Therapeutic evaluation of herbal foot bath for tinea pedis: Impact on fungal clearance, adverse reactions and patient well-being

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Abstract: We aimed to analyze the curative effect of herbal foot bath on tinea pedis patients, and observe its effect on fungal clearance rate, adverse reactions and patients' quality of life. One hundred patients with tinea pedis admitted to an outpatient clinic of Shunde Hospital of Guangzhou University of Chinese Medicine from July 2022 to December 2023 were selected and 50 cases each for the treatment group and 50 cases each for the control group were chosen at random. The control group was treated with Dakening Cream, while the treatment group was treated with the Chinese herbal foot - soaking liquid. The TCM syndrome score and quality of life score were compared before and after therapy, and the curative impact, fungus clearance rate, and safety of the two groups were examined. The treatment group's overall effective rate was greater than the control group's (P<0.05). Following therapy, both groups' primary and secondary symptom scores were lower than they were before to treatment, and the treatment group's scores were lower than the control group. And it is even lower in the treatment group. (P<0.05). When compared to the control group, the treatment group's fungal clearance rate was greater and their recurrence rate was lower (P<0.05). Adverse reaction rates were comparable across the two groups (P>0.05). Following therapy, both groups' SF-36 ratings were higher than their pre-treatment levels, with the treatment group outperforming the control group and it is higher in the treatment group (P<0.05). Patients' quality of life can be improved by using a herbal foot bath to treat tinea pedis, which can successfully relieve symptoms and has a high fungus clearance rate, few side effects and a low recurrence rate.

Keywords: tinea pedis; Herbal foot bath; TCM syndrome integral; fungal clearance rate; adverse reactions; quality of life

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INTRODUCTION

Tinea pedis, sometimes referred to as "beriberi," is a common foot skin condition that is extremely infectious and well-liked worldwide. It is mostly brought on by infection with pathogenic fungus (Song et al., 2022). Related reports show that the prevalence of tinea pedis is about 50%-60%, and the high likelihood of recurrence has negatively impacted patients' quality of life. (Leung et al., 2023). At present, western medicine mainly treats the disease with antibacterial drugs, among which Dyclonine cream is widely used. Although it has the advantages of economy and convenience, it can alleviate symptoms to some extent. However, this medication's clinical effectiveness in treating tinea pedis alone is poor; it has a lengthy half-life, a sluggish onset, and makes drug resistance easy to develop. (Tayah and Eid, 2023; Nowicka and Nawrot, 2021). Traditional Chinese medicine (TCM) has a certain position in treating tinea pedis. Because of the diversified manifestations of tinea pedis, TCM records the name of the disease less. In ancient times, it was mostly discussed by tinea. Later, with the understanding of the pathogenesis and characteristics of the disease, more vivid names appeared, such as "smelly snail", "beriberi sore" and "foot dampness" (Ward et al., 2022; Son and Lee, 2022). Traditional Chinese medicine (TCM) pays attention to external treatment and mainly uses local drugs to achieve targeted treatment. The Chinese herbal foot - soaking liquid

is a formulated prescription. It is based on traditional Chinese medicine theories, refers to the pharmacological effects of various traditional Chinese medicines, and combines years of clinical experience. Combining the pharmacological benefits and clinical experience of several traditional Chinese medicines, such as Cortex Phellodendri, with the idea of traditional Chinese medicine, herbal foot baths 10% white vinegar, Kochia scoparia, Sophora flavescens and so on. However, at present, there are few reports on the curative effect and mechanism of herbal foot bath solution in the treatment of tinea pedis. In view of this, we chose 100 outpatients from our hospital Between July 2022 and December 2023 and performed a randomized controlled trial to assess the safety and efficacy of a herbal foot bath solution in treating tinea pedis in order to further confirm the therapeutic efficacy of this medication.

MATERIALS AND METHODS

Sample size calculation method

The estimation of the sample size is based on Estimation of Sample Size in Clinical Research, edited by Wu Shengxian and Wang Chengxiang. The methods for estimating the sample size in the single - sample mean test or the paired sample mean test are as follows:. According to the literature and preliminary experiments, the minimum sample size of a single group is calculated to be. Considering a 20% exclusion or dropout rate, the expected number of participants in a single - group is 50. Therefore,

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a total of 100 participants are planned for this clinical trial, with 50 in each group.

General data

A total of 100 patients with tinea pedis who were admitted to our hospital between July 2022 and December 2023 were split into two groups at random: 50 in the treatment group and 50 in the control group. The control group's average age was 36.52±8.78 years, and its members ranged in age from 26 to 50. There were 21 girls and 29 men. The average duration of the illness was 2.86±1.14 years, with a range of 1-5 years. The average body mass index (BMI) is $21.58\pm1.05 \text{ kg/m}2/\text{m}2$, with a range of 20-24 kg/m2. The treatment group's age ranged from 27 to 48 years old, with an average age of 36.96±8.16 years. The average duration of the illness was 2.94±1.20 years, with 26 men and 24 females. The average BMI is (21.66±1.10) kg/m2/m2, with a range of 20–24 kg/m². The balance is high (P > 0.05)when compared to the two groups' overall statistics. This study has been approved by the Medical Ethics Committee of our hospital, with the ethics approval number (202110023).

Selection criteria

(1) Inclusion criteria: It conforms to the relevant diagnostic criteria in Guidelines for Diagnosis and Treatment of Tinea Hand and Foot (Revised Edition, 2017) and Dermatology (8th Edition); The Diagnostic Efficacy Criteria for Diseases and Syndromes of Traditional Chinese Medicine provide pertinent diagnostic criteria, it is dialectically damp-heat accumulation type, the main symptoms are blisters, erosion and immersion, and the secondary symptoms are itching, pain or fever, red tongue, yellow fur and slippery pulse; Microscopic examination of fungi was positive; Did not receive antimicrobial treatment one month before joining the group; Good treatment compliance; The treatment compliance is good. The age range is from 25 to 50 years old (25 years old \leq age \leq 50 years old). (2) Exclusion criteria: liver and renal insufficiency; Pregnant or lactating women; Combined with malignant tumor; Long-term use of glucocorticoids and immunosuppressants; Combined with other bacterial infectious diseases; Allergic to drugs known in this study; Quit halfway; Mental abnormality. (3) Exclusion criteria: Participants who fail to take medications, attend follow up visits, or keep records on time and as required; Those who develop severe diseases in other systems during the trial: Those who voluntarily discontinue the treatment: Patients who stop treatment due to adverse drug reactions should be included in the cases of adverse reactions.

Methods

Grouping Method

All patients were numbered according to the order of their visits (from 1 to 100). In an Excel spreadsheet on a computer, 100 random numbers were generated sequentially and numbered. Then, the generated random numbers were sorted in ascending order. The first 50 random numbers were assigned to the control group, and

the last 50 random numbers were assigned to the treatment group. The treatment method corresponding to each number was written into an envelope. Patients opened the corresponding envelopes in the order of their visits and received the corresponding treatments.

Treatment methods

During the treatment period, both groups were instructed to avoid using shoes, socks and other items that are in direct contact with the skin with others, wear shoes and socks with good air permeability, and continue to work, rest, and eat healthily. Dakening cream was administered to patients in the control group. (Xi 'an Janssen Pharmaceutical Companies Co., Ltd., National Medicine Zhunzi H61020001), and the feet were washed with warm water before each use, and the cream was evenly applied to all skin surfaces of the feet, twice a day, for four weeks in total. A follow - up was conducted once 4 weeks after the completion of the treatment. The prescription included 15 g of Sophora flavescens, 20 g of Cortex Phellodendri, 30 g of Taraxacum, 20 g of Kochiae Fructus, and 20 g of Cortex Dictamni Radicis. The treatment group was given herbal foot-soaking solutions and 10g Zanthoxylum bungeanum. Take 4,000 ml white vinegar, soak all the medicines in a glass container for 20 days, take out 500 ml medicinal juice every day, add it into 1,000 ml boiling water, cool to a suitable temperature and soak the feet for 30 min, once a day and two weeks is a treatment course. The treatment period was 2 weeks for one course. Patients were required to have a follow - up visit every 2 weeks. A total of 2 treatment courses were carried out. A follow - up was conducted once 4 weeks after the completion of the treatment. All the above Chinese medicines were provided by the Chinese Medicine Pharmacy Room of Guangzhou University of Chinese Medicine's Shunde Hospital.

Observation indicators (1) Clinical efficacy: Using the Guiding Principles for Clinical Research of New Chinese Medicine as a guide, compare the symptoms and indicators before and after therapy, and score according to the conditions of immersion, erosion, skin lesions, itching and exudation, with 0 being asymptomatic, 1 being mild, 2 being moderate and 3 being severe. See table 1 for details, and calculate the efficacy index (i) of all patients, I= (Cure: I=100%, negative under microscope; Remarkable effect: negative by microscopic examination, I: 70%-100% (including 70%, excluding 100%); Effective: negative by microscopic examination, I: 30%-70% (including 30%, excluding 70%); Invalid: microscopic examination positive, I < 30%. Cure rate plus designated effective rate plus effective rate equals the total effective rate. (2) Score for TCM syndrome: Use the "Diagnostic Efficacy Standard of TCM Syndrome" to grade mild, moderate, and severe symptoms before and after treatment. The primary symptom receives 2,4,6 points, while the secondary symptom receives 1,2,3 points. The severity of the symptoms increases with the score. (3) Fungal clearance rate: After the treatment, all patients were examined by fungal fluorescence staining to determine whether they were cleared. If the results were negative, they were cleared, and if the results were positive, they were not cleared. Fungal clearance rate = (negative number/total number) ×100%. (4) Recurrence rate: At the 4th week after the completion of treatment in both groups, the skin lesion conditions and pruritus symptoms were observed and recorded. The recurrence status was evaluated in combination with the laboratory test results; Recurrence: The reappearance of rashes and pruritus symptoms, along with a positive result in fungal microscopy; Non recurrence: No rashes and no subjective discomfort; The recurrence rate is calculated as follows: Recurrence rate = (Number of recurrence cases / Total number of cases) × 100%. (5) Adverse reactions: During each follow - up visit, detailed records were made on whether the subjects experienced any adverse events, including liver function abnormalities, kidney function abnormalities, gastrointestinal reactions, skin pruritus, skin erythema, and burning sensation. The incidence of adverse reactions is calculated as: Incidence of adverse reactions = (Number of cases with adverse reactions / Total number of cases) × 100%. (6) Quality of life: Using the health status questionnaire (SF-36) (Ware and Sherbourne, 1992), which includes eight aspects including pain, mood, and vitality, the score was directly linked to the quality of life before and after treatment. The score had a maximum score of 100.

STATISTICAL METHODS

Software called SPSS23.0 was used to process the data. The independent sample T test was applied, the measuring data were expressed as $(\overline{x}\pm s)$, and the counting data were expressed as frequency and rate (%). The $\chi 2$ test was used for the comparison. Statistical significance is defined as P < 0.05.

RESULTS

Clinical efficacy

The treatment group's overall effective rate was greater (P < 0.05) than that of the control group. Refer to table 2. Prior to treatment, the two groups' TCM syndrome scores were equal (P > 0.05); following treatment, both groups' primary and secondary symptom ratings were lower than their pre-treatment scores, and the treatment group's score was lower than the control group's (P < 0.05). Refer to fig. 1 and table 3.

Fungal clearance rate and recurrence rate

When compared to the control group, the treatment group's fungal clearance rate was greater and their recurrence rate was lower (P<0.05). Refer to fig. 2 and table 4.

Adverse reactions

In both groups, there were no abnormalities in urine routine or liver function. Adverse reaction rates were comparable across the two groups (P>0.05). Refer to table 5.

Quality of life

After therapy, the scores of quality of life in the two groups were greater than before treatment, and the scores in the treatment group were higher (P<0.05). See table 6 and fig. 3

DISCUSSION

Current situation of treating tinea pedis with Dakening Cream

The primary clinical signs and symptoms of tinea pedis are peeling, blisters, cracking, etc. In severe cases, erosion will occur, mainly involving the soles of feet and toes and their sides. In severe cases, it may spread to the dorsum of feet, which can be divided into erosive type, blister type and scaly keratinization type (Ward et al., 2022). Studies have pointed out that fungi are the key pathogens of tinea pedis, such as Trichophyton floccosum, Trichophyton rubrum, Trichophyton mentagrophytes, etc., and Trichophyton rubrum is the main pathogen (Liu et al., 2019; Vazheva and Zisova, 2021). Therefore, the main principle of Western medicine in treating this disease is anti - bacterial therapy. At present, Western - medical treatments include external and internal therapies. Commonly used clinical preparations are gels, sprays, and ointments, with the main purpose of rapidly relieving symptoms and eliminating pathogenic bacteria (Hoang et al., 2021). Dakening Cream is a commonly used external treatment in Western medicine. Its main ingredient is miconazole nitrate, which has a good effect in treating fungal - infectious skin diseases. Its main antibacterial mechanism is to block the ergosterol synthesis pathway, thereby destroying the fungal cell membrane and causing the fungi to gradually die. It has the advantage of broad - spectrum antifungal activity (Asghar et al., 2023). However, due to the diverse conditions of tinea pedis and its relatively high recurrence rate, the long - term effect of using Dakening Cream alone is not ideal. Therefore, it is particularly important to seek a more effective and safe external treatment regimen.

Study on the efficacy of chinese herbal foot - soaking liquid in treating tinea pedis and the scores of traditional chinese medicine syndromes

Imidazole nitrate, the primary ingredient in Dakening cream, is effective in treating fungal infectious skin conditions. Its main antibacterial principle is to destroy the fungal cell membrane by blocking ergosterol synthesis pathway, thus gradually making it necrotic, which has broad-spectrum antifungal advantages (Shahid *et al.*,2022; Rasner *et al.*, 2022). However, due to the diversification of tinea pedis and the high recurrence rate, the long-term effect of dakening alone is not ideal. Tinea pedis is classified as "foot dampness" and "stinky snail" in traditional Chinese medicine and the illness progresses slowly, mainly due to the invasion of external poison, heat and humidity into the skin, which belongs to the damp-heat accumulation type.

Table 1: Symptom Scoring Criteria

Symptom	1 point	2 points	3 points
soak	1 toe seam	Two toe seams	> 2 toe seams
erode	<3 cm2	$3 \text{ cm}2 \leq \text{erosion} < 5 \text{ cm}2$	≥5 cm2
Skin lesion	<3 cm2	$3 \text{ cm}2 \leq \text{Skin lesions} < 5 \text{ cm}2$	≥5 cm2
itch	once in a while	frequent	last
exude	punctiform	lamellate	Liuzi

Table 2: Comparison of clinical efficacy between the two groups n(%)

Group	Cure	show effect	effective	be invalid	Total effective rate
Control group (n=50)	12(24.00)	14(28.00)	4(8.00)	20(40.00)	30(60.00)
Treatment group (n=50)	22(44.00)	13(26.00)	8(16.00)	7(14.00)	43(86.00)
χ^2					8.574
\overline{P}					0.003

Table 3: Comparison of TCM Syndrome Integral between the two groups ($\bar{x}\pm s$, score)

Crosse	Main symptom		Secondary disease		
Group	Before treatment	After the treatment	Before treatment	After the treatment	
Control group (n=50)	7.12±1.10	3.56±0.54*	6.12±1.14	3.16±0.47*	
Treatment group (n=50)	7.24 ± 1.06	1.92±0.34*	6.34 ± 1.22	1.12±0.33*	
t	0.556	18.173	0.932	25.118	
P	0.580	< 0.001	0.354	< 0.001	

Note: Compared with before treatment, * P < 0.05.

Table 4: Comparison of fungal clearance rate and recurrence rate between the two groups n(%)

Group	Fungal clearance	e rate	recurrent rate		
· ·	Not cleared	clear away	No recurrence	recur	
Control group (n=50)	21(42.00)	29(58.00)	37(74.00)	13(26.00)	
Treatment group (n=50)	6(12.00)	6(12.00) 44(88.00)		4(8.00)	
χ^2	11.416		5.741		
$\stackrel{\cdot \cdot \cdot}{P}$	< 0.001		0.017		

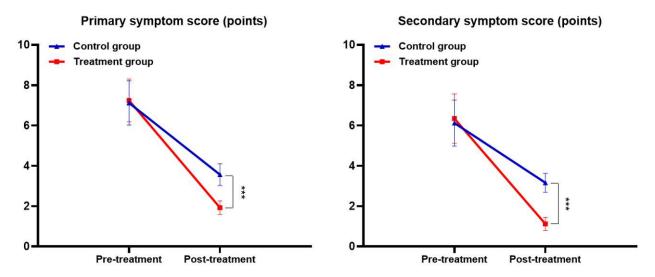


Fig. 1: Comparison of TCM syndrome points between the two groups (***P<0.001)

Table 5: Comparison of Adverse Reactions between Two Groups n(%)

group	Gastrointestinal reaction	Pruritus cutanea	Skin erythema	Causalgia	Total rate	incidence
Control group (n=50)	0	1(2.00)	0	0	1(2.00)	
Treatment group (n=50)	1(2.00)	0	1(2.00)	1(2.00)	3(6.00)	
$\chi 2$					0.260	
_ <i>P</i>					0.610	

Table 6: Comparison of quality of life scores between the two groups ($\overline{x}\pm s$, score)

	ache		mood	mood vitality			physiological function	
Group	Before	After the	Before	After the	Before	After the	Before	After the
	treatment	treatment,	treatment	treatment,	treatment	treatment,	treatment	treatment,
Control aroun (n=50)	73.56	91.24	70.24	90.38	72.58	90.66	75.16	90.94
Control group (n=50)	± 5.34	±2.41*	± 3.46	±4.10*	± 4.05	$\pm 2.41*$	± 2.34	$\pm 2.36*$
Treatment group (n=50)	73.12	95.32	70.58	94.66	72.68	96.56	75.32	95.48
Treatment group (n=30)	± 5.74	±1.33*	± 3.09	±2.55*	± 3.88	±1.77*	± 2.20	$\pm 1.05*$
t	0.397	10.481	0.518	6.268	0.126	13.952	0.352	12.428
P	0.692	< 0.001	0.605	< 0.001	0.900	< 0.001	0.725	< 0.001
	Physiological function S		Social function mental health		th	Overall he	alth	
Group	Before	After the	Before	After the	Before	After the	Before	After the
	treatment	treatment,	treatment	treatment,	treatment	treatment,	treatment	treatment,
Control group (n=50)	73.64	91.24	70.24	89.56	69.34	90.52	72.36	91.12
Control group (II–30)	± 4.80	±1.06*	± 2.66	±3.34*	± 2.46	$\pm 2.33*$	± 4.16	±1.02*
Treatment aroun (n=50)	73.16	95.30	70.18	94.16	69.68	95.02	72.72	96.34
Treatment group (n=50)	± 4.44	±1.59*	± 2.34	±2.73*	± 2.11	$\pm 1.36*$	± 4.03	±1.26*
t	0.519	15.023	0.120	7.540	0.742	11.794	0.440	22.769
P	0.605	< 0.001	0.905	< 0.001	0.460	< 0.001	0.661	< 0.001

Note: Compared with before treatment. * P < 0.05.

The treatment should be mainly based on expelling insects and relieving itching, clearing heat and detoxifying. With a variety of medications, adaptable techniques and excellent safety, the external therapy of traditional Chinese medicine has been continuously updated in recent years. As a result, traditional Chinese medicine's antibacterial formulations have been progressively adopted and used in clinics, but there is no standard scheme. Analysis of the reasons reveals the following: In the composition of the Chinese herbal foot - soaking liquid, Sophorae Flavescentis Radix is the dried root of Sophora flavescens ait of the Leguminosae family. It has the effects of killing insects, clearing heat, and removing toxicity, and is a key ingredient in the liquid (Sun et al., 2022). Phellodendri Chinensis Cortex is a bitter - cold herb, mainly targeting the lower energizer. It can clear heat, dry dampness, purge fire, and remove toxicity (Zhou et al., 2022). Taraxaci Herba, also known as Herba Taraxaci Mongolici, has the effect of relieving fever and clearing heat (Wu et al., 2024). Kochiae Fructus can effectively remove damp - heat and wind - evil from the skin, playing an antipruritic role (Xiao et al., 2018). Dictamni Cortex is mainly used for treating damp - heat sores and scabies. It can expel wind, remove toxicity, clear heat and dry dampness (Chen et al., 2021). Zanthoxyli Pericarpium has the effects of killing insects, relieving itching, warming the middle - energizer, and relieving pain (Chen et al., 2024). White vinegar can kill insects and remove toxicity (Cortesia et al., 2014). The combination of

these herbs is in line with the pathogenesis of tinea pedis, giving full play to the effects of clearing heat, removing toxicity, killing insects, and relieving itching, and significantly improving the clinical efficacy.

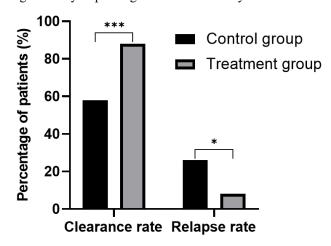


Fig. 2: Comparison of fungal clearance rate and recurrence rate between the two groups (*P<0.05, **P<0.001).

Study on the fungal clearance rate of chinese herbal foot - soaking liquid in treating tinea pedis

The fungal clearance effect is also one of the important criteria for evaluating the efficacy of tinea pedis treatment. The results of this study showed that the fungal clearance

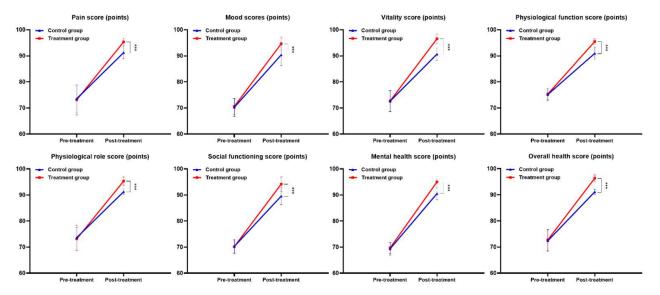


Fig. 3: Comparison of quality of life scores between the two groups (***P<0.001)

rate of the treatment group was higher than that of the control group, and the recurrence rate was lower than that of the control group, suggesting that the external care treatment of tinea pedis patients with Chinese herbal foot soaking liquid had a significant fungal clearance effect and a low recurrence rate. Modern medicine indicates that sophorae flavescentis radix contains alkaloid components, which not only have obvious bactericidal effects but also can play a certain role in expelling insects (Zhong et al., 2017). Phellodendri Chinensis Cortex contains components such as phellodendrine and berberine, which have obvious inhibitory effects on fungi causing skin diseases and can also play a certain role in anti - ulcer and anti - inflammation. Taraxaci Herba contains components such as taraxasterol, taraxacin, organic acids, and inulin, which have the effect of eliminating a variety of bacteria. Dictamni Cortex is an important herb for treating skin diseases. Many alkaloids in its components have inhibitory effects on a variety of bacteria and fungi. Kochiae fructus contains volatile oils, saponins, terpenoids, etc., which can play roles in anti - inflammation, anti - allergy and anti bacteria.

Zanthoxyli Pericarpium has the effects of analgesia, anti-inflammation, insect - killing, and bacteriostasis. White vinegar can damage the growth environment of fungi and inhibit their reproduction and survival. The Chinese herbal foot - bath treatment has the following advantages: ① Keeping the foot - soaking time at about 30 minutes each time can soften the thickened or eroded stratum corneum at the affected area, which is convenient for scraping off the stratum corneum, and at the same time, the fungi in the stratum corneum will also be removed. ② Soaking feet in warm water can improve the blood circulation in the feet, which is conducive to promoting metabolism and laying a foundation for the full play of the drug effect.

Study on the safety and quality of life of chinese herbal foot - soaking liquid in treating tinea pedis

In addition, the safety of drug use has always been a hot spot in clinical treatment. In the results of this study, there were no abnormalities in liver function and urine routine in both groups. Only one case in the control group had skin itching, and one case each of gastrointestinal reaction, skin erythema, and burning sensation occurred in the treatment group, with a total of 3 cases of adverse reactions. There was no significant difference between the groups, which confirmed that the external care treatment of tinea pedis patients with Chinese herbal foot - soaking liquid had good safety. This is mainly because Chinese herbal foot - bath is mainly administered through the skin, which can avoid irritation to the liver and gastrointestinal tract. Moreover, the components of the liquid pay attention to the proportioning and will not produce obvious drug interactions, resulting in mild gastrointestinal reactions. However, if the temperature of the liquid is not properly controlled, it may cause discomfort such as skin erythema and burning sensation. Therefore, when using the Chinese herbal foot - soaking liquid, the temperature should be adjusted to a tolerable level to avoid scalding caused by excessive temperature and ensure the safety of treatment. Finally, the results of this study showed that the quality - of - life scores of both groups after treatment were higher than those before treatment, and the score of the treatment group was higher than that of the control group, indicating that this treatment plan for tinea pedis patients could significantly improve the quality of life and was highly favored by patients.

Research prospects

There are still some deficiencies in this study at present. For example, the sample size included is relatively small, and long - term follow - up has not been carried out, which may limit the universality of the research results. Since the

condition of this disease is prone to recurrence and difficult to cure radically, the research on its recurrence mechanism has not been carried out in - depth, and the comparability and reproducibility of the treatment results are poor, which is not conducive to in - depth research. In addition, this study lacks a comparison with the results of the placebo group and further experiments are needed to supplement it in order to obtain more comprehensive clinical results. Therefore, the standardization of clinical research on traditional Chinese medicine needs to be further improved. In future clinical research, the sample size should be further expanded, the follow - up time should be extended, and attention should be paid to the standardization of the design to deeply explore the mechanism of traditional Chinese medicine in treating tinea pedis. Combining with modern clinical research methods, the prevention and treatment of tinea pedis by traditional Chinese medicine will be carried forward.

In conclusion, the external care treatment of tinea pedis with Chinese herbal foot - soaking liquid has significant efficacy, can effectively relieve symptoms, has a high fungal clearance rate, few adverse reactions, and a low recurrence rate, which is helpful to improve the quality of life of patients. It fully demonstrates the advantages of traditional Chinese medicine and lays a solid foundation for the modern research of traditional Chinese medicine on tinea manuum and tinea pedis.

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