi-Verfahren · TCM · Expertenkonsens · Best Practice

Zusammenfassung

Einleitung: Erektile Dysfunktion (ED) ist eine weit verbreitete Störung mit weltweit rapide zunehmender Häufigkeit. Die Akupunktur, ein Behandlungsverfahren aus dem Bereich der Traditionellen Chinesischen Medizin (TCM), hat eine lange Tradition in der Behandlung von ED. Allerdings existiert derzeit kein Best-Practice-Behandlungsprotokoll. Eine kürzlich durchgeführte systematische Übersichtsarbeit und Metaanalyse bestätigte die große Vielfalt der Akupunkturbehandlungen bei ED und kam zu dem Schluss, dass es dringend notwendig ist, die Akupunkturbehandlung bei ED zu standardisieren. Die Autoren führten daher ein Delphi-Verfahren durch mit dem Ziel, einen Expertenkonsens als Grundlage für die Entwicklung eines Best-Practice-Protokolls zu erzielen. **Methoden:** Das Delphi-Verfahren umfasste vier Runden von Fragebögen mit geschlossenen und offenen Fragen. Elf Akupunkturexperten nahmen daran teil. Als Therapieziel wurde das Erreichen einer für die sexuelle Befriedigung ausreichenden Erektion definiert. **Ergebnisse:** Es wurde ein Konsens über 24 Akupunkturpunkte erzielt, die 12 TCM-Syndromen entsprechen. Die Syndrome waren KI Yang xu, KI Yin xu, KI Qi xu, KI und HT nicht harmonisiert, LR Qi-Stagnation, LR Qi-Stagnation und Hitze, Leber-Blut xu, Leber-Blut xu und Leber-Qi-Stagnation, feuchte Hitze, die in den unteren Jiao5 sinkt, HT und GB Qi xu, SP xu und HT Blut xu sowie Yin xu. Die empfohlene optimale Dosis lag bei 11 bis 15 Behandlungen ein-oder zweimal wöchentlich. **Schlussfolgerung:** Es wurde ein auf Expertenkonsens basierendes, halbstandardisiertes Best-Practice-Behandlungsprotokoll für die Behandlung von ED entwickelt. Darüber hinaus verdeutlichte das Delphi-Verfahren auch Unstimmigkeiten hinsichtlich der Frage, welche Zeichen und Symptome ein TCM-Syndrom darstellen. Weitere Delphi-Studien, die ein breiteres Spektrum von Experten aus verschiedenen Akupunktur-Traditionen einbeziehen, sind erforderlich, um einen weitergehenden

Konsens zu erreichen. Dennoch bietet das in diesem Artikel vorgestellte Best-Practice-Protokoll einen ersten Ausgangspunkt für die Umsetzung eines stärker standardisierten Therapieansatzes. Eine kürzlich durchgeführte Metaanalyse kam zu dem Schluss, dass weitere qualitativ hochwertige klinische Studien zu diesem Thema erforderlich sind, und dieser Artikel bietet daher ein erstes standardisiertes Behandlungsprotokoll zur Akupunktur bei ED.

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Introduction

Erectile dysfunction (ED) is probably one of the male health issues with the most rapidly increasing prevalence worldwide. It is estimated that about 322 million men worldwide will suffer from ED in 2025 [1]. One of the reasons for this is the fact that ED is not an isolated syndrome but mostly a symptom related to a wide variety of underlying diseases such as cardiovascular diseases. Generally, men suffering from ED have an increased risk of all-cause mortality [2]. Moreover, several pharmacological treatments such as alpha blockers, antihypertensives, antidepressants, antipsychotics, antiepileptics, antiandrogens, diuretics, and cancer treatments may induce ED as a side effect [3].

Over the last years, the symptomatic treatment with pharmacotherapy such as PDE5 inhibitors has become the first-line treatment for ED and has improved life for many men suffering from ED [3]. However, not all patients benefit from the use of PDE5 inhibitors; they are effective in only 60–70% of the patients [4]. Thus, for a substantial number of patients, pharmacological treatment options are not available. In addition, PDE5 inhibitors are not without side effects and can induce headache, flushing, gastric problems, nasal congestion, vision problems, dizziness, and priapism [4, 5]. In a recent publication, the authors discuss exactly these challenges related to the pharmacological treatment options for ED and call for “*simpler, cheaper, and equi-effective*” treatments with fewer side effects. Furthermore, they request a long-term causal-therapeutic intervention in addition to the date symptomatic treatment [6].

Acupuncture as a non-pharmacological treatment option for ED has not received more attention and is not intuitive because it has a long tradition [7] and is still applied, despite the availability of PDE5 inhibitors. To date, there are mainly two reasons why men suffering from ED turn to acupuncture: (i) they wish to avoid the common side effects of PDE5 inhibitors and (ii) they understand acupuncture as a non-pharmacological treatment option and thus a means to take control over their own health status [8].

Generally, acupuncture has the potential to regulate the autonomic nervous system, stimulate nerve endings, and activate various transmitters in the central nervous system [9, 10]. Transmitters such as dopamine, acetylcholine, NO, oxytocin, adrenocorticotropin have a promoting effect on erection [11]. Consequently, acupuncture stimulation has been shown to directly improve the blood supply of the corpus cavernosum, a pathway, which is likely to improve the firmness of the erection and the erectile function [12]. Thus, it is plausible to hypothesise that acupuncture treatment for ED may provide a combination of local as well as systemic stimulatory effects on erection.

A recent systematic review and meta-analysis confirms that acupuncture may provide a useful treatment option for ED. The analysis revealed that a combination of PDE5 inhibitors and acupuncture exhibits a better effect on erection than medication alone. Nonetheless, rigorous clinical studies with large sample sizes and objective measures are still warranted, and one of the reasons why it is still difficult to draw firm conclusions from existing studies is the fact that a best-practice treatment protocol for the acupuncture treatment of ED, which could serve as a basis for these studies, is not available [9].

Even though considerable progress has been made over the last decades in understanding the physiological mechanisms of action of acupuncture, the selection of the appropriate points for needling in a clinical setting is still usually based on the ancient system of traditional Chinese medicine (TCM). Even though in modern acupuncture philosophy the TCM system may be mainly understood as an educational approach in order to select treatment approaches, the system is still central in order to select the combination of acupuncture points used in clinical applications [13]. What makes the standardisation of acupuncture treatments even more complex is the fact that the concept of diagnosing a “syndrome” is central within this system in order to identify the appropriate treatment approach. In conclusion, due to educational and cultural differences in countries where acupuncture is practiced, it must be taken into account that clinical acupuncturists as well as acupuncture researchers may apply different traditions with regard to diagnosing TCM syndromes and accordingly influencing choice of acupuncture treatment [14, 15].

Despite the current diversity of treatment approaches, the recent meta-analysis concluded that acupuncture treatment for ED may provide a clinically effective add on intervention to pharmacological treatment. Nonetheless, the authors also conclude that more high-quality studies are needed. Possibly the most important precondition to improve the quality of research in this field and to make the studies comparable is the availability of a best-

practice, standardised treatment protocol for the acupuncture treatment of ED.

In conclusion, there is currently no consensus or standard acupuncture protocol for the treatment of ED available [16]. However, if the quality of acupuncture clinical trials for the treatment of ED are to be improved beyond the standardised reporting of clinical trials (see, e.g., the STRICTA checklist) [15, 17], then at least a more semi-standardised treatment approach would be most useful. Such an expert opinion-based best-practice protocol will not only help to improve the quality of clinical trials but also will inform and improve clinical practice. Consequently, there is a need for a semi-standardised treatment protocol which includes recommendations on which points to use and which dosing would be optimal [18]. One of the best approaches to develop a best-practice acupuncture treatment for ED is to use a Delphi process to reach expert consensus [9]. Therefore, the aim of this study was to develop a best-practice acupuncture (TCM) treatment protocol by means of a Delphi process.

Methods

TCM treatment of ED usually includes acupuncture treatment as well as the use of herbal medicine. However, a very limited number of TCM herbs are approved and available from safe sources in Europe. Moreover, the legislation in Norway and many of the EU countries prohibits the use of Chinese herbal medicine. Therefore, only an acupuncture treatment setting which includes diet and lifestyle advice was investigated in the Delphi process study [19, 20].

The Delphi process aims to build consensus by using a series of questionnaires delivered using multiple iterations to collect real-world knowledge from a group of experts. The method has been widely used in concept framework development in medical research [21].

One central advantage is that the Delphi process provides anonymity to respondents and an opportunity to freely express opinions; moreover, it prevents individual dominance in the group [22]. Limitations concerning Delphi studies are that they are time-consuming, often have low response rates, and lack detailed information on how they are conducted, which results in low repeatability and limited external validity [21]. Currently, there are no guidelines or recommendations on the appropriate sample size for expert consensus in a Delphi process. However, it is established that a minimum sample size of 10 experts is adequate for content validity [22, 23].

Delphi Process Participants and Recruitment

The recruitment for participants to the Delphi process started on May 15 and ended on November 1, 2020. Thirty-four English-speaking national and international TCM acupuncturists were contacted through Messenger, e-mail, and telephone and invited to participate in the panel. The participants were found through personal network as well as through a snowballing approach [24]. The criteria used to identify potential participants included English-speaking practitioners with TCM training and a minimum of 5-year experience and previous experience (>5 patients) in

Table 1. Demographic of the Delphi participants

Characteristics	n = 11	%
Gender		
Male	6	55
Female	5	45
Age		
20–25 years	0	0
25–35 years	0	0
36–45 years	5	45
46–55 years	5	45
65+	1	10
Level of TCM education		
Diploma	2	18.18
Graduate diploma	2	18.18
Bachelor's degree	4	36.36
Master's degree	1	9.09
PhD	0	0.00
Equivalent to diploma/bachelor's	1	9.09
Doctor of acupuncture and CM (DACM)	1	9.09
Years in acupuncture practice		
0–5 years	1	9.09
6–10 years	2	18.18
16–20 years	5	45.45
21–25 years	1	9.09
25+ years	2	18.18
Acupuncture patients seen/week		
16–35	3	27
36–50	3	27
51–80	4	36
Not currently in practice	1	10
Patient consults for ED related treatment, %		
0–25	10	90
26–50	1	10
Country of practice		
Australia	1	9.09
Austria	1	9.09
Denmark	1	9.09
Germany	1	9.09
Norway	1	9.09
Poland	1	9.09
Sweden	1	9.09
Switzerland	1	9.09
UK	1	9.09
USA	2	18.18

treating male health issues. The aim was to ensure a widespread distribution of qualified participants from as many different Western countries as possible.

Study Design

The primary data source in this modified Delphi process consisted of four rounds of questionnaires with open-ended and closed questions. The study built on the work of Smith et al. [25], where the items were modified to fit the subject of this Delphi process [26]. Permission to use the questionnaire was obtained by e-mail from the principal researcher Caroline Smith May 11, 2020. The first round in the Delphi survey commenced on August 14, 2020, and the fourth and final round concluded on June 6, 2021.

Each round took 6–12 weeks. To improve the response rate, which often is low in Delphi processes [25], the principal researcher (M.L.D.) sent three reminders including one personalised response after each round to ensure an adequate response rate. The participants remained anonymous through the whole process to encourage freedom of expression [25].

The four steps of the Delphi process were as follows:

- round 1: identify the TCM syndromes relevant in an ED diagnosis
- round 2: reduce the list of syndromes and determine relevant symptoms and signs for the syndromes to make an accurate TCM diagnosis of ED
- round 3: investigate the syndromes that were rated as uncertain in round two
- round 4: establish a best-practice scenario based on the result of the first three rounds and determine what constitutes good clinical practice for optimal results for this condition.

Data Analysis

The data were analysed by descriptive statistical calculation by M.L.D. The data were entered into Excel and analysed for mean, median, and sum of appropriateness. The RAND appropriateness method was applied to quantitatively assess the importance for inclusion and the agreement of the panellist. In case of missing data, attempts were made to obtain information by contacting the participant.

Ethics

The Norwegian Centre for Research Data AS has concluded that the processing of personal data in this project complies with the data protection regulations (June 3, 2020 [ref. No. 235359]).

Results

Twelve participants from ten different countries signed the consent form and completed one or more rounds. The median/mean clinical experience of the subjects was 16–20 years. Demographic of the Delphi participants are shown in Table 1.

Key Aspects and Components of Acupuncture for ED (Round 1)

The initial list of TCM syndromes with symptoms and signs the panellist expected to see in men with ED is shown in Table 2. Thirty syndromes with an interrelated list of symptoms and signs were suggested by the 11 participants who responded within the timeframe.

Acupuncture treatment protocol parameters are shown in Table 3. The panellists indicated that a treatment protocol in a future clinical study should consist of semi-standardised components (some fixed treatment components and some individualised). The majority recommended a treatment frequency of once or twice a week and that de qi (needle sensation or response) should be obtained. An additional recommendation was to needle deep with strong de qi sensation directed towards the genitals. A majority suggested that regardless of syndrome, a combination of manual acupuncture and

Table 2. TCM syndromes with symptoms and signs expected to be seen in men with ED

TCM syndromes	Symptoms	Tongue	Pulse	n = 11/%
LR Qi stagnation	ED ED worse with stress Grumpy Overworked Pain or tinnitus Emotional constrain Stressed Frustration Easy to anger Anger Moody Depression Heaviness Tension Pain Low energy Disrupted sleep Sexual repression Chronic constipation Digestion problems	Pink with white coating Pale-pink Pale Pale red Orange sides Liver lines Red edges Red sides Dry	Wiry on left Guan position Wiry Wiry/Xian Mai String-like Tense	8 (73%)
KI Yang xu/vacuity	ED Lack of morning erection Difficulty achieving/maintaining an erection Lower back pain Low libido Sore back and knees Back pain or knee pain Chilliness, especially in the lower body Cold genitals Cold tip of penis Cold lower limbs Frequent urination Nocturia Tinnitus Weakness Tired Exhausted Faintness Cold Yin vacuity heat symptoms Pale face Dark eyes Freeze easily Aversion to cold Low energy Listless	Pale Pale, pink Pale, white Pale and swollen Pale, wet Swollen Moist Greasy coating or wet White coating Tooth marks	Deep on left Du position Disappear Xu Weak/Xu Mai Weak in the Chi position Deep, weak Deep, slow, weak Deep, weak, thin Deep, thin	6 (55%)
Damp heat in the lower abdomen/lower burner/LR	“Shrivelled” penis which struggles to be firm Agitation	Red Thick, yellow coating Yellow coating	Superficial, pounding in Chi positions Rapid	3 (27%)
Damp-heat sinking to the lower Jiao	Genital eczema Epididymitis or heat, swelling or pain in testicles Prostate enlargement Constipation/diarrhoea Pain History of genital infections Chronic prostatitis Inguinal tension Yellowish urine Difficult urination Dark urine, maybe scanty	Yellow-coated tongue Especially in the rear Greasy, yellow coating	Wiry Fast Slippery	

Table 2 (continued)

TCM syndromes	Symptoms	Tongue	Pulse	n = 11/%
Liver Blood xu	Difficult to maintain erection Decreased libido Poor sleep Low energy	Pale	Weak Xu or Xi mai Xu	2 (18%)
LR Qi stagnation + heat	More anger Wakes up often Toss and turn Headaches	Red	Wiry on left Guan position Jump Elevated	1 (9%)
LR Qi stagnation + phlegm + heat	More anger Wakes up often Toss and turn Headaches	Thick yellow coating	Wiry on left Guan position Wiry, deep, wide	1 (9%)
Liver and kidney vacuity	Lower back pain Knee pain Fatigue	Pale Thin coating	Deep	1 (9%)
GB Qi deficiency	Fear of sexual encounter following previous failure due to ED, can accompany/be a part of other patterns Indecision	Pale	Weak	1 (9%)
KI Yang xu + Lr Qu xu	Tired Exhausted Grumpy Easily cold Often stomach/digestive issues – LR invades ST		Wiry on left Guan position + weak in left Chi position	1 (9%)
KI Yang xu with dampness	Lack of libido Lack of energy Heaviness Lower back ache Aversion to cold	Thick, big, pale, wet White coating	Slow Slippery	1 (9%)
KI Yin xu	Increased libido High libido Failure to achieve or maintain full erection Frequent ejaculation Premature ejaculation Back pain or knee pain Tinnitus Night sweat No desire to drink Dry mouth Age	Red Dry Scanty coat No coating	Elevated in left Chi position Thin Rapid Superficial	1 (9%)
KI Qi xu	Fatigue Tiredness Aversion to moving No energy No sexual drive	Pale, thick	Empty, weak, deep	1 (9%)
KI deficiency (QI, Yin and yang)		Pink with scanty coating	Deep, thin, and thready	1 (9%)
Sp Qi xu	Anxiety Poor digestion Fatigue	Pale Thick white coating or tooth marks	Deep, weak	1 (9%)
SP Qi xu with dampness	Tiredness Loose stools Abdominal fullness – cold, raw food, beer	Pale Swollen Coating	Rapid Slippery (Wiry)	1 (9%)

Table 2 (continued)

TCM syndromes	Symptoms	Tongue	Pulse	n = 11/%
Damp heat	Short erection Premature ejaculation Moist and smelly scrotum Yellow urine Feeling of heaviness in the legs	Sticky, yellow coating	Fast and soft	1 (9%)
Damp accumulation		Pink with thick white coating Flabby and/or tooth marks	Slippery, slow	1 (9%)
Phlegm in lower Jiao	Lazy Unmotivated Unconcentrated	Yellowish, greasy coating	Slippery/Hua Mai	1 (9%)
HT and KI	Emotional Sleep disturbance	Red on the tip Peeled	Fine Rapid	1 (9%)
HT blood xu (Yin xu)	Achieves a soft erection Erection disappears during intercourse Anxious	Pale Red tip (yin xu)	Fine	1 (9%)
Ki and HT not harmonising	Nocturnal emissions Palpitations Fear Depression Sore back and/or knees	Pale with little white coating	Thin Weak Deep Dong Mai pulse	1 (9%)
Blocked heart	Pressure in the chest Sleeping issues Anxiety	Normal	Hidden	1 (9%)
Shen disturbance, lack of root	Fear Restlessness Lack of sleep Depression	Pale, dry, crack on top	Thin, weak, weak in HT position	1 (9%)
HT and GB xu	ED worse with partner, better alone	Pale	Thin Reduced pounding	1 (9%)
SP xu and HT blood xu	Overthinking sexual performance Can masturbate but not have sex with another	Pale	Fine	1 (9%)
Blood xu	Pale face Poor memory Tiredness Depression Palpitations	Pale, dry	Thin, weak	1 (9%)
Blood stagnation	Often no symptoms but clear signs	Purple protruding subl. veins	–	1 (9%)
Blood stasis	Generally older patients: red/purplish skin/dark blood vessels on face/nose Possible history of heart disease, high blood pressure, lack of physical exercise Cardiovascular problems Diabetes Long-term illness Prostate hypertrophy Pressure on chest	Purplish Visible tongue veins Dark, purple in patches or all over dark swollen veins beneath tongue Routine eye test may reveal distorted blood vessels	This, deep, slippery Choppy	1 (9%)
Yin xu	ED Lower back pain Night sweat Seminal emission Spermatorrhea	Cracks No coating	Rapid Thin Empty	1 (9%)

Table 2 (continued)

TCM syndromes	Symptoms	Tongue	Pulse	n = 11/%
Combination of liver blood xu and LR Qi stagnation				1 (9%)
Combination of LR Qi stagnation and phlegm in lower Jiao				1 (9%)

moxa (burning of dried leaves of the *Artemisia vulgaris*) will provide the best result.

Table 4 provides an overview of acupoints (as shown in Table 4). A list of 28 acupoints for ED found in the literature was presented to the panellist. There was a consensus of 17 acupoints, in addition the panellist suggested 26 acupoints plus three point combinations.

Co-Interventions

There was consensus of the use of herbs as an essential co-intervention, and exercise and dietary therapy is prescribed by the majority. Kegels (exercises to strengthen pelvic floor muscles) and relationship therapy are also considered to be essential co-interventions in the treatment of ED. The panellists gave also advice on self-care which includes rest and relaxation, regular sleep, stress reduction, lifestyle changes, dietary advice, relationship therapy, and to refrain from ejaculation during treatment process.

Therapeutic Relationship

Since ED is perceived as a taboo topic [27], the panellists were asked for recommendations and advice regarding the patient/practitioner relationship. The panellists emphasised the importance of building trust, to have a non-judgmental attitude, to be open minded, and to encourage the patient to speak freely. They also recommend asking straightforward questions and at the start of the conversation clarifying that they also will be asked a series of questions regarding sexual function. The therapist should emphasise that ED is a common disorder like any other disorders so that the patient has no reason to be ashamed. The recommendation was “simply to normalise the subject.”

Using the Best Clinical Judgement (Round 2)

Following analysis of the first round, a summary report based on the results from the first round was circulated to the participants, who were invited to participate in the second round. The participants were asked to rate the appropriateness of the suggested 30 TCM syndromes by choosing a number from 1 to 9, where 1 indicates that it is “highly inappropriate” and 9 indicates that it is “highly appropriate” [28]. Syndromes with median scores in the

1–3 range were classified as inappropriate and were not further investigated. Those in the 4–6 range were classified as uncertain and were investigated further in round 3. Those in the 7–9 range were rated as appropriate and were further investigated for determining symptoms and signs. There was a consensus on eight syndromes in the round 2. In addition, fourteen syndromes, combined syndromes, combination of syndromes, and imbalances in substances were rated in the 4–6 range as uncertain and taken forward for further development to round 3. The rated appropriateness of the 30 syndromes is shown in Table 5.

Refining the Best Clinical Judgement (Round 3)

Newly nominated items from round 2 were presented. Of the 13 syndromes rated in this round, consensus was achieved on four (median score ≥ 7). The results of the rating of the TCM syndromes in round 3 are shown in Table 5.

The participants were asked to rate the appropriateness of a list of acupoints suggested in round 1, where 1 indicates that it was highly inappropriate and 9 indicates that it was highly appropriate for treating ED. Only those considered to be highly appropriate (7–9) were included in the final list (shown in Table 6). The final list of acupoints from rounds 1 and 3 is shown in Table 7.

Finalising the Protocol (Round 4)

The Delphi panellists were asked to rate to what extent they thought the syndromes determined in this Delphi process represent best-practice acupuncture for treating ED, where 1 indicated that it was highly inappropriate and 9 indicated that it was highly appropriate for treating ED. The median score was 8. The panellists were also asked to rate to what extent the consensus acupoints represented best-practice acupuncture for treating ED. The median was 6. Furthermore, they were asked to list three acupoints relevant for each syndrome from the consensus list of acupoints (shown in Table 8).

Finally, they were asked “to what extent do you think the results of this Delphi process could be used as a treatment protocol for later clinical study”? The median score was 7, which is considered appropriate without disagreement.

Table 3. Acupuncture treatment protocol parameters

Treatment parameters	n = 11	%
Treatment protocol in a clinical study should be		
Individualised	3	27
Semi-standardised (some fixed treatment components and some individualisation)	8	73
All standardised (all fixed standardised components)	0	0
Treatment frequency		
Once a week	8	73
Twice a week	8	73
Three times a week	1	9
Four times a week	0	0
Five times a week	0	0
Six times a week	0	0
Every day	0	0
Attaining De qi is important for the result		
Yes	10	91
No	1	9
Retention of needles		
20 min	5	45
25 min	2	18
30 min	6	54
45 min	1	9
Other: depends: 30 min for deficient conditions, 20 for excess conditions	1	9
45–60 min in excess, less in def patterns	1	9
No retention on Ren 1 and Du 1	1	9
20–30 min	1	9
For obtaining best results		
Manual acupuncture only provides the best results	1	9
Moxa only provides the best results	0	0
Manual acupuncture and moxa are the best combination	7	64
Manual acupuncture and electro-acupuncture are the best combination	4	36
Electro-acupuncture alone provides the best results	0	0
The number of treatments necessary to achieve “an erection adequate for sexual satisfaction”		
0–5 treatments	0	0
5–10 treatments	4	36
11–15 treatments	4	36
15–20 treatments	3	27
20–25 treatments	1	9
25++ treatments	1	9
Essential co-interventions		
Kegels (exercises to strengthen pelvic floor muscles)	5	45
Herbs	11	100
Dietary therapy	9	82
Exercise	10	91
Relationship therapy	6	55

The TCM Treatment Protocol

Twelve syndromes with symptoms and signs and 24 acupoints for the treatment of ED have been established for the use in a future clinical trial. The treatment protocol consists of semi-standardised components where additional acupoints (shown in Table 7) can be selected based on the patient's syndrome and symptoms in addition to the main acupoints (shown in Table 8), with 11–15 treatments given in a treatment frequency of once or twice a week. Needling should be deep in di-

rection towards the genitals, and strong de qi should be obtained (also towards the genitals). A combination of manual acupuncture and moxa is recommended regardless of syndrome. There are different opinions in the TCM literature related to the use of moxa for heat syndrome, e.g., yin xu and damp heat, in the literature [29, 30]. Herbs, Kegel exercises, relationship therapy, exercise, and dietary therapy are essential co-interventions in the treatment of ED. Self-care advice according to the TCM principle includes rest and

Table 4. Overview of acupoints for ED, $n = 11$ (%)

Acupoints in the literature	Strongly disagree, n (%)	Disagree, n (%)	Agree, n (%)	Strongly agree, n (%)	Taken forward, n (%)
CV 3	0 (0)	0 (0)	5 (45)	6 (55)	x
CV 4	0 (0)	0 (0)	4 (36)	7 (64)	x
CV 5	0 (0)	3 (27)	5 (45)	1 (9)	
CV 6	0 (0)	1 (9)	4 (36)	6 (55)	x
KI 1	1 (9)	5 (45)	3 (27)	2 (18)	
KI 2	0 (0)	3 (27)	4 (36)	3 (27)	
KI 3	0 (0)	0 (0)	4 (36)	6 (55)	x
KI 6	1 (9)	0 (0)	4 (36)	5 (45)	x
KI 7	0 (0)	1 (9)	2 (18)	8 (73)	x
KI 12	0 (0)	1 (9)	4 (36)	6 (55)	x
KI 27	1 (9)	6 (55)	4 (36)	0 (0)	
SP 6	0 (0)	0 (0)	6 (55)	4 (36)	x
ST 30	0 (0)	1 (9)	4 (36)	6 (55)	x
ST 36	0 (0)	0 (0)	5 (45)	6 (55)	x
LR 2	0 (0)	1 (9)	7 (64)	2 (18)	x
LR 3	0 (0)	1 (9)	3 (27)	7 (64)	x
HT 7	0 (0)	0 (0)	6 (55)	9 (82)	x
PC 6	0 (0)	1 (9)	8 (73)	2 (18)	x
BL 15	0 (0)	3 (27)	7 (64)	1 (9)	
BL 23	0 (0)	0 (0)	5 (45)	6 (55)	x
BL 24	0 (0)	3 (27)	6 (55)	2 (18)	
BL 32	0 (0)	0 (0)	3 (27)	8 (73)	x
BL 54	0 (0)	4 (36)	4 (36)	2 (18)	
LI 4	1 (9)	1 (9)	6 (55)	1 (9)	
LI 11	1 (9)	6 (55)	3 (27)	0 (0)	
SI 4	2 (18)	6 (55)	1 (9)	1 (9)	
GV 4	0 (0)	0 (0)	5 (45)	6 (55)	x
GV 20	1 (9)	0 (0)	3 (27)	4 (36)	

Participant suggestions of acupuncture points for treating ED not mentioned in the above list: Ki 9, KI 10, KI 11, KI 14, SP 10, ST 29, LR 1, LR 4, LR 5, LR 6, LR 8, LR 10, LR 13, GB 27, GB 30, HT 5, CV 1, CV 15, CV 17, GV 1, BL 33, BL 35, extra point below BL 35, BL 52, PC 7, PC 8. Combination of points: (LR 14 + GB 25 + CV 17/15), (LR 8 + KI 10), (HT 5 + SI 7).

relaxation, regular sleep, stress reduction, lifestyle changes, and to refrain from ejaculation during treatment.

Cardinal Symptoms in Relation to Syndromes and Acupoints for ED

In view of ED in the ancient system of TCM, there are some cardinal symptoms to some of the syndromes. For example, in Ki Yang Xu, the patient may suffer from lack of morning erection, low libido, and cold genitals in addition to cold, weak, sore back. The relevant acupoint in the protocol for Ki Yang xu syndrome is CV 4. Men presenting with symptoms such as achieving easy erection that does not last, excessive sex drive, and premature ejaculation will pertain to the syndrome Ki Yin Xu and according to the protocol should be treated with acupoints KI 6 and CV 4. In addition to the regular LR Qi stagnation symptoms, men with ED often present with a lack of desire, and the preferred acupoints are LR 3 and LR 5 based on the recommendations of the expert practi-

tioners. In HT and GB Qi xu syndrome, HT 7 is the suggested acupoint in the protocol and the cardinal symptoms are fear of sex, reluctance to be involved in close relationships, and ED being worse with a partner than when alone. Genital itching and/or dampness are symptoms related to damp heat sinking to lower Jiao/damp heat in LR and KI, and the acupoint of choice is LR 5 (Fig. 1).

Discussion

Summary of Main Results

The Delphi process provided a protocol based on a consensus of recommendations of expert TCM practitioners. The protocol equips acupuncture practitioners with a toolbox of 12 syndromes with accompanying symptoms and signs that the acupuncture experts considered to be fundamental as best-practice acupuncture for treating ED. Furthermore, the protocol constitutes semi-standardised components and lists 24 acupoints

Table 5. Appropriateness of the 30 syndromes

Syndrome	Rating round 2 (median)	Rating round 3 (median)	Symptoms and signs
LR qi stagnation	Appropriate (8)	Consensus	Items added
KI Yang xu/vacuity	Appropriate (8)	Consensus	
KI and HT not harmonising	Appropriate (8)	Consensus	Items added
Damp-heat sinking to the lower Jiao	Appropriate (7)	Consensus	Items added
Liver blood xu	Appropriate (7)	Consensus	Items added
KI Yin xu	Appropriate (7)	Consensus	
KI Qi xu	Appropriate (7)	Consensus	Items added
HT and GB xu	Appropriate (7)	Consensus	Items added
SP xu and HT blood xu	Uncertain (6)	Appropriate (7)	Items added
KI Yang xu with dampness	Uncertain (6)	Inappropriate (5)	
Yin xu	Uncertain (6)	Appropriate (7)	
GB Qi deficiency	Uncertain (5)	*	
Liver blood xu and liver Qi stagnation	Uncertain (5)	Appropriate (7.5)	Items added
LR Qi stagnation and heat	Uncertain (5)	Appropriate (7)	
Blood xu	Uncertain (5)	Inappropriate (5)	
Blood stasis	Uncertain (5)	Inappropriate (6.5)	
Shen disturbance, lack of root	Uncertain (5)	Inappropriate (4)	
LR Qi stagnation and phlegm and heat	Uncertain (4)	Inappropriate (5)	
KI deficiency (Qi, Yin and Yang)	Uncertain (4)	Inappropriate (6.5)	
SP Qi xu	Uncertain (4)	Inappropriate (3)	
SP Qi xu with dampness	Uncertain (4)	Inappropriate (5)	
HT blood xu (Yin xu)	Uncertain (4)	Inappropriate (4)	
Liver and KI vacuity	Inappropriate (3)		
KI Yang xu and Liver Qu xu	Inappropriate (3)		
Liver Qi stagnation and phlegm in lower Jiao	Inappropriate (3)		
Damp accumulation	Inappropriate (3)		
Phlegm in lower Jiao	Inappropriate (3)		
HT and KI	Inappropriate (2)		
Blood stagnation	Inappropriate (2)		
Blocked heart	Inappropriate (2)		

*GB Qi deficiency was considered the same syndrome as HT and GB xu and therefore merged.

relevant for the treatment of ED. The optimal dose sufficient to achieve “an erection adequate for sexual satisfaction” is 11–15 treatments given in a treatment frequency of once or twice per week. Moreover, this protocol contributes to establishing a best-practice treatment protocol for the use in future clinical trials and may thus contribute to standardization and comparability of future studies on ED.

Co-Interventions

Despite that an acupuncture-only protocol was explored and developed in this Delphi process, the experts recommend the use of herbs as an essential co-intervention, in addition to exercise and dietary therapy. Self-care advises such as rest and relaxation, regular sleep, stress reduction, Kegel exercises, lifestyle changes, relationship therapy, and to refrain from ejaculation during treatment process are considered essential for the result of the treatment. Lifestyle advice regarding ED is supported by medical research [31, 32]. Moreover, the experts suggested that a combination of manual acupuncture and moxibustion will provide the

best result regardless of syndrome. Moxibustion is well known and commonly used intervention alone or in combination with acupuncture in the treatment of ED [5]. However, moxibustion techniques were not included in this first Delphi study on acupuncture and ED. Nonetheless, a standardised protocol is also needed for needle stimulation and moxibustion techniques. These issues could be further explored in a new Delphi study.

Adequate Dose of Treatment

In general, clinical studies in the West have been conducted using significantly fewer number of treatments compared to Chinese trials, where a treatment course consists of daily treatment for 10 days and three or more treatment courses. According to the authors, for some conditions, 6 weeks of treatment is needed to obtain any clinical improvement and twice the time to achieve optimal effect of the treatment [14]. Clinical outcomes in acupuncture trials may be dose-dependent and influenced by the applied acupuncture protocol. [14, 16] The recommendation that 11–15 treatment will be sufficient

Table 6. Appropriateness of the suggested acupoints for ED (acupuncture point median rating)

LR 5	9	Highly appropriate
KI 11	8	Highly appropriate
CV 1	8	Highly appropriate
GV 20	8	Highly appropriate
LR 8	7	Highly appropriate
GV 1	7	Highly appropriate
ST 29	7	Highly appropriate
KI 10	6	Inappropriate
KI 14	6	Inappropriate
HT 5	6	Inappropriate
LR 8 + KI 10	6	Inappropriate
BL 33	5	Inappropriate
BL 35	5	Inappropriate
BL 52	5	Inappropriate
GB 27	5	Inappropriate
PC 7	5	Inappropriate
SP 10	5	Inappropriate
Ki 9	4	Inappropriate
PC 8	4	Inappropriate
LR 14 + GB 25 + CV 17/15	4	Inappropriate
CV 15	3	Inappropriate
CV 17	3	Inappropriate
LR 1	3	Inappropriate
LR 4	3	Inappropriate
LR 6	3	Inappropriate
LR 10	3	Inappropriate
LR 13	3	Inappropriate
Extra point below BL 35	3	Inappropriate
HT 5 + SI 7	3	Inappropriate
GB 30	2	Inappropriate

Table 7. Complete list of acupoints from rounds 1 and 3

KI 3, KI 6, KI 7, KI 11, KI 12, BL 23, BL 32
LR 2, LR 3, LR 5, LR 8
SP 6, ST 29, ST 30, ST 36
HT 7, PC 6
CV 1, CV 3, CV 4, CV 6, GV 1, GV 4, GV 20

Table 8. Acupoints relevant for each syndrome

Syndrome	Acupuncture points
Ki Yang xu	CV 4
Ki Yin xu	KI 6, CV 4
Ki Qi xu	KI 3, BL 23
Ki and HT not harmonised	HT 7, KI 6
LR Qi stagnation	LR 3, LR 5
LR Qi stagnation and heat	LR 2, LR 3
Liver blood xu	LR 3, LR 8
Liver blood xu and liver Qi stagnation	LR 3
Damp-heat sinking to the lower Jiao	LR 5
HT and GB Qi xu	HT 7
SP xu and HT blood xu	SP 6, ST 36
Yin xu	KI 6, SP 6

to achieve “an erection adequate for sexual satisfaction” needs to be verified and validated in further clinical studies.

Comparing TCM Syndromes in the Protocol to the TCM Literature

According to the TCM system, the literature kidney or liver syndromes of disharmony are often involved in ED [33]. Ten out of 12 syndromes in the protocol involve kidney and liver/gallbladder pathology. The list of syndromes in the protocol includes combinations of syndromes and imbalances in substances (Qi, Xue, Jinye, Jing, and Shen) not presented in the TCM literature. [33, 34]. Similar differences have been described between clinical acupuncturist and Delphi experts in a study on hot flashes based on TCM acupuncture treatment. This divergence may be due to the lack of a common ground and understanding of TCM syndromes, deriving from differences in education or in-depth knowledge and experience in addition to the subjective nature of syndrome differentiation – resulting in discrepancies in which symptoms comprise each syndrome [35]. According to the TCM literature, the interrater agreement on syndrome differentiation appears to be very low, and the diagnostic accuracy for differentiation of syndromes is not better than chance [36–38]. Combined with the lack of international standards, attaining consensus in syndrome differencing is a challenging endeavour [38].

TCM and modern medicine share to some extent similarities in how models of illness and health are interrelated and diagnosis making builds upon assessing symptoms and signs from the patients in both medical systems, though the framework and language of physiology and pathophysiology differ widely. [13, 39] The TCM model of pathophysiology is complex and involves interrelated organs and systems [34]. Therefore, it may turn out that there are several different theories that still will lead to clinical valid results even if practitioners assess symptoms, syndromes, and diagnosis differently [40].

The Selection of Acupoints

The finalised list of acupoints in the protocol has some deviations compared to the TCM literature. The acupoints ST 29, KI 11, LR 5, LR 8, and GV 1 have not been reported to be used in research literature for ED but were rated appropriate for the treatment protocol by the expert practitioners. ST 29 is a point frequently used in research for women with polycystic ovary syndrome [41]. KI 11, LR 5, LR 8, and GV 1 are local points for urogenital issues and may be relevant in the treatment of ED [42]. Nine of the points from published studies on ED presented in round 1 did not make it to the

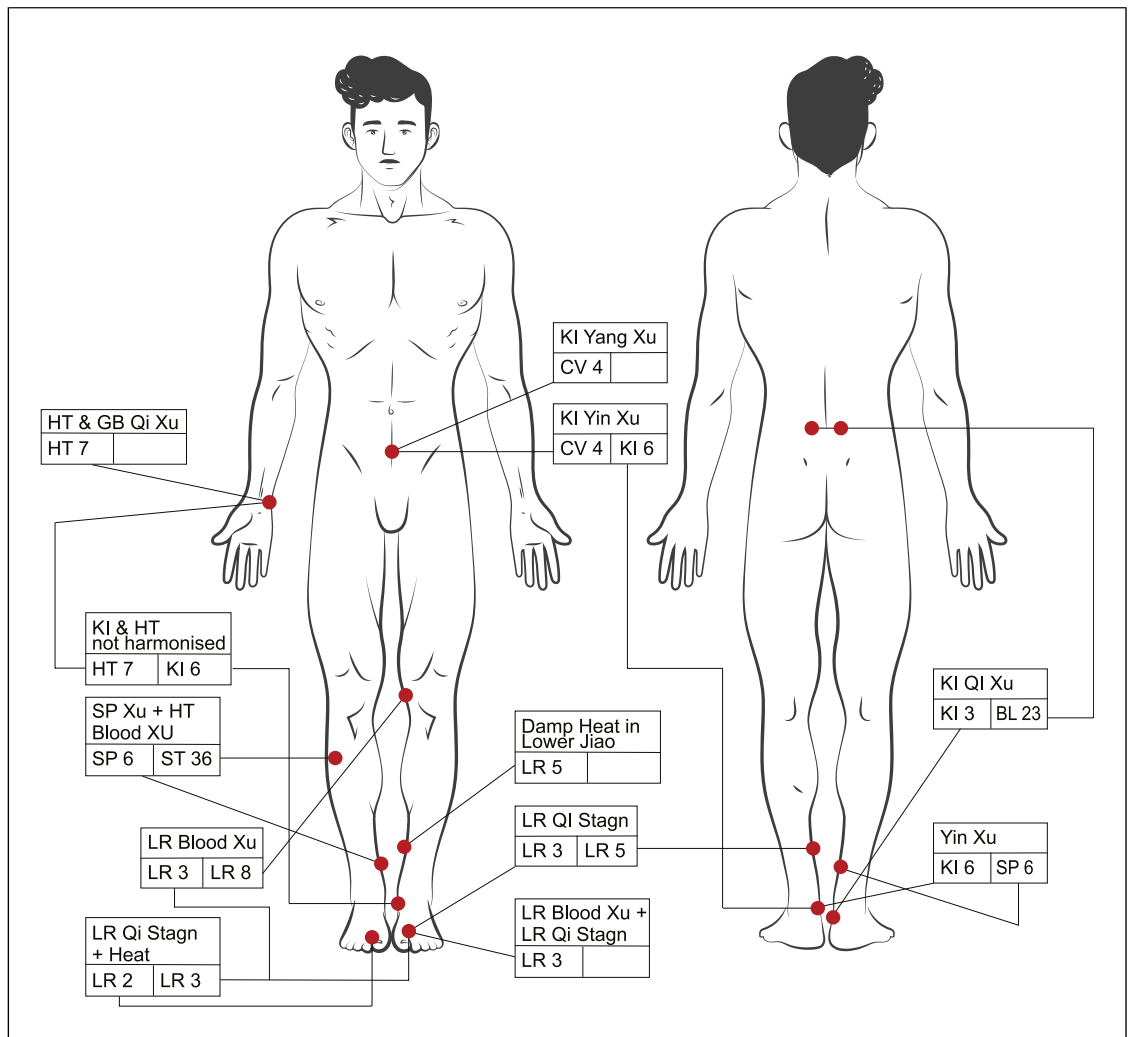


Fig. 1. Acupuncture figure showing syndromes and acupoints. KI Yin xu: KI 6, CV 4, KI Qi xu: KI 3, BL 23, Ki and HT not harmonised: HT 7, KI 6, LR Qi Stagnation: LR 3, LR 5, LR Qi stagnation and Heat: LR 2, LR 3, Liver Blood xu: LR 3, LR 8, Liver Blood xu and Liver Qi stagnation: LR 3, Damp-heat sinking to the lower Jiao: LR 5, HT and GB Qi xu: HT 7, SP

xu and HT Blood xu: SP 6, ST 36, Yin xu: KI 6, SP 6. Disclaimer: The illustration may not be used for precise point location as the accuracy and precision concerning anatomy in the figure is not optimal. The additional acupoints are CV 1, CV 3, CV 6, GV 1, GV 4, GV 20, KI 7, KI 11, KI 12, BL 32, ST 29, ST 30, PC 6.

consensus list. None of them (CV 5, KI 1, KI 27, BL 15, 24, 54, LI 4, LI 11, SI 4) are referred to be used for ED in the available English TCM literature. Hence, this might reflect why there was no consensus on these points.

A recent study using data mining technology searching Chinese databases and PubMed found that the most frequently used acupoints for ED are CV 4, BL 23, SP 6, GV 4, ST 36, CV 3, BL 32, CV 6, KI 3, and LR 3 [43], which is in concordance with our protocol. The most common acupoint combinations for ED are BL 31, BL 33, BL 32, BL 34, SP 6, BL 23, and CV 4 [43]. ST36, LR3, SP6, and PC6 are the most frequently selected acupoints in clinical settings for a wide variety of conditions [44–46]. The same acupoint may be used to treat many different diseases as individual acupoints have a wide variety of indications [44, 45].

Strengths and Limitations

Unlike in focus groups, participants in Delphi studies remain anonymous to each other, which reduces the effect of dominant participants influencing the outcome [25]. The expert groups are varied in composition representing acupuncture participants from ten different countries in three continents. However, all members of the panel live in the Western part of the world. Secondly, a comprehensive approach was chosen to identify items that might constitute an adequate acupuncture protocol for the treatment of ED in a clinical trial. Thirdly, different education emphasise male health to a varying degree. In opposite to Western medicine, male health has not received the same appreciation and popularity as women-related issues in clinic and research in the acupuncture profession. This is an initial attempt to gather information across the community of acupuncture.

This study has the potential to motivate other researchers to investigate acupuncture treatment for ED in their own countries – hopefully contributing to further knowledge and development of a standardised treatment protocol.

This study has also limitations. Firstly, despite the careful selection of panel members and following the Delphi methodology rigorously, the results of this consensus may not cover the opinion of the entire acupuncture community. Secondly, the legislation in Norway and EU prohibits the use of Chinese herbal medicine; therefore, an acupuncture-only treatment setting was investigated in this study. Other limitations could relate to the participation of experts. The acupuncture training and experience of the experts have certainly influenced their responses to the Delphi rounds and the final protocol. The result reflects the opinions of the panellists. Another panel, e.g., with experts of an Asian origin, may come to different results. Another potential limitation is that the data analysis was performed by only one researcher.

Implications for Clinical Practice

ED is a health condition which affects all aspects of life, potentially with severe consequences for quality of life and well-being. For the relative high number of men (30–40%) where pharmacological treatment such as PDE-5 inhibitors is not an option, other treatment modalities are required. Acupuncture alone or in combination with PDE5 inhibitors could be a solution for this group. Acupuncture may be a long-term causal-therapeutic intervention, simple, and equi-effective with few side effects for the treatment of ED as requested [31].

Acupuncture is widely used in women-related issues, and a significantly larger proportion of acupuncturists offer treatment for gynaecological ailments. Further, there appears to be a larger proportion of acupuncture research related to women's health [8]. Our concern is that male diseases have not received the same extent of attention within the acupuncture profession. The taboos surrounding of ED prevent many men from seeking help for this condition [27], as well as refrain acupuncture practitioners to treat this common ailment. However, in Chinese medicine, sexual health is seen as an important aspect of good quality of life and should be a part of the clinical interview [5]. The recommendation of the experts is to “simply to normalise the subject.” This protocol will hopefully inspire more practitioners to include male health issues, such as ED in their practice by having the tools for diagnosis and treatment in hand.

Implications for Further Research

This study has developed a protocol for the use in clinical practice and clinical trials. Despite the challenges we faced, we see this as a first step towards an international consensus in Western societies in how to treat ED with acupuncture in TCM based clinical trials. However, further investigation and validation of syndromes,

symptoms, and signs regarding ED is necessary. Although the experts gave the treatment protocol a high score, it has not yet been verified in a clinical trial that the outcome will result in “an erection adequate for sexual satisfaction.” Therefore, its clinical effectiveness needs to be demonstrated. Nonetheless, ED is an under-researched and possibly tabooed area in acupuncture research.

Conclusions

The results of the Delphi study introduce for the first time a consensus-based protocol for the acupuncture treatment of ED. Eleven acupuncture experts were able to reach consensus on 12 syndromes with symptoms and signs for the treatment of men with ED. The treatment protocol consists of semi-standardised components including 24 acupoints for treatment of ED. About 11–15 treatments given once or twice a week was considered to be an optimal dose sufficient to achieve “an erection adequate for sexual satisfaction.” Nonetheless, the results should be used with caution as large inconsistencies and discrepancies were discovered, and clinical effectiveness needs to further be elucidated.

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Statement of Ethics

Consent to participate statement: Informed consent was obtained from participants to participate in the study; approved by NSD (Data Protection Services) number 235359, June 04, 2020.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

M.L.D.: conceptualization, methodology, data collection and analysis, project administration, writing – original draft preparation, and writing – reviewing and editing. T.A.: conceptualization, supervision, and writing – reviewing and editing. F.M.: conceptualization, supervision, and writing – reviewing and editing.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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