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Effects Of Mentholatum On Onychomycosis Of The Toenail

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EFFECTS OF MENTHOLATUM

ON ONYCHOMYCOSIS OF THE TOENAIL

by

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Abstract

As many as 25% of the population age 60 years and older may be affected by onychomycosis, a chronic infection that is difficult to cure. Onychomycosis can cause pain and soft tissue injury that can lead to infection affecting gait from discomfort. Current oral medications available for the treatment of onychomycosis are costly and can pose the risk of serious side effects. The purpose of this study was to determine if the use of Mentholatum was an effective and cost-efficient means to treat onychomycosis of the toenail in elders. The Neuman Systems Model was used as the theoretical framework: specifically, Neuman's secondary prevention interventions to support system stabilization. The null hypothesis of this study was stated as follows: There will be no effect on the onychomycosis of the toenails in the elderly treated with Mentholatum. A quasi-experimental design was used to compare photographs of the toenail prior to treatment and photographs of the toenail at completion of the treatment. The subjects were drawn from three nursing homes in a southern state. Permission was obtained from residents and

their responsible party for participation in the study. The 33 subjects ranged from 65 to 96 years. The Mentholatum was applied twice daily by a nurse researcher assistant. Digital photographs of the elder's toe were graded by a panel of experts, three physicians and a podiatrist. The nail changes were graded on a 5-point Likert scale. The outcomes of the study revealed 90% of the subjects experienced some positive change in the nail growth, which indicated a statistical significance. Therefore, the null hypothesis was rejected. Because of the limitation in the length of the study, there was no determination if nail cure could be achieved.

Dedication

This thesis is dedicated to my husband, Troy, who has moved mountains for me to complete this year. I love you.

To my children, Sarah, Megan, Daniel, Seth, and Anna, you are my heartbeat.

Without all of you, none of this would have been of any worth to me.

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Chapter I

The Research Problem

Onychomycosis is a fungal nail infection which is known to be difficult to treat and can frequently have a negative impact on one's quality of life (Drake, 1997). Although onychomycosis can be asymptomatic, if symptomatic, the thickened, dystrophic nails can result in discomfort, pain, soft tissue injury, and infection. Onychomycosis accounts for 60% of consultations for nail disorders (Havu et al., 2000). Onychomycosis is the nail disease most commonly encountered by clinicians (Gupta & Ryder, 2002). Gupta and Ryder (2002) reported 2% to 18% of the population is affected by onychomycosis, with higher prevalence in those ages 60 years and older, diabetic, or HIV positive.

Because of increased use of alternative approaches by American citizens to both treat illness and promote health, the President of the United States in 2000 issued an executive order for the formation of a commission to develop policy recommendations on complementary and alternative medicine (CAM). The White House Commission

recognized the need for scientific research to determine which CAM practices were "clinically effective and cost-effective" (White House Commission on Complementary and Alternative Medicine, 2003, ¶17). The purpose of this research was to evaluate the effectiveness of Mentholatum as an alternative treatment for onychomycosis of the toenail in the elderly.

Establishment of the Problem

Onychomycosis occurs when the nail or nail bed is infected by fungi or yeast. The organism enters the hyponychium from the surrounding skin, producing inflammation, which results in hyperkeratosis and onycholysis. The combined effects of the detachment of the plate from the nail bed and subungual thickening often produce discomfort as well as potentially serious complications for vulnerable adults (Rodgers & Bassler, 2001). Schein et al. (1997) reported 54% of the patients with onychomycosis experienced discomfort. Bending (2002) stated approximately one third of fungal skin infections are related to onychomycosis and predicted an increase of onychomycosis due to an aging population and a greater number of people who are immunocompromised.

Onychomycosis affects the quality of life of those who are afflicted with the disease. Guttman (2002)

reported onychomycosis' "greatest impact on the quality of life were for emotions, followed by symptoms, and then function" (Guttman, 2002, p. S11). Contributing factors to the emotional impact were concerns the disease would worsen, shame, frustration, and embarrassment (Guttman, 2002). This finding was supported by Schein et al. (1997), who reported 67% of the patients with onychomycosis experienced embarrassment related to the nail's appearance and 40% of the patients were limited in their choice of shoes.

The prevalence of onychomycosis varied among reports. Roberts (1992) estimated an incidence of 2.8% in males and 2.6% in female patients, whereas Heikkila and Stubbs (1995) estimated 8.4% of the population, and Gupta et al. (2000) reported 16.7% of patients had abnormal nails with 8% mycologically confirmed onychomycosis. While the prevalence of onychomycosis varied by study, all researchers reported greater incidence in males.

The prevalence of onychomycosis with a co-morbidity was evaluated by Ramano, Massai, Asta, and Signorini (2001) who reported a 6% dermatophyte nail infection in patients with diabetes mellitus, while Gupta, Konnikov, and MacDonald (1998) estimated one third of diabetics will develop onychomycosis. de Ocariz, Arenas, Ranero-Juárez, and Monroy-Ramos (2001) reported nail changes were present

in 16.11% of patients with a venous leg ulcer, with 59% of the nail changes attributed to onychomycosis. This high incidence among patients with vascular disease was confirmed by Gupta et al. (2002) in 49.2% of the patients with vascular disease, 22.4% of the nail changes were onychomycosis confirmed by mycology. Further, Gupta, Lynde, and Jain (1997) reported 27% of patients with psoriasis and abnormal nails had onychomycosis.

The cost for the treatment of dermatophyte toenail onychomycosis in the United States as reported by Gupta (2002) is griseofulvin (Fulvicin, Grifulvin V) at a dose of 500 mg twice daily for 12 months at $1,072.80 with the additional cost of consultation, return visits, mycological exam, and laboratory testing (referred to as additional costs) of $396; itraconazole (Sporanox) at a dose of 200 mg a day for 12 weeks at $1,246.58 with the additional costs totaling $215, and terbinafine (Lamisil) at a dose of 250 mg a day for 12 weeks at $701.40 with the additional costs totaling $245. Fluconazole (Diflucan) was included, although it is not been approved for treatment of onychomycosis, at a dose of 150 mg weekly for 12 months at $638.04 with additional costs totaling $366. The patient's systemic functions should be monitored with the use of these drugs. For example, kidney function should be monitored with the use of itraconazole and griseofulvin,

liver function should be monitored with the use of itraconazole and terbinafine, and itraconazole should also be monitored for congestive heart failure.

Because of the evidence that a significant number of the population may be afflicted with onychomycosis, the nurse practitioner should be vigilant in the examination of the patient's nails. While discomfort and potential risks of serious complications resulting from the infection certainly warrant treatment, the nurse practitioner should consider cost, drug interactions in patients in polypharmacy, and the difficulties of differential diagnosis for abnormal nails. There is no research into the alterative therapy of Mentholatum as a treatment for onychomycosis. If effective, Mentholatum ointment will be able to reduce discomfort, which will positively impact the quality of life and do so at a cost less than traditional medication.

Significance to Nursing

The nurse practitioner approaches the whole person when providing care. With the increased use of CAM, the nurse practitioner must be aware of what CAMs are and their effects. If the client utilizes CAM, the nurse practitioner should be able to give knowledgeable information regarding safety and efficacy and aid the

client in health care decision making. A supporting and accepting atmosphere should be provided, so that the nurse practitioner and the client can explore if and how CAM and traditional medicine could be blended. It is essential that the practitioner does not dismiss CAM as irrelevant or noncontributory to the health of the client. Such a dismissal could result in the nurse practitioner reducing the effectiveness of treatment and the willingness of the client to seek treatment from that provider. Research concerning the efficacy of the alternative treatment of onychomycosis with Mentholatum ointment will provide the practitioner with information to aid clients in determining their choice of treatment.

Theoretical Framework

The Neuman Systems Model has been selected for the theoretical framework of this research. The Neuman Systems Model has its foundations in Gestalt's theory of an organism maintaining homeostasis, Bernard Marx's philosophy of the parts are determined by the whole, Pierre de Chardin's philosophy of life's wholeness, Caplan's conceptual model of levels of prevention, and Han Seyle's definition of stress. Additionally, Betty Neuman utilized her own philosophies and experience to develop the model (Tomey & Alligood, 2002).

A wholistic approach for client care is utilized, in which the client's continuous adjustment to maintain stability with the environment is assessed and interventions are planned. Neuman identified five variables in man which interact with the environment: psychological, sociocultural, physiological, developmental, and spiritual. When stressors, either interpersonal or extrapersonal, are introduced, disharmony of the system's parts may develop and illness ensues. These stressors must penetrate the system's lines of defense. The normal life of defense is maintained by the client and is utilized to resist deviations from wellness. The flexible line of defense is the client's ability to rapidly adjust to stressors to maintain wellness. The lines of resistance are those resources used to defend against stressors (Neuman, 1982).

The model also includes three levels of intervention for a systematic approach, once stressors are suspected or have been identified. The first level, primary prevention, is implemented to support the client's flexible line of defense so that stability may be maintained. As related to this study, the client would need education regarding proper shoe fit and nail and skin care of the foot. The second level is secondary prevention. Once symptoms of stress have developed, the client's lines of resistance

need strengthening to stabilize the system and reduce the response to the stressors. This study introduced an intervention for onychomycosis, which if effective, is less costly than the currently available traditional treatments. The final level, tertiary prevention, is implemented after either level one or level two, or both, have been resolved and interventions are then implemented to prevent recurrence. Effectively treated onychomycosis would be followed by continued education regarding proper foot care and continued monitoring for relapse. The client and the nurse practitioner working collaboratively may be at any and all of the levels at the same time in the treatment and education of the client (Neuman, 1982).

This study was concerned with secondary prevention. In clients with onychomycosis, lines of resistance have been interrupted and disharmony has occurred. Determining the effects of Mentholatum on onychomycosis can provide information that impacts the lines of resistance and system stability.

Assumptions

This study was based on the following premises:

1. Onychomycosis can be accurately diagnosed without verification of mycology.

2. Onychomycosis is a painful soft tissue condition that is expensive to treat.

3. The condition of onychomycosis is a disharmony of the individual lines of resistance.

Purpose of the Study

The purpose of this study was to determine if the use of Mentholatum is an effective and cost-efficient means to treat onychomycosis of the toenails in elders.

Statement of the Problem

Onychomycosis can be the cause of pain, soft tissue injury, and infection and can have an effect on gait due to discomfort. The results from the use of Mentholatum in treating onychomycosis is unknown. A review of the literature has revealed no research on this treatment. Also, there are cost implications when compared to mouth prescriptive medications.

Research Hypothesis

The null hypothesis was stated as follows: There is no effect on onychomycotic toenails in elders treated with Mentholatum ointment.

Definition of Terms

For the purpose of this research, certain terms required definitions relating to their function within the study:

Mentholatum: an ointment with active ingredients of camphor at 4.8% and Menthol at 2.6%. The operational definition for this study was Mentholatum is an over-the-counter ointment with the active ingredients of camphor at 4.8% and Menthol at 2.6%. The over-the-counter drug used was Vicks Vaporub®.

Onychomycosis: a chronic fungal or yeast infection of the nail bed with involvement of the nail plate. The operational definition for this study was onychomycosis is a chronic fungal condition of the toenail as diagnosed by the attending physician.

Elder: an adult whose age ranged from 60 to 100 years. The operational definition of elder was an adult who is a resident of a nursing home and has been diagnosed with onychomycosis of the toenail.

Summary

Onychomycosis can affect 2% to 18% of the population, with a higher incidence in the elderly, diabetics, and HIV positive. It is a chronic disease and can be difficult to cure. Onychomycosis can cause soft tissue injury which can

lead to infection. Current oral medications are costly and pose risks of serious side effects. The Neuman Systems Model was used as the theoretical framework. The hypothesis of this study was that there is no effect on the onychomycosis of the toenails in elders treated with Mentholatum. The purpose of this study was to determine if the use of Mentholatum ointment is an effective and cost-efficient means to treat onychomycosis of the toenails in elders.

Chapter II

Review of the Literature

To determine the current status of research regarding the treatment of onychomycosis, a review of literature was conducted. Five research articles were reviewed for this study. Syed, Qureshi, Ali, and Ahmed (1999) examined the efficacy of butenafine and 5% *Melaleuca alternifolia* in the treatment of onychomycosis. Lebwohl et al. (2001) examined the safety and efficacy of terbinafine as a treatment. Smith, Stein, Fivenson, and Atillasoy (2000) examined the safety of terbinafine in patients who were over the age of 60 years. de Ocariz et al. (2001) examined the frequency of onychomycosis in patients with chronic venous insufficiency who had cutaneous manifestations. Baran et al. (2000) reported on the effects of treating onychomycosis with a combination therapy of amorolfine 5% solution nail lacquer and oral terbinafine with terbinafine alone.

Syed et al. (1999) studied the efficacy and tolerability of 2% butenafine and 5% *Melaleuca alternifolia* stated in a topical cream as a treatment for

onychomycosis. Syed et al. (1999) stated that 30% of all mycotic infections are the chronic disease of onychomycosis. Onychomycosis is both difficult to diagnose and treat because the parasitic infection can build an effective barrier to the penetration of antimycotic agents when located in dead keratinized tissue, such as the toenail. Butenafine was defined as an antimycotic fungicidal, a "pheno-substituted benzylamine derivative" (p. 285). The other active agent of the cream, *Melaleuca alternifolia*, was defined as an essential oil which contained "terpinen 4-ol, cheole and viridiflorene" (p. 285). Onychomycosis was defined as the clinical diagnosis of at least a 25% involvement of one of the great toenails by a fungal infection, which was confirmed by a positive culture. Clinical success was defined as 100% remission or a 90% to 99% improvement in the treated toenail. Mycological cure was defined as a negative fungal culture, utilizing a wet potassium hydroxide (30%) test.

Syed et al. (1999) used a randomized, double-blind, placebo-controlled study. The population for the study was obtained by referrals from medical officers or registered medical practitioners. The officers and practitioners had been informed by the researchers that pregnant and lactating women were not candidates for enrollment in the study. The sample was obtained by a baseline screening

process which excluded subjects by specified criteria. These criteria included:

> Onychomycosis caused by molds, bacteria or *Candida spp.*, a history of psoriasis, any serous concurrent disease, hypersensitivity to *Melaleuca alternifolia* oil, azole or benzylamine derivatives and concomitant therapy with drugs appearing to affect the bioavailability of benzylamine . . . patients who had received systemic antifungal treatment within the previous three months or who were using topical treatment the two weeks preceding the study were not enrolled. (p. 285)

The sample (N = 60) included 31 males and 29 females. Their ages ranged from 18 years to 80 years, with a mean of 29.6 years. In the sample group, 48.3% were diagnosed with onychomycosis less than one year, and 51.7% had been diagnosed for one to 3 years. Thirteen subjects had used systemic medication longer than one year prior to the study, and 12 subjects had used topical treatment in the 6 months preceding the study.

The researchers followed the Helsinki declaration recommendations for informed consent. All 60 subjects gave consent for treatment. The subjects were then randomly assigned to either the treatment group or the control group. Randomization was affected by the subject receiving a precoded tube of cream. The active tube would contain both agents, while the placebo would contain only the 5% *Melaleuca alternifolia*. There were 40 active tubes and 20 placebo tubes. The study protocol limited active treatment

to 8 weeks. The groups were comparable statistically for the area of toenail infected as well as age and race. The subjects were instructed by the researchers in the three times a day application of the cream and application of an occlusive dressing. All subjects were determined to be compliant with the treatment and were included in the efficacy analysis.

The efficacy, tolerability of the cream, and overall success of the treatment were determined by weekly examination. Also, laboratory cultures obtained at weeks 8, 24, and 36 were included in the evaluation. Upon examination, a determination was made if the toenail was ready for debridement. Debridement was done with a nail clipper. At 4 weeks, 4 males and 5 females had treated nails which were debrided; at 5 weeks, 9 males and 4 females' treated nails were debrided. Seven males and 3 females were debrided after 6 weeks.

At the end of the study, the code was broken, and Syed et al. (1999) discovered that all 32 of the debrided nails were from the active group. The researchers utilized the Cochran-Mantel-Haenszel test to compare the "clinical effectiveness and overall success of treatment" (p. 285) between the active and placebo groups. To determine if there was homogeneous between treatment and cure, the researchers used the Breslow-Day test. To compare the

relationship between treatment and outcome, the researchers used the Fisher's two-tailed test. Causative dermatophytes were determined by laboratory culture. In this study, *Trichophyton rubrum* was isolated in 93.3% of the subjects, *Trichophyton tonsurans* in 5%, and *Trichophyton memtagrophytes* in 1.7% of the subjects.

In the active group, 4 subjects reported mild inflammation. The inflammation was not severe enough to interrupt treatment. The result was that 93.3% of the subjects experienced no side effects.

At 36 weeks, an overall cure rate for the active group was 80%, while the placebo group's overall cure rate was negligible ($p < .0001$). Reported relapses in the active group after one year was negligible.

The researchers concluded that this treatment, when compared with systemic antimycotic treatment, was "significantly better" (p. 286). Syed et al. (1999) cited the result of an 80% cure rate, only 6.7% of the subjects reported mild side effects, and zero relapse, while systemic treatments were "accompanied by precarious drug related side effects and required long-term regimes to achieve resolution" (p. 286). Syed et al. found that *Melaleuca alternifolia* alone "did not show the expected response" (p. 286). The researchers did not indicate what response they had expected. The researchers suggested that

the application of the placebo treatment for only 8 weeks was "insufficient to render its full potency" (p. 285).

Syed et al. (1999) concluded that the findings of the study were that the topical application of 2% butenafine and 5% *Melaleuca alternifolia* in cream, along with debridement, was "safe, tolerable and significantly more effective than placebo to cure toenail onchycomosis" (p. 286).

Syed et al.'s study is germane to this researcher because it provided insights into some of the components used to identify a population with a disease process determination of the sample subjects and tests utilized to compare and analyze the findings of the two treatment groups. This researcher questions the term *placebo* when there was an expected response in its application. In this researcher's study, patients were similarly excluded if there was a diagnosis of psoriasis, had received a systemic antifungal treatment in the 3 months prior to beginning the study, or had received a topical antifungal treatment in the 2 weeks prior to beginning the study.

In another study Lebwohl et al. (2001) stated that the usual cause of onychomycosis is dermatophytes. There may also be nondermatophytes present. Nondermatophytes role in onychomycosis is unclear and a "subject of debate among mycologists" (p. 359). The purpose of this study was

to determine terbinafine's efficacy in treating onychomycosis associated with a combination of dermatophyte and nondermatophyte or nondermatophyte alone. The primary efficacy variable was defined by Lebwohl et al. (2001) as effective treatment. The efficacy variables were defined as unaffected nail length and nail involvement at baseline. The secondary variable was defined as no nail involvement at 48 weeks and negative mycology. Terbinafine was defined as a "synthetic antifungal agent of the allylamine class" (p. 359). Effective treatment was defined as a specimen with both a negative culture and KOH microscopy and a minimum of 5 mm growth of unaffected nail to no nail involvement. Complete cure was defined as negative mycology along with no nail involvement. Isolated nondermatophytes were identified as *Alternaria, Aspergillus*, and *Candida*. The isolated dermatophyte was "usually" *Trichophyton* rubrum (p. 358).

Lebwohl et al. (2001) used a randomized, multicenter, double-blind, placebo-controlled study. The sample (N = 97) was randomized to the eight study centers. There were 32 subjects in the placebo group and 65 subjects in the treatment groups.

The subjects were both male and female. The ages ranged from 18 to 70 years. The three subject groups received either terbinafine 250 mg once a day for 24

weeks, terbinafine 250 mg once a day for 12 weeks, then placebo for 12 weeks or placebo for 24 weeks.

Evaluation of the target toenails was done before treatment was initiated, then at 12, 18, and 24 weeks during treatment. Subjects were evaluated every 6 weeks after treatment was completed up to week 48. Nails were evaluated for estimated percentage of involved nail, unaffected length of nail, and nail growth. Subjects and investigators rated the overall effectiveness of treatment.

In approximately 70% of the subjects, a mixture of dermatophytes and nondermatophytes was isolated from the target nail. In the remaining subjects, nondermatophytes alone were isolated. *Candida* was isolated in 33% of the sample, 9% in the placebo group, and 23% in the treatment groups. In 3 of the 9 subjects of the placebo group and 3 of the 23 in the treatment groups *Candida albicans* were identified specifically.

Lebwohl et al. (2001) based end-of-the-study results on the "last post-baseline nonmissing observations up to and including week ninety six" (p. 359). If relapse was detected between weeks 48 and 96, the subjects were no longer included in the positive category. Adverse events were reported as similar between the placebo group and the treatment groups, with 69.2% of the treatment group

experiencing adverse events versus 65.2% of the placebo group. Gastrointestinal complaints of "dyspepsia, abdominal pain, and flatulence" were more common in the treatment group. In the treatment group 20% of the subjects reported incidents of gastrointestinal symptoms versus 12.5% of the placebo group subjects. Reversible taste abnormalities were also more common for the treatment groups than for the placebo group.

At the end of the study, Lebwohl et al. (2001) identified effective treatment for all isolates in the 12-week treatment group to be 67.7% (21 of 31 subjects), for the 24-week treatment group 63.6% (21 of 33 subjects), and for the treatment groups pooled 65.6%. Complete cure for all isolates in the 12-week treatment group was 38.7% (12 of 31 subjects), for the 24-week treatment group 39.4% (13 of 33 subjects), and for the treatment groups pooled 39.1%. Negative mycology for all isolates in the 24-week treatment group was 74.2% (24 of 31 subjects), for the 24-week treatment group 72.7% (24 of 33 subjects), and for the treatment groups pooled 73.4%.

End-of-the-study results for the 12 subjects who were in the 12-week treatment group who cultured positive for *Candida* specifically were as follows: 83.3% negative mycology (10 of 12 subjects), 83.3% effective treatment (10 of 12 subjects), and 33.3% complete cure (4 of 12

subjects). The results for the 11 subjects who were in the 24-week treatment group and who cultured positive for *Candida* specifically were 100% negative mycology (11 of 11 subjects), 81.8% effective treatment (9 of 11 subjects), and 54.5% complete cure (6 of 11 subjects).

End-of-the-study results for the 3 subjects who were in the 12-week treatment group and who cultured positive for *Alternaria* specifically were 100% negative mycology (3 of 3 subjects), 66.7% effective treatment (2 of 3 subjects), and 33.3% complete cure (1 of 3 subjects). The results for the 5 subjects who were in the 24-week treatment group who cultured positive for *Alternaria* specifically were 40% negative mycology (2 of 5 subjects), 20% effective treatment (1 of 5 subjects), and none with a complete cure.

End-of-the-stay study for the 2 subjects who were in the 12-week treatment group who cultured positive for *Aspergillus* specifically were 100% negative mycology (2 of 2 subjects), 100% effective treatment (2 of 2 subjects), and 50% complete cure (1 of 2 subjects). The results for the 5 subjects who were in the 24-week treatment group who cultured positive for *Aspergillus* specifically were 60% negative mycology (3 of 5 subjects), 40% effective treatment (2 of 5 subjects), and 40% complete cure (2 of 5 subjects).

In the end-of-study results for the placebo group, 9 subjects cultured *Candida*, 6 subjects cultured *Alternaria*, and 4 subjects cultured *Aspergillus*. There were 7 subjects who had negative mycology at the end of the study. There were no subjects for the effective or complete cure results.

Lebwohl et al. (2001) concluded that receiving terbinafine for 24 weeks was no more effective than a 12-week course. They also concluded that both regimens were tolerated well and were safe. The isolation of nondermatophytes, other than *Candida*, *Alternaria*, and *Aspergillus*, was insufficient to allow conclusions to the efficacy of terbinafine regarding those organisms. Lebwohl et al. (2001) concluded that treatment of onychomycosis, in which the nondermatophyte species (*Candida, Alternaria*, and *Aspergillus*) were specifically isolated was similar to both nondermatophytes and dermatophytes. Lebwohl et al. (2001) stated further clarification was needed for the "spectrum of activity and *in vivo* efficacy of terbinafine" (p. 360).

The study reviewed was germane to this researcher because it provided insight into the efficacy and safety of terbinafine. If the use of Mentholatum on onychomycosis shows some efficacy of treatment, then there is the potential for comparison of efficacy, costs, safety, and

adverse events between terbinafine and Mentholatum in the treatment of onychomycosis.

Smith et al. (2000) studied the safety and efficacy of terbinafine as treatment for onychomycosis of the toenails in patients older than 60 years. These researchers stated onychomycosis of the toenail is a common disease. The prevalence of onychomycosis may be 2% to 8% of the population and even higher for elderly patients.

Smith et al. (2000) used an open-label, multicentered prospective study to evaluate the safety and efficacy of terbinafine as a treatment. Criteria for inclusion in this study included ". . . age 60 years or older, a diagnosis of onychomycosis confirmed by positive potassium hydroxide (KOH) preparation at baseline, and toenails capable of regrowth" (p. 859). Any patient who had received systemic antifungal therapy 3 months prior to the initiation of the study or who had received topical antifungal therapy one week prior to the initiation of the study were excluded. Also, any patient with a diagnosis of psoriasis was immunosuppressed or immunodeficient, had at baseline serum hepatic enzyme values greater than 1.5 times normal upper limits, or any toenail abnormalities which interfered with normal toenail appearance were excluded.

At the conclusion of baseline evaluations, those patients who were eligible were given a 12-week supply of terbinafine 250 mg to be self-administered on a once-a-day dose schedule. Follow-up evaluations were conducted at 6, 12, 24, 36, 48, and 72 weeks.

Safety was assessed at baseline by physical examination and laboratory evaluations of hematology, blood chemistry, and urinalysis. At weeks 6 and 12, safety and tolerance were assessed by physical examination and a repeat of the laboratory evaluations. All follow-up visits included assessment of the extent of target toenail involved and "global assessments of therapeutic efficacy" (p. 860) as well as reporting of any adverse event experienced by the participant.

The sample (N = 30) evaluated for safety included 22 males and 8 females, ages 61 years to 84 years, with a mean of 67.6 years. The sample population was Caucasian. The duration of current episode of onychomycosis was 24 months to 552 months, with a mean of 210.4 months.

The sample evaluated for efficacy included 13 males and 2 females. Their ages ranged from 61 years to 79 years, with a mean of 66.8 years. All of the sample population were Caucasian. The mean duration of the current episode was 186.4 months, with a range of 24 months to 552 months.

For both samples, over half of the population had been treated previously for onychomycosis. Prior treatment therapies included systemic and topical antifungal therapies and nail avulsion.

Patient compliance was defined as at least 80% use of the terbinafine. This use was assessed by tablet counts at weeks 6 and 12. The mean compliance to the safety population was 98.5% at 6 weeks and 98.0% at 12 weeks. Mean compliance was not given for the efficacy population.

No study participants in the safety group withdrew because of adverse events. Twenty-nine participants (96.7%) completed the course of antifungal treatment, and 27 participants (90%) completed follow-up through week 27. No serious adverse events or deaths were reported during the period of study. Mild or moderate adverse events reported during the treatment period were transient. Investigators "attributed a possible, probable, or definite causal relationship between an adverse event and the study drug in 13 patients" (p. 860). Of the 13 patients, there were 18 reported adverse events. These events included gastrointestinal system disorders, skin disorders, respiratory disorders, and central and peripheral nervous system disorders. Although reported in other studies of terbinafine, there were no reports of taste or ocular disturbances in this study.

Twenty-eight participants (93.3%) received concomitant medication during the treatment. The medications were both prescription and over-the-counter. The most common prescription medications were cardiovascular agents. The prescription medications included ACE inhibitors, beta blockers, calcium channel blockers, diuretics, benzothiazepine derivatives, estrogen, organic nitrates, thyroid hormones, and sulfonamides. The over-the-counter medications included acetaminophen, aspirin, NSAIDS, expectorants, and vitamin and mineral supplements.

Terbinafine is "metabolized by at least seven isoenzymes of the P-450 system" (p. 863). Of the 30 participants, 16 were concomitantly taking medications that were metabolized by the P-450 system. There were no reported interactions between these medications and the terbinafine.

Of the efficacy population, only one did not complete the study. At week 72 or the last observation, 46.7% of the patients experienced cure. Mycological cure did not fall below 92.9% after week 24. Ten of the remaining 14 participants reported at the end of the study to be "satisfied or very satisfied" with the appearance of the target nail.

As the increase of the elderly population continues, the significance of medical and quality of life issues of onychomycosis will continue for this population. Smith et al. (2000) concluded that in the presence of concomitant drug therapies systemic terbinafine can be used safely and effectively to treat onychomycosis of the toenail in the elderly.

Smith et al.'s (2000) study is germane to this researcher because it identified frequently used medications, both prescription and over-the-counter, utilized by the elderly population and the safety of concomitant systemic terbinafine therapy.

In the study by de Ocariz et al. (2001), the researchers stated that the prevalence of chronic venous insufficiency is high, especially in the elderly. Chronic venous insufficiency represents 1% to 6% of all general dermatological consultations. The cutaneous manifestations of chronic venous insufficiency may also be termed as venous leg ulcer or cutaneous vascular complex of the leg. These manifestations are divided into three grades of severity. Grade I is the presence of edema, grade II is the presence of hyperpigmentation, and grade III is the presence of an ulcer. The purpose of this study was to determine the frequency of nail pathology and

onychomycosis in those patients with cutaneous manifestations of chronic venous insufficiency.

Onychopathy may originate because of vascular abnormalities such as arterial insufficiency or diabetes mellitus and others. The determination of the etiology of nail changes may be difficult due to the limited number of reactive patterns of the nail when affected by disease.

de Ocariz et al. (2001) used a prospective, observational, and transversal study. The sample (N = 36) consisted of patients examined by a physician at the dermatology department and were determined to have venous leg ulcers. Thirty of the participants were female (83.33%) and 6 participants were male (16.67%). The mean age of the sample population was 46.39 years. Because previous studies reported relationships between age and other systemic diseases, de Ocariz et al. excluded participants who were over 59 years of age or had other systemic diseases.

A dermatologist examined all participants, graded all venous ulcers, and described the nail changes. Mycological examinations by KOH and culture were performed on all patients. Functional studies were performed on 27 of the 36 participants to classify the venous insufficiency as superficial or deep.

Venous leg ulcer classification results were 10 participants (27.77%) had grade I, 12 participants (33.33%) had grade II, and 14 participants (38.88%) had grade III. Fourteen participants were identified with superficial venous insufficiency; 6 of whom had grade I severity, 5 had grade II, and 3 had grade III. Thirteen participants were identified with deep venous insufficiency; 2 of whom had grade I severity, 3 had grade II severity, and 8 had grade III. While no statistically significant relationship was identified between the presence of nail changes and cutaneous disease, participants with deep venous insufficiency exhibited nail pathology more frequently.

Nail alterations were found in 22 (61.11%) of the participants. Thirteen (59.09%) of the participants were identified with onychomycosis by mycologic culture or KOH. Fungi could not be identified in the remaining 40.91% of the participants. Of those participants diagnosed with onychomycosis, the venous leg ulcer classification was as follows: 3 participants (23.07%) had grade I, 4 (30.77%) had grade II, and 6 (46.16%) had grade III. Even though there was increased frequency of onychomycosis of the participants with more severe cutaneous disease, there was no statistically significant difference between the groups.

de Ocariz et al. (2001) reported clinical features of nail changes to be similar for the mycotic and nonmycotic groups: color changes (mycotic group 100%, nonmycotic group 88.88%), nail plate thickening (mycotic group 84.61%, nonmycotic group 55.55%), nail plate opacity (mycotic group 76.92%, nonmycotic group 44.44%), and subungual keratosis (mycotic group 69.23%, nonmycotic group 33.33%).

de Ocariz et al. (2001) concluded nail pathology was related more to vascular affection than to the severity of cutaneous affection. These researchers also identified a higher incidence of onychomycosis in this study population than had been reported in the literature for the diabetic or general dermatological population.

de Ocariz et al.'s (2001) study is germane to this research in that it provided insight into the relationship of nail pathology and vascular affection. The co-morbidities of cutaneous affections and diagnosed vascular diseases were considered in this researcher's study.

The purpose of the study conducted by Baran et al. (2000) was to compare the treatment of onychomycosis with the combination therapy of terbinafine and amorolfine and terbinafine alone. Like terbinafine, amorolfine inhibits ergosterol production by interference of the 14-reductase

and 7,8-isomerase stages. Baran et al. also evaluated the cost per cure ratios.

Baran et al. (2000) utilized a multicentre, randomized, prospective, open study. Inclusion criteria were severe dermatophyte toenail onychomycosis with matrix region involvement, ambulatory adult, presence of dermatophytes confirmed by mycology, and normal liver function at assessment. The subjects (N = 147) were randomized to one of three groups. Group 1 received terbinafine 250 mg daily for 6 weeks and applied 5% amorolfine nail lacquer weekly for 15 months. Group 2 received terbinafine 250 mg daily for 12 weeks and applied 5% amorolfine nail lacquer weekly for 15 months. Group 3, the control group, received terbinafine 250 mg daily for 12 weeks.

Baseline characteristics for treatment group (n = 50) were as follows: gender (33 males, 66%; 17 females, 34%), mean age of 46.9 years, duration of onychomycosis was 9.1 years, and interval since last antifungal treatment was 22.6 months. Baseline characteristics for treatment group 2 (n = 48) were as follows: gender (21 males, 44%, 27 females, 56%), mean age of 47.2 years, duration of onychomycosis was 10 years, and interval since last antifungal treatment was 22.1 months. Baseline characteristics for treatment group 3 (n = 49) were as

follows: gender (29 males, 59%; 20 females, 41%), mean age of 46.7 years, duration of onychomycosis was 9.7 years, and interval since last antifungal treatment was 26.2 months.

Subjects were assessed by investigators at inclusion, 6 weeks, 3 months, and every 3 months to month 18. Nail sampling was done at the inclusion visit and at 3 months. A single reference laboratory was utilized for all mycological testing. Liver function tests were performed monthly while the subjects were receiving terbinafine.

Success was defined as a negative result on mycological testing. Cure for the combined therapy group was classified only if subjects were clinically and mycologically clear. If subjects of this group were not discovered to be clear, they were classified as failures. In the other two groups, success was defined as no remaining lesion on the nail or no greater than 10% of residual disease of the nail. Failure was defined as less than a 20% reduction of total diseased nail surface.

Fifty percent of group 1 subjects, 68.8% of group 2, and 42.9% of group 3 completed the study. The two primary reasons for subjects withdrawing from the study were adverse events and lack of clinical response. In group 1, 4 subjects withdrew for adverse events and 13 for inefficacy of treatment. In group 2, 4 subjects withdrew

for adverse events and 3 for inefficacy of treatment. In group 3, 4 subjects withdrew for adverse events and 16 for inefficacy of treatment. There were no deaths related to treatment. The most common adverse events included abdominal pain, nausea, urticaria, and liver function modifications. The four subjects who presented with abnormal liver function were withdrawn from the study. In all three groups, the adverse events related to the treatment were highest during the first 6 weeks.

A comparison of cost-per-cure ratio was also evaluated (costs were reported in French franc [FF]): For group 1, effectiveness 44%, cost 1118.20 FF, and cost-per-cure ratio margin 196.92; for group 2, effectiveness 72.3%, cost 1677.90 FF, cost-per-cure ratios mean 1571.55 FF.

Baran et al. (2000) pointed out, unlike most previous trials, the subjects of this study were deliberately selected because of nail matrix involvement. "These infections are generally considered to be the most difficult to cure" (p. 1182). At the end of the 18-month study, 75.7% of the remaining subjects had, by mycological testing, no remaining infection. Baran et al. (2000) concluded that "substantial synergy may be generated by the combination of terbinafine and amorolfine in the treatment of severe toenail onychomycosis" (p. 1178).

Lebwohl et al. (2001) found a 12-week course of oral terbinafine was both safe and efficacious in the treatment of onychomycosis. The researchers also found terbinafine was well-tolerated. Smith et al. (2000) reported that terbinafine was a safe treatment choice for patients with onychomycosis who were over the age of 60 and on concomitant drug therapy. Baran et al. (2000) reported that their study results indicated that the combination of oral terbinafine and amorolfine had substantial positive effects on the treatment of onychomycosis. de Ocariz et al. (2001) discovered nail changes to be common in patients' cutaneous manifestations of chronic venous insufficiency and that half of these patients' nail changes could be attributed to onychomycosis. Syed et al. (1999) compared efficacy of treating onychomycosis with 2% butenafine and 5% *Melaleuca alternifolia* and 5% *Melaleuca alternifolia* in a placebo. While the combination cream was found to be an effective and well-tolerated treatment for onychomycosis, *Melaleuca alternifolia* alone had little effect on the disease.

Chapter III

The Method

The purpose of this study was to assess the effects of Mentholatum on onychomycosis of the toenail in elders. Research has confirmed that onychomycosis impacts the overall health and quality of life of those who are afflicted. The advanced practice nurse needs to be cognizant of the impact of onychomycosis and the treatments available. With the increase of the use of complimentary and alternative medicines, the nurse practitioner must become an active participant in the study of their effects and efficacies.

Design of the Study

The pre-post, quasi-experimental design was utilized to measure the effects of applying Vick's Vaporub® to onychomycosis of the toenails. Gillis and Jackson (2002) described quasi-experimental design as one which has not met the requirements for classical experimental design. In this quasi-experimental design, there was no randomization of subjects to a control group. Although limited in

controls, this design was appropriate in the current study because it measured the effects of treatment.

Variables

The dependent variable in this study was onychomycosis of the toenail. The treatment variable was application of Vick's Varporub®. Controlled variables included the co-morbidities of atherosclerosis, arteriosclerosis, peripheral vascular disease, and diabetes mellitus.

Limitations

The population for this study was limited to elders who reside in a nursing home. The information of this study is applicable to the study sample and may not adequately represent the general population of elders. In addition, the therapeutic dosing of Vick's Vaporub® is unknown. The length of study time may not allow for adequate treatment time. Inconsistency in the application of treatment by nursing home staff may be a limiting factor. External validity may be strengthened by nursing home staff receiving identical instruction, written instruction for reference, and written orders.

Setting, Population, and Sample

The setting for this study was three nursing homes in a southern state. All the nursing homes are in rural communities and have only physician providers. The population included all residents of the nursing home. The sample consisted of those residents diagnosed with onychomycosis of the toenail and who, along with the responsible party, signed a consent form for participation in the study.

Methods of Data Collection

Instrumentation. The instrument used to collect a visual recording of treatment effects was a digital camera. Data were gathered using four researcher-developed instruments. The first was the Inter-rater Reliability Survey (see Appendix A) which includes two sections. The first section had five photographs of onychomycosis toenails. The second section asks for panel member's determination of severity of onychomycosis for each photograph. The second instrument was the Demographic Survey (see Appendix B) which also includes two sections. The first section has five questions requiring a response from the panel member. The second section is provided for photographic identification, including a picture and date for four points of treatment. The third instrument is the

Physician Evaluation Survey (see Appendix C). This includes three questions. The first two questions require initial determination of onychomycosis severity and significant changes on initial states of the nail using three additional pictures. The third question is optional and allows for comment reflecting photographs and nail appearance. The fourth instrument is the treatment survey (see Appendix D). On this survey, the number of treatments given and omitted were recorded weekly.

Procedure. Following approval of the Committee on Use of Human Subjects in Experimentation at Mississippi University for Women (see Appendix E), the researcher contacted the administrators of the three nursing homes by letter (see Appendix F). The letter requested consent to conduct the research within the facility. After consent was obtained, the researcher in-serviced the nursing staff on the purpose of the study, method of treatment application, and significance of consistency of application (see Appendix G). Five photographs were evaluated by the panel to establish inter-rater reliability). Then those residents who were diagnosed with onychomycosis of the toenail by their attending physician were contacted by the researcher and informed of the study (see Appendix H). Consent was obtained for participation from the resident and his or her responsible party (see

Appendix I). Photographs of the affected nail were made prior to beginning treatment and then orders for treatment were written on the resident's chart. Photographs of the affected nail treated were made every 4 weeks after the initiation of treatment until the study was completed. At the completion of the study, the photographs were placed on the Demographic Survey and the demographic information entered by the researcher. The panel members then completed the Physician Evaluation Survey. During the course of the treatment, medication administration records for each patient were reviewed for missed applications of treatment. Data were then submitted to a statistician for appropriate analysis utilizing a *t* test and calculation of statistical percentages and means. The inter-rater reliability was determined by utilizing correlations and percentages. The Demographic Survey was analyzed utilizing percentages and correlations of the frequency of the co-morbidities and presence of onychomycosis.

Chapter IV

The Findings

The purpose of this study was to determine if the use of Mentholatum was an effective and cost-efficient means to treat onychomycosis of the toenail in elders. The design was pre-post, quasi-experimental to address the null hypothesis. The hypothesis stated there would be no effect on the onychomycosis of the toenail. In this chapter the sample and analysis of the data will be described in relation to the hypothesis.

Description of the Sample

Purposive sampling was utilized for collection of data from nursing home residents. The residents were from three nursing homes in a small town in a southern state. Attending physicians identified those residents diagnosed with onychomycosis. The residents and their responsible party, who signed a consent form for participation, comprised the sample. Forty-one residents began the study. Thirty-two residents continued to participate until completion of the study. The final sample consisted of 32

residents who had signed a consent form and received treatments for 72 days.

Demographic Data

Demographic data were collected for all participants in regard to age, gender, race, and co-morbidities of atherosclerosis, arteriosclerosis, peripheral vascular disease, and diabetic mellitus. All subjects (N = 32) were residents in one of three nursing homes. The ages ranged from 65 years to 96 years. The mean age was 83 years. The remainder of the data regarding the sample's demographics may be seen in Table 1.

Table 1

Demographic Characteristics of the Sample Expressed in Frequency and Percentage

Variable	*f*[a]	%
Age (years)		
65	2	6.3
67	2	6.3
77	1	3.1
80	3	9.3
81	1	3.1
82	3	9.3
83	4	2.5
84	1	3.1
85	3	9.3

(*table continues*)

Table 1 (*continued*)

Variable	*f*[a]	%
86	1	3.1
87	2	6.3
88	2	6.3
89	2	6.3
90	2	6.3
94	1	3.1
96	1	3.1
Gender		
Male	12	37.5
Female	20	62.5
Ethnic origin		
African American	1	3.1
Caucasian	31	96.9
Co-morbidity		
Atherosclerosis	3	9.3
Arteriosclerosis	7	21.9
Peripheral vascular disease	10	31.2
Diabetes mellitus	17	53.1

Note. Only subjects who completed the study are reported.

[a]$N = 32$.

Inter-rater Reliability

Inter-rater reliability was assessed by having the raters-doctors independently rate the severity of five photographs on a 5-point Likert scale. Once these measurements were obtained, an intraclass correlation

coefficient was calculated to provide an estimate of the reliability of observational coding. In short, an intraclass correlation is a reliability measurement that measures the extent to which all raters mean exactly the same thing by their rating (Sattler, 1992). The intraclass correlation coefficient estimate for the raters used in this study was .90, with a two-sided 95% confidence interval from .67 to .99. This is considered to be an acceptable level of inter-rater agreement according to Sattler (1992).

Level of Onychomycosis Pre-treatment

In general, physician ratings indicated that the mean level of onychomycosis severity before the use of Mentholatum ointment was $M = 3.85$. Based on the 5-point Likert scale utilized in this study, a mean of 3.85 indicates that the average level of onychomycosis severity for the 32 subjects prior to the administration of Mentholatum ointment was judged to be moderately severe, while a standard deviation of .96 indicates that the majority of severity ratings lie within the moderate to severe range. The remainder of the data regarding the level of onychomycosis may be seen in Table 2.

Table 2

Percentages of Subjects within each level of Pre-treatment Severity Index

Level of pre-treatment	*f*[a]	%
Minimal	0	0.0
Slightly Moderate	4	12.5
Moderate	8	25.0
Moderately severe	9	28.1
Severe	11	34.4

Note. Percentages were rounded to the nearest 10th.
[a]*N* = 32.

Level of Onychomycosis Post-treatment

Following the administration of Mentholatum ointment, the average physician rating of change for the subjects was *M* = 2.45. Based on the 4-point Likert scale used in this study, a mean of 2.45 indicates that the average level of change after the administration of the ointment was judged to fall between minimal change and new nail growth range (*SD* = .59). Most of the subjects of this study had a moderate to severe level of onychomycosis before treatment and that the level of change following the Mentholatum ointment was deemed to be minimal to

moderate with signs of new nail growth. Ninety percent of the subjects of this study did experience a change of some degree in the growth and appearance of the nail. The remainder of data regarding the level of onychomycosis post-treatment may be viewed in Table 3 and Figures 1 and 2.

Table 3

Percentages of Subjects Within Each Level of Post-Treatment Onychomycosis Change Rating by Pre-Treatment Severity Index

	No change		Minimal change		New nail growth		Normal nail growth	
Level	*f*	%	*f*	%	*f*	%	*f*	%
Slightly moderate	0	0.0	4	100.0	0	0.0	0	0.0
Moderate	1	12.5	3	37.5	5	50.0	0	0.0
Moderately severe	1	11.0	2	22.0	6	67.0	0	0.0
Severe	1	9.0	3	27.0	7	64.0	0	0.0

Note. $N = 32$. Percentages were rounded to the nearest 10^{th}.

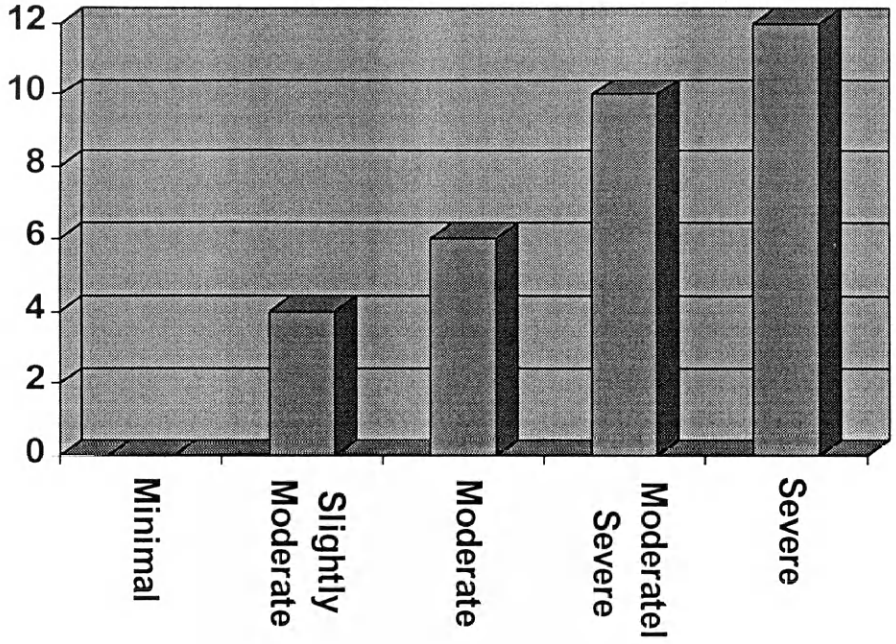

Figure 1. Number of subjects in each of the pre-treatment severity categories.

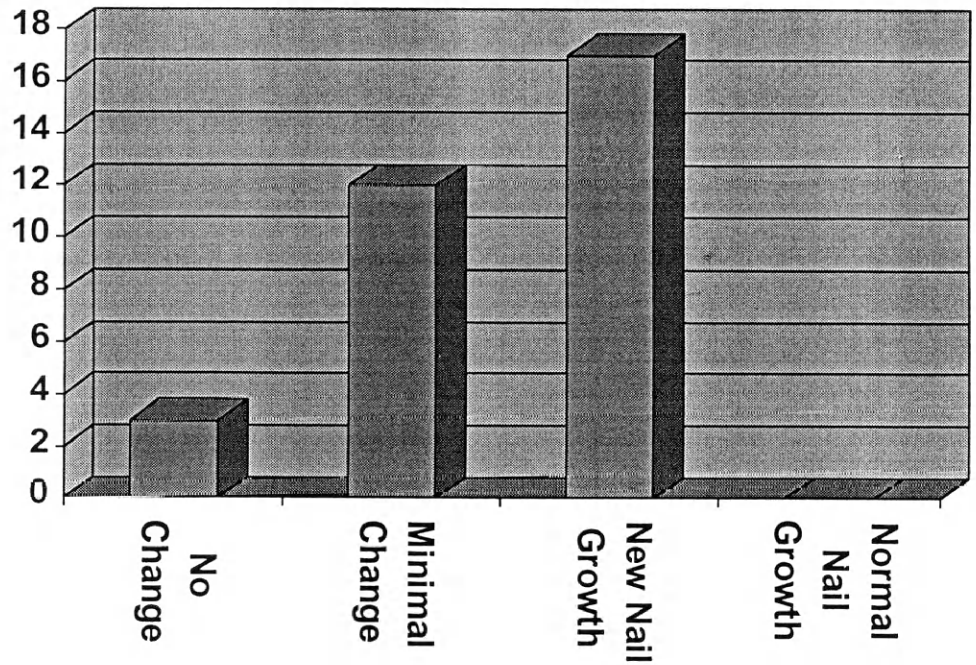

Figure 2. Number of subjects in each of the pre-treatment change categories.

In order to assess if those individuals who experienced no or minimal change were significantly different from those individuals who experienced moderate change in terms of pre-treatment onychomycosis ratings, a two-sample *t* test was conducted. This analysis revealed that those individuals who were rated as demonstrating new nail growth (n = 17, M = 4.02) had higher levels of onychomycosis ratings before treatment than those individuals who demonstrated no change to minimal change (n = 15, M = 3.43), although not to a significant degree (t = 1.78; á = .05 two-tail).

Summary

Ninety percent of the subjects demonstrated some change in the nail growth. Three subjects had no change in the nail growth (M = 9.37). Twelve subjects had minimal change in the nail growth (M = 37.5). Seventeen of the subjects had new nail growth (M = 53.12).

Chapter V

The Outcomes

Onychomycosis is the most commonly encountered nail disease. The thickened, dystrophic nails can result in pain, discomfort, soft tissue injury, and infection. Higher prevalence of the disease, those age 60 years and older and in the immunocompromised, place these populations at greater risk if the complications of onchomycosis develop. The purpose of this study was to determine if the application of Mentholatum ointment to the onychomytotic toenail of elders would affect nail growth. With the utilization of complementary and alternative medicines on the rise in the United States, the nurse practitioner should be able to give knowledgeable information regarding their safety and efficacy. The Neuman Systems Model was the theoretical framework for the study. Neuman (1982) identified three levels of intervention for a systematic approach when stressors have impacted one's lines of resistance.

The researcher utilized a pre-post, quasi-experimental design. The severity of pre-treatment

onychomycosis was measured on a 5-point Likert scale. Following a course of treatment, the effect on nail growth was measured on a 4-point Likert scale. The null hypothesis stated there would be no effect on onchomycotic toenails in elders treated with Mentholatum ointment.

The setting for the research was three nursing homes in a small town in a southern state. The 32 subjects ranged from 65 to 96 years.

In this chapter the findings, as well as the conclusions reached by the researcher, will be discussed. The implications of the research for nursing science, the limitations of the study, along with recommendations for further research will be set forth.

Summary and Discussion of the Findings

Findings from this study, regarding the effects of Mentholatum on onychomycosis of the toenail, showed a significant change in nail growth post-treatment. Ninety percent of the subjects showed some nail growth change.

The sample population was residents of three nursing homes in a southern state. Forty-one subjects began the study. The reasons for subjects being withdrawn were the following: subject request to be withdrawn; hospitalization, where treatments were omitted; subject noncompliant to treatment regimen; and deaths, which were

unrelated to the treatment. The 32 subjects who completed the 72 days of treatment application comprised the final sample population. The mean age was 83 years. There were 12 males and 20 females. Thirty-one of the subjects were Caucasian and one was African-American.

There were 4,577 total applications of the twice-a-day treatment for the subject population. There were 31 missed treatments, for a mean of less than 1%. The causes for missed treatment were unknown.

Interrater reliability was established by having the raters independently rate the severity of five photographs of omchomycotic nails on a 5-point Likert scale. The intraclass correlation coefficient estimate for the raters used in this study was .90, with a two-sided 95% confidence interval from .67 to .99.

The raters, utilizing a 5-point Likert scale, indicated the severity of pre-treatment onychomycosis in the subject population. The level of onychomycosis severity before the use of Mentholatum ointment was judged to be moderately severe (M = 3.85), while a standard deviation of .96 indicates the majority of severity ratings lie within the moderate to severe range. At the end of the treatment course, the raters utilized a 4-point Likert scale. The average physician rating of change for the subjects was M = 2.45 (SD = .59). The mean of 2.45

indicates the average level fell between minimal change and new nail growth. A two-sample *t* test was conducted to assess if those individuals who experienced no or minimal change were significantly different from those individuals who had experienced moderate change. This analysis revealed that those individuals who demonstrated new nail growth (n = 17, M = 4.02) had higher levels of onychomycosis rating before treatment than those individuals who demonstrated no change to minimal change (n = 15, M = 3.43), although not to a significant degree (t = 1.78; p = .09, á = .05). This pattern of results tends to indicate that those who had greater onychomycosis symptomatology pre-treatment tended to display more new nail growth than those subjects with less severe onychomycosis. This pattern can be interpreted as change is easier to detect with more severe onychomycosis.

Conclusions

Based on the findings of this study, the following conclusions were drawn:

1. The application of Mentholatum to onychomycosis of the toenail in elders positively affected the growth of the nail.
2. The subjects who demonstrated new nail growth had a higher level of onychomycosis pre-treatment,

than those subjects who had no change to minimal change.

Significance for Nursing

A number of implications for nursing science were derived from the study. Addressed are implications for nursing practice, education, and research.

Practice. Findings indicated the use of complementary and alternative medicines can and do impact treatment options for the clients of nurse practitioners. In order to provide accurate counseling to clients about those treatment options, the nurse practitioner must be aware of current complementary and alternative medicine practices and their efficacy. Because nurse practitioners are recognized as a professional health care resource, clients should be able to rely on the nurse practitioner for a holistic approach to their care. The nurse practitioner can provide secondary and tertiary interventions once the diagnosis of onychomycosis has been made by collaborating with the client on the most appropriate treatment and establishing realistic, obtainable goals for an optimal state of well-being.

Education. Schools of nursing at all levels should include educational opportunities on complementary and alternative medicines. All practicing nurses could

encounter clients who may be utilizing complementary or alternative medicines. The nurse must be aware of how complementary or alternative medicines may impact the client or how they may interact with conventional medical treatment regimens. All nurses, whether a student or experienced, need educational opportunities to remain up-to-date with current complementary and alternative medicines.

Research. Findings from this study indicate that the use of Mentholatum may have an impact on onchomycosis. Additional research needs to be conducted to determine to what degree the treatment will ultimately affect the disease. Further studies of the long-term use of Mentholatum are needed to determine the potential for cure of onychomycosis. This researcher also recommends study of younger aged populations and the response to the application of Mentholatum to onychomycosis of the finger nail.

Limitations

The design of the study imposed a number of limitations that constrained the conclusions drawn from the research. The study was limited to elders who resided in a nursing home, which may limit generalization to elders who reside outside an institutional setting. The

inclusion of only elders in the study further limited the ability to generalize to other populations of different ages. The sample was purposive to a quasi-experimental design, which contributed to a weaker design than if a randomized experimental design was used.

Further limiting the study was the time between treatment onset and the conclusion of data collection. The length of time did not allow for completion of a toenail growth cycle. Therefore, no conclusion could be made regarding the potential for overall nail appearance to improve of the possibility for mycologic cure. The total size of the sample population limits to some degree the generalization of the study than a study of a large sample population.

Recommendations for Future Research

The researcher made the following recommendations for future research based on the findings from this study:

1. Replication of the study that allows data collection for the length of a full toenail growth cycle.
2. Conduction of an experimental study of elders outside an institutional setting.
3. Conduction of an experimental study of different age populations.

4. Conduction of an experimental study of the effects of Mentholatum on onychomycosis of the fingernail.

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APPENDIX A

INTER-RATER RELIABILITY SURVEY

Inter-rater Reliability Survey

Dr. #_____ Date of Evaluation:_____

Instructions: Please review the severity of the onychomycosis of the photographs and circle the level of severity most appropriate for each particular photograph.

Photograph #1

#1	#2	#3	#4	#5
Minimal	Slightly moderate	Moderate	Moderately severe	Severe

Photograph #2

#1	#2	#3	#4	#5
Minimal	Slightly moderate	Moderate	Moderately severe	Severe

Photograph #3

#1	#2	#3	#4	#5
Minimal	Slightly moderate	Moderate	Moderately severe	Severe

Photograph #4

#1	#2	#3	#4	#5
Minimal	Slightly moderate	Moderate	Moderately severe	Severe

Photograph #5

#1	#2	#3	#4	#5
Minimal	Slightly moderate	Moderate	Moderately severe	Severe

APPENDIX B

DEMOGRAPHIC SURVEY

Demographic Survey

Demographics of the subject:

1. Subject #:_____
2. Age:_____
3. Gender
   - ❑ a. Male ❑ b. Female
4. Race:_____
5. Co-morbidities present:
   - ❑ a. Atherosclerosis
   - ❑ b. Arteriosclerosis
   - ❑ c. Peripheral vascular disease
   - ❑ d. Diabetes mellitus

Photographs

#1 (Date) #2 (Date)

#3 (Date) #4 (Date)

APPENDIX C

PHYSICIAN EVALUATION SURVEY

Physician Evaluation Survey

Dr. _____
Date of Evaluation:_____
Subject #:_____

1. **Instructions:** Please review the severity of the onychomycosis of the first photograph and circle the level of severity most appropriate for this particular photograph.

#1	#2	#3	#4	#5
Minimal	Slightly moderate	Moderate	Moderately severe	Severe

2. **Instructions:** Please review the subsequent photographs for nail changes in comparison to the first photograph. Answer the following only in regard to the final photograph.

#1	#2	#3	#4
No changes	Minimal change	New nail growth	Normal nail growth

3. Comments regarding the photographs and nail appearance (optional):

_____
_____
_____
_____
_____
_____
_____

APPENDIX D

TREATMENT SURVEY

Treatment Survey

1 = All treatment given
2 = Treatments omitted (in parenthesis the number of treatments omitted)

Patient ID Number	Week #							
	1	2	3	4	5	6	7	8

Treatment Survey

1 = All treatment given
2 = Treatments omitted (in parenthesis the number of treatments omitted)

Patient ID Number	Week #					
	9	10	11	12	13	14

APPENDIX E

APPROVAL OF MISSISSIPPI UNIVERSITY FOR WOMEN'S COMMITTEE ON USE OF HUMAN SUBJECTS IN EXPERIMENTATION

MISSISSIPPI UNIVERSITY FOR WOMEN

Admitting Men Since 1982

Office of Academic Affairs
Eudora Welty Hall
W-Box 1603
Columbus, MS 39701
(662) 329-7142
(662) 329-7141 Fax

www.muw.edu

March 3, 2003

Ms. Susan D. Cappleman
c/o Dr. Patsy Smyth
P. O. Box W-910
Campus

Dear Ms. Cappleman:

I am pleased to inform you that the members of the Committee on Human Subjects in Experimentation have approved your proposed research provided the consent form be amended to add: "Failure to participate will not affect you in any way."

I wish you much success in your research.

Sincerely,

Vagn K. Hansen, Ph.D.
Provost and Vice President
for Academic Affairs

VH:wr

cc: Mr. Jim Davidson
Dr. Patsy Smyth
Dr. Mary Pat Curtis

APPENDIX F

LETTER TO ADMINISTRATOR OF FACILITY

1850 CR 748
Dumas, MS 38625
December 2, 2002

Jerry Green, Administrator
Tippah County Nursing Home
1007 City Avenue North
Ripley, MS 38663

Dear Mr. Green,

I am a graduate student at Mississippi University for Women in Columbus, MS, pursuing a Master of Science in Nursing, specializing as a Family Nurse Practitioner. I expect to graduate in August 2003.

I am requesting permission to conduct a portion of my research on the effects of applying Mentholatum ointment to toenails which have been diagnosed with onychomycosis. Members of your nursing home's medical staff who are in good standing will make the diagnosis of onychomycosis and will be participating in the review of the effects of the Mentholatum. A consent form will be signed by the residents and the responsible party of that resident.

I am also requesting that Mentholatum be applied twice daily by your nursing staff. I will supply all the materials necessary for the application. There will be no cost to the participants. However, I will be unable to reimburse the nursing home for the time of the nursing staff.

I would appreciate your allowing me access to the residents of the nursing home. If you have any questions or concerns, please feel free to contact me.

Sincerely,

Susan Cappleman

Attachment: Consent Form

APPENDIX G

INSERVICE FOR NURSING HOME STAFF

Inservice for Nursing Home Staff

My name is Susan Cappleman. I am a registered nurse in graduate school at Mississippi University for Women School of Nursing. I am doing a study that will observe the effects of applying Mentholatum ointment, specifically Vick's Vaporub®, on the onychomycosis of the toenail. This is a fungal infection that involves the nail or nail bed. The organism enters the hyponychium from the surrounding skin, producing inflammation which results in hyperkeratosis and onycholysis. Although onychomycosis can be asymptomatic, if sympotomatic, the thickened, dystrophic nail can result in discomfort, pain, soft tissue injury, and infection.

I have received permission from nursing home administration to conduct a study in this facility. Only those patients who have given their consent and the consent from their responsible party obtained will be participating in the study.

The attending physician will be aware of those patients who have consented and will allow an order for the application of the ointment to be written. All the attending physicians of this facility are participating.

The ointment will be applied by you, the nursing staff, twice a day. You will apply one-half inch of ointment to the designated great toe or toes. The toe or toes will be identified on the order and the time of application will be the facility's usual b.i.d. dosing schedule.

The ointment will be supplied by me for each patient. There will be paper that is marked with a 2-inch measure with one-half inch markings to allow for accurate dispensing of the ointment. You will then be able to transfer the ointment from the paper to the great toe of the resident. Lightly massage the ointment onto the nail and the surrounding skin of the nail.

There is no cost to the patient. The patient may decline to participate in the study or change his or her mind at any time during the study and withdraw. His or her decision to decline to participate in the study or to withdraw from the study will in no way affect his or her care from the attending physician.

It is essential to the outcome of this study that the applications be consistent between all the staff who apply the ointment.

APPENDIX H

SCENARIO FOR INTRODUCING THE STUDY TO RESIDENTS AND THEIR RESPONSIBLE PARTY

Scenario for Introducing the Study to Residents and Their Responsible Party

My name is Susan Cappleman. I am a registered nurse in graduate school at Mississippi University for Women School of Nursing. I am doing a study that will observe the effects of applying Mentholatum ointment, specifically Vick's Vaporub®, on fungal toenails.

Your physician has diagnosed you with a fungal infection of your toenail. Participation in this study is absolutely voluntary. If you are not interested in participating, it will in no way affect your treatment by your physician. Your name will not be used in any of the results of the study. I will keep your identity confidential if you should choose to participate. The risk associated with this study is a possible skin sensitivity to the Mentholatum. If that should occur, the ointment will be stopped immediately.

If you are interested in participating, your responsible party will need to agree to the study as well. I will be happy to answer any questions you and your responsible party may have.

APPENDIX I

CONSENT OF RESIDENT AND RESPONSIBLE PARTY FOR PARTICIPATION IN INTER-RATER RELIABILITY SURVEY

Consent for Participation

My name is Susan D. Cappleman. I am a registered nurse in graduate school at Mississippi University for Women School of Nursing. I am doing a study that will observe the effects of applying Mentholatum ointment (Vick's Vaporub®) on fungal toenails. The goal of the study is to gain knowledge that may help future patients.

Participation in the study is voluntary and you have the right to refuse to participate or you may agree to take part in the study now and then change your mind. You may withdraw from the study at any time up to the time analysis of data begins. I cannot promise that this treatment will benefit you. Declining to participate will in no way affect your care given by your physician. During the course of the study, you will not be able to take antifungal medications.

Photographs will be made of the toes. The photographs will be viewed by a group of physicians and a podiatrist to measure the effectiveness of the Mentholatum. All of the results of the study will be reported as a group, not as individuals. Your identity will be kept confidential from all parties except me.

The risk is possible skin sensitivity to the Mentholatum. If this should occur, participation in the study would stop immediately and would in no way affect your care. There will be no cost to you for participation. Your regular physician will be monitoring you throughout the application of the Mentholatum.

Your participation would require:

1. Carefully reading and consideration of the consent form and to ask any questions you have before signing the consent form.
2. Allowing Mentholatum to be applied to the toenail and surrounding tissue twice a day by the nursing home staff. The estimated time of the study is 3 months.
3. Allowing photographs of your toes to be made before treatment begins and each month after until the study is completed.

At the end of the study, you will be informed of the results. If you have any questions regarding the study, please call me at (662) 837-1404. A copy of the consent form can be made available on request. Your signature will indicate that you have read and understood the consent form, have had all your questions answered, and have decided to participate.

_____	_____
Date	Participant's Signature
_____	_____
Date	Responsible Party's Signature
_____	_____
Date	Investigator's Signature