



**THE EFFICACY OF TIME-RESTRICTED EATING (TRE) IN
IMPROVING THE DISEASE SEVERITY, WEIGHT LOSS,
SLEEP QUALITY, AND QUALITY OF LIFE IN
PLAQUE-TYPE PSORIASIS**

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**MASTER OF SCIENCE
IN
DERMATOLOGY**

**SCHOOL OF ANTI-AGING AND REGENERATIVE MEDICINE
MAE FAH LUANG UNIVERSITY**

2025

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**THIS THESIS IS A PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE DEGREE OF
MASTER OF SCIENCE
IN
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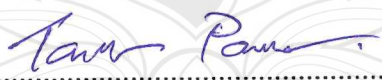
Thesis Title: The Efficacy of Time-restricted Eating (TRE) in Improving the Disease Severity, Weight Loss, Sleep Quality, and Quality of Life in Plaque-type Psoriasis

Author: Hsu Pyay Zaw

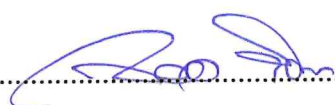
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Hsu Pyay Zaw

Thesis Title	The Efficacy of Time-restricted Eating (TRE) in Improving the Disease Severity, Weight Loss, Sleep Quality, and Quality of Life in Plaque-type Psoriasis
Author	Hsu Pyay Zaw
Degree	Master of Science (Dermatology)
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ABSTRACT

Background: Chronic plaque-type psoriasis is a systemic immune-mediated inflammatory disorder frequently associated with obesity, metabolic dysfunction, sleep disturbance, and impaired quality of life. Time-Restricted Eating (TRE), a subtype of intermittent fasting, has shown potential benefits in metabolic regulation and inflammatory modulation; however, evidence in psoriatic populations remains limited.

Objective: This study aimed to evaluate the effectiveness, safety, and patient satisfaction of a 16:8 TRE regimen on psoriasis severity, anthropometric parameters, sleep quality, and dermatology-specific quality of life in overweight and obese adults with chronic plaque-type psoriasis.

Methods: A 12-week, prospective, single-arm clinical trial was conducted in 18 adults aged 30–60 years with a BMI of 25–35 kg/m² and clinically stable chronic plaque-type psoriasis. Participants practiced daily TRE with an 8-hour eating window and 16-hour fasting period, without calorie restriction. Outcomes measured at baseline, Weeks 4, 8, and 12 included Psoriasis Area and Severity Index (PASI), body weight, BMI, and waist circumference. Pittsburgh Sleep Quality Index (PSQI) and Dermatology Life Quality Index (DLQI) were assessed at baseline and Week 12. Adherence, side effects, and patient satisfaction were systematically recorded.

Results: TRE led to statistically and clinically significant improvements across all primary outcomes. Mean PASI decreased from 9.21 to 6.00 (34.85% reduction, $p < 0.001$), with 44.4% achieving PASI-50 response. Participants experienced clinically meaningful reductions in body weight (–4.57 kg; 5.63%), BMI (–1.62 kg/m²; 5.61%), and waist circumference (–4.36 cm; 4.65%) ($p < 0.001$ for all). Sleep quality improved

substantially, as reflected by a 29.89% reduction in PSQI scores, and 13 out of 18 patients achieved good sleep quality after the intervention ($p < 0.001$). DLQI scores improved by 23.26% ($p = 0.005$), with two-thirds of participants reporting better quality of life. Reported adverse effects were mild, transient, and resolved during early adaptation. Overall acceptability was high, with 17 out of 18 participants expressing willingness to continue TRE.

Conclusion: A 12-week Time-Restricted Eating regimen is a safe, feasible, and effective non-pharmacologic intervention that improves psoriasis severity, metabolic parameters, sleep quality, and dermatology-specific quality of life in overweight and obese individuals with chronic plaque-type psoriasis. TRE demonstrates high adherence and satisfaction and may serve as a valuable adjunctive lifestyle therapy in psoriasis care. Larger controlled trials are warranted to confirm these findings and elucidate underlying mechanisms.

Keywords: Fasting and Psoriasis, Time-restricted Eating in Psoriasis, Adjunctive Treatment in Psoriasis, Sleep in Psoriasis, Quality of Life in Psoriasis, Weight Loss in Psoriasis

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ABBREVIATIONS AND SYMBOLS

ADAMTSL5	ADAMTS-like protein 5
ADF	Alternate Day Fasting
ANOVA	Analysis of Variance
BMI	Body Mass Index
CAM	Complementary and Alternative Medicine
cAMP	Cyclic Adenosine Monophosphate
CKD	Chronic Kidney Disease
CRP	C-Reactive Protein
CVD	Cardiovascular Disease
DLQI	Dermatology Life Quality Index
DM	Diabetes Mellitus
ESRD	End Stage Renal Disease
GCP	Good Clinical Practice
HLA	Human Leucocyte Antigen
IBD	Inflammatory Bowel Disease
IF	Intermittent Fasting
IGF	Insulin-like Growth Factor
IL	Interleukins
INF	Interferon
JAK-STAT	Janus Kinases—Signal Transducer and Activator of Transcription
LCD	Low Calorie Diet
MADF	Modified Alternate Day Fasting
MD	Mediterranean diet
mDCs	Myeloid Dendritic Cells
MetS	Metabolic Syndrome

ABBREVIATIONS AND SYMBOLS

mTOR	Mammalian Target of Rapamycin
NAFLD	Non-alcoholic Fatty Liver Disease
OSA	Obstructive Sleep Apnoea
PASI	Psoriasis Area and Severity Index
pDCs	Plasmacytoid Dendritic Cells
PDE-4	Phosphodiesterase-4
PsA	Psoriatic Arthritis
PSQI	Pittsburgh Sleep Quality Index
QoL	Quality of Life
SD	Standard Deviation
SPSS	Statistical Package for Social Sciences
Th	T helper
TNF	Tumor Necrosis Factor
TRE	Time-Restricted Eating
VLCKD	Very Low-Calorie Ketogenic Diet
Vs	Versus
WHO	World Health Organization

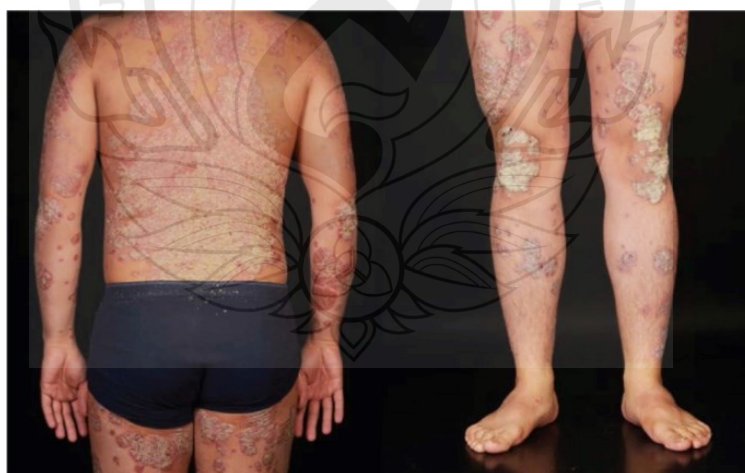
CHAPTER 1

INTRODUCTION

1.1 Background

There has been a continual increment in the prevalence of psoriasis from 2.3 percent in 1999 to 2.8 percent in 2013. Psoriasis patients still had a greater chance of mortality from all causes than people without the illness (hazard ratio 1.21; 95% confidence interval 1.13–1.3).¹

Psoriasis is a papulosquamous inflammatory skin disorder that is immune-mediated, chronic, relapsing-remitting, and can affect the joints, nails, and other organs.^{2,3} There are various forms of psoriasis, including pustular, inverse, guttate, plaque, and erythrodermic.⁴ The chronic plaque-type is the most common morphologic kind of psoriasis, characterized by well-defined, erythematous plaques with a silvery-white scale that are mostly found on the extensor parts of the elbows and knees, buttocks, scalp, and lower back⁵ in a symmetrical distribution pattern as shown in Figure 1.1.⁴



Source ⁴

Figure 1.1 Chronic plaque-type psoriasis. Widespread, symmetrically distributed, and well-defined erythematous, scaling plaques. Extensor surfaces are typically affected

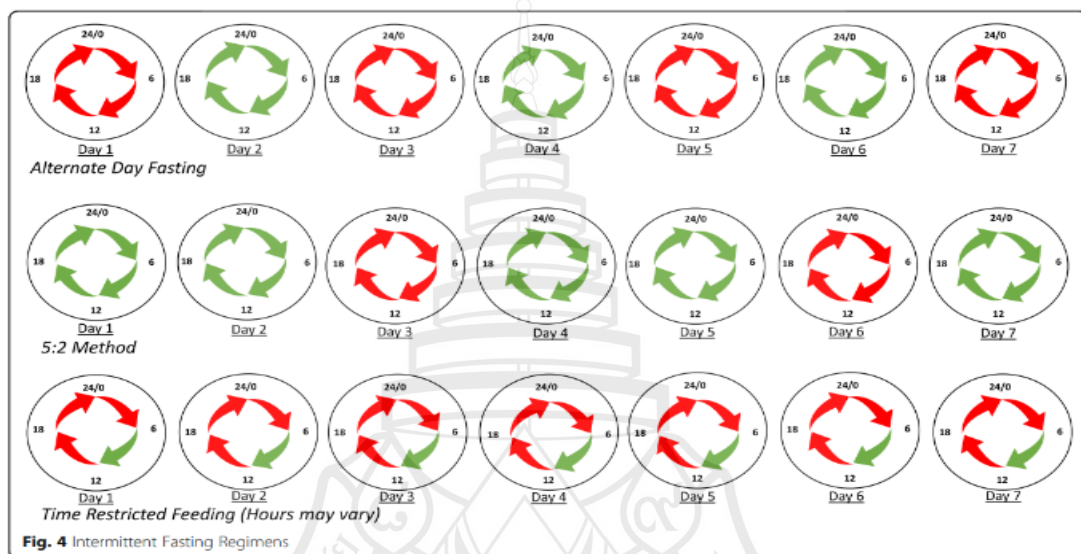
This formation of plaques is due to abnormal hyperplasia of keratinocytes.⁶ According to current theories, the development of psoriasis is dependent on T helper (Th)1/Th17 cells infiltrating the skin, which in turn triggers the release of excess pro-inflammatory factors by macrophages and dermal dendritic cells, including interleukins (IL) - 1, 2, 6, 8, 12, 17, 22, 23, C-reactive protein (CRP), and interferon (IFN) - γ and tumor necrosis factor (TNF) - α which maintain inflammation and lead to aberrant keratinocyte proliferation. Of them, IL-23 can in turn activate Th17 cells inducing acanthosis and dermal inflammation. Therefore, it appears that the IL-23/Th17 axis is a significant factor in psoriasis and explains why psoriatic keratinocytes are hyperplastic.⁶⁻⁸

In addition to being an autoimmune inflammatory skin disease, psoriasis is a complex, ailment brought on by the combination of environmental and hereditary causes.^{9,10} Psoriasis and HLA-Cw6 are linked genetically, and environmental factors that may contribute to the condition include stress, medications, alcohol, trauma, infections, smoking, and nutrition.⁶

Research has demonstrated that psoriasis and obesity are strongly correlated.¹¹ Regardless of age, sex, ethnicity, or smoking history, a retrospective research of 1.5 million participants revealed that the incidence of psoriasis was substantially higher in obese individuals than in those of normal weight.¹² In addition, compared to lean women, obese women had higher levels of the two main psoriasis cytokines, IL-17 and IL-23.¹³ Thus, it stands to reason that losing weight in these individuals will lessen the inflammation brought on by obesity, which would then improve skin conditions.¹⁴

Dietary interventions are the least expensive and generally safe weight loss strategies available. Daily calorie restriction can improve health and increase longevity although it is challenging to put into reality. In this case, intermittent fasting (IF) has emerged as a technique that improves compliance by avoiding rigorous and impractical daily calorie restriction. Compared to a daily calorie restriction diet, which results in the loss of both muscle mass and adipose tissue, IF causes a greater reduction of adipose tissue while maintaining muscle mass, hence having an equivalent or even better benefit.¹⁵ Moreover, reduced oxidative stress, synchronization of the circadian rhythm, and extra anti-inflammatory effects of IF benefit psoriasis.¹⁶

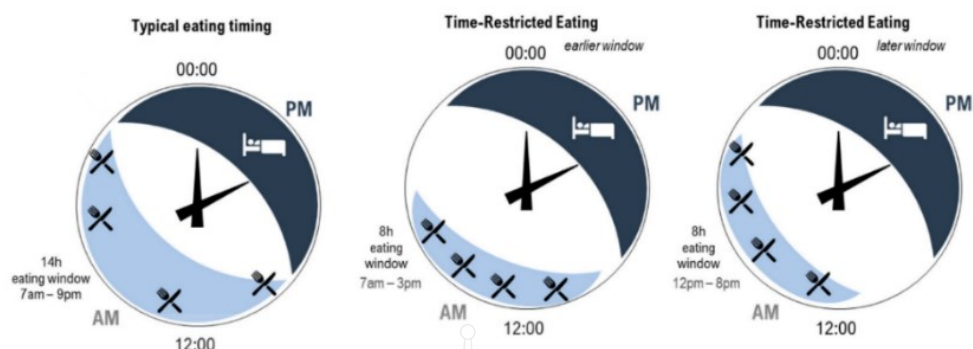
The term "intermittent fasting" (IF) refers to a broad range of dietary plans that alternate between periods of complete fasting or rigorous calorie restriction. These different regimens are: (1) alternate day fasting (ADF), which consists of one fasting day, followed by a non-fasting day, (2) repeating fasting 2-3 times per week (5:2 or 4:3) and (3) a daily plan that includes 16/18/20-hour nocturnal fasting period and an 8/6/4-hour single eating interval, which is also known as Time-Restricted Eating (TRE).¹⁵



Source ¹⁷

Figure 1.2 Intermittent fasting regimens

Out of all these protocols, TRE is the only one that does not require calorie counting. Those following the TRE regimen can consume any kind of food limitlessly throughout the day, but during the nighttime fasting period, they are not allowed to consume any energy-producing food or beverages. For this reason, it is thought that the most suitable IF method to incorporate into daily routines is TRE. It is interesting to note that, in human subjects, TRE trials had lower dropout rates than research including other intermittent fasting regimens.¹⁸



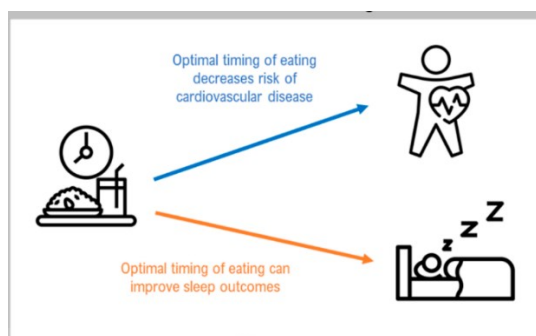
Source¹⁹

Figure 1.3 Three eating patterns are shown on 24-hour clocks, with the knife and fork in light blue (eating time) and the bed in dark blue (sleeping time), throughout the day. The interval between the first and last meal is reduced for time-restricted eating patterns

Reportedly, practicing TRE in a way that is in harmony with the circadian cycle can benefit metabolic processes, body composition, and the avoidance of chronic disease development.²⁰

Psoriasis is also linked to several other comorbidities, including eating disorders, diabetes mellitus (DM), hypertension, sleep problems, psychological disorders like anxiety and depression, and a lower quality of life (QoL).^{21,22} Psoriasis and these comorbid diseases, such as obesity, share elevated levels of TNF- α , IL-6, and CRP.²¹ Although it is yet unclear how common sleep difficulties are in people with psoriasis, many of these patients report having poor-quality sleep, which is linked to a lower QoL for physiological, psychological, and metabolic reasons.²¹

Sleep and eating habits are also known to be related, and new studies have shown a connection between adult sleep quality and quantity and nutrition.^{19,23} A study by Gupta et al. 2022 suggests that sleep functions as a mediator, and that insufficient sleep moderates the association between TRE and cardiovascular disease (Figure 1.3).¹⁹



Source¹⁹

Figure 1.4 Current knowledge about how eating, sleeping, and cardiovascular disease are related

Psoriatic individuals who experienced sleep issues had a lower quality of life. Thus, when treating psoriatic patients, symptoms of poor quality of life and sleep disturbance must be taken into account. Only two studies revealed adverse events, and in one of them, mild side effects such as fatigue, dizziness, headache, decreased appetite, upper abdominal pain, dyspepsia, and constipation were noted.^{24,25} It is uncertain whether any negative outcomes occurred in other studies.²⁶ Therefore, to ensure or discover the unwanted impacts of TRE, more studies are needed.

The previous study populations had different levels of therapy since participants did not stop taking their prescribed biological or systemic medicines. This discrepancy between the pharmaceutical therapies calls into question the veracity of the claim that TRE reduces the severity of psoriasis.²⁷ To prove the sole effect of TRE on psoriasis, patients taking any systemic medication need to be excluded.

Previously, there were no such studies of TRE in psoriasis which include all perspectives of life including physical appearance, sufferings from skin lesions, sleeping, socializing, and at the same time, the disadvantages of adopting TRE. That is why, to fill in the gaps and to connect the previously researched points in one line, this study will be conducted.

1.2 Research Question

Can Time-restricted eating (TRE) for 8 hours per day without calorie restriction lead to the betterment of patients suffering from chronic plaque-type psoriasis, both clinically, physically, psychologically, and somnologically?

1.3 Objectives

1.3.1 General Objectives

To study the efficacy of Time-Restricted Eating (TRE) for 8 hours per day without limiting calorie intake and without the impact of disease-specific systemic medications in overweight and obese patients with chronic plaque-type Psoriasis

1.3.2 Specific Objectives

1.3.2.1 Primary outcomes

To compare Psoriasis Area and Severity Index (PASI) scores before, during, and after adapting to the TRE as a non-conventional intervention in overweight and obese patients with chronic plaque-type Psoriasis

To explore the effects of TRE on body weight, sleep quality, and life quality

1.3.2.2 Secondary outcomes

To observe the patients' satisfaction after practicing TRE

To identify the side effects of TRE in psoriasis patients

1.4 Research Hypothesis

Pursuing the Time-Restricted Eating diet plan consisting of 16 hours of the fasting period and 8 hours of the limitless eating window for twelve weeks can not only

1. Reduce the PASI score but also
2. Bring down body weight and BMI,
3. Lessen waist circumference,
4. Lower PSQI score, and
5. Decrease DLQI score in individuals with chronic plaque-type Psoriasis.

1.5 Conceptual Framework

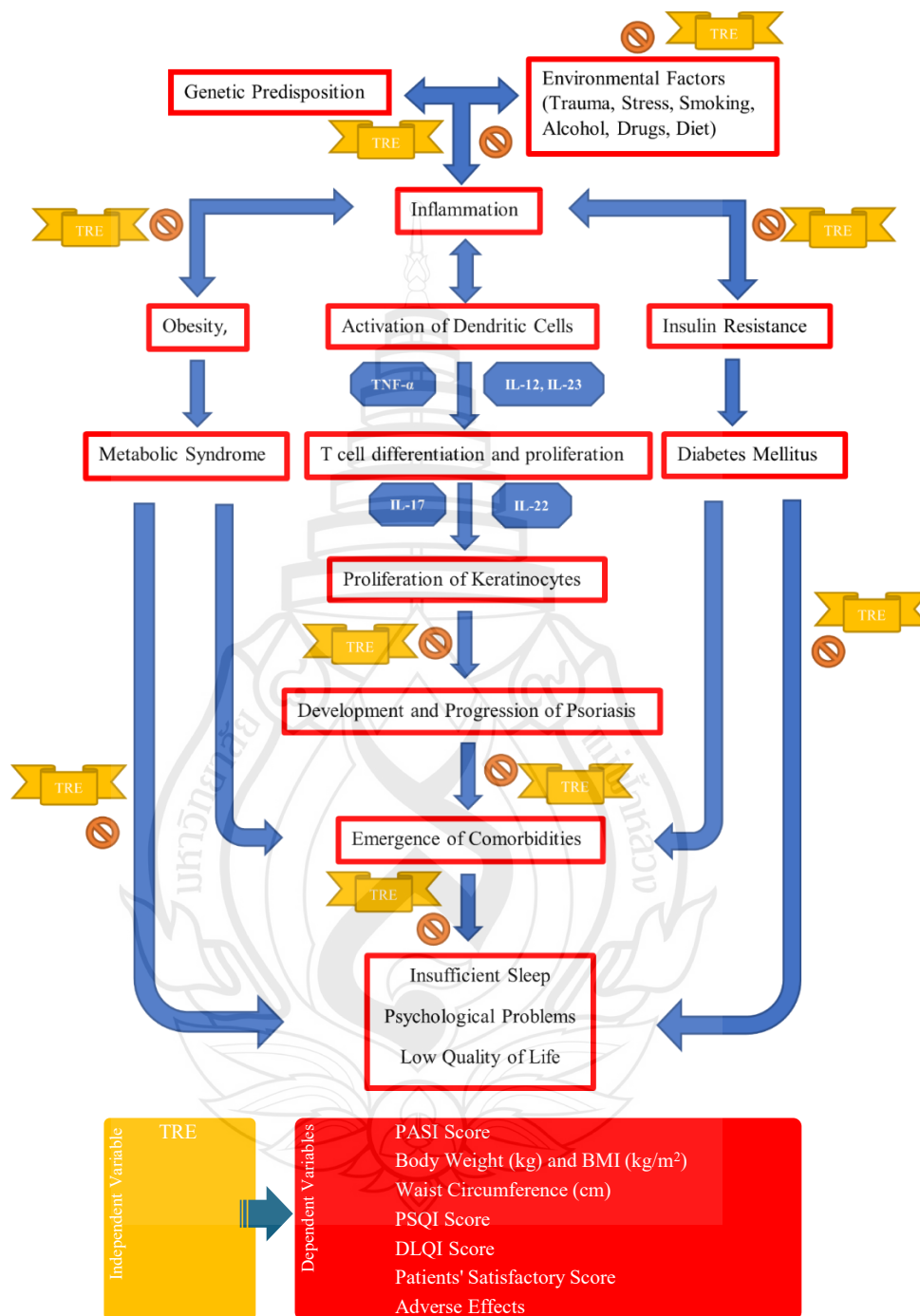


Figure 1.5 Conceptual framework, TRE: Time-restricted eating, PASI: Psoriasis area and severity index, PSQI: Pittsburgh sleep quality index, DLQI: Dermatology life quality index

1.6 Scope of Research

The study will involve 22 willing participants, of any gender, any Fitzpatrick skin type (I through VI), aged 30 to 60 years, with a BMI of 25-35 kg/m², chronic plaque-type psoriasis, who have previously seen a dermatologist, meet the inclusion criteria, and are now living in Thailand. Those patients will be recruited from Mae Fah Luang University Hospital, Bangkok.

A 12-week single-arm clinical trial using the Time-Restricted Eating (TRE) diet plan will be carried out. All participants will be asked not to consume any calories during the scheduled 16-hour fasting window, but they can eat as much as they like during the eating window.

The researcher will get in touch with each participant once a week to discuss protocol, monitor adverse events, promote adherence, and provide support for any issues that may arise throughout the intervention.

Participants will be expected to attend in-person follow-up appointments once every four weeks, in Weeks 4, 8, and 12, to have their PASI score evaluated, have skin lesions photographed, and have anthropometric measurements taken. When the intervention ends in Week 12, the patients must re-complete the PSQI and DLQI surveys and ascertain their level of satisfaction, noting down any negative impacts of the intervention.

1.7 Operational Definition

1.7.1 Plaque-type Psoriasis

An inflammatory and proliferative chronic skin disorder, plaque-type psoriasis is typified by erythematous plaques covered in silvery scales, particularly on the scalp, lumbosacral region, and extensor surfaces.

1.7.2 Non-Conventional Intervention

Conventional therapeutic measures for Psoriasis include topical and systemic drugs, phototherapy, and biologic agents. Non-conventional interventions for Psoriasis include lifestyle modifications, psychosocial interventions, and complementary and

alternative medicine (CAM). Lifestyle modifications mean dietary alterations, exercise programs, weight reduction, alcohol abstinence, smoking cessation, etc. Psychosocial interventions include cognitive and behavioral treatments and peer-to-peer support programs. In terms of CAM, there are many measures involved such as acupuncture, hypnotherapy, meditation, climatotherapy, and cupping.

1.7.3 Time-Restricted Eating

Time-restricted feeding (TRF) is a dietary approach that keeps food consumption within a set 6- to 10-hour window each day, without changing the composition or amount of the meal.

1.7.4 Psoriasis Area and Severity Index (PASI)

It is a method for determining the extent and severity of psoriasis. Calculating PASI needs 2 major steps: (1) assessing the severity of skin lesions, and (2) determining the Body Surface Area (BSA) covered with lesions. There are five scoring systems for erythema, induration, and scaling: score 0 if absent, score 1 if mild, score 2 if moderate, score 3 if severe, and score 4 if very severe, as shown in Figure 1.6.



Source²⁸

Figure 1.6 Psoriatic severity scoring

Also, the percentage of each region's surface area covered in plaques must be specified to calculate a score (Figure 1.7):

0 = No involvement

1 = <10% involvement

2 = 10-29% involvement

3 = 30-49% involvement

4 = 50-69% involvement

5 = 70-89% involvement

6 = 90-100% involvement

The head and neck account for 10% of the body's surface area, whereas the upper extremities, trunk, and lower extremities make up 20%, 30%, and 40% of the total. So, to get the final PASI score, the following formulas can be used:

Total head PASI = Area score for head (0-6) x 0.1 x Total grading of redness, thickness, and scaling for the head (0-12)

Total upper limbs PASI = Area score for arms (0-6) x 0.2 x Total grading of redness, thickness, and scaling for arms (0-12)

Total Trunk PASI = Area score (0-6) x 0.3 x Total trunk redness, thickness, and scaling score (0-12)

Total lower limbs PASI = Area score for legs (0-6) x 0.4 x Total grading of redness, thickness, and scaling for legs (0-12)

Total PASI of the entire body = Total head PASI + Total upper limbs PASI + Total Lower Limbs PASI + Total Trunk PASI

To avoid handling mathematics, the following PASI calculator, created by Dr. Michela Corti (Figure 1.7) can be utilized for easier assessment of PASI scores.

Name: (optional)
 Birth date: (optional)
 PASI =

Source ²⁹

Figure 1.7 Psoriasis area and severity index (PASI) calculator (1.7.3)

1.7.5 Body Weight

Body weight will be measured in kilograms (kg) by the weighing machine from PROGRESS® company. At the same time, height measurement in meters (m) will be included to calculate Body Mass Index (BMI). To examine the reduction in central obesity, waist circumference, measured at the smallest part between the costal margin and the iliac crest, will also be included.

1.7.6 Sleep Quality

The Pittsburgh Sleep Quality Index (PSQI) will be used to evaluate the sleep quality. Clinical populations use this self-rated, 19-item questionnaire, to evaluate the quality of their sleep during the past month. The 19 pieces are divided into 7 parts, which include:

1. Length of sleep,
2. Disruption of sleep,
3. Latency of sleep,
4. Dysfunction during the day as a result of excessive sleepiness,
5. Efficiency of sleep,
6. General quality of sleep, and
7. Usage of sleeping pills.

Scores for each aspect of sleep are assigned from 0 to 3, where 3 denotes the highest level of dysfunction. After adding the scores together for the sleep components, a total score between 0 and 21 is produced, with the higher total score indicating worse sleep quality. A person who gets a PSQI score > 5 is a poor sleeper.³⁰

1.7.7 Quality of Life (QOL)

Patients' QOL will be determined according to the Dermatology Life Quality Index (DLQI), which is a widely used quality-of-life measure primarily used in dermatology. This 10-item assessment looks at six different aspects that may affect one's quality of life.³¹ These elements include daily activities, recreation, work, and academic performance, emotional states and symptoms, interpersonal interactions, and treatment.³¹ The scores for each of the ten questions range from 0 (not at all) to 3 (very much). After summing the results of each question, the total DLQI is calculated, producing a value between 0 and 30.³¹ A score of 0-1 marks no effect, a score of 2-5 shows a small effect, a score of 6-10 suggests a moderate effect, a score of 11-20

indicates a very large effect, and a score of 21-30 means an extremely large effect on the patient's life.

1.7.8 Patients' Satisfaction

Once the intervention has concluded, patients will be asked to rate their level of satisfaction using the following grading scales (0–3) for each of the four areas:

0 = Unsatisfied, No improvement in disease severity, life quality, sleep quality, and weight reduction

1 = Somewhat satisfied, Slight improvement in disease severity, life quality, sleep quality, and weight reduction

2 = Moderately satisfied, Visible improvement in disease severity, life quality, sleep quality, and weight reduction

3 = Very satisfied, Significant improvement in disease severity, life quality, sleep quality, and weight reduction

1.7.9 Side Effects of TRE

The patients will be asked to note down the symptoms of side effects such as hunger, cravings, headaches, fatigue, insomnia, irritability, decreased concentration, nausea, constipation, and any other symptoms experienced throughout the TRE period.

1.7.10 Efficacy of TRE

The efficacy of TRE refers to the amelioration of PASI score, reduction of body weight, BMI, and waist circumference, enhancing sleep quality, improving quality of life, and fulfilling expectations of patients suffering from plaque-type psoriasis without any major adverse effects.

CHAPTER 2

LITERATURE REVIEW

2.1 Psoriasis

2.1.1 History

Skin changes caused by Psoriasis have been recorded since the time of the Bible. For centuries, psoriasis was mistaken for leprosy, leading to the social exclusion of numerous psoriasis sufferers during the Middle Ages.⁹ The first clinical description of psoriasis was provided by English physician Robert Willan at the start of the 1800s.³⁰ For at least three millennia, people have suffered from and researched this illness, and as a result, numerous potential reasons have been postulated.^{9,32}

2.1.2 Epidemiology

The National Psoriasis Foundation estimates that 125 million people worldwide—roughly 2-3 percent of the world's population—have psoriasis.⁹ Zuccotti et al. n.d. once stated that “the incidence of Psoriasis differs based on geography and ethnicity; a higher prevalence is observed in Caucasians than in Asians and African Americans.”¹⁰ Psoriasis can start at any point in life and typically lasts for the rest of one's life. Every age is susceptible to this illness, including childhood; nevertheless, there are two age ranges where psoriasis development peaks (16-22 and 57-60 years).³³ It affects both men and women equally.^{10,34}

It is hard to follow patterns in psoriasis incidence and prevalence. However, in several nations, there appears to be a rising trend.³⁵ In 1984, 0.17% of Chinese people had psoriasis; 25 years later, 0.59% of people had the disease, according to another study.^{36,37} Spain had a 1.43% frequency in 1998; fifteen years later, 2.31% was observed.^{38,39} According to data on the prevalence in the US, between 2004 and 2010, the frequency increased from 1.62% to 3.10%.^{40,41} From the 1970s to 2000, the yearly incidence of psoriasis nearly doubled,⁴² suggesting that the triggers should receive more attention.

2.1.3 Etiology

Psoriasis is an immune-mediated inflammatory disease that is persistent and recurrent. It is known to be triggered by environmental factors and to have a hereditary predisposition.⁹

2.1.3.1 Genetic Predisposition

Psoriasis manifests in recipients of bone marrow transplants from donors who have the disease and subsides in recipients from donors who do not, suggesting the existence of a genetic susceptibility to the illness.⁴³

HLA-Cw6, HLA-B13, HLA-B17, HLABw57, and HLA-DR4 are specific HLA types that have been linked to psoriasis, and people who carry HLA-Cw6 appear to be at a 10-fold increased risk of developing the condition.⁹ Psoriasis appears to be a polygenic form of inheritance with varying penetrance, according to twin studies.^{9,10} Thirty percent of psoriatic patients had a first- or second-degree relative who had a history of the illness in their family. If one parent has psoriasis, the likelihood of developing Psoriasis appears to be roughly 20%, and if both parents have it, the likelihood is approximately 75%.⁴⁴

Additionally, patients with early disease onset, Psoriasis in the family and HLA-Cw6 have a more severe disease course than those with late-onset Psoriasis who do not carry this gene.^{9,45,46} Psoriatic patients have significant genetic heterogeneity, which may contribute to modest variations in the pathophysiology of the disease.⁹

2.1.3.2 Environmental Factors

In addition to the genetic factors, many environmental components also play a role in the development and aggravation of Psoriasis.⁹ The following environmental factors may also contribute to the development of psoriasis lesions or exacerbate existing lesions:

1. Physical factors (such as subcutaneous and intradermal injections, surgeries, immunizations, tattoos, insect bites, abrasions, burns (including sunburns), acupuncture, ultraviolet radiations, and X-rays);
2. Chemical factors (such as chemical burns, topical treatments, etc.);
3. Skin conditions (such as rosacea, fungal infections, and allergic contact dermatitis);
4. Infections (primarily streptococcal pharyngitis, viral infections);

5. Medications (such as β -adrenolytics, angiotensin-converting enzyme inhibitors, lithium, terbinafine, non-steroidal anti-inflammatory drugs, anti-malarial drugs, tetracyclines, and rapid withdrawal of systemic corticosteroids);

6. Obesity;

7. Diet;

8. Stress;

9. Tobacco use;

10. Alcohol intake.⁶

Many microbial infections are linked to the onset and/or exacerbation of psoriasis. A previous tonsillar *Streptococcus pyogenes* infection is strongly associated with the production of guttate psoriasis.⁹ *Staphylococcus aureus*, *Malassezia*, and *Candida albicans* colonization of the skin and/or gut has been linked to disease aggravation as well.^{47,48}

Injury to the skin can also produce a new lesion, which is known as the Koebner phenomenon, and is an indicator of disease activity and may have a prognostic value.⁹ Tattoos are another contributing factor since the injecting of pigments into the skin causes epidermal imbalance and a localized inflammatory response, which may be the precursor to psoriasis.¹⁰

The aforementioned medications, alcoholism, smoking, high-fat diets, and long-term psychological stress can also have an impact on the development and clinical manifestation of psoriasis.⁹

2.1.4 Pathogenesis

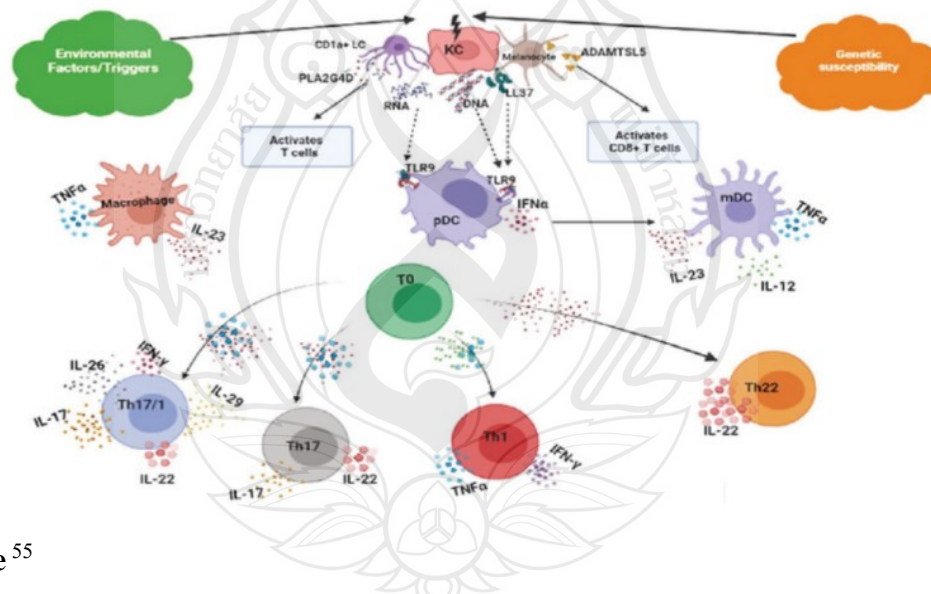
Psoriasis is characterized by continuous inflammation, which causes (1) abnormal keratinocyte proliferation and defective differentiation leading to epidermal hyperplasia, (2) immune cells infiltrating the dermis, and (3) increased dermal capillary density and permeability.^{49,50} The genesis of psoriasis can be divided into two phases: an initial phase that may be brought on by hereditary or environmental causes such as medicines, trauma, and infections, and a maintenance stage characterized by an ongoing clinical advancement.⁵⁰

2.1.4.1 Initiation Phase

The production of ADAMTS-like protein 5 (ADAMTSL5) by damaged melanocytes, the antimicrobial peptide Cathelicidin (LL-37) by injured keratinocytes,

and other possible autoantigens in psoriasis all stimulate plasmacytoid dendritic cells (pDCs), which in turn starts the proinflammatory cytokine cascade. IFN- α is released by pDCs in response to these stimuli, encouraging local myeloid dendritic cells (mDCs) to migrate to nearby lymph nodes by activating them.⁵¹

The activation of mDCs is also facilitated by other innate immune cells, such as keratinocytes, macrophages, and natural killer T-cells. Following activation, mDCs release TNF- α , IL-12, and IL-23, which induce naïve T cells to differentiate and proliferate into mature Th1, Th17, and Th22 lymphocytes. These lymphocytes subsequently enter the circulation and develop the capacity to colonize the skin.⁵² Th1 lymphocytes that are activated emit TNF- α and IFN- γ , while Th17 and Th22 lymphocytes secrete IL-17 and IL-22, respectively, yielding keratinocyte proliferation and poor differentiation which are typical of Psoriasis development.⁵³ TNF- α also activates the expression of C-reactive protein and several cytokines such as IL-6 and IL-23.⁵⁴



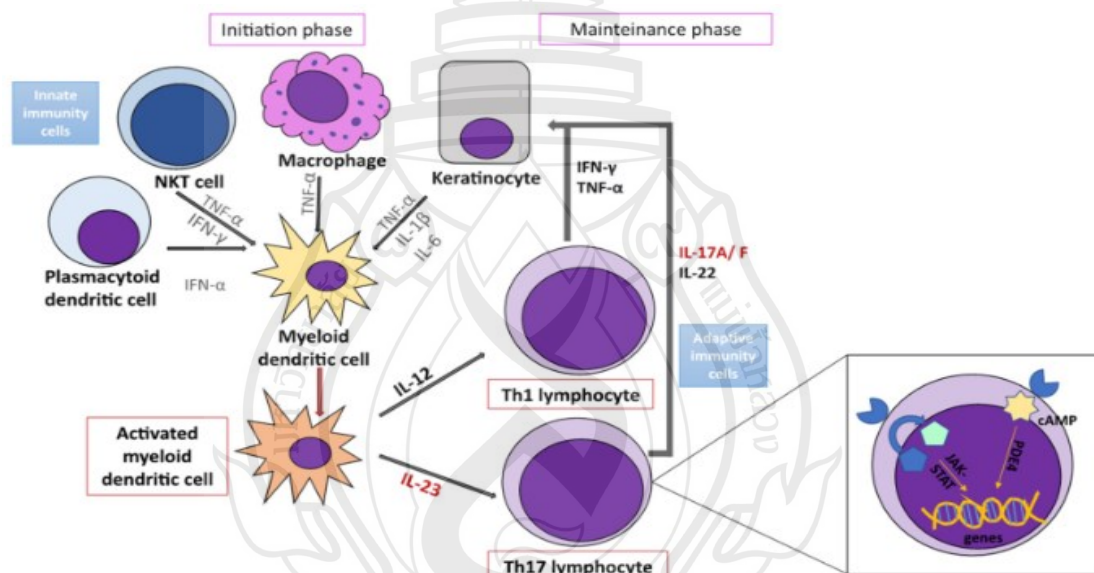
Source⁵⁵

Figure 2.1 Immunopathogenic cascade in psoriatic inflammation. KC: Keratinocyte, pDC: plasmacytoid dendritic cell, mDC: myeloid dendritic cell, LC: Langerhans cell

2.1.4.2 Maintenance Phase

In addition to being followers, keratinocytes also secrete cytokines, chemokines, and antimicrobial peptides (AMPs) in response to stimulation. These

mediators encourage T lymphocyte activation and the recruitment of additional inflammatory cells, particularly neutrophils, dendritic cells, and macrophages. In the end, this causes chronic inflammation or the disease maintenance phase to emerge. Furthermore, the inflammatory cascade promotes angiogenesis, which facilitates the immune cells' continued infiltration into the psoriatic lesion.⁵¹ The final mechanism by which the cytokines exert their effects is through the activation of intracellular pathways. Therefore, The JAK-STAT pathway (from Janus Kinases—Signal Transducer and Activator of Transcription proteins) is triggered by INF- γ , IL-12, IL-22, and IL-23, while phosphodiesterase-4 (PDE-4) prevents the cyclic adenosine monophosphate-derived cAMP signaling molecule from having an anti-inflammatory effect.⁵¹



Source⁵¹

Figure 2.2 Key signaling pathways and effector cells in the immunopathogenesis of psoriasis

2.1.4.3 Summary of Immunopathogenesis of Psoriasis

Psoriasis is caused by way of an intricate inflammatory cascade that is initiated by innate immune cells in the immunopathogenesis of the disease (keratinocytes, dendritic cells, natural killer T-cells, macrophages). Simultaneously, the illness advances and is sustained by their engagement with T cells, which are adaptive immune cells. The IL-23/Th17 axis is the primary mechanism of the illness causing

keratinocyte proliferation, release of AMP and proinflammatory cytokines, chemokines, and proinflammatory cytokines, as well as the creation of a constructive feedback loop that perpetuates inflammation. Cells' cytokines trigger signaling and transcription pathways (cAMP, JAK-STAT) to increase the transcription of messenger genes and cytokines linked to the disease's pathogenesis (Figure 2.2).⁵¹

2.1.5 Clinical Features

A papulosquamous condition, psoriasis, can vary in appearance, distribution, severity, and duration. Scaling papules (raised lesions less than 1 cm in diameter) and plaques (raised lesions greater than 1 cm in diameter) are the hallmarks of papulosquamous diseases. Tinea infections, pityriasis rosea, and lichen planus are other papulosquamous illnesses with comparable features. The unique features that can differentiate psoriasis from other similar conditions are erythematous well-defined, circular plaques with grey or silvery-white scales, mostly symmetrically distributed on the scalp, elbows, knees, lumbosacral areas. Another possibility is that psoriasis—known as Koebner's phenomenon—may appear at the site of trauma or damage.⁵⁶

The most typical and classic form of psoriasis presentation is psoriasis vulgaris, also known as chronic plaque psoriasis. The other types of psoriasis are pustular, erythrodermic, and guttate. Psoriasis vulgaris can manifest as persistent, stable lesions or plaques that enlarge and develop quickly. Approximately one-third of patients experience itching and pain, primarily as a result of the psoriatic area becoming dry and cracked.⁹

Early lesions often begin as tiny pinpoint papules that exhibit scales and removing them may reveal minute bleeding spots, called the Auspitz sign.⁵⁷ Woronoff's ring, a white blanching ring, can be seen in the skin around a psoriatic plaque.⁹ When a disease is dormant, the few plaques that already exist hold their current size and no new ones develop. The development of new, tiny lesions and the expansion of preexisting lesions are indicators that the illness is getting worse.

The plaques might take on many shapes as they gradually expand peripherally. For example, in Psoriasis gyrata, the predominant pattern is a curved linear one; in Annular Psoriasis, the central clearing causes lesions that resemble rings; and in Psoriasis Follicularis, tiny scaly papules are visible at the pilosebaceous follicle opening⁵⁶. Rupoid and ostraceous refer to distinct forms of psoriasis on plaque. Like limpet

shells, rupioid plaques are tiny and extremely hyperkeratotic. Ostraceous Psoriasis is characterized by hyperkeratotic plaques that resemble oyster shells and have concave centers.⁵⁶

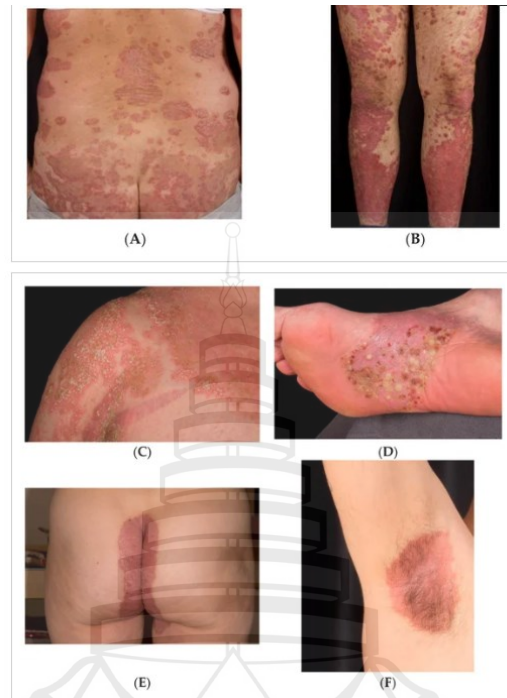
There are psoriasis vulgaris variations specific to certain sites. Intertriginous locations can experience flexural or inverse psoriasis. In the nasolabial folds, postauricular area, pre-sternal area, and eyebrows, seborrheic psoriasis develops. Psoriatic nail disease, which affects fingernails more frequently than toenails and has a spectrum of clinical signs from subungual hyperkeratosis, onycholysis, pitting, and severe onychodystrophy, is most frequently associated with patients with psoriatic arthritis.⁵⁸

Guttate psoriasis, frequently affecting children, adolescents, and young adults, is a type of acute psoriasis that appears in the trunk and extremities and is characterized by papules that are less than 1 cm in diameter. It usually appears two weeks following a viral or β -hemolytic streptococcal infection, as well as acute stressful life events. It usually goes away on its own in three to four months, though the Prognosis throughout time is uncertain. In some cases, a chronic plaque type could develop from it, and during the course of persistent plaque psoriasis, some guttate lesions may also develop.⁵⁹

Pustular Psoriasis, another acute form of Psoriasis, causes small, sterile, monomorphic pustules to appear on painfully inflamed skin. It might manifest as acrodermatitis continua of Hallopeau or palmoplantar pustulosis in a confined setting, or it can be extensive and possibly fatal. Hyperkeratosis and pustule clusters on the hands and/or feet are the hallmarks of palmoplantar pustulosis, and a rare, persistent pustular eruption of the fingers and toes is called acrodermatitis continua. Plaque psoriasis may develop following pustular episodes or preexist in patients with widespread pustular psoriasis. This kind of psoriasis may also result from a persistent illness or from abruptly stopping systemic and, in rare cases, ultra-potent topical corticosteroids.⁹

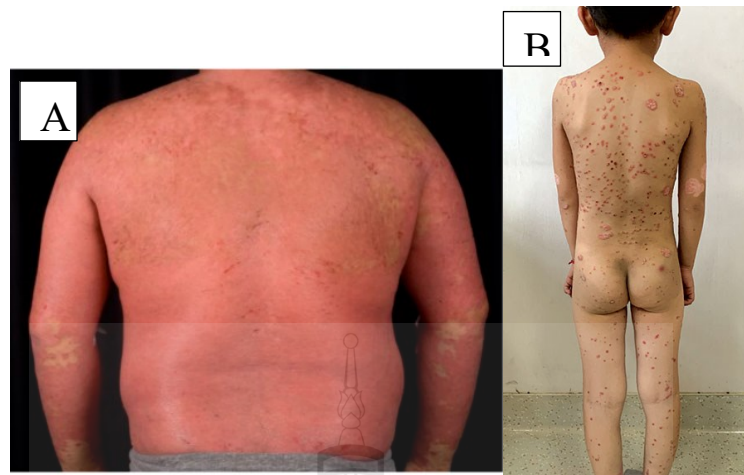
Erythrodermic psoriasis, occupying greater than 90% of the skin's surface, is a life-threatening disease. Due to altered skin thermoregulation, loss of body heat and hypothermia may ensue together with high output heart failure, infection, and metabolic abnormalities such as anemia and hypoalbuminemia brought on by iron, vitamin B12, and folate deficiency. It could first appear as chronic plaque psoriasis that gets worse

over time as the plaques get larger and more confluent. Additionally, tar, medications, infections, or stopping corticosteroids can all cause erythroderma.⁵²



Source⁵⁰

Figure 2.3 Psoriasis's clinical signs. Erythematous, scaly plaques on the trunk and extensor surfaces of the limbs are the hallmark of psoriasis vulgaris (A, B). (C) Generalized pustular psoriasis. (D) Localized pustular psoriasis on the foot soles. Psoriasis Palmoplantar Pustulosis is the name given to this variation, which usually also affects the palms of the hands. (E, F) Reverse Psoriasis that affects the skin's folds (axillary, intergluteal, inframammary, and vaginal involvement)

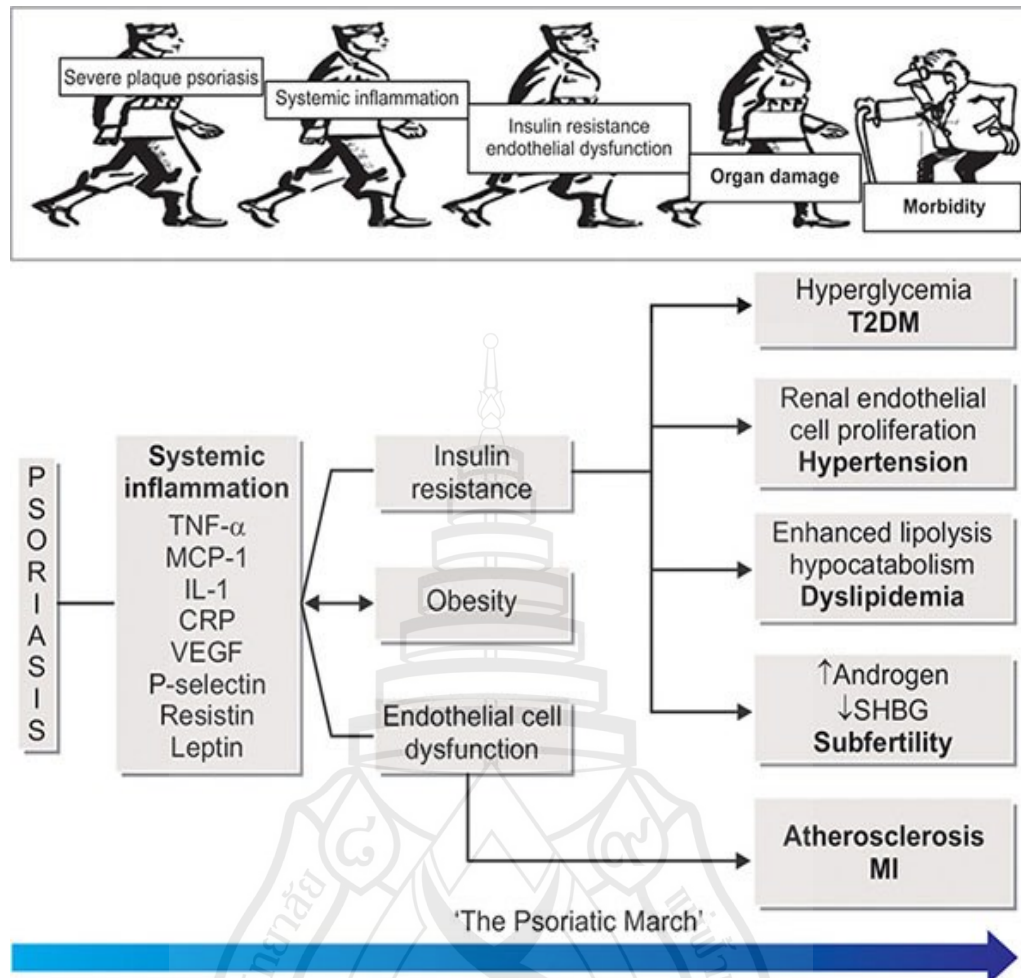


Source ^{50,62}

Figure 2.4 Other types of psoriasis (A) Erythrodermic Psoriasis. (B) Guttate Psoriasis

2.1.6 Complications and Comorbidities

More people are becoming aware that psoriasis extends beyond the skin.⁶⁰ The immune system's involvement in disease-specific pathways that start with hereditary and perhaps environmental variables has been referred to as the "march of psoriasis". As a result of persistent inflammation, this eventually causes psoriasis to manifest and other co-morbidities, which raise the patients' overall morbidity and mortality rates.³³



Source ⁶¹

Figure 2.5 The Psoriatic March, TNF, tumor necrosis factor; MCP-1, monocyte chemoattractant protein-1; IL, interleukin; CRP, C-reactive protein; VEGF, vascular endothelial growth factor; T2DM, type 2 diabetes mellitus; SHBG, sex hormone binding globulin; MI, myocardial infarction

2.1.6.1 Cardio-vascular diseases (CVD)

Psoriatic patients have a greater frequency of total atherosclerotic cardiovascular disease as opposed to controls, and those with moderate to severe psoriasis have higher chances of suffering from myocardial infarction and ischemic stroke.⁶³ Asian psoriatic patients should undergo proper medical screening for potential cardiovascular comorbidities, according to a countrywide population-based retrospective cohort study involving over 1.7 million Koreans over a 15-year follow-up period.⁶⁴

A higher likelihood of CVD is linked to several variables, such as smoking, high blood pressure, obesity, age, and family history. Patients with psoriasis also frequently exhibit many of these risk factors. As opposed to the general population, individuals with mild to severe psoriasis had 10-year risks of 11.8% greater for stroke and 28% more for coronary heart disease, according to a retrospective data analysis by Kimball et al. in 2010.⁶⁵

2.1.6.2 Metabolic Diseases

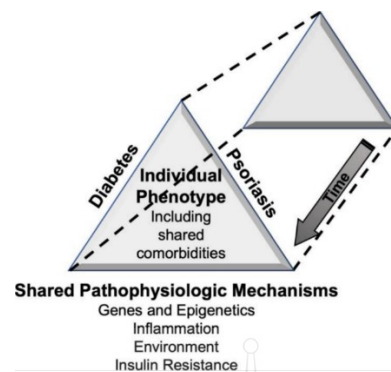
1. Metabolic Syndrome (MetS)

In comparison to non-Psoriatic people, Psoriatic patients have at least a doubled risk of MetS. Obese participants showed a clear tendency toward a rise in psoriasis risk in proportion to the number of MetS components. Specifically, 20–50% of Psoriatic patients have MetS. Many observational studies have consistently validated the strength of this association. There is growing evidence that there are common metabolic risk factors, genetic background, and pathogenic pathways between MetS and Psoriasis.⁶⁶

2. Pre-diabetes and Type 2 Diabetes Mellitus (DM)

In 2013, Armstrong et al. carried out a meta-analysis and systematic review of 27 observational studies. They discovered that the overall frequency of DM was greater in psoriasis patients (59%) and in those with severe psoriasis (up to 97%).⁶⁷

One significant pathophysiologic mechanism connected to psoriasis and diabetes is insulin resistance. Insulin resistance is present at clinical levels in psoriasis patients, according to two cross-sectional investigations.⁶⁰ Moreover, individuals with Psoriasis exhibit insulin resistance caused by the dysregulation of inflammatory mediators (such as cytokines and adipokines). In instances of hyperinsulinemia, which are frequently observed in Type 2 DM, insulin can attach to Insulin-like Growth Factor (IGF) receptors, causing fibroblast and keratinocyte proliferation.⁶⁸ There are four primary pathophysiologic processes associated with Type 2 DM: inflammation, environment, genes and epigenetic modifications, and insulin resistance that result in beta-cell malfunction. Thus, Abramczyk et al. 2020 concluded that because of their shared pathophysiologies, DM and psoriasis frequently occur concurrently (Figure 2.8).⁶⁹



Source ⁶⁹

Figure 2.6 Diabetes and psoriasis: Different sides of the same prism

3. Lipid Metabolism

Hypercholesterolemia and hyperlipidemia were significantly linked to psoriasis. Psoriasis, hypertriglyceridemia, and low high-density lipoprotein were linked to visceral fat through the same pathway, which included Insulin resistance, tumor necrosis factor, adiponectin, and serum IL-6.⁶³

2.1.6.3 Autoimmune Thyroid Disease

Significantly greater serum CRP levels and PASI scores are found in patients with thyroid dysfunction compared to those without thyroid dysfunction.⁶⁰ According to Taiwanese cohort research, Psoriasis patients had a higher risk of incident hyperthyroidism, Hashimoto thyroiditis, Graves' disease, and hypothyroidism than controls.⁷⁰

2.1.6.4 Gout

According to Yilmaz et al's cross-sectional study in 2017, Psoriasis patients' serum uric acid levels were significantly greater than the controls', and their PASI scores and serum uric acid levels were positively correlated.⁷¹

2.1.6.5 Involvement of other organs

1. Nervous System Disease

Psoriasis sufferers have been linked to a higher incidence of Parkinson's disease and migraines, and there may be a connection between psoriasis and schizophrenia due to Th17 and pro-inflammatory cytokines. Three systematic reviews and meta-analyses have found a correlation between psoriasis and a higher risk of multiple sclerosis, and vice versa.⁶³

2. Gastrointestinal Disease

Patients with psoriasis were shown to have a higher frequency of gastrointestinal symptoms, including bloating and fullness, abdominal discomfort, diarrhea, and mucus or blood in the stool, suggesting a co-existence with inflammatory bowel disease (IBD). Additionally, two meta-analyses discovered significant bidirectional relationships between IBDs and psoriasis.⁶³

3. Liver Disease

Non-alcoholic fatty liver disease (NAFLD) is more common in psoriasis patients and is associated with higher pro-inflammatory states, bacterial translocation, and MetS prevalence (TNF- α , TGF- β level, and bacterial translocation).⁶³

4. Chronic Kidney Disease (CKD)

There may be a reciprocal relationship between CKD and psoriasis. In Korea, A higher incidence of end-stage renal disease (ESRD) has been associated with psoriasis, with the likelihood of ESRD varying depending on the kind of treatment and the existence of arthritis in the patient.⁷²

5. Musculoskeletal System

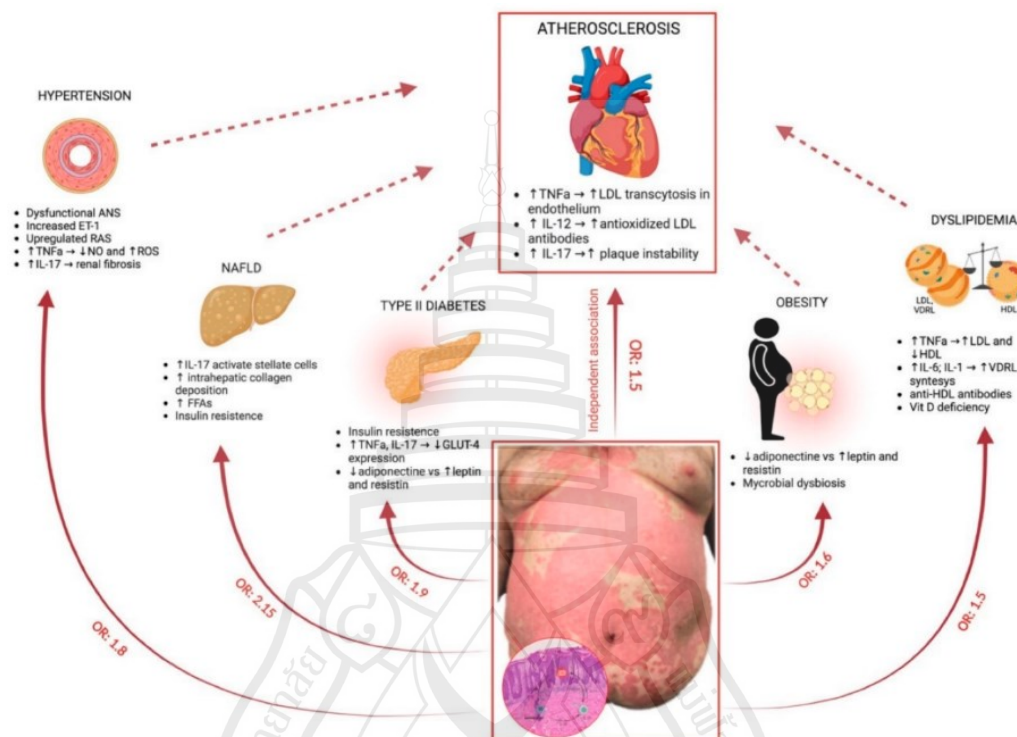
Psoriatic Arthritis (PsA), which has a strong correlation with psoriasis, occurs in almost one-third of individuals with psoriasis. The longer a psoriasis patient experiences cutaneous symptoms after it first appears, the higher the risk of PsA. Compared to psoriasis patients, PsA patients had higher rates of comorbidity and a heavier clinical burden.⁶³

2.1.6.6 Psychological Problems

Patients with psoriasis exhibit a range of psychological issues, such as low self-esteem, dysfunctional sexuality, anxiety, and depression. Around eighty percent of patients report that the illness negatively affects their lives for several reasons, such as physical symptoms, unpleasant physical appearance, increased alcohol use, irritation, anger, nervousness, and unhappiness.⁷³ The biggest risk factors for psoriasis patients who also had depression were age (20–50), gender, significant comorbid conditions, and poor income.⁶³

Psychological stress has been shown to contribute to psoriasis exacerbation in psoriatic individuals, and increased stress reactivity has been linked to an earlier development of psoriasis.⁷⁴ People who experience pathological anxiety are often less

responsive to treatment and frequently show significant declines in their health-related quality of life. Psoriasis is a chronic, deforming, and stigmatizing condition; thus, medical professionals must be mindful of the emotional and psychological effects it has on their patients.⁹



Source⁷⁵

Figure 2.7 The molecular mechanisms that relate psoriasis to its comorbidities. The Odds Ratio (OR) for developing various comorbidities in a patient with psoriasis is displayed by continuous red arrows, while discontinuous red arrows link all of these disorders to atherosclerosis. (↑ increased, ↓ decreased)

2.1.7 Psoriasis and Obesity

It has been stated^{74,76} that obesity may increase the likelihood of developing psoriasis as well as a precursor to it. Furthermore, obesity appears to be involved in the aggravation of psoriasis after it has begun.⁷⁷ Due to the Koebner phenomenon, obesity itself may exacerbate psoriasis by causing more friction and damage in the intertriginous zones and around the waist.⁷⁸

Body fat will excessively build up as obesity progresses, resulting in the development of harmful white adipose tissue that becomes inflamed and hypertrophied.⁷⁹ Adipose-related inflammation is further associated with low-grade chronic systemic inflammation,⁸⁰ which triggers the immune cascade that includes dendritic cells as well as T-helper lymphocytes (mainly Th1, Th17, and Th22) and pro-inflammatory cytokines (mainly IL-1, IL-6, TNF- α , IL-12, and IL-23).⁸¹ Following this, hypertrophic adipocytes begin to express a wide range of pro-inflammatory adipokines (such as resistin, chemerin, and leptin),⁸² while the expression of adiponectin and omentin, two anti-inflammatory adipokines, is blocked.⁶⁶ Figure 2.10⁸³ has clarified the pathophysiological link between psoriasis and obesity.⁸¹

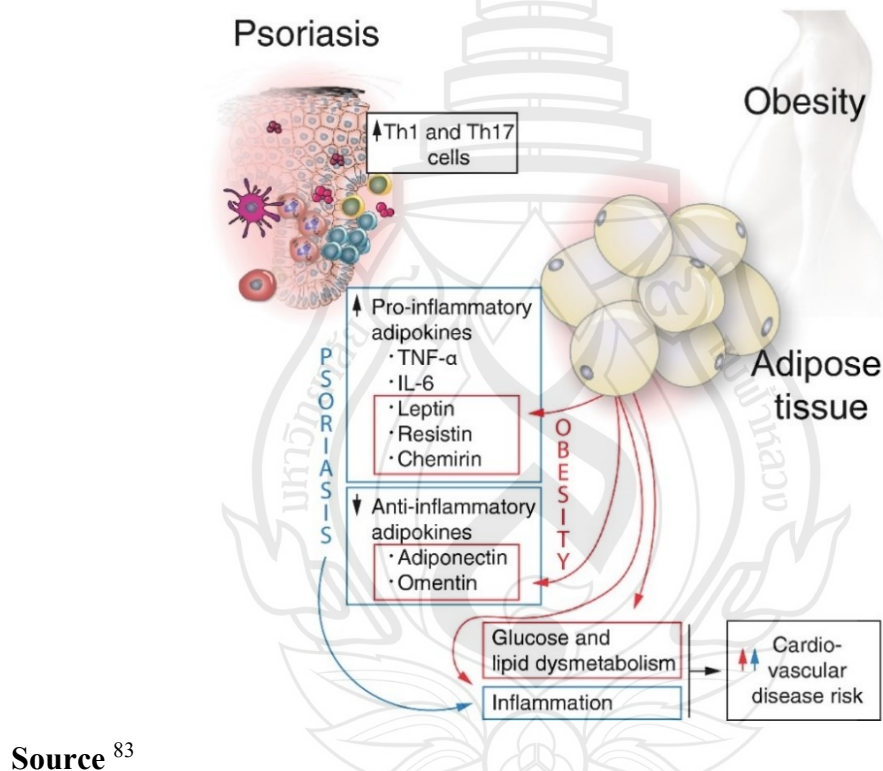


Figure 2.8 The triad Psoriasis-Obesity-Adipokine profile

Some adipokines have been extensively researched in light of the role that obesity plays in psoriasis development.⁸⁰ Lower levels of plasma adiponectin in Psoriatic patients might make skin lesions more severe.⁸⁴ Thus, adiponectin is against inflammation at a cellular level by normalizing the Th1-Th17/Th2 lymphocyte ratio,

impeding IL-17A production.⁸⁵ On the other hand, as weight decreases, adiponectin levels in the blood rise, and psoriatic lesions get better at the same time.⁸⁶

Leptin, another adipokine, is in charge of raising the pro-inflammatory cytokines that encourage keratinocyte growth. Patients with psoriasis and obesity were shown to have significantly higher amounts of leptin, and a high level of leptin was strongly correlated with both the Body Mass Index and the PASI score.⁸⁰

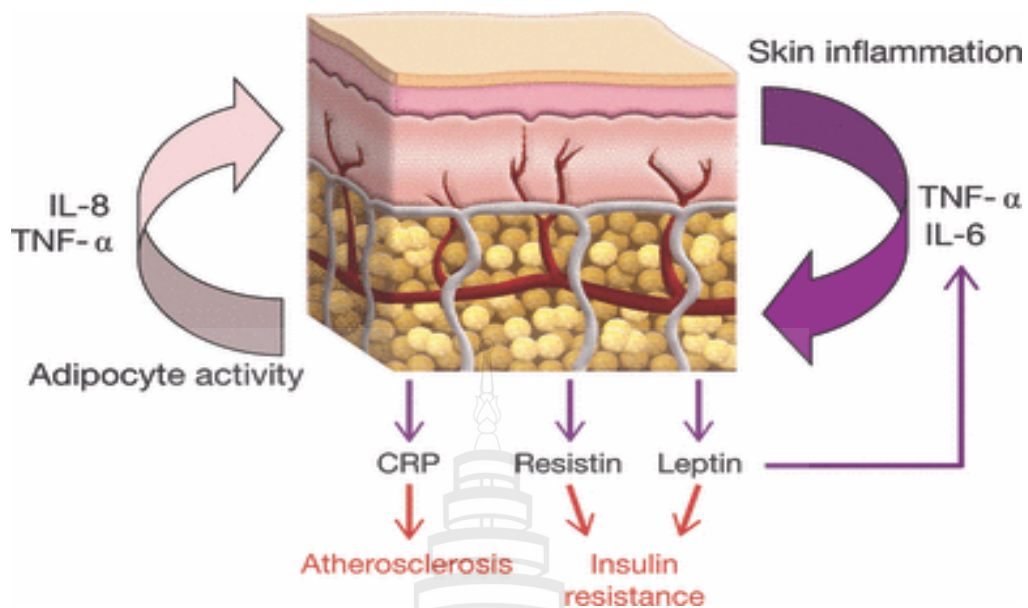
As resistin triggers many molecular and cellular processes in psoriatic skin, it is currently considered another adipokine that may be a biomarker in the etiology of psoriasis. Previous research has shown a clear relationship between the severity of Psoriasis and plasma resistin levels,⁸⁷ and there is a robust link between elevated plasma resistin levels in Psoriasis patients and the DLQI.⁸⁰

Adipokine, chemerin, functions as a component that attracts human blood plasmacytoid dendritic cells (pDCs), encouraging the recruitment and migration of these cells in psoriatic skin⁸⁸. There was a reported positive association in Psoriasis, CRP, inflammatory cytokines, and chemerin levels.^{89,90}

In comparison to patients with a normal BMI, Coimbra et al. 2010a found that a significant proportion of Psoriatic patients were overweight or obese. Additionally, these patients had greater amounts of leptin, resistin, TNF- α , and IL-6 and lower levels of adiponectin.^{9,91}

The relationship between BMI and Psoriasis was also confirmed by a retrospective study including 1.5 million US patients, which stated that 9.5% of patients with normal weight had psoriasis, 11.9% of overweight patients had it, 14.2% of grade I obese patients had it, and 17.4% of grade II–III obese patients had it,¹² the greater the BMI, the more chance of having Psoriasis. According to certain research, people who are obese have a higher likelihood of psoriasis treatment failure.^{92,93}

Accordingly, psoriasis is a chronic inflammatory immune-mediated condition that is made worse by obesity, with adipose tissue malfunction in the obese population aggravating its cardio-immune-metabolic consequences⁸⁴ as illustrated in Figure 2.11.



Source³³

Figure 2.9 A conceptual model of the immunological interaction between the inflammatory process of psoriasis and adipocytes' non-professional immune functions, as well as the impact this interaction has on the synthesis of metabolically active mediators. CRP: C-reactive protein, IL: interleukin, TNF: tumor necrosis factor

Thus, treating obesity by adhering to weight-loss plans can reduce psoriasis's clinical symptoms, boost drug effectiveness, prevent metabolic problems, and improve patients' general health.^{80,81} Studies have proved that following particular dietary guidelines can help minimize the flare of Psoriasis and enhance treatment effects for the condition.⁸⁰

2.1.8 Psoriasis and Sleep

For overall health and well-being, sleep is crucial.⁹⁴ Disturbances in sleep can have a significant influence on daily functioning since they may cause issues with attention, poor performance at work or school, and vehicular or transportation accidents.^{95,96} Chronic sleep disturbance can also lead to a number of detrimental health consequences, such as heart disease, type 2 diabetes, obesity, depression, and high blood pressure, and all-cause mortality.^{97,98}

People who have psoriasis are substantially more prone to suffer sleep problems. According to a case-controlled study conducted in 2018, 53.6% of Psoriasis

patients report having poor sleep quality (PSQI >5), which is greater than the general population (21.9%).⁹⁹ Sleep disruption was seen in as many as 85.4% of psoriatic individuals, according to a 2016 systematic review and meta-analysis.¹⁰⁰ It is also more common for those with psoriasis to be diagnosed with sleep-related ailments including restless legs syndrome, obstructive sleep apnea (OSA), and insomnia.¹⁰¹ Another 2016 cohort study also discovered that in comparison to psoriasis patients without sleep problems, concomitant sleep disorder sufferers were much more likely to have ischemic heart and stroke events.¹⁰²

Inadequate sleep quantity and insufficient sleep quality are two types of contributing variables. The American Academy of Sleep Medicine defines insufficient sleep duration as sleeping less than seven hours per day on average.⁹⁶ Post-sleep restoration, depth, latency, and continuity of sleep are some of the factors that affect how well we sleep.⁹⁴

Although psoriasis pruritus is less frequent than scabies or atopic dermatitis, it can still interfere with sleep because it usually gets worse at night.¹⁰³ In addition, psoriasis skin lesions can impair thermoregulation, slow down the loss of body heat, and decrease sweat rate and capacity to dissipate heat,¹⁰⁴ hence diminishing the ability to induce sleep and decreasing deep sleep.¹⁰⁵ Poor sleep quality is often linked to depression, a common co-morbidity in psoriasis patients.¹⁰⁶ All of these findings point to a higher likelihood of sleep disturbance in psoriasis patients.¹⁰⁷

The hypothalamic-pituitary-adrenal (HPA) axis's function and sleep deprivation are correlated in both directions. Sleep disruptions are caused by boosting the activity of the same axis, which in turn causes higher activation of the HPA axis and the symptoms of insomnia.¹⁰⁸ Cortisol and pro-inflammatory cytokines, such as interleukin 6 (IL-6) and TNF- α , are secreted more frequently as a result, which has a deleterious effect on the immunological and autonomic nervous systems. It also impairs cognitive performance and alters pain perception.¹⁰⁹ Many studies show that those who experience sleep loss have lower serum adiponectin levels or higher levels of ghrelin and leptin.¹¹⁰ It is believed that this imbalance between the latter adipokines is connected to heightened hunger.¹¹¹ Furthermore, irregular sleep cycles and their control have been linked to increased concentrations of substance P found in the perilesional skin of Psoriatic individuals.¹¹²

Due to bad sleeping habits, underlying sleep problems (insomnia, obstructive sleep apnea), and pruritus and pain symptoms, adults with Psoriasis suffer from a lack of sleep.¹¹³ Lack of sleep is another comorbidity associated with Psoriasis that can lead to worse quality of life, inadequate disease treatment, and greater use of medical services. Given the harmful implications on health, routine screening and treatment for sleep deficits are crucial.¹¹³

2.1.9 Psoriasis and Quality of Life

Recent studies indicate that skin conditions may significantly impact one's ability to operate in all spheres of life, including social, professional, and sexual domains, as well as the perception of one's quality of life.^{114,115} One of the key goals these patients have for their appointment to the dermatologist is to improve their quality of life. As such, it necessitates particular consideration and consistently highlights the significance of this field in medical practice.¹¹⁶

Both personal and professional relationships may suffer as a result of psoriasis. Unfavorable bodily perception and low self-worth result in social disengagement and hinder their ability to start and finish education or work.¹¹⁶ Treatment costs and the number of days off work have an impact on patients' financial status and quality of professional life. A study conducted in Britain found that 26 days out of the year, around 60% of psoriasis patients are on sick leave.¹¹⁷ The degree of psoriatic alterations has a major impact on the level of somatic functioning. Studies have shown that psoriasis can cause a range of symptoms, including burning, itching, and pain.¹¹⁸ Consequently, physical discomfort increases with the severity of the illness. According to findings by other researchers, people with moderate to severe psoriasis experience rejection from their close surroundings. Attempts to prevent skin-to-skin contact are indicative of environmental rejection in this group of individuals. Psoriasis patients' social functioning is negatively impacted by such behavior.¹¹⁹

The effect of psoriasis on individuals' quality of life was correlated with age. Younger patients were more likely to report feeling stressed and anxious about the disease's recurrences. Patients were more likely to feel ashamed of their disease if they had lesions on socially visible areas such as their hands, faces, scalps, etc. Patients' health-related quality of life was significantly impacted by a number of characteristics,

including younger age, female gender, lesions on exposed locations, and recent diagnosis (less than 12 months).¹²⁰

There is evidence linking depression, anxiety, and psychological stress to a decline in life satisfaction.¹²¹ A high DLQI score is connected with moderate to severe psoriasis. Regardless of the existence of concomitant psoriatic arthritis or the type of treatment received, increases in DLQI scores were directly and moderately correlated with higher PASI scores.¹²² Consequently, reduction in DLQI scores and improvement in PASI are observed with effective therapeutic techniques.¹²³

2.1.10 Management of Psoriasis

Due to its chronic nature and tendency to relapse, Psoriasis frequently requires long-term therapy. Psoriasis treatments options are influenced by the severity of the ailment, comorbid conditions, and accessibility to medical treatment. The two types of psoriatic patients are usually mild or moderate to severe psoriasis, depending on the clinical severity of the lesions, the percentage of body surface area affected, and the patient's quality of life.¹²⁴ The PASI score is a tool for grading clinical illness severity and responsiveness to therapy.⁵⁰

There are three types of psoriasis treatments: topical, systemic, and phototherapeutic.¹²⁵

2.1.10.1 Topical treatments

Topical treatments are recommended for psoriasis that affects less than 10% of BSA, psoriasis in sensitive areas such as the face, genitalia, and flexures, or as adjuvants for systemic medications or UV light for psoriasis that affects more than 10% of BSA (moderate/severe psoriasis) and refractory psoriasis of the scalp or palmoplantar area.¹²⁶

Throughout time, the use of more traditional topical medications like coal tar and anthralin has decreased. Nevertheless, they are less expensive and can still be applied to treat severe psoriasis that is not responding to other therapies.¹²⁶

Topical corticosteroids (TCS) reduce inflammation, restrict cell proliferation, and constrict blood vessels by downregulating inflammatory pathways. Topical vitamin D analogs limit keratinocyte growth while encouraging differentiation. They should be used with caution in renal-impaired patients. By decreasing T cell activation and IL-2 and IFN- γ production, topical calcineurin inhibitors, including

tacrolimus and pimecrolimus, are used to treat psoriatic lesions in the face and intertriginous areas. Burning sensations and skin irritation are the most frequent adverse effects of topical calcineurin inhibitors and vitamin D analogs. Thick scales on psoriasis plaques are broken down with topical keratolytics such as salicylic acid and tazarotene. Salicylic acid lessens scaling, while retinoid tazarotene prevents keratinocyte proliferation.¹²⁷

To reduce side effects, the location of the lesions ought to be taken into account while choosing the strength and formulation of corticosteroids.¹²⁷ In order to improve the absorption of topical corticosteroids (TCS) and calcineurin inhibitors into the psoriatic plaques, salicylic acid can be administered in combination with these drugs to treat thick limited plaques.

Low-to mid-potent TCS are used for psoriasis of the face or flexures, whereas high-potent TCS are used for palmoplantar or thick psoriasis lesions. It may be easier to prevent long-term daily TCS with the inclusion of non-corticosteroid therapy. Intertriginous and face psoriasis can be treated with tacrolimus and pimecrolimus.

Tazarotene is usually used in combination with other drugs, such TCS, to treat stable plaque psoriasis. Vitamin D analogs and TCS work well together to treat palmoplantar psoriasis and persistent plaques on the limbs.

Salicylic acid, coal tar, TCS, vitamin D analogs, and anthralin in a range of forms, including solutions, foams, and shampoos, are examples of topical treatments for scalp psoriasis.

Nail psoriasis can be treated with TCS, tazarotene, and vitamin D analogs.¹²⁶

It's crucial to be mindful of potential compatibility problems while utilizing various topical medications. For instance, salicylic acid deactivates calcipotriene. However, salicylic acid is necessary for anthralin's chemical stability^{126,128}. Patients may be advised to apply different drugs at different times throughout the day when combination therapy is indicated. To minimize side effects, more potent medicines must be administered for a brief period and patients should have full instructions on how to utilize these drugs. Every patient receiving topical medication should have routine examinations to detect any early onset of side effects¹²⁶. Patients with psoriasis

typically have poor adherence to topical medication, especially over the long term, which may limit its practical efficacy.¹²⁵

2.1.10.2 Systemic treatments

Systemic medications need to be initiated if there is PASI >10, or involvement of scalp, face, hands, nails, palmoplantar, or genital areas despite PASI being <10, or uncontrollable condition with topical treatments, or severe impact of quality of life (DLQI ≥10), or presence of active Psoriatic arthritis¹²⁹. The main treatment for moderate-to-severe psoriasis is systemic therapy. When psoriasis affects 3~5% to 10% of the body's surface area, it is considered moderate; when it affects 10% or more, it is considered severe.¹²⁷

Methotrexate (MTX) is an analog of folic acid that prevents the production of purines and thymidine, hence inhibiting DNA synthesis. Up to a maximum of 25 mg per week, the initial suggested dose of 7.5–10 mg per week may be taken.¹³⁰ The most typical adverse effects include elevated liver transaminase, leucopenia, and nausea. It is still a widely used, reasonably priced first-line medication despite the possible side effects and teratogenicity; long-term treatment is possible with strict monitoring of liver function and complete blood count.⁵⁰

Cyclosporine suppresses the immune system, and it belongs to the class of calcineurin inhibitors and inhibits T cells. For up to two years, cyclosporine can be used as a maintenance medication and to promote remission in psoriasis.¹³¹ Important possible side effects include non-melanoma skin cancer, hypertension, and nephrotoxicity. Cyclosporine is used as a short-term, intermittent treatment, only up to 10–16 weeks, the dosage being 2.5–5.0 mg/kg of body weight. It is advised to taper off the medication to avoid relapse.¹³¹

The retinoid used to treat psoriasis is called acitretin. Through its action on nuclear receptors, it influences transcriptional processes and restores normal keratinocyte differentiation and proliferation.^{132,133} At first, 0.3–0.5 mg/kg of body weight of acitretin is given daily, and 1 mg/kg/day is the maximum dosage. The most frequent adverse effect, which manifests dose-dependently in all individuals, is cheilitis. Teratogenicity, hepatitis, effluvium, and conjunctivitis are further side effects.⁵⁰

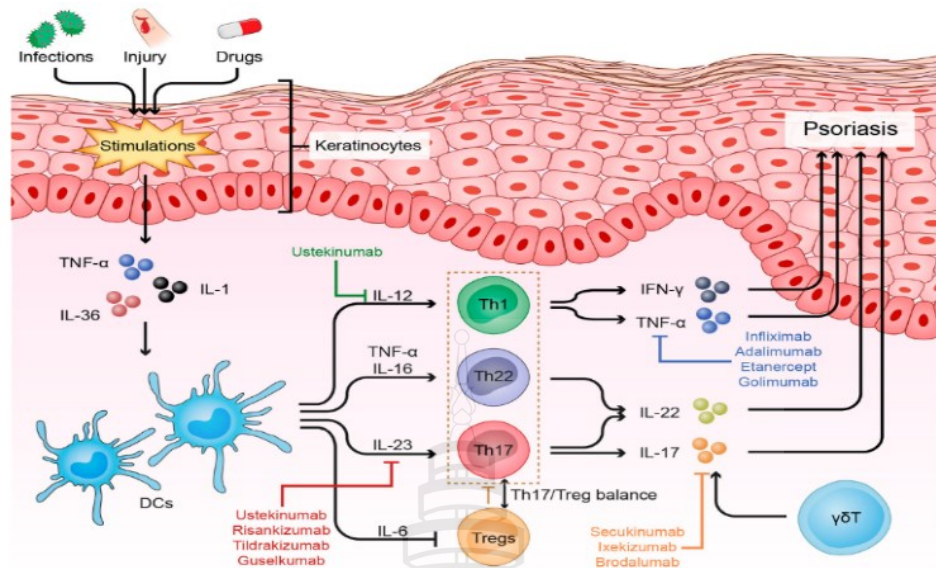
The phosphodiesterase-4 inhibitor apremilast prevents the second messenger cAMP from being hydrolyzed. As a result, pro-inflammatory cytokines TNF- α , IFN- γ , and IL-12 are expressed less frequently, and IL-10 levels are raised. The anti-inflammatory effects of apremilast on keratinocytes, fibroblasts, and endothelial cells were demonstrated to be extensive.¹³⁴

A class of drugs known as TNF- α inhibitors targets the cytokine, TNF- α , which is involved in inflammation. Etanercept, infliximab, and adalimumab are the three TNF- α inhibitors that are often utilized in moderate-to-severe psoriasis, with approved efficacies and long-term safety profiles.¹³⁵ Nonetheless, numerous severe side effects were documented, including life-threatening infections, reactivation of hepatitis B and C, tuberculosis, lupus produced by drugs, and problems of the demyelinating central nervous system.¹³⁶

Effective IL23 inhibitors for psoriasis treatment include ustekinumab, guselkumab, risankizumab, and tildrakizumab. The sole biologic that targets both IL-12 and IL-23 by blocking their shared p40 subunit is ustekinumab. IL-23 inhibitors also show good safety profiles, strong efficacy, and easy-to-follow dosage schedules.¹³⁷

Secukinumab, Ixekizumab, and Brodalumab are examples of IL-17 inhibitors that either target the IL-17 ligand or its receptor. For treating plaque psoriasis, brodalumab exhibits a significant response, quick onset of action, and long-lasting efficacy. With no increased risk of serious illnesses or cancer, IL-17 inhibitors have an acceptable safety profile. On the other hand, there have been reports of mucocutaneous candidiasis and inflammatory bowel disease aggravation.¹³⁸ Injection site responses and upper respiratory tract infections are frequent side effects. There has been a case of suicidal thoughts in a patient receiving brodalumab.¹³⁹

Numerous innovative treatments for the complex, multifactorial disease psoriasis have emerged in recent years. Although targeted medications have advanced, psoriasis remains a treatable but incurable ailment. High clinical efficacy is demonstrated by targeted medicines in inhibiting IL-23 and IL-17.⁵⁰



Source ⁷⁵

Figure 2.10 Overview of Psoriasis molecular pathogenesis and targeted therapies

Photoaging, blistering, pruritus, erythema, and photocarcinogenesis are examples of adverse consequences. Combining systemic retinoids with narrowband UV-B radiation may be more beneficial and reduce the incidence of skin cancer.¹⁴⁰ In PUVA therapy, DNA synthesis is suppressed by using psoralens, like methoxalen, and then exposed to UV-A radiation. Oral PUVA works better than UV-B, but because prolonged usage increases the risk of skin cancer, it is no longer recommended. Burning, itching, gastrointestinal distress, hypertrichosis, and photoaging are possible side effects. The primary difficulty with phototherapy is that patients must travel to participate in office-based sessions.¹²⁷

Table 2.1 Phototherapies for Psoriasis

Type of phototherapy	Combination therapy	Adverse effects	Additional information
Excimer laser	None	Burning, Erythema, Hyperpigmentation	Adverse effects localized to treatment area

Table 2.1 (continued)

Type of phototherapy	Combination therapy	Adverse effects	Additional information
Photochemotherapy (ultraviolet-A phototherapy combined with methoxsalen)	Topical vitamin D analogs, Topical retinoids, Oral retinoids	Erythema, Irregular pigmentation, Nausea, Vomiting, Pruritus, Xerosis	Erythema usually peaks in 48-96 hours
Ultraviolet B Broad band (290 to 320nm) Narrow band (311nm)	Topical vitamin D analogs, Topical retinoids, Oral retinoids, methotrexate, cyclosporine, etanercept	Burning, Erythema, Photoaging, Pruritus	Available for home use

Source ¹⁴¹

2.1.10.4 Treatment Plans

In a study conducted by Yan et al. in 2021,¹⁴² the treatments available for Psoriasis manifesting the skin only and for systemic Psoriasis have been outlined as shown in Figures 2.12 and 2.13.

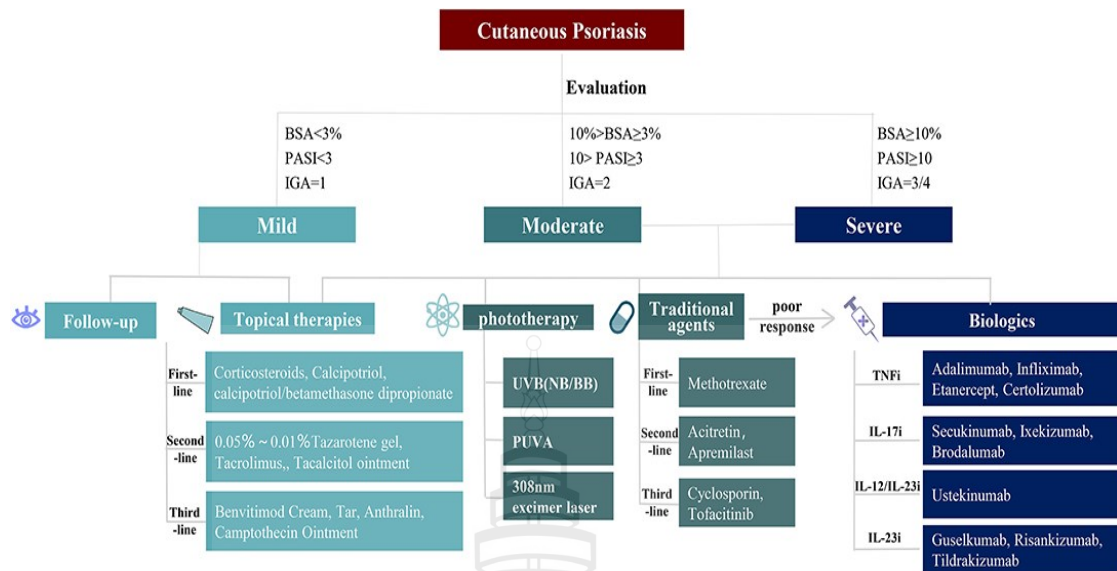
Source ¹⁴²

Figure 2.11 Therapies for cutaneous psoriasis. *BSA*, body surface area; *PASI*, psoriasis area, and severity index; *IGA*, investigator's global assessment; *UVB*, ultraviolet radiation b; *NB*, narrow band; *BB*, broad band; *PUVA*, psoralen plus ultraviolet radiation a

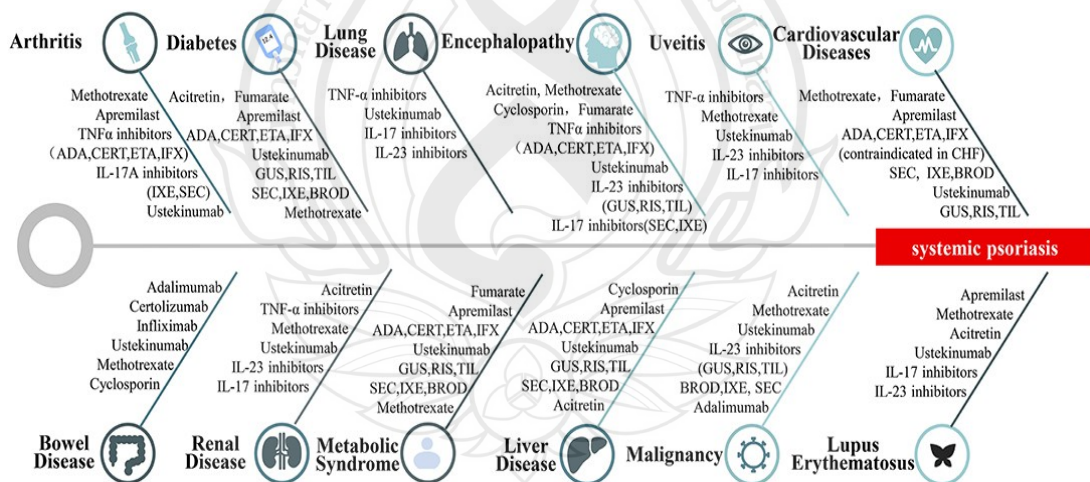
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Figure 2.12 Therapies for systemic psoriasis: a.

2.1.10.5 Challenges in the Current Treatments of Psoriasis

For psoriasis, there are numerous therapy choices. They do not, however, come without adverse effects. Unwanted impacts ranging from nausea, vomiting, organ

failures, and severe life-threatening infections to malignancy, systemic medications are not the best solutions yet. The high expense of biologic therapy, which has been detailed in Table 2.2 together with the adverse effect profiles, is another major concern. Patients and healthcare systems are burdened financially by these medications, which are frequently costly.

Table 2.2 Medications to treat Psoriasis and Psoriatic arthritis. CBC = complete blood count; FDA = U.S. Food and Drug Administration; LFTs = liver function tests; PPD = purified protein derivative

Drug	Dosage	Monitoring	FDA pregnancy category	Comments	Estimated cost*
Topical therapies					
Corticosteroids	Once or twice daily to affected areas	-	C	Use with caution in children; limit duration of potent steroid use	-
Tacrolimus (Protopic) and pimecrolimus (Eidel)	Twice daily to affected areas	-	C	Less effective for plaque psoriasis than facial or intertriginous psoriasis; approved for use in children older than two years; boxed warning about risk of malignancy with long-term use	\$170 per 30-g tube
Tazarotene (Tazorac)	Once daily to affected areas	-	X	Perilesional adverse effects are common; approved for treatment of psoriasis in person older than 18 years and for treatment of acne in person older than 12 years	\$225 per 30-g tube
Vitamin D analogs	Twice daily to	-	C	Appears safe for use in children; additional benefit if combined with topical corticosteroids; inactivated by ultraviolet A light	-

Table 2.2 (continued)

Drug	Dosage	Monitoring	FDA pregnancy category	Comments	Estimated cost*
Systemic therapies					
Acitretin (Soriatane)	10 to 50 mg orally per day	Renal function tests, LFTs, lipid panel, and CBC every one to two week until level stabilize (typically four to eight weeks)	X	Often used at reduce doses with phototherapy	\$770 to \$1,900 per month, depending on dosage
Adalimumab (Humira)	80 mg subcutaneously on day 1, 40 mg one week later, then 40 mg every other week	LFTs, CBC [‡]	B	Order baseline PPD tuberculin test; moderately painful injection site reaction may occur; live vaccines are contraindicated	\$2,300 for two 40-mg/0.8-mL syringes
Cyclosporine (Sandimmune) †	2.5 to 5.0 mg per kg per day, in two divided oral doses	Blood pressure; CBC; LFTs; lipid panel; and magnesium, uric acid, blood urea nitrogen, creatinine, and potassium level every two weeks for the first three months of therapy, then monthly if stable	C	May be used continuously for one year; optimal use is intermittent (12 weeks for flare-up suppression); no data for treatment of psoriasis in children	\$200 to 400 per month, depending on dosage
Etanercept (Enbrel) †	50 mg subcutaneously twice per week or three months, the 50mg once per week	LFTs, CBC [‡]	B	Order baseline PPD tuberculin test; pruritic injection site reaction may occur; live vaccines are contraindicated; evaluated in children older than four years, but not approved by the FDA	\$2,300 for four 50-mg syringes

Table 2.2 (continued)

Drug	Dosage	Monitoring	FDA pregnancy category	Comments	Estimated cost*
Infliximab (Remicade) †	5 mg per kg per dose infusion at weeks 0, 2, and 6, then every six to eight weeks	LFTs, CBC‡	B	Order baseline PPD tuberculin test; live vaccines are contraindicated; infusion reaction are common and may be minimized with azathioprine (Imuran) or methotrexate	\$3,200 for four 100-mg syringes
Methotrexate †	7.5 to 25 mg orally per week	LFTs, renal function tests, CBC, and platelet count every one to two months	X	Can be used long-term if patient has no signs of toxicity supplement with folate	\$8 to \$30 per month, depending on dosage
Ustekinumab (Stelara) †	45 mg in patients < 100 kg (222lb) and 90 mg in patients 100 kg or more, given subcutaneously at weeks 0 and 4, then every 12 weeks	—	B	Order baseline PPD tuberculin test; generally well tolerated	\$6,300 for one 45-mg/0.5-mL syringes

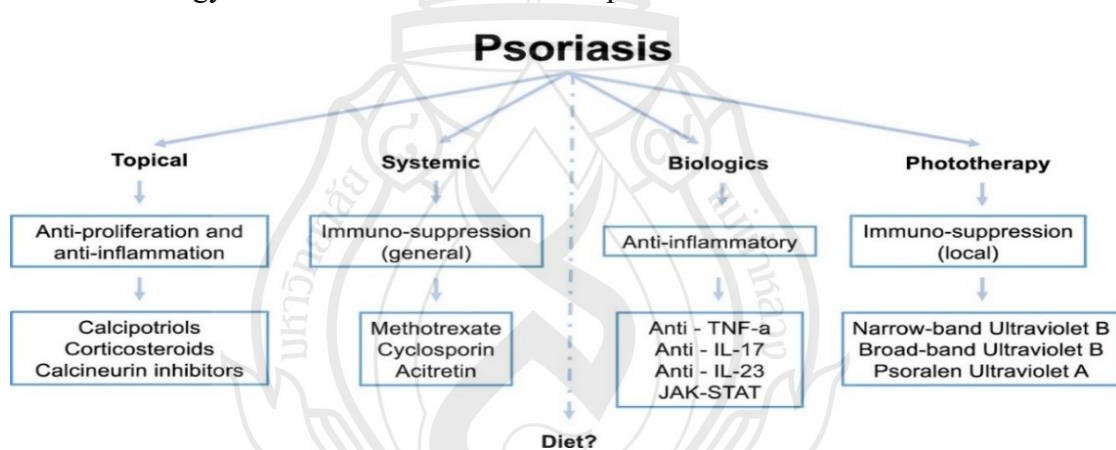
Note †—Useful in patients with psoriatic arthritis. ‡—Frequency based on clinical judgment. *—Retail pricing estimate based on data collected at <http://www.goodrx.com> (accessed January 15, 2013)

Source ¹⁴¹

In a survey done in 2022,¹⁴³ 24.5% of psoriasis sufferers said that they were either marginally or not at all satisfied with their therapies, and most expected a more affordable treatment plan. Although there have been major advancements in the treatment of psoriasis, there is still a need for more accessible, affordable, quicker, longer-acting, and more efficient therapies.¹⁴³

Psoriasis cannot be cured; instead, symptom management is the mainstay of treatment. Research indicates that when the severity of psoriasis lessens in individuals, quality of life also tends to improve.¹⁴¹ However, because of side effects, delayed onset of action, and less improvement, patients are far from satisfied and adherence to some treatments.¹⁴⁵ Another issue raised is the psoriasis therapies' long-term effectiveness.¹⁴⁶ The financial impact of Psoriasis is substantial and rises as more comorbidities associated with the disease develop.^{147,148}

Owing to these difficulties and the patients' demand for faster, longer-acting, and more efficient, less expensive, and easier-to-access treatment, medical professionals are focusing on lifestyle modification strategies, particularly the simplest and most affordable dietary interventions, and researching their mechanisms and efficacies not only on skin lesions but on other comorbidities. Figure 2.15²⁷ illustrates the diet ideology out of other main treatment options.



Source²⁷

Figure 2.13 Psoriasis treatment options. JAK-STAT, janus kinase and signal transducer and activator transcription IL, interleukin; TNF-α, tumor necrosis factor-α

2.2 Dietary Interventions in Psoriasis

The importance of nutrition in managing psoriasis has been the subject of a growing corpus of scientific literature, and several dietary studies are currently gaining

popularity, despite the fact that there are currently no scientifically established dietary guidelines for the condition.

A few particular diets have been researched concerning psoriasis management: the Mediterranean diet (MD), low-calorie diets (LCDs), very low-calorie ketogenic diets (VLCKD), intermittent fasting (IF), and gluten-free diets (GFD).¹⁴⁷

2.2.1 Calorie Restriction Diet Patterns

2.2.1.1 Low-calorie diets (LCDs)

LCDs reduce energy use in an attempt to aid with weight loss. An analysis of a Cochrane review on lifestyle changes for psoriasis showed six randomized control trials (RCTs) evaluating the impact of a low-calorie diet on 499 obese people.¹⁴⁹ In comparison to standard therapy, the analysis revealed that low-calorie diets may improve baseline PASI in obese psoriatic individuals by at least 75%.¹⁴⁷

A new meta-analysis of the research indicates that a low-calorie diet is the most important diet type that offers clear treatment benefits for psoriasis.^{150,151} Previous research has indicated that a 500 kcal caloric restriction below the estimated dietary requirement, consisting of 60% carbohydrates, 25% fat, and 15% protein, along with at least four sessions of 40 minutes of moderate exercise per week, significantly improves the clinical symptoms of psoriasis.¹⁴

2.2.1.2 Very low-calorie ketogenic diet (VLCKD)

Carbohydrate restriction is the primary prerequisite for being categorized as a ketogenic diet. Ketogenic diets with very low energy content (300–500 kcal/d) were tested on obese or overweight Psoriatic patients. In their 2021 study, Castaldo et al. examined how a 4-week very-low-calorie ketogenic diet (VLCKD) of less than 500 kcal/d affected the degree of psoriasis in thirty individuals who were overweight or obese. Each day, the participants were given 10–20 g of carbohydrates (400–500 g/d from veggies), 20–30 g of fats, and 1.4 g of protein per kilogram of ideal body weight.¹⁵² The dermatology life quality index (DLQI), PASI, and itching intensity all significantly improved after 4 weeks ($p \leq 0.05$). However, after four weeks, there was no discernible change in weight loss from the baseline.¹⁵² An obese female patient with relapsing severe Psoriasis was indicated a VLCKD diet as a case study and 4 weeks after intervention, her PASI was significantly decreased ($>80\%$), and shed 11 kg compared to the baseline.¹⁵³

2.2.1.3 Mediterranean diet (MD)

The main components of the Mediterranean diet include whole grains, legumes, fish, nuts, fruits, and vegetables; dairy, meat, and alcohol are also included in moderation. Monounsaturated fatty acids (MUFA) are found in foods like extra-virgin olive oil (EVOO). A 2019 study found that patients with diets rich in extra virgin olive oil, seafood, and veggies had lower PASI scores, while patients with diets high in dairy products had higher PASI scores.¹⁵⁴

2.2.1.4 Gluten-free diet (GFD)

For Psoriasis sufferers, avoiding a protein called gluten—which is abundant in wheat, barley, and rye—through a gluten-free diet can be beneficial.⁸⁰ Psoriasis is associated with a higher frequency of celiac disease than the general population.¹⁵⁵ Gluten ingestion triggers the celiac disease, which affects the small intestine. Numerous research investigations have demonstrated the positive effects of a GFD on the severity of Psoriasis in individuals with celiac disease or antibodies specific to gluten.¹⁴⁷

2.2.1.5 Intermittent fasting (IF)

Although the effects of intermittent fasting on dermatoses are still little understood, this diet has a number of interesting clinical uses. Intermittent fasting (IF) involves ingesting few or no calories for a length of time that might range from hours to days. This often results in a fasting metabolic state.¹⁵⁶

The three most studied intermittent fasting regimens are daily time-restricted eating (TRE), modified alternate-day fasting (MADF), which includes two days per week (5:2 intermittent fasting), and alternate-day fasting (ADF) (Figure 2.12). When adopting TRE, a person limits their daily meal consumption to 6–8 hours. This dietary approach might improve adherence to calorie restriction.¹⁵⁷

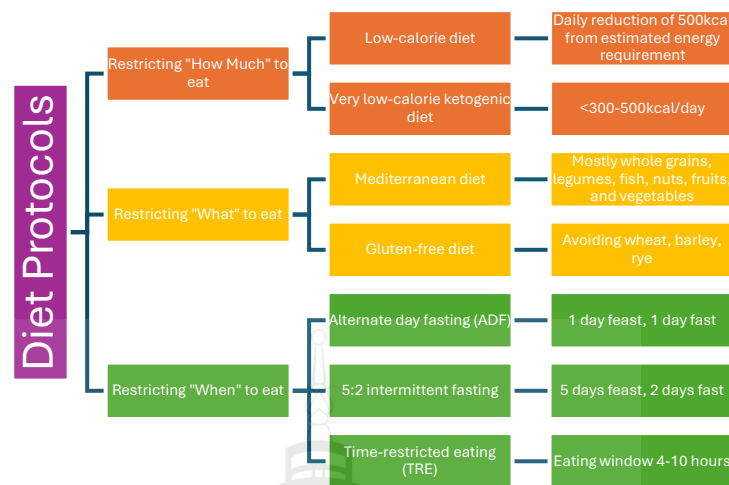


Figure 2.14 Dietary interventions for psoriasis

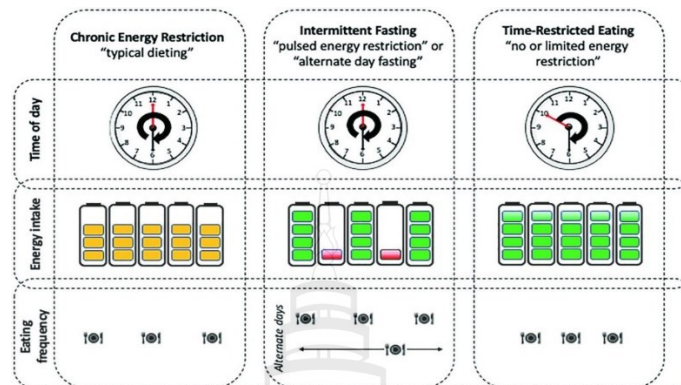
A physiological reaction brought on by intermittent fasting increases antioxidant defenses, DNA repair, protein quality control, autophagy, and mitochondrial biogenesis while lowering inflammation.²⁶ Benefits of IF for chronic disorders such as obesity, diabetes, heart disease, cancer, IBD, and neurodegenerative brain diseases have been demonstrated in animal models. IF improves visceral fat mass, serum indicators of inflammation and oxidative stress, insulin resistance, dyslipidemia, and hypertension, as well as cardiometabolic risk factors in humans.¹⁵⁶ In a meta-analysis evaluating the impact of three different types of IF on weight loss, it was shown that whereas the 5:2 diet led to weight reduction ranging from 1.70% to 7.97%, ADF interventions caused body weight to drop between 0.77% and 12.97%. The range of body weight loss resulting from TRE was 0.95% to 8.6%. According to the study's findings, IF is a viable substitute for a calorie-restriction diet in weight loss.¹⁵⁸

Frequent IF can ensure that the body undergoes critical cellular processes that may lessen systemic inflammation and alter the severity of inflammatory diseases like psoriasis.¹⁵⁶ Patients with mild psoriasis who followed a 5:2 diet showed a significant decrease in thickness and scaling, according to one pilot study.¹⁵⁹

2.2.2 Time-Restricted Eating (TRE)

Nowadays, "intermittent fasting" is a concept that many are familiar with. The diet pattern with alternating fasting and eating intervals is referred to by this general phrase. Of all the methods, TRE is the most natural, safest, economical, and reliable

because it does not require calorie restriction during the meal window. Patients can be instructed, "Eat anything as much as you like; all you have to do is stop when the timer sounds."



Source ¹⁶⁰

Figure 2.15 Categorization of popular diet practices

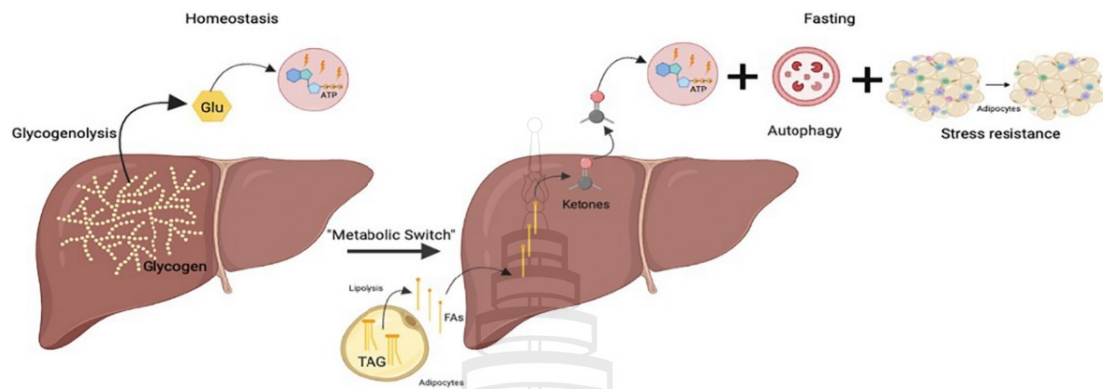
This dietary strategy has been investigated in two studies that looked at the impact of fasting during Ramadan on Psoriasis. Almutairi et al. 2022 evaluated how 121 Kuwaiti patients with stable chronic plaque psoriasis responded to fasting throughout Ramadan.¹⁶¹ For a month, the participants observed the customary Ramadan fast, which calls for abstaining from food, liquids, and tobacco use during the day. The participants consumed two major meals each day: one before sunrise and one after. While there was no weight reduction reported by the participant after one month, the mean PASI was considerably lower than the baseline.¹⁶¹ Another study (n = 108) looked into how 1 month of Ramadan fasting affected the severity of psoriasis in those with moderate-to-severe psoriasis. After the fasting, a noteworthy decline in the average PASI score was noted in comparison to the baseline.¹⁶⁰

2.2.2.1 Mechanism of TRE

1. Fasting and Metabolic Switch

One common explanation for the advantages of intermittent fasting is that it regularly induces a fasting metabolic state. The terms "fed" and "fasting" relate to the two metabolic states that exist in humans. Triglycerides, which are lipids stored in adipose tissues, are produced during the fed state and are mostly sourced from glucose obtained from meals. A person's glycogen stores run low after around 12 hours

without food, at which point the body starts to metabolize the triglycerides that are kept in adipocytes for energy. The metabolic transition from the fed to the fasting state is represented by this change from glycogenolysis in the liver to lipolysis in adipose tissue, which is finally manifested by an increase in serum ketone levels.^{26,163}



Source^{27,163}

Figure 2.16 The “Metabolic Switch.” Homeostasis: the preferred energy source, glucose, is released by glycogenolysis and taken up by cells, where it is transformed into ATP. During a fast, sustained glycogenolysis gradually exhausts glycogen stores, which causes lipolysis to release free fatty acids. Hepatocytes absorb the free fatty acids and transform them into the ketone molecules β -hydroxybutyrate, acetone, and acetoacetate. To produce energy, cells switch from using glucose to using ketone bodies. Adenosine triphosphate (ATP); fatty acids (FAs); glucose (Glu); and triacylglycerols (TAGs)

Regular switching back and forth between the fed and fasted metabolic states is beneficial for cellular functions as well as illness symptoms. In a fed metabolic state, cells undergo actions related to growth and plasticity. An individual's protection against oxidative and metabolic stress is strengthened by the removal and repair of damaged molecules by cellular mechanisms that occur during a fast. In addition, the state of fasting helps to reduce inflammation, boost stress tolerance, and regulate blood sugar.²⁶

2. Timing of food intake and Circadian rhythm

Circadian rhythms communicate food and fasting and start wake and sleep cycles at the right biological times. Obesity, type 2 diabetes, and cardiovascular disease are more likely to occur when circadian cues are not followed in eating and sleeping patterns.^{164,165} Individual endogenous circadian rhythms' ability to modify meal timing may help lower the burden of cardiometabolic diseases.¹⁶⁶

The autonomous master clock in the hypothalamic suprachiasmatic nucleus (SCN) regulates the endogenous circadian system. It is synced by ambient light and entrains secondary clocks in peripheral body tissues.¹⁶⁵ The integration of erroneous signals during meal consumption at night can cause homeostasis to be disturbed (circadian misalignment)¹⁶⁵. Morning meals burn more calories than isocaloric evening meals because diet-induced thermogenesis (DIT) peaks in the morning.¹⁶⁶ Thus, compared to other types of TRE, daytime TRE might be more advantageous.¹⁵⁷

Reduced sleep time, later sleep schedules, and calorie intake after 8:00 PM are all linked to higher BMI.¹⁶⁷ According to Xiao et al., eating more in the morning was linked to 50% fewer chances of being overweight or obese, whereas eating more in the evening was linked to 80% greater odds of being overweight or obese.¹⁶⁸

3. Relationship Between TRE and Serum Inflammatory Markers

IFN- γ , TNF- α , IL-9, IL-12, IL-17, IL-22, and IL-23 are among the inflammatory markers that are highly linked to psoriasis.¹⁶⁹ Almeneesier et al. looked at the connection between proinflammatory cytokines IL-1, IL-6, and IL-8 in serum levels and Ramadan diurnal intermittent fasting. When compared to non-fasting, researchers found a significant decrease in IL-1, IL-6, and IL-8 during both Ramadan and non-Ramadan fasting,¹⁷⁰ pointing to a substantial correlation between a decrease in certain inflammatory markers and intermittent fasting. This study is special since the researchers kept track of individuals' energy expenditure, meal composition, and sleep/wake patterns over the whole investigation.

Similar cross-sectional research was conducted in 2012 by Faris et al., comparing the serum levels of immune cells and proinflammatory cytokines in 50 Ramadan fast participants. Comparing Ramadan to baseline, they showed a significant drop in all tested biomarkers.¹⁷¹

4. Previous trials of TRE in Psoriasis

In a multicenter observational study, Damiani et al. examined the impact of Ramadan fasting on PASI scores in individuals with mild to severe psoriasis. A total of 108 adult patients with moderate to severe plaque psoriasis fasted for 17 hours every day during the month of Ramadan. Researchers found a -0.9 ± 1.2 ($p < 0.0001$) difference between the PASI before and after the fasting interval that is statistically significant.¹⁶²

There was another large-scale prospective observational study conducted throughout the month of Ramadan, with 121 chronic plaque psoriasis patients who fasted for almost 14 hours every day from sunrise to sunset. Throughout the intervention, the patients' oral or topical psoriasis medications were continued. At the end of the trial, the mean PASI was 3.51 ± 1.26 , which has reduced from the baseline mean 4.23 ± 3.22 .¹⁶¹

2.2.2.2 Additional Advantages of TRE

1. No need to count calories

Because TRE does not require participants to track their food consumption or count calories, it's an innovative approach to diet therapy. All that is asked of the subjects is to eat at a designated window of time and fast for the rest of the day. Restricting the time spent eating to 4–10 hours each day causes an inadvertent 10%–30% (200–600 kcal/day) decrease in energy consumption. Having to regularly and meticulously monitor energy intake is a major cause of subject attrition in ADF and daily CR trials. In contrast, TRE diets can avoid this necessity and still result in significant weight loss by allowing participants to watch the clock rather than monitor energy intake. Long-term adherence to this treatment could be significantly increased by this TRE's special feature.¹⁷²

2. Weight Loss

TRE promotes weight loss mostly due to the unintentional 10–30% lower energy consumption.¹⁷³ The purpose of trials has been to ascertain how TRE affects weight loss. Patients who followed TRE (8 hours) lost more weight in a randomized controlled experiment than those who ate during a window of at least 12 hours.¹⁷⁴ These findings suggest that timing TRE to the circadian rhythm of the body is a more successful weight-loss method.

In addition, TRE can be adjusted to accommodate a patient's current food habits and preferences, which could improve patient compliance.¹⁵⁷ According to a randomized controlled experiment, participants followed the TRE plan an average of six days a week. TRE was associated with higher mood, more energy, and less depression, all of which increased the plan's adherence as a lifestyle strategy.¹⁷⁴

3. Appetite Regulation

Weight loss may be aided by the improved management of hunger that IF brings about. Subjective hunger did not change, and posttreatment feelings of fullness increased in an 8-week ADF experiment conducted by Hoddy et al. These increases in fullness were accompanied by an increase in the potent satiety hormone peptide YY.¹⁷⁵

4. Sleep Modification

An increasing body of research indicates that eating at night is linked to shorter sleep duration and lower sleep quality.¹⁷⁶ The study by Cienfuegos et al. found that sleep quality did not alter after 8 weeks of 4- or 6-hour TRE.¹⁷³ Similarly, Gabel et al.¹⁷⁷ saw no change in the quality of sleep following a 12-week 8-hour TRE.

It should be highlighted that the majority of study participants were sound sleepers at baseline, even if the initial results indicate that TRE has little impact on the quality of sleep. During the 8-week trial, individuals who had baseline subthreshold insomnia no longer had clinically significant insomnia, according to Cienfuegos et al., although there were no changes in the length of sleep with 4- or 6-hour TRE.¹⁷³

IF has been shown in certain studies to enhance the length, quality, and latency of sleep. People who practiced ADF or TRE, for instance, experienced fewer sleep interruptions and had better REM (rapid eye movement) and deep sleep.¹⁷⁸ These improvements could also be related to insulin sensitivity, melatonin, and circadian rhythm modulation, as well as different hormonal and metabolic responses.¹⁵⁷

5. Glycemic Control

The HbA1c, insulin resistance, and fasting insulin levels in healthy persons with obesity and prediabetes were all predicted to decrease with the implementation of intermittent fasting regimens.¹⁷²

Comparing TRE versus non-TRE methods, a network meta-analysis of 12 randomized controlled trials including 730 participants revealed that TRE can successfully lower body weight and improve insulin resistance.¹⁵⁷ A 10-hour TRE window reduced the average daily calorie intake by 28% in comparison to the consumption of a control group in a randomized controlled experiment intended to assess the advantages of TRE in overweight patients with type 2 diabetes.¹⁷⁹ After completing the 12-week study, every participant reported no negative side effects (e.g., headaches, thirst, or diarrhea). In the TRE group, an 18% decrease in fasting blood glucose was observed, and no hypoglycemic episodes occurred.

6. Improvement in Liver Fibrosis

There is very little human research on NAFLD and TRE; a large portion of the available data originates from research done during Ramadan, when fasting is observed for 30 days in a row between 12 and 14 daylight hours. However, because it may contain more sugar and fat, the food consumed during the Ramadan vacation may not be typical of a usual diet. Despite this, research has shown enhancements in indicators of noninvasive liver fibrosis, including insulin resistance, inflammatory markers, and the fibrosis-4 score, as well as weight loss when compared to controls.¹⁸⁰ Thus, TRE is a safe and effective means to improve fibrosis using methods that are both reliant on and separate from weight loss, such as diverting metabolic processes from hepatic lipogenesis, as well as to improve insulin resistance and metabolic syndrome.¹⁵⁷

7. Lowering Cardiovascular Risks

The studies that are currently available suggest that TRE may be beneficial for blood pressure and the lipid profile, while more research is required. TRE reduced systolic blood pressure in six of the 19 studies included in a meta-analysis (a total of 97 participants).¹⁸¹ An analysis of 91 studies with 4431 participants revealed the impact of Ramadan fasting on cardiometabolic risk variables in healthy individuals.¹⁸² This analysis found that fasting reduced the risk factors for cardiometabolism, such as a decrease in serum triglyceride, total cholesterol, and low-density lipoprotein levels and an increase in high-density lipoprotein levels.

2.2.2.3 Practical Considerations for TRE

1. Patient Safety

Numerous clinical studies have shown that intermittent fasting for brief periods of time is safe and bearable. According to an observational study conducted during Ramadan with 121 volunteers, the only adverse effects of the five weeks of intermittent fasting were fatigue, constipation, and sensations of hunger. No significant adverse effects were recorded.¹⁶¹ Furthermore, a 2021 RCT showed that 8-hour TRE for a year was both safe and practicable for 20 healthy males.¹⁸³

2. Initial Adjustment Period

It takes about one to two weeks for most people to acclimate completely to this new eating schedule. Although reports of dizziness and constipation have been made during the first phase, these side effects typically go away by the second week of fasting.¹⁷³ During this initial phase, headaches are also commonly observed. Dehydration from inadequate water intake, which can happen when diet is restricted, is typically the cause of headaches.¹⁸⁴ Adding 1.5 L of water to one's daily consumption may aid people with headaches when fasting.¹⁸⁵

3. Individuals Not Fit For TRE

It is not advised for pregnant or nursing women to practice intermittent fasting, including TRE, as there has not been research done to determine whether these diets are safe for these groups. Fasting should not be done by children younger than twelve. Additionally, individuals with a background in eating disorders and those with a BMI of less than 18.5 are not advised to engage in intermittent fasting. Because of the significant daily fluctuations in their schedules and eating habits, shift workers may find it difficult to stick to fasting regimens. TRE may be difficult for persons who have to take their medications with food at particular times of the day. Therefore, medical experts should evaluate the patient's prescription schedule prior to proposing a certain fasting approach.¹⁷²

4. Monitoring Adherence

Clinical trials for fasting frequently utilize written records of the first and last calories ingested or daily food diaries to evaluate compliance. Adherence rates of at least 80% have been recorded for these trials.¹⁵⁶ TRE with an 8-hour window was followed for 6 weeks in individuals aged 55-79, and 84% of the participants showed perfect adherence.¹⁸⁶

2.3 Conclusion

Numerous researchers have examined the relationship between diet, sleep habits, and overall well-being in both healthy persons and individuals with Psoriasis. Yet, out of all the diet plans, the majority of studies on IF in therapeutic settings involve Ramadan fasting, with only a one-month study period. Ramadan studies are also susceptible to confounding because of the feast-like food consumed every day and the shifts in eating times that interfere with sleep. As a result, more research must be done on the anti-psoriatic effects of longer-term daytime TRE. Furthermore, previous research findings indicate a small decrease in PASI scores transmitted by IF; nonetheless, the majority of these investigations have shown that IF did not influence sleep or DLQI ratings.

Thus, the goal of this research is to investigate the multifaceted benefits of 12-week-long daytime TRE, such as improvements in anthropometric measurements, sleep, DLQI, and PASI scores, and to identify any unintended effects. The ultimate goal is to determine whether daytime TRE could be a therapeutic lifestyle intervention that is safe, effective, feasible, and affordable for patients with chronic plaque-type Psoriasis.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Study Design

This study is a quasi-experimental prospective study.

3.2 Study Population

Twenty-two voluntary subjects of any gender and any Fitzpatrick skin type (I through VI) with chronic plaque-type psoriasis, aged between 30-60 years, with BMI 25-35 kg/m², who have already been consulted by a dermatologist, have met the inclusion criteria and, are currently residing in Thailand will be enrolled. Those patients will be recruited from Mae Fah Luang University Hospital, Bangkok, Thailand.

3.3 Study Location

Mae Fah Luang University Hospital, Bangkok

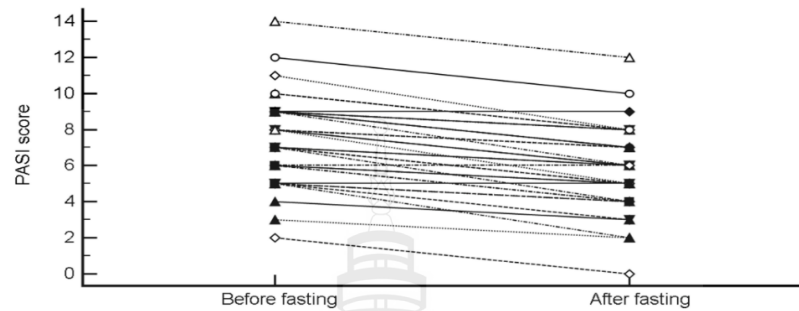
3.4 Sample Size Calculation

The Standard Deviations and Means from the reference paper, a multicenter study of Adawi M et al.,⁷ the impact of Intermittent Fasting (Ramadan Fasting) on Psoriatic Arthritis Disease Activity, Enthesitis, and Dactylitis, were used to determine the sample size in this study.

The Psoriasis Area Severity Index (PASI) dropped from 7.46 ± 2.43 at baseline to 5.86 ± 2.37 after one month of Ramadan fasting, according to that multicenter study.

Figure 3.1 displays the mean Psoriasis Area and Severity Index (PASI) scores prior to and following the Ramadan fast.

PASI decreased from 7.46 ± 2.43 to 5.86 ± 2.37 (mean difference -1.59 (95% CI, -1.87 to -1.32), $p < 0.0001$; H-L median difference -1.5 (95% CI, -2 to -1.5), $p < 0.0001$) (Figure 4).



Source ⁷

Figure 3.1 Mean psoriasis area and severity index (PASI) scores before and after Ramadan fasting

Mean before $\mu_1 = 7.46$

Mean after $\mu_2 = 5.86$

Standard Deviation σ before = $S_1 = 2.43$ Standard Deviation σ after = $S_2 = 2.37$

Sample size $n = 37$

$$Sp^2 = \frac{S_1^2(n-1) + S_2^2(n-1)}{(n+n) - 2}$$

$$Sp^2 = \frac{(2.43)^2 (37-1) + (2.37)^2 (37-1)}{(37+37) - 2}$$

$$Sp^2 = \frac{(5.9049)36 + (5.6169)36}{72}$$

$$Sp^2 = \frac{212.5764 + 202.2084}{72}$$

$$Sp^2 = 5.7609$$

Pooled Variance $\sigma^2 = 5.7609$

Set $\alpha = 0.05$ (two-tailed), $Z_{0.025} = 1.96$, $\beta = 0.2$, $Z_{0.2} = 0.84$

$$n = \frac{((Z_{\alpha/2} + Z_{\beta})^2 \sigma^2)}{(\mu_1 - \mu_2)^2}$$

$$n = \frac{((1.96 + 0.84)^2 5.7609)}{(7.46 - 5.86)^2}$$

$$n = \frac{7.84 \times 5.7609}{2.56}$$

$$n = 17.64 \sim 18$$

Set loss to follow up = 20% then drop out number = $18 \times 0.2 = 3.6 \sim 4$

So, the total sample size = $18 + 4 = 22$

Given the anticipated 20% dropout rate, 22 volunteers ($n = 22$) should be enlisted. Twenty-two willing individuals will be invited by the researcher to take part in the study.

3.5 Inclusion Criteria

3.5.1 Those between the ages of 30 and 60

3.5.2 Those who have been clinically diagnosed with Psoriasis by a dermatologist

3.5.3 Those presenting with active but clinically stable chronic plaque-type Psoriasis with any Psoriasis Area and Severity Index (PASI) score value, not taking any systemic medications specific for Psoriasis

3.5.4 Those with BMI 25-35 kg/m²

3.5.5 Those who can give informed consent to following the procedure and photographing the skin lesions

3.5.6 Those who can comply with dietary instructions

3.5.7 Those who are willing to use Fasting Tracker mobile application to record diet and sleep during the intervention period

3.5.8 Those who can attend all scheduled visits through the study period

3.5.9 Those who are willing to provide personal and contact information to communicate with the researcher throughout the study period

3.5.10 Those who are willing to apply measures to prevent pregnancy throughout the study period

3.6 Exclusion Criteria

3.6.1 Those with other types of psoriasis (Guttate, Erythrodermic, and Pustular psoriasis)

3.6.2 Those with type 1 or 2 diabetes mellitus

3.6.3 Those with a history of or current cardiac condition(s) such as uncontrolled hypertension, severe congestive heart failure, cardiac arrhythmias

3.6.4 Those with renal and liver impairment

3.6.5 Those with active gastric ulcer disease

3.6.6 Those with gout

3.6.7 Those with active or chronic severe infections, including HIV, hepatitis B virus, and hepatitis C virus infections and latent tuberculosis

3.6.8 Those with previous or active malignancies

3.6.9 Those with a history of or current eating disorders (anorexia, bulimia, etc.)

3.6.10 Those who are cachexic, defined as having lost at least 5% of their body weight in the previous six months without experiencing simple starvation, or those who have shed at least 2% of their body weight and have a BMI of less than 20 kg/m² or sarcopenia (as defined by Fearon et al.)

3.6.11 Those who have been using medical treatment for weight reduction

3.6.12 Those who are pregnant, having pregnancy plans, or breastfeeding

3.7 Discontinuation Criteria

3.7.1 Subject who wants to drop out of the program due to any reason

3.7.2 Subject who gets pregnant during the program

3.7.3 Subject who suffers from serious complication or illness from the treatment, such as irresistible headache or dizziness even with increasing the water intake, new onset or worsening of insomnia, mood swings negatively impacting daily life, blurred vision, slurred speech, disorientation, seizures, loss of consciousness which might indicate severe hypoglycemia

3.7.4 Subject who cannot comply with the instructions and who fails to come to regular follow-ups during and after the study

3.8 Variables of the Research

3.8.1 Independent variable

Time-Restricted Eating 8 hours per day for 12 weeks (about 3 months)

3.8.2 Dependent variables

3.8.2.1 Psoriasis Area and Severity Index (PASI) score

3.8.2.2 Dermatology Life Quality Index (DLQI) score

3.8.2.3 Pittsburgh Sleep Quality Index (PSQI) score

3.8.2.4 Body Weight and BMI

3.8.2.5 Waist Circumference

3.8.2.6 Patient's Satisfaction score

3.8.2.7 Adverse effects

3.9 Materials and Methods

3.9.1 Documents including the detailed instructions of Time-Restricted Eating

3.9.2 Smartphone application, "Intermittent Fasting 16:8" for iPhones and "Fasting: Intermittent Fasting" for Android devices to monitor the daily eating and fasting windows

3.9.3 Pittsburgh Sleep Quality Index (PSQI) Questionnaires containing 19 items

3.9.4 Dermatology Life Quality Index (DLQI) Questionnaires including 10 items

3.9.5 Weighing machine with Height measurement from PROGRESS® company

3.9.6 Measuring tape for weight circumference

3.9.7 Volunteers profile record

3.9.8 Informed consent form

3.9.9 Side effect assessment form

3.9.10 PASI scoring form on erythema, indurations, and desquamation for independent dermatologists

3.9.11 High-resolution camera to record the skin lesions for assessing PASI score

3.9.12 Patients' satisfaction score sheet for participants

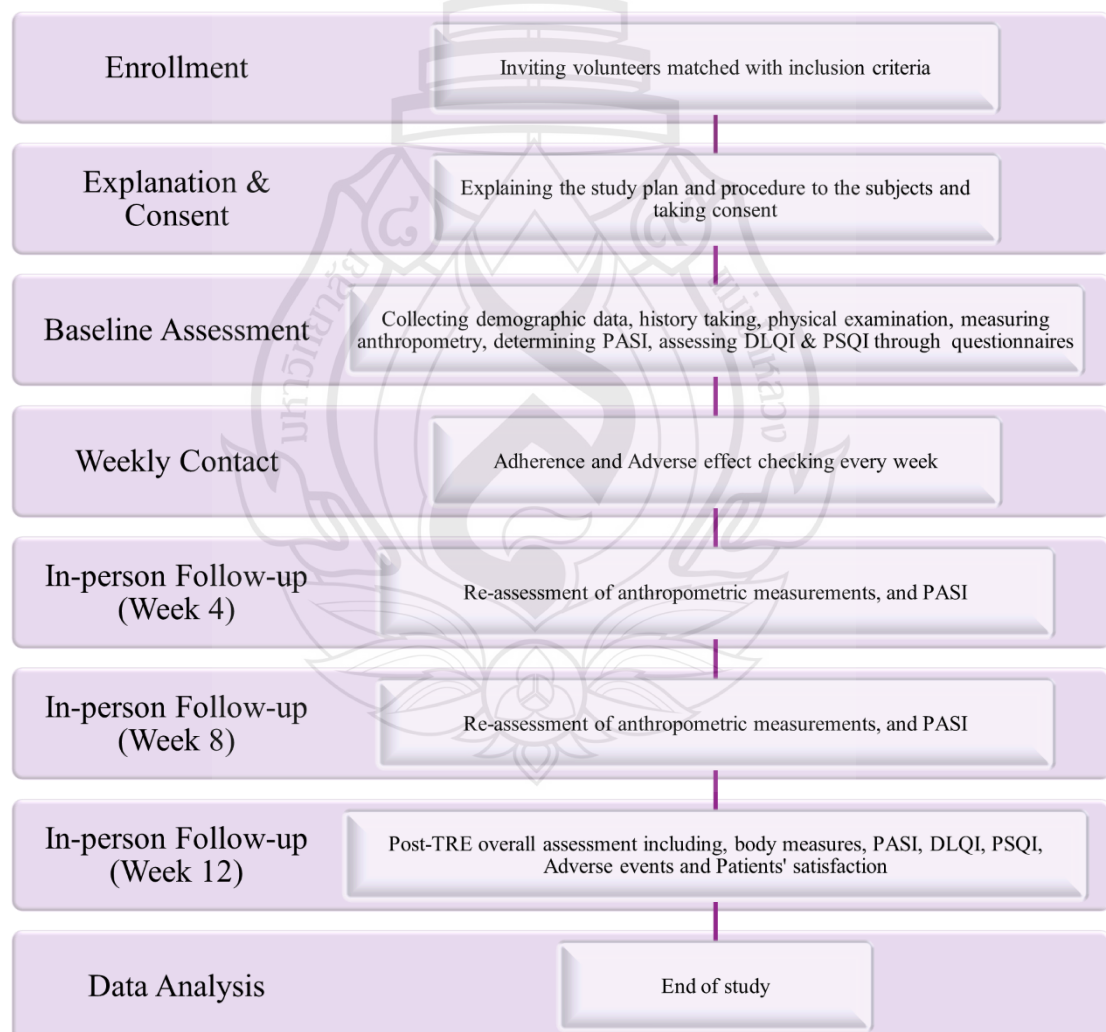


Figure 3.2 Outline of the study

3.10 Study Procedures

3.10.1 Preparation of the participants

3.10.1.1 Patients who meet even one of the exclusion criteria will not be allowed to participate in the study. Patients will be recruited based on the inclusion criteria.

3.10.1.2 The researcher will explain the research's aim and objective, detailed procedures, advantages, and expected side effects of the treatment to the patients. After clearly understanding the rules to follow and the results to expect at the end of the intervention, the subjects must sign a written informed consent form agreeing that they have volunteered to participate in the research according to their wills and that their pre- and post-intervention parameters and photographs can be distributed to the public.

3.10.1.3 Detailed history-taking concerning the patients' disease will be done.

3.10.1.4 Demographics of the patients will be collected in detail.

3.10.1.5 The photograph of the lesions will be taken before the treatment, 4th, 8th, and 12th week respectively using the Fujifilm XL100 digital camera.

3.10.1.6 The dermatologist will be consulted to confirm the PASI score of each patient by looking at the photos of the skin lesions and the body surface area involved.

3.10.1.7 The concepts of PSQI score and DLQI score will be explained to the participants before starting the intervention, and the answered responses will be recorded by the researcher.

3.10.1.8 The contact numbers of the patients will be requested to deliver reminder messages and calls about eating and fasting windows to ensure compliance and progress.

3.10.1.9 The researcher's contact number will be provided to each participant so that they can notify the researcher about the timing of daily first and last meals and some adverse events.

3.10.1.10 The participants will be provided with a transportation fee of 200 baht per follow-up visit, that is at Weeks 4, 8, and 12.

3.10.2 Instruction for Time-Restricted Eating

3.10.2.1. Intervention

To test the study objectives, a 12-week TRE single-arm clinical trial will be conducted. During the planned 16-hour fasting window, all participants will be requested to refrain from consuming any calories, but during the eating window, they are free to consume as much as they desire. The participants can select any of the following fasting schedules: 4 p.m. to 8 a.m., 5 p.m. to 9 a.m., 6 p.m. to 10 a.m., or 7 p.m. to 11 a.m.; however, they must follow their chosen schedule for the whole 12-week period.

The fasting window will be gradually increased, with the first week acting as a preparatory and training period because it will be difficult to restrict the eating window suddenly to only 8 hours per day, and the participants will need to practice fasting habits step by step. Fasting for 12 hours a day is started on Days 1 and 2, and it is extended to 13 hours a day on Days 3 and 4. Then on Days 5 and 6, the window for fasting will be extended to 14 and 15 hours, respectively. Participants can transition into the 16-hour fasting zone starting on Day 7. When they are fasting, they will be urged to stay hydrated. There will be no dietary limits on the quantity or kinds of food they may eat within the 8 hours.

At the baseline visit, participants will receive instructions on how to follow the TRE protocol to encourage adherence to the intervention. Participants will leave this session with leaflets that outline what is allowed (water, unsweetened teas) and what is not allowed (any calorie-containing food or drink, such as coffee creamer, sweet teas, alcohol, and snacks) to eat or drink during fasting windows.

The participants will also be given instructions on how to record the times they first and last ingest calories each day using a mobile phone Fasting Tracker application, named “Fasting: Intermittent Fasting 16:8”.

Each participant will receive weekly contact from the researcher, who will also monitor adverse events, encourage adherence, go over the protocol, and offer support for any problems encountered during the intervention. During the communications, questions on daily activities, alterations to regular routines, and any

changes in health will be asked. Throughout the trial, adherence and adverse events will be routinely monitored, and participant feedback will be obtained directly using an intervention-specific interview guide at various intervals.

Responses and remarks from participants will be recorded. Figure 3.3 lists the questions that will be asked during each conversation.

3.10.2.2 Adherence

The eating time log from the smartphone fasting tracker app will be used to estimate participants' self-reported adherence to the research regimen. If a participant fasted for 14–16 hours a day from weeks two through twelve of the intervention, they would be deemed an adherent. All volunteers must adhere to the prescribed treatment protocols for the whole 12-week research study.

3.10.2.3 Adverse Effect Recording

Every volunteer will receive a side effect assessment form to document any unwanted effects they may encounter. If the volunteers experience intolerable negative effects, they must inform the researcher and heed their advice on whether to continue or stop TRE and what steps to take later.

3.10.2.4 Follow up

A follow-up appointment will be required of the participants once every four weeks to assess the PASI score, take photos of skin lesions, obtain anthropometric measurements, and identify any issues or unfavorable effects of the intervention.

3.11 Outcomes Measurement and Data Collection

3.11.1 Clinical Evaluation

3.11.1.1 Psoriatic Area and Severity Index (PASI) score

The PASI score will be used in this study to gauge the degree and severity of psoriasis. The PASI score is a reliable measure of psoriasis severity and a patient's response to treatment.¹⁸⁴ It generates a score in the range of 0 to 72. It integrates the evaluation of 4 body areas: the head and neck, trunk, upper limbs, and lower limbs. Three signs—erythema, thickness/induration, and desquamation/scaling—are used to determine the severity of the lesions within each location. Each sign is rated on a five-

point scale. Lastly, a formula is used to compute the PASI score (Figures 3.4 and 3.5),⁹ a PASI score of 5 to 10 is regarded as a moderate disease, and a score over 10 indicates a severe one.¹⁸⁷

Score	0	1	2	3	4	5	6
Erythema	none	mild	moderate	severe	very severe	—	—
Induration							
Desquamation							
True Area (%)	0	1-9	10-29	30-49	50-69	70-89	90-100

Head (H)	Score		
Erythema		□	
Induration		□	
Desquamation		□	
Sum		□ □	
x Area		□ □	
=		□ □	
x 0.1 =		□ . □	

Lower Limbs (LL)	Score		
Erythema		□	
Induration		□	
Desquamation		□	
Sum		□ □	
x Area		□ □	
=		□ □	
x 0.4 =		□ . □	

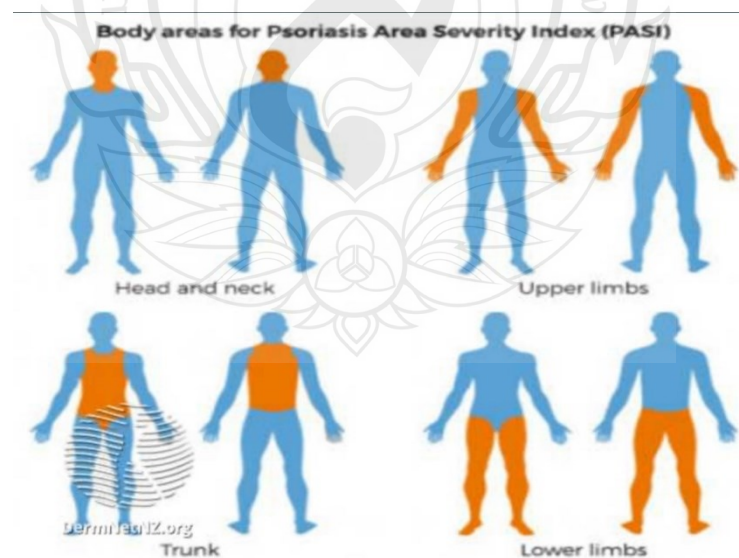
Trunk (T)	Score		
Erythema		□	
Induration		□	
Desquamation		□	
Sum		□ □	
x Area		□ □	
=		□ □	
x 0.3 =		□ . □	

Upper Limbs (UL)	Score		
Erythema		□	
Induration		□	
Desquamation		□	
Sum		□ □	
x Area		□ □	
=		□ □	
x 0.2 =		□ . □	

$$\text{PASI} = (\text{H}) \square . \square + (\text{T}) \square . \square + (\text{UL}) \square . \square + (\text{LL}) \square . \square = \square . \square$$

Source⁹

Figure 3.3 Psoriasis area and severity index (PASI) score assessment (H, head; LL, lower limbs; T, trunk; UL, upper limbs)



Source²⁸

Figure 3.4 Body areas for PASI scoring



Source²⁸

Figure 3.5 Severity scoring of erythema, induration and desquamation for PASI

Thus, in this study, the participants' PASI scores will be evaluated at baseline, Week 4, Week 8, and Week 12. The PASI scores will be assessed 1-3 days prior to the start of the TRE and 1-3 days following the 12-week TRE by an independent Dermatologist. To compare the PASI changes between pre- and post-TRE intervention, photos of the skin lesions will be taken at each evaluation period by using the Fujifilm X-T100 Camera.

3.11.2 High-resolution Camera to Record the Skin Lesions

The FUJIFILM X-T100's natural skin tone, exquisite color reproduction, minimal noise in low light, and superior edge-to-edge resolution are all necessary to make every aspect of the images appear exceptional. An APS-C sized picture sensor, which is 14 times larger than the sensor used in traditional smartphones, is included with the Fujifilm X-T100. This is crucial for taking higher-quality pictures in dim lighting. (<https://fujifilm-x.com/global/products/cameras/x-t100/>).



SPECIFICATIONS		
Model Name	FUJIFILM X-T100	
Number of effective pixels	24.2 million pixels	
Image sensor	23.5mm×15.7mm (APS-C) CMOS with primary color filter	
Sensor Cleaning system	Ultra Sonic Vibration	
Storage media	SD Card (≤2GB) / SDHC Card (≤32GB) / SDXC Card (≤256GB) UHS-I*	
File format	Still image	JPEG (Exif Ver 2.3*) 14bit RAW (RAF-format) / RAW+JPEG (Design rule for Camera File system compliant, DPOF-compatible)
	Movie	Movie File Format: MOV Movie Video Compression: H.264 Audio: Linear PCM Stereo
Number of recorded pixels	L: (3:2)6000×4000 (16:9)6000×3376 (1:1)4000×4000 M: (3:2)4240×2832 (16:9)4240×2384 (1:1)2832×2832 S: (3:2)3008×2000 (16:9)3008×1688 (1:1)2000×2000	
Lens mount	FUJIFILM X mount	
Sensitivity	Standard Output	AUTO1 / AUTO2 / AUTO3 (up to ISO6400) / ISO200 to 12800 (1/3 step)
	Extended output	ISO100 / 25600 / 51200
Exposure control	TTL 256-zones metering, Multi / Spot / Average	
Exposure mode	P (Program AE) / A (Aperture Priority AE) / S (Shutter Speed Priority AE) / M (Manual Exposure)	
Exposure compensation	-5.0EV ~ +5.0EV, 1/3EV step (movie recording: -2.0EV ~ +2.0EV)	
Face/Eye Detection	Yes	
Shutter type	Focal Plane Shutter	

Source Fuji Flim X Global

Figure 3.6 FUJIFILM X-T100 camera and its specifications

3.11.3 Dermatology Life Quality Index (DLQI)

A popular quality-of-life measure used specifically in dermatology is DLQI. This 10-item test evaluates six distinct factors that could have an impact on quality of life.³¹ These elements include daily activities, recreation, work and academic performance, emotional states and symptoms, interpersonal interactions, and treatment.³¹ Each of the ten questions has a score ranging from 0 (not at all) to 3 (very much). The total DLQI is determined by adding the scores of all the questions, which yields a number between 0 and 30.⁶⁴ More impairment to quality of life corresponds with higher scores. This questionnaire has also received the formal permission of the developers to translate into Thai and has already been validated and widely used in Thailand.¹⁸⁸

Table 3.1 DLQI Scores and Interpretation

DLQI Score	Interpretation
0-1	No effect
2-5	Small effect
6-10	Moderate effect
11-20	Very large effect
21-30	Extremely large effect

Source ¹²⁰

Therefore, DLQI will be assessed in the participants at the baseline and at the end of the intervention to identify any changes after 12 weeks of TRE.

3.11.4 Pittsburgh Sleep Quality Index (PSQI)

With the Thai-validated version of the PSQI, sleep quality will be evaluated. The Thai-PSQI is comparable to the original English version and is a viable and reliable measure for screening and recognizing the existence of serious sleep disorders.¹⁸⁹ The seven factors that are taken into consideration are subjective sleep quality, sleep latency, duration, habitual sleep efficiency, sleep disturbances, usage of sleep drugs, and dysfunction of the day after throughout the previous month. The global PSQI score ranges from 0 to 21, with each component being evaluated from 0 to 3. Poorer sleep quality is indicated by higher scores. A cutoff point for inadequate sleep quality was established as a PSQI score of ≥ 5 .¹¹²

Participants will be asked to complete the PSQI questionnaires twice: once before the commencement of TRE and once after it has ended, as this study will also look at how TRE affects sleep quality.

3.11.5 The Weighing Machine and Measuring Tape

Evaluation of the efficacy of Time-Restricted Eating for 8 hours per day by measuring the weight, height, BMI, and Waist circumference before starting the 12-week TRE period, during the 4th week, 8th week, and lastly, after the 12th week.

The weighing scale that will be utilized in the study is from PROGRESS^o Healthcare Pte Ltd which was established in 1968 to supply medical, dental, and scientific devices. The scale has a large round dial and a clear screen that is easy to

read. When a person stands on it, the pointer will go to the corresponding reading, the weight limit being 120 kilograms. There is also an aluminum alloy height measuring rod which is retractable, height adjustable, with scales ranging from 70 to 190cm. The base of the machine is also stable and made of heavy-duty steel plate, non-shaking, and comfortable. The scale has professional-grade reliability, accuracy, and ease of use. When standing, the participants need to be empty-handed, stand barefoot on the mechanical scale placing both upper limbs dangling on each side of the body to ensure the best measurement results.

According to the World Health Organization (WHO), it is suggested to measure the waist circumference in the horizontal plane midway between the lowest ribs and the iliac crest using the measuring tape. According to the WHO STEPS protocol, the tape should fit snugly around the torso without being too tight. The subject's position during the test has an impact on the measurement's accuracy. In order to ensure that the lungs are at their functional residual capacity at the end of a normal expiration, the WHO STEPS protocol advises that the person stand with their arms at their sides, their feet close together, and their weight evenly distributed across their feet.¹⁹⁰



Source ¹⁹¹

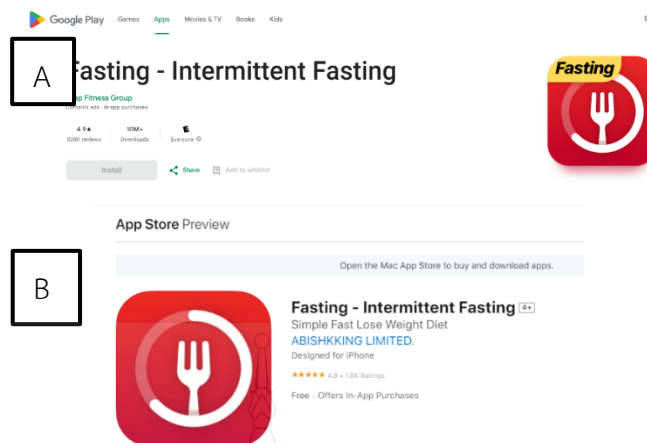
Figure 3.7 The weighing scale that will be used

3.11.6 Fasting Tracker Mobile Application

This fasting tracker mobile application, named “Fasting: Intermittent Fasting” is compatible with both iOS and Android systems. With ratings of 4.8 and 4.9 stars out of 5 on the Google Play Store (<https://play.google.com/store/apps/details?id=bodyfast.zero.fastingtracker.weightloss&hl=en&gl=US>) and Apple’s App Store (<https://apps.apple.com/us/app/intermittent-fasting-16-8/id1498018285>), this well-known fasting app is trusted by users worldwide. Although there are some in-app purchases, the free version itself is very user-friendly and sufficient for this study. Most of the users have given great reviews of this application. One of the preferred features is that it tells the users what fasting stage they are in and gives a brief description of what their body is going through. In addition, on most days, it displays stories on the benefits of fasting, the difference between physical and emotional hunger, how to stay consistent, how to lose weight efficiently, and be healthy, etc. It also helps with tracking how much water the users have drunk and reminds them to drink water at regular intervals, which would also help relieve the dehydration-induced headache during fasting.

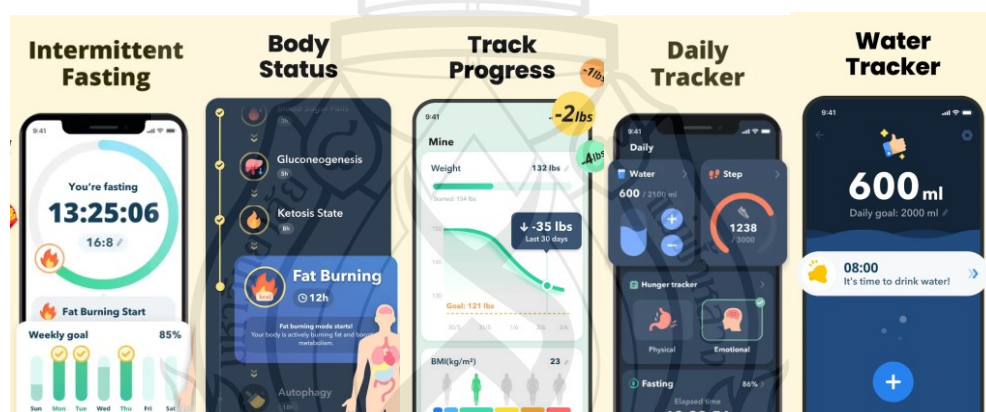
The features of this fasting application are (<https://apps.apple.com/us/app/intermittent-fasting-16-8/id1498018285>)

1. Timer: Set the timer to begin reminding users as they proceed through the plan.
2. Statistics: Users' goals, weight trends, emotions, etc. are all tracked via intuitive graphs.
3. Custom: Establish the objective and modify the time for eating and fasting.
4. Check Status: Be aware of your body's condition and what is going on inside it.
5. using only one click, you may start or stop your fast using Smart Tracker. Keep track of how long you fast automatically on graphs.
6. Learn: Answer frequently asked topics with articles and advice based on science.



Source ^{192, 193}

Figure 3.8 The fasting tracker mobile application which is compatible with both (A) Android and (B) iOS systems



Source ^{192, 193}

Figure 3.9 The features of “Fasting: Intermittent Fasting” mobile application

3.11.5 Patients’ Satisfaction Assessments

Once the intervention has concluded, patients will be asked to rate their level of satisfaction with the intervention using the following grading scales (0–3) for each of the four areas:

0 = Unsatisfied, No improvement in disease severity, life quality, sleep quality, and weight reduction

1 = Somewhat satisfied, Slight improvement in disease severity, life quality, sleep quality, and weight reduction

2 = Moderately satisfied, Visible improvement in disease severity, life quality, sleep quality, and weight reduction

3 = Very satisfied, Significant improvement in disease severity, life quality, sleep quality, and weight reduction

3.11.6 Assessment of Adverse Events of TRE

The patients will be provided with side effect assessment form since the start of intervention, and they will have to note down the symptoms of unfavorable effects such as hunger, fatigue, insomnia, irritability, decreased concentration, nausea, constipation and headaches throughout the TRE period. The incidence of all identified adverse effects during the whole study will be evaluated collectively.

In the study by Shalabi H et al.¹⁸⁸ on intermittent fasting in the Saudi population, participants most frequently reported headache and fatigue as their symptoms (Figure 3.8).

Table 3.2 Symptoms within the first month of adopting an intermittent fasting diet

Symptoms	Mild	Moderate	Severe	Not sure	Not at All
Headache	53 (36.1%)	26 (17.7%)	11 (7.5%)	17 (11.6%)	40 (27.2%)
Mood swings	46 (31.3%)	24 (16.3%)	15 (10.2%)	19 (12.9%)	43 (29.3%)
Palpitations	24 (16.3%)	18 (12.2%)	11 (7.5%)	16 (10.9%)	78 (53.1%)
Fever	10 (6.8%)	4 (2.7%)	4 (2.7%)	10 (6.8%)	119 (81%)
Flu	18 (12.2%)	3 (2%)	7 (4.8%)	11 (7.5%)	108 (73.5%)
Low Blood Sugar	18 (12.2%)	15 (10.2%)	9 (6.1%)	26 (17.7%)	79 (53.7%)
Lethargy	41 (27.9%)	34 (23.1%)	25 (17%)	4 (2.7%)	43 (29.3%)
Constipation	29 (19.7%)	19 (12.9%)	9 (6.1%)	15 (10.2%)	75 (51%)
Dizziness	41 (27.9%)	25 (17%)	16 (10.9%)	9 (6.1%)	56 (38.1%)
Vomiting	16 (10.9%)	6 (4.1%)	4 (2.7%)	8 (5.4%)	113 (76.9%)
Dehydration	27 (18.4%)	18 (12.2%)	5 (3.4%)	8 (5.4%)	89 (60.5%)
Bloating	17 (11.6%)	10 (6.8%)	9 (6.1%)	15 (10.2%)	96 (65.3%)
Polyuria	29 (19.7%)	25 (17%)	14 (9.5%)	15 (10.2%)	64 (43.5%)

Source ¹⁹⁴

3.12 Data Analysis

For analysis, the data will be anonymized and entered into the statistical package of social sciences (SPSS), version 20 on a personal computer.

The application of inclusion and exclusion criteria will establish patients' eligibility for this study, and patient data will be analyzed confidentially. The analysis will be done on the study trial outcomes from Mae Fah Luang University Hospital, Bangkok.

3.12.1 Descriptive statistics

3.12.1.1 Descriptive statistical analysis will be used to capture the general demographic information of the participants, including means, medians, modes, percentages, and standard deviations. If the data is continuous, it will be described using the average mean and standard deviation. If data are viewed as counting numbers, descriptive statistics will be used to characterize the data in terms of frequency and percentage.

3.12.1.2 Subjects' adverse effects and satisfactory scores will also be analyzed by descriptive statistical analysis

3.12.2 Inferential statistics

3.12.2.1 Comparison of the mean of the PASI score values, body weight, and waist circumference values from baseline to each follow-up visit at the 4th, 8th and 12th weeks will be assessed by using repeated measures analysis of variance (repeated measures ANOVA test).

3.12.2.2 To compare the pre- and post-TRE impacts on DLQI, and PSQI, Paired t-test will be used.

3.12.2.3 The significance level will be set at p-value <0.05.

Table 3.3 Types of statistical tests to be used in the study

No.	Variables	Times	Test to be used
1.	PASI score	4 times	Repeated Measures ANOVA
2.	Body Weight	4 times	Repeated Measures ANOVA
3.	Waist Circumference	4 times	Repeated Measures ANOVA
4.	DLQI score	2 times	Paired t-test

Table 3.3 (continued)

No.	Variables	Times	Test to be used
5.	PSQI score	2 times	Paired t-test
6.	Patients' Satisfaction Score	1 time	Descriptive analysis
7.	Adverse Effects	1 time	Descriptive analysis

3.13 Ethical Consideration

The Good Clinical Practice (GCP) guidelines, which include safeguarding the safety and effectiveness of newly developed compounds, defining the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors, and protecting human rights as a subject in clinical trials, will be strictly adhered to in this study. The following factors should be taken into account for general comprehension:

3.13.1 The objective, methodology, and potential negative effects of the study are all fully understood by the volunteers.

3.13.2 Prior to the study, volunteers agree to complete an informed consent form. They will not suffer any consequences if they decide to leave the research at any point.

3.13.3 There is no cost for this research. The subjects and the researcher have no conflict of interest.

3.13.4 In any event, the researcher will assume full responsibility for the participants' care to the greatest extent practicable.

3.13.5 The information provided the volunteers will all be highly confidential.

3.14 Study Approval Statement

The Mae Fah Luang Research Ethics Committee evaluated and approved this study protocol (approved EC protocol code: 24134-20). Every technique was used in compliance with the applicable rules and regulations.

CHAPTER 4

RESULT

4.1 General Characteristics of the Subjects

Table 4.1 Baseline characteristics of subjects (n=18)

Demographic Characteristics	n=18
Age (years), Mean $\pm$ SD	41.44 $\pm$ 9.21
Age Range (years)	
30-39	9
40-49	7
50-60	2
Disease Duration (years), Mean $\pm$ SD	8.86 $\pm$ 6.7
Disease Duration Range (years)	
1 to 5 years	8
6 to 10 years	5
>10 years	5
Gender	
Male	11
Female	7
Current Psoriasis Treatments Received	
Topical Treatment Only	9
Topical Treatment + Phototherapy	9

In accordance with the inclusion criteria, twenty-two participants in total were recruited. Unfortunately, four of them were unable to continue participating in the study until the end due to personal reasons, so they had to be excluded, leaving just 18 participants for the entire 12-week study period.

Each individual's baseline attributes are listed in Table 4.1. The findings show that 18 patients had plaque-type psoriasis, with varying degrees of chronicity, from less

than a year to five years to more than ten years. The sample is primarily composed of younger to middle-aged people, with a mean age of 41.44 ± 9.21 , which may represent the typical age range when psoriasis significantly influences quality of life, even if the gender distribution is more male ($n=11$) than female ($n=7$). In terms of the present course of treatment, half of the subjects had topical therapy alone, while the other half received both topical therapy and phototherapy, evening out the treatment effect.

Table 4.2 Baseline clinical characteristics of subjects ($n = 18$)

Baseline Clinical Characteristics	n = 18
Baseline PASI Score, Mean $\pm$ SD	9.21 ± 7.69
Baseline Psoriasis Severity	
Mild (PASI 0-5)	6
Moderate (PASI 6-10)	6
Severe (PASI >10)	6
Baseline Body Weight in kg, Mean $\pm$ SD	81.18 ± 13.71
Baseline BMI, Mean $\pm$ SD	28.86 ± 3.63
Baseline Waist Circumference, Mean $\pm$ SD	93.61 ± 13.37
Baseline PSQI Score, Mean $\pm$ SD	7.06 ± 2.92
Baseline Sleep Grading	
Good sleep qualities (PSQI 0-5)	5
Mild sleep difficulties (PSQI 6-10)	11
Moderate sleep difficulties (PSQI 11-15)	2
Severe sleep difficulties (PSQI 16-21)	0
Baseline DLQI Score, Mean $\pm$ SD	7.17 ± 4.71
Baseline QOL Grading	
No effect (DLQI 0-1)	1
Small effect (DLQI 2-5)	9
Moderate effect (DLQI 6-10)	3
Very large effect (DLQI 11-20)	5
Extremely large effect (DLQI 21-30)	0

The average Psoriasis Area and Severity Index (PASI) score, as reported in Table 4.2, is 9.21 (SD = 7.69). Mild, moderate, and severe cases of psoriasis were equally distributed in severity. The study's generalizability is strengthened by this even distribution, which ensures representation across all severity levels.

The study group includes both overweight and centrally obese patients, as evidenced by the mean baseline body weight of 81.18 kg (SD = 13.71), mean body mass index (BMI) of 28.86 (SD = 3.63), and mean waist circumference of 93.61 cm (SD = 13.37).

The mean score for sleep quality as determined by the Pittsburgh Sleep Quality Index (PSQI) was 7.06 (SD = 2.92). With 5 participants reporting good sleep quality and 2 having moderate sleep issues, the majority of participants (n=11) had mild sleep difficulties. There were no reports of serious sleep problems.

For life quality, the Dermatology Life Quality Index (DLQI) showed a mean baseline score of 7.17 (SD = 4.71). Nine of the 18 participants perceived psoriasis to have a minor effect on their quality of life, whereas 3 and 5 patients reported moderate to very large effects. Only one individual experienced no impact on the quality of life.

4.2 Clinical Evaluation

4.2.1 Primary Outcomes

4.2.1.1 Psoriasis Area and Severity Index (PASI) for Psoriasis Severity

PASI scores were recorded at baseline, week 4, week 8, and week 12. The analysis utilized repeated measures ANOVA to assess the differences in PASI scores across the different time points. The scores showed a significant decrease over the 12 weeks, with the mean PASI scores at week 4 being 7.42 (SD = 6.07), week 8 at 6.36 (SD = 5.66), and week 12 at 6.00 (SD = 6.68). The assumption of sphericity was violated, according to Mauchly's test ($\chi^2 = 19.946$, $p = 0.001$). Consequently, the Greenhouse-Geisser correction ($\epsilon = 0.713$) was applied. The results showed a statistically significant effect of time on PASI scores, $F(2.139, 36.370) = 12.159$, $p < 0.001$, with a substantial effect size (partial $\eta^2 = 0.417$). This finding indicates that the mean PASI scores differed significantly across the four time points. Pairwise

comparisons with Bonferroni adjustment revealed significant reductions in mean PASI scores at several time points:

1. PASI scores at Week 4 (7.42) were significantly lower than at Baseline (9.21) (mean difference = 1.78, $p = 0.022$).

2. PASI scores at Week 8 (6.36) were significantly lower than at Baseline (9.21) (mean difference = 2.85, $p = 0.002$) and also significantly lower than Week 4 (7.42) (mean difference = 1.067, $p = 0.031$).

3. PASI scores at Week 12 (6.00) were significantly lower than at Baseline (9.21) (mean difference = 3.21, $p = 0.002$), which is 34.85% reduction. However, the reduction from Week 8 to Week 12 was not statistically significant, suggesting a plateau in PASI improvement during the latter phase of the intervention.

Table 4.3 Means and SDs of PASI score throughout the 12-week TRE period (n = 18)

	Mean PASI	Std. Deviation PASI
Baseline	9.21	7.69
Week 4	7.42	6.07
Week 8	6.36	5.66
Week 12	6.00	6.68

Note $p = 0.003$

Table 4.4 Post-hoc comparison of PASI score (n = 18)

Comparison	Mean Difference	Std. Error	p -value
Baseline vs Week 4	1.783	0.529	0.022
Baseline vs Week 8	2.850	0.626	0.002
Baseline vs Week 12	3.206	0.697	0.002
Week 4 vs Week 8	1.067	0.333	0.031
Week 4 vs Week 12	1.422	0.705	0.358
Week 8 vs Week 12	0.356	0.530	1.000

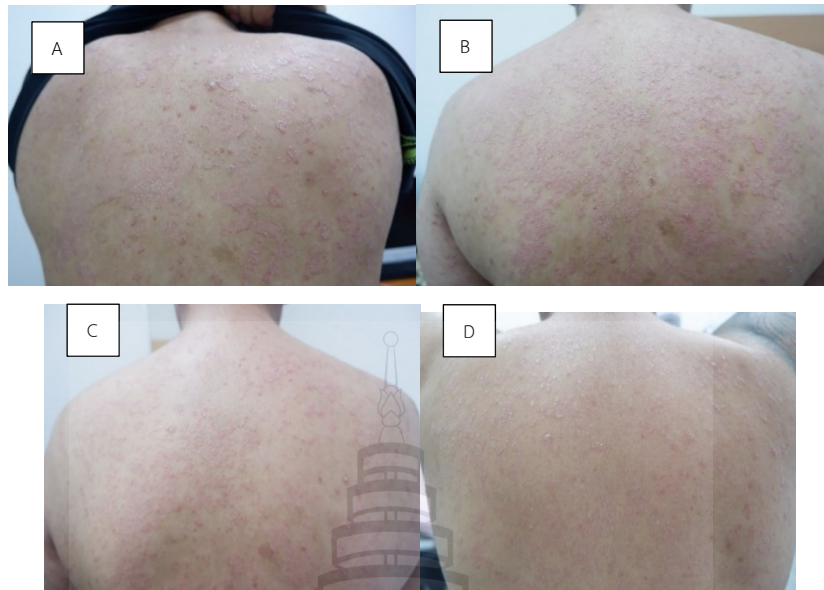


Figure 4.1 Serial changes of Psoriatic skin lesions on the back: (A) Baseline (B) Week 4 (C) Week 8 (D) Week 12



Figure 4.2 Serial changes of Psoriatic skin lesions on the belly: (A) Baseline (B) Week 4 (C) Week 8 (D) Week 12



Figure 4.3 Serial changes of Psoriatic skin lesions on the left malleolus: (A) Baseline (B) Week 4 (C) Week 8 (D) Week 12

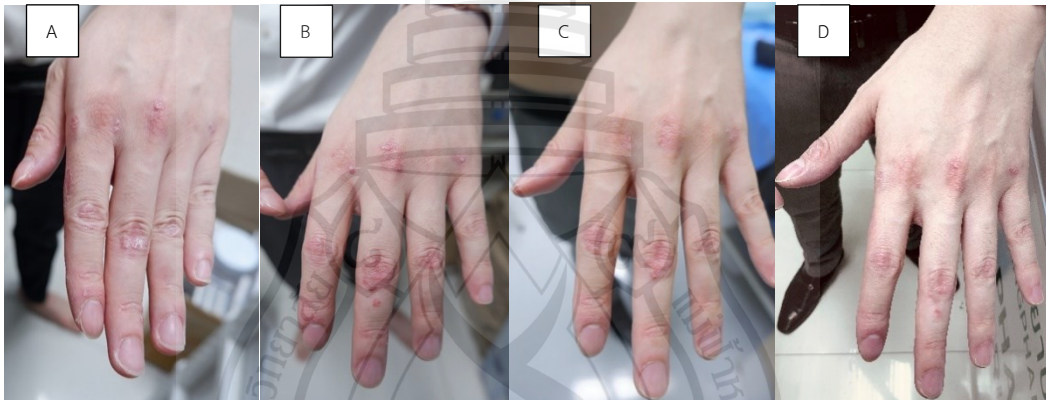


Figure 4.4 Serial changes of Psoriatic skin lesions on the left hand: (A) Baseline (B) Week 4 (C) Week 8 (D) Week 12

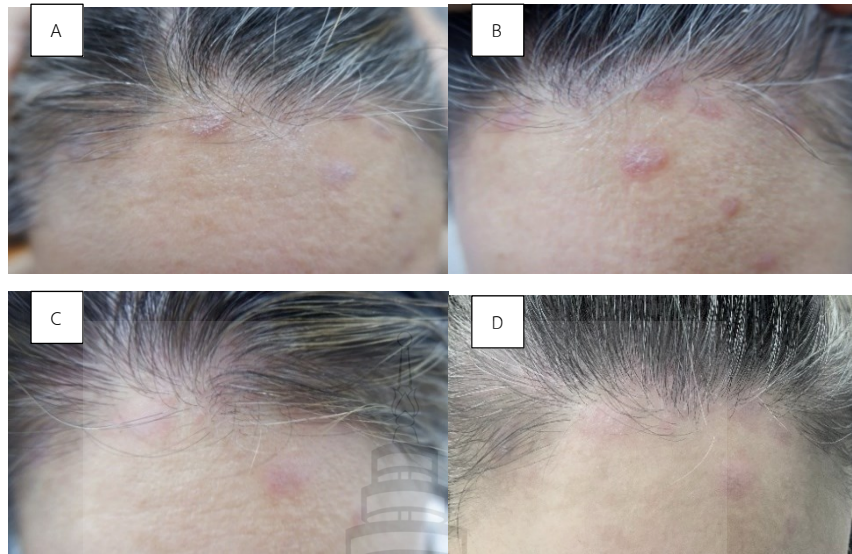


Figure 4.5 Serial changes of Psoriatic skin lesions on the forehead: (A) Baseline (B) Week 4 (C) Week 8 (D) Week 12

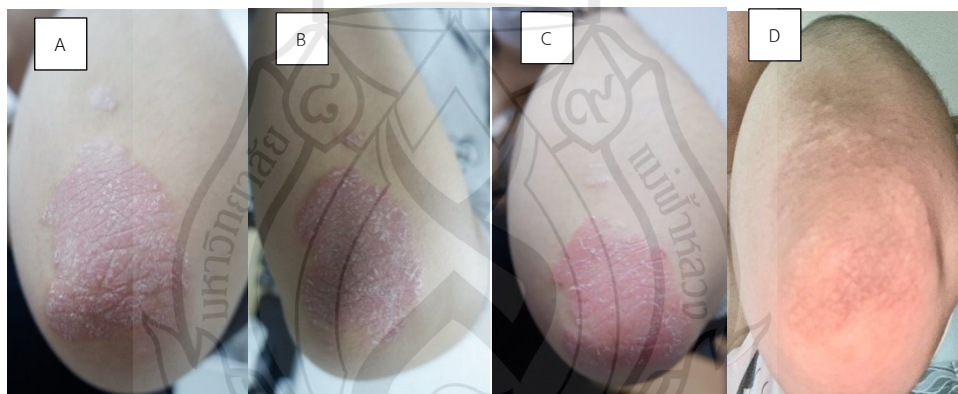


Figure 4.6 Serial changes of Psoriatic skin lesions on the left elbow: (A) Baseline (B) Week 4 (C) Week 8 (D) Week 12

4.2.1.2 Body Weight, Body Mass Index, and Waist Circumference

Analysis of anthropometric data revealed significant reductions across several key indicators following the time-restricted eating (TRE) intervention. Specifically, the mean body weight decreased progressively from a baseline of 81.18 ± 13.71 kg to 76.61 ± 13.79 kg by week 12. This sustained reduction of 4.71 kg over the 12-week period was accompanied by a corresponding decrease in the mean Body Mass Index (BMI) from 28.86 to 27.18, indicating a positive shift towards healthier weight

categories. Moreover, mean waist circumference also exhibited a consistent decline, moving from 93.61 cm at baseline to 89.19 cm at the study's conclusion.

1. Body Weight

To look at how time affected body weight, a repeated-measures ANOVA was used. Mauchly's test revealed that the sphericity assumption had been violated ($\chi^2 = 19.612, p = 0.002$). Thus, the Greenhouse-Geisser correction ($\epsilon = 0.593$) was used. $F(1.78, 44.95) = 44.945, p < 0.001$, and a large effect size (partial $\eta^2 = 0.726$) indicated that time had a statistically significant impact on body weight. Pairwise comparisons with Bonferroni adjustment showed significant weight reductions at each time point compared to baseline, with the most substantial decrease observed between baseline and week 12 (mean difference = 4.57 kg, $p < 0.001$), representing a decline of 5.63%.

1) Body weight at Week 4 (80.05 kg) was significantly lower than at Baseline (81.18 kg), with a mean difference of 1.13 kg ($p = 0.009$).

2) Body weight at Week 8 (78.11 kg) was significantly lower than at Baseline (81.18 kg), with a mean difference of 3.07 kg ($p < 0.001$), and also significantly lower than Week 4 (80.05 kg), with a mean difference of 1.94 kg ($p < 0.001$).

3) Body weight at Week 12 (76.61 kg) was significantly lower than at Baseline (81.18 kg), with a mean difference of 4.57 kg ($p < 0.001$); significantly lower than Week 4 (80.05 kg), with a mean difference of 3.44 kg ($p < 0.001$); and significantly lower than Week 8 (78.11 kg), with a mean difference of 1.50 kg ($p = 0.007$).

All 18 participants achieved weight loss by week 12, with individual reductions ranging from 1.0 kg to 9.0 kg. Notably, 11 participants achieved clinically significant weight loss of $\geq 5\%$, and one of them achieved $\geq 10\%$ weight loss by week 12.

Table 4.5 Means and SDs of Body Weight throughout the 12-week TRE period (n = 18)

	Mean Body Weight	Std. Deviation Body Weight
Baseline	81.18	13.71
Week 4	80.05	13.93
Week 8	78.11	14.04
Week 12	76.61	13.79

Note $p < 0.001$

Table 4.6 Post-hoc comparison of Body Weight (n = 18)

Comparison	Mean Difference	Std. Error	<i>p</i> -value
Baseline vs Week 4	1.128	0.299	0.009
Baseline vs Week 8	3.067	0.395	< 0.001
Baseline vs Week 12	4.567	0.574	< 0.001
Week 4 vs Week 8	1.939	0.279	< 0.001
Week 4 vs Week 12	3.439	0.545	< 0.001
Week 8 vs Week 12	1.500	0.386	0.007

2. BMI

The impact of time on BMI was evaluated using a repeated-measures ANOVA. The assumption of sphericity was violated, according to Mauchly's test ($\chi^2 = 22.179, p < 0.001$). The Greenhouse-Geisser correction ($\varepsilon = 0.559$) was thus used. With a considerable effect size (partial $\eta^2 = 0.697$), the analysis showed that time had a statistically significant impact on BMI ($F(1.68, 28.49) = 39.031, p < 0.001$). Pairwise

comparisons using Bonferroni adjustment demonstrated significant reductions in mean BMI:

1) BMI at Week 4 (28.45) was significantly lower than at Baseline (28.86), with a mean difference of 0.41 ($p = 0.006$).

2) BMI at Week 8 (27.73) was significantly lower than at Baseline (28.86) (mean difference = 1.12, $p < 0.001$) and significantly lower than Week 4 (28.45) (mean difference = 0.71, $p < 0.001$).

3) BMI at Week 12 (27.24) was significantly lower than at Baseline (28.86) (mean difference = 1.62, $p < 0.001$), significantly lower than Week 4 (28.45) (mean difference = 1.21, $p < 0.001$), and significantly lower than Week 8 (27.73) (mean difference = 0.50, $p = 0.020$). These results indicate a consistent and significant reduction in BMI throughout the intervention period, finishing with a mean reduction of 5.61%.

Table 4.7 Means and SDs of BMI throughout the 12-week TRE period (n = 18)

	Mean BMI	Std. Deviation BMI
Baseline	28.86	3.63
Week 4	28.45	3.68
Week 8	27.73	3.70
Week 12	27.24	3.66

Note $p < 0.001$

Table 4.8 Post-hoc comparison of BMI (n = 18)

Comparison	Mean Difference	Std. Error	p-value
Baseline vs Week 4	0.413	0.103	0.006
Baseline vs Week 8	1.124	0.154	< 0.001
Baseline vs Week 12	1.620	0.225	< 0.001
Week 4 vs Week 8	0.711	0.108	< 0.001
Week 4 vs Week 12	1.207	0.207	< 0.001
Week 8 vs Week 12	0.496	0.146	0.020

3. Waist Circumference

Mean waist circumference also significantly decreased throughout the intervention period. It reduced from a baseline of 93.61 cm (SD = 13.37) to 89.25 cm (SD = 12.63) by Week 12.

The influence of time on waist circumference was investigated using a repeated-measures ANOVA. Mauchly's test revealed that the sphericity assumption was violated ($\chi^2 = 12.376, p = 0.030$). As a result, the Greenhouse-Geisser correction ($\epsilon = 0.672$) was used. The findings revealed a strong effect size (partial $\eta^2 = 0.753$) and a statistically significant relationship between time and waist circumference ($F(2.015, 34.251) = 51.727, p < 0.001$). Pairwise comparisons with Bonferroni adjustment revealed significant reductions in mean waist circumference across all measured time points:

1) Waist circumference at Week 4 (92.15 cm) was significantly lower than at Baseline (93.61 cm), with a mean difference of 1.46 cm ($p = 0.001$).

2) Waist circumference at Week 8 (90.33 cm) was significantly lower than at Baseline (93.61 cm), with a mean difference of 3.27 cm ($p < 0.001$), and was significantly lower than at Week 4 (92.15 cm), with a mean difference of 1.82 cm ($p < 0.001$).

3) Waist circumference at Week 12 (89.25 cm) was significantly lower than at Baseline (93.61 cm), with a mean difference of 4.36 cm ($p < 0.001$), significantly lower than at Week 4 (92.15 cm), with a mean difference of 2.90 cm ($p < 0.001$), and was significantly lower than at Week 8 (90.33 cm), with a mean difference of 1.08 cm ($p = 0.021$). Overall, the mean drop of 4.65% was observed.

Table 4.9 Means and SDs of Waist Circumference throughout the 12-week TRE (n = 18)

	Mean Waist Circumference	Std. Deviation Waist Circumference
Baseline	93.61	13.37
Week 4	92.15	13.34
Week 8	90.33	13.10
Week 12	89.25	12.63

Note $p < 0.001$

Table 4.10 Post-hoc comparison of Waist Circumference (n = 18)

Comparison	Mean Difference	Std. Error	<i>p</i> -value
Baseline vs Week 4	1.456	0.296	0.001
Baseline vs Week 8	3.272	0.421	< 0.001
Baseline vs Week 12	4.356	0.504	< 0.001
Week 4 vs Week 8	1.817	0.278	< 0.001
Week 4 vs Week 12	2.900	0.408	< 0.001
Week 8 vs Week 12	1.083	0.319	0.021

4.2.1.3 Sleep Quality and Quality of Life

A paired samples t-test was conducted to evaluate the efficacy of time-restricted eating (TRE) on sleep quality and quality of life in Psoriasis patients (n = 18).

1. Sleep Quality (PSQI)

Sleep quality, assessed by the Pittsburgh Sleep Quality Index (PSQI), demonstrated statistically significant improvement following the TRE intervention, $t(17) = 4.776$, $p < 0.001$, with a 95% confidence interval ranging from 1.18 to 3.04 points.

Mean PSQI score decreased from 7.06 ± 2.92 at baseline to 4.94 ± 2.55 post-intervention, representing a mean reduction of 2.11 points (SD = 1.875, SE = 0.442), representing a 29.89% improvement. The effect size was large (Cohen's $d = 1.126$), indicating substantial clinical significance. When examining the categorical grading distributions, substantial clinical improvements were observed. At baseline, the majority of participants (n = 11) experienced mild sleep difficulties, with 5 reporting good sleep qualities and 2 experiencing moderate sleep difficulties. Following the TRE intervention, this distribution shifted markedly: 13 participants achieved good sleep qualities, only 5 remained in the mild sleep difficulties category, and no participants suffered from moderate or severe sleep difficulties anymore. Overall, 17 participants demonstrated improvement in their PSQI scores, while only one participant experienced a worsening of sleep quality.

Table 4.11 Summary of Changes in Sleep Quality (n = 18)

Outcome	Baseline	Post-TRE	Changes
Good sleep quality	5	13	+8
Mild sleep difficulty	11	5	-6
Moderate sleep difficulty	2	0	-2
Summary of improvement			
Participants Improved			17
Participants Worsened			1
Participants Unchanged			0

2. Quality of Life (DLQI)

Similarly, TRE led to a statistically significant improvement in dermatology-related quality of life as assessed by the Dermatology Life Quality Index (DLQI). Mean DLQI score decreased from 7.17 ± 4.71 at baseline to 5.50 ± 5.26 post-intervention, representing a mean reduction of 1.67 points (23.26%) (SD = 2.169, SE = 0.511). This improvement reached statistical significance, $t(17) = 3.260$, $p = 0.005$, with a 95% confidence interval spanning from 0.59 to 2.75 points. The effect size was medium (Cohen's $d = 0.768$), indicating clinically meaningful improvement.

The categorical distribution of quality-of-life outcomes revealed meaningful shifts in symptom impact. Baseline assessment showed that 9 participants experienced a small effect on quality of life, 5 experienced a very large effect, and 3 experienced a moderate effect, with only one experiencing no effect. Post-intervention, the distribution became more favorable: 5 reported no effect on quality of life, another 5 reported a small effect, 5 more reported a moderate effect, and 3 continued to experience a very large effect. In total, 12 participants showed improvement in their DLQI scores, 5 remained unchanged, and only one participant experienced a worsening in quality-of-life scores.

Table 4.12 Summary of Changes in Quality of Life (n = 18)

Outcome	Baseline	Post-TRE	Changes
No Effect	1	5	+4
Small Effect	9	5	-4
Moderate Effect	3	5	+2
Large Effect	5	3	-2
Summary of improvement			
Participants Improved			12
Participants Worsened			1
Participants Unchanged			5

4.2.2 Secondary Outcomes

4.2.2.1 Side Effect Profile

The study documented thirteen side effects experienced by participants during the TRE intervention. The incidence and distribution of these side effects across the 12-week period are presented below:

Appetite-Related Symptoms

1. Hunger: Hunger manifestation was the most prominent early-stage side effect, affecting 4 participants in Weeks 1-3, declining to 1 participant by Week 4, and resolving completely by Week 5 (total reports: 13).

2. Craving for Food: Food cravings followed a similar but more gradual trajectory. Beginning with several 2 participants at baseline, cravings decreased to 1 by Week 2 and declined to zero reports by Week 5 and remained absent through Week 12 (total reports: 5).

Sleep-Related Outcomes

1. Inability to Sleep: Sleep disturbances showed marked improvement during the intervention. Baseline insomnia was found in 3 participants, the second-highest prevalent symptom. Progressive improvement was observed, with scores declining to 2 (Week 2), then 1 (Weeks 3-5), and ultimately reaching complete resolution (score of 0) by Week 6, which was maintained through Week 12 (total reports: 8).

2. Sleepiness: Sleepiness was reported by 1 participant per week during Weeks 1-3, resolving by Week 4 (total reports: 3).

3. Unadjustable Sleep Schedule: Sleep schedule irregularity, initially was informed by 1 participant, normalized by Week 4, and remained stable through the endpoint (total reports: 3).

Gastrointestinal Symptoms

1. Constipation: Constipation demonstrated a more persistent pattern, with 2 participants affected in Weeks 1-4, reducing to 1 participant in Week 5, resolving by Weeks 6-9, and reappearing in 1 participant during Weeks 10-12 (total reports: 12).

2. Bloating and Belching: These symptoms were absent at baseline but appeared transiently during Weeks 2-3 (only in 1 participant). Complete resolution occurred by Week 4 and was maintained through Week 12 (total reports: 2).

3. Stomachache: Abdominal pain was minimal at baseline (only in 1 participant), and resolved completely by Week 2, remaining absent throughout the remainder of the intervention (total reports: 1).

Cognitive and Energy-Related Symptoms

1. Inability to Concentrate: Concentration difficulties, affecting 1 participant in Week 1, resolved completely by Week 2, and remained resolved throughout the study (total reports: 1).

2. Fatigue: Fatigue was sporadically reported, with isolated cases in Week 1 and Week 4 (total reports: 2).

Dermatological and Systemic Symptoms

1. Dry Skin: Skin dryness was not present at baseline but appeared transiently during Week 2 (only in 1 participant), potentially representing a temporary adaptation response. It was resolved by Week 3 and remained absent through Week 12 (total reports: 1).

2. Fever with Aches and Pains: Systemic symptoms were absent at baseline but appeared transiently at Week 4 and Week 7, in 1 participant respectively, possibly representing intercurrent illness episodes rather than direct intervention effects. These symptoms were absent at all other time points. total reports: 1).

3. Shaking Hands: Tremor was absent at baseline and appeared only once during the intervention period (Week 4, only in 1 participant), resolving spontaneously by Week 5 and remaining absent thereafter, total reports: 1).

The data demonstrate consistent improvement across virtually all symptom categories, with the majority of symptoms showing either complete resolution or substantial reduction. Notably, 10 participants reported no side effects throughout the intervention. The number of asymptomatic participants increased progressively from 10 in Week 1 to 18 in Weeks 7-12, with peak asymptomatic status achieved by Week 7 and maintained through the conclusion of the study.

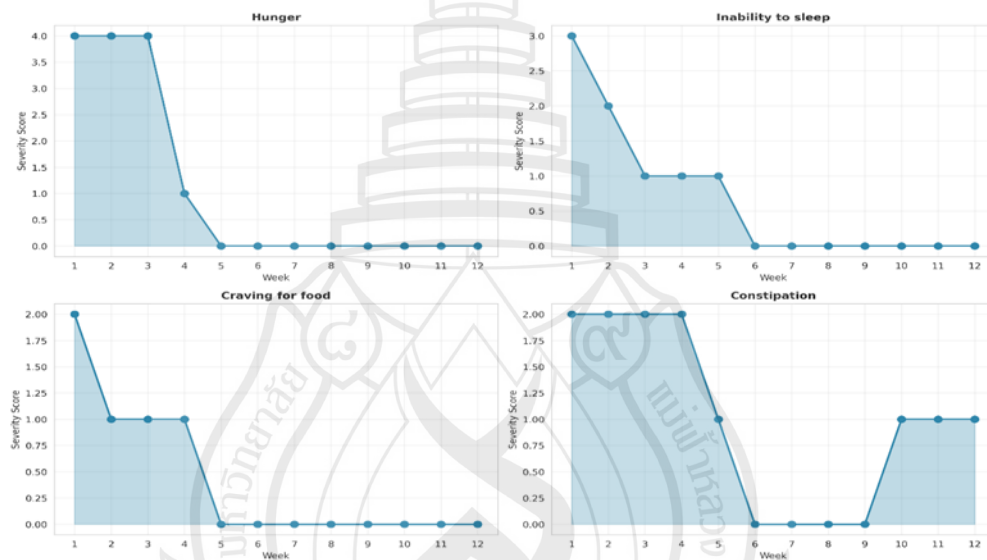


Figure 4.7 Major symptoms during TRE intervention

4.2.2.2 Patients' Satisfaction Level

The mean satisfaction score was 2.22 (SD = 0.548) on a scale from 1 to 3, with 1 being the lowest satisfaction and 3 being the highest. The skewness value (0.159) suggests that the distribution of scores was relatively symmetrical. Table 4.3 presents the frequency distribution for the patient satisfaction categories.

Table 4.13 Frequency Distribution of Patient Satisfaction Levels (n = 18)

Satisfaction Level	Frequency
Somewhat satisfied, Slight improvement	1
Moderately satisfied, Visible improvement	12
Very satisfied, Significant improvement	5

The majority of participants (n=12) were moderately satisfied, reporting visible improvements. Five other patients were very satisfied with significant improvements. Only one participant reported being somewhat satisfied with a slight improvement. Cumulatively, 17 out of 18 patients reported at least moderate satisfaction with the TRE intervention.

4.2.2.3 Willingness to Continue TRE Intervention

Participants were asked about their willingness to continue the TRE intervention. The results are summarized in Table 4.4.

Table 4.14 Frequency Distribution of Willingness to Continue TRE (n = 18)

Willingness	Frequency
No	1
Yes	17

A strong majority of the study population (n=17) expressed a willingness to continue with the TRE intervention, while only one participant was not willing to continue.

4.2.3 Compliance with TRE

Compliance is of immense importance in this study to generate accurate results. The fasting adherence and compliance patterns among 18 participants engaged in a 12-week TRE intervention with a 16:8 protocol (16 hours fasting, 8 hours eating window) demonstrate significant adaptation over time. Across the entire 12-week intervention period, the following statistics characterize the overall fasting behavior:

1. Mean Fasting Hours: 15.86 ± 1.09 hours
2. Median Fasting Hours: 16.00 hours
3. Range: 12 - 20 hours
4. Interquartile Range:
 - 1) 25th Percentile: 15.00 hours
 - 2) 75th Percentile: 16.00 hours

Participants selected their fasting schedule from three different ones based on their lifestyle preferences, as shown in Table 4.5.

Table 4.15 Fasting Periods chosen by the participants (n = 18)

Fasting Period	Number of Participants
7 pm - 11 am	8
6 pm - 10 am	7
5 pm - 9 am	3

The most popular fasting window (7 pm - 11 am) was chosen by nearly half the participants. The 7 pm - 11 am group showed the highest overall compliance and included the top performer (V2). The 6 pm - 10 am choosers demonstrated consistent mid-to-high performance across all participants; those who perform fasting between 5 pm and 9 am had the highest variability, with one exceptional performer (V1) and one struggling participant (V10).

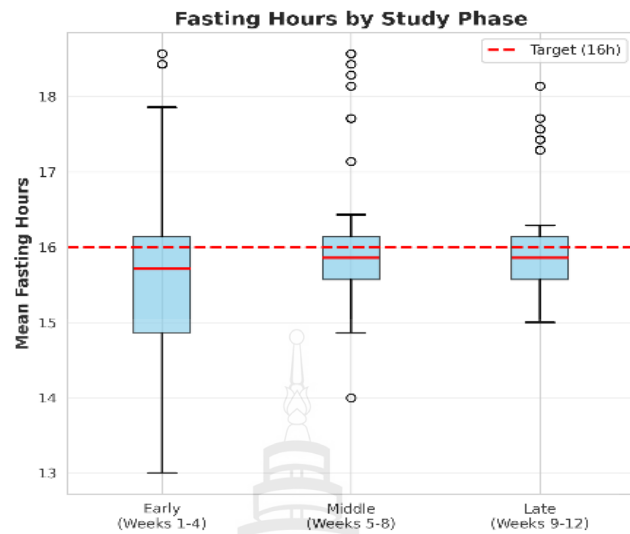


Figure 4.8 Compliance of Fasting (14-16 hours) apart from the earliest week

Compliance is defined as achieving 14-16 hours of fasting on any given day starting from the second week of TRE. According to Figure 4.15 below, all the participants could fast for at least 14.0 hours a day, and the maximum hours of fasting were 18.6 hours. Therefore, it is evident that the participants were able to maintain performance through 12 weeks, producing credible and precise results with no evidence of significant burnout or dropout in the data.

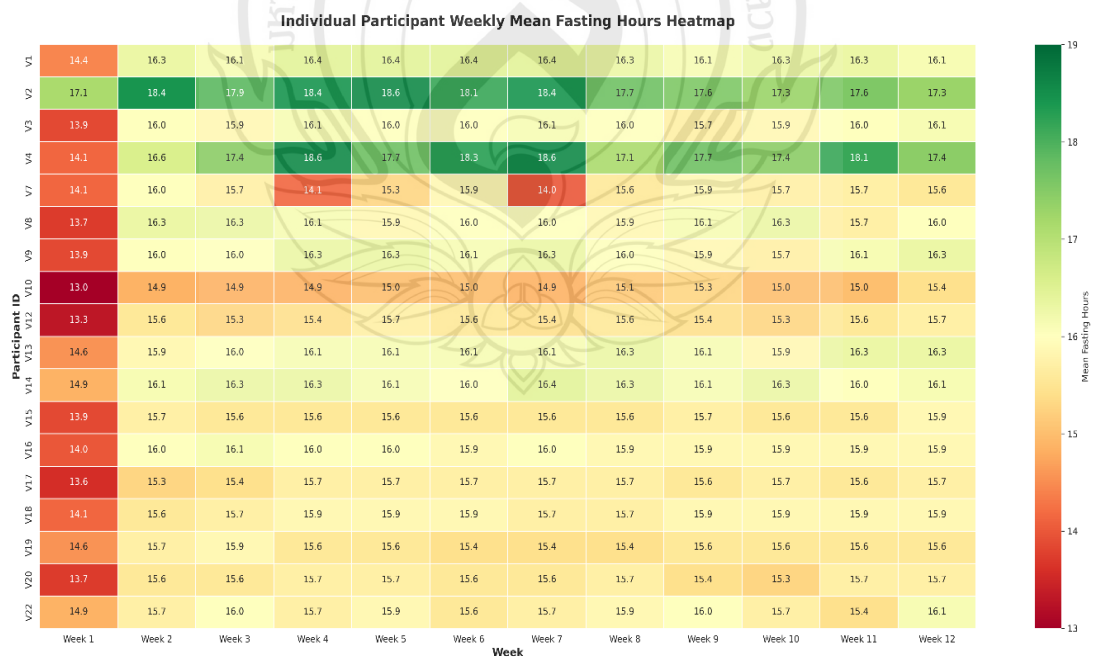


Figure 4.9 Heatmap showing the Weekly Mean Fasting Hours of each participant

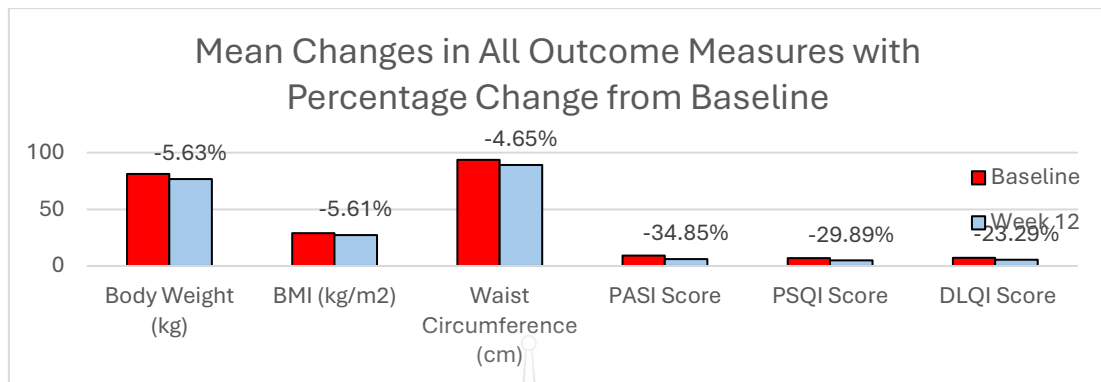


Figure 4.10 Comprehensive Summary of TRE Intervention Outcomes

4.3 Summary of Findings

In summary, this 12-week prospective intervention study demonstrates that time-restricted eating (TRE) produces significant improvements across multiple domains in patients with chronic plaque-type Psoriasis. The key findings include:

1. Progressive and sustained weight loss of 5.63% with
2. Corresponding reduction in BMI (5.61%) and
3. Decrement in waist circumference (4.65%);
4. Significant improvement in psoriasis severity with a 34.82% reduction in PASI scores;
5. Marked enhancement of sleep quality with 17 participants showing improvement; and
6. Meaningful improvements in dermatology-specific quality of life in 12 out of 18 participants.

These results suggest that TRE represents a promising adjunctive therapeutic approach for psoriasis management, addressing not only the cutaneous manifestations but also the metabolic and lifestyle comorbidities commonly associated with this chronic inflammatory condition.

CHAPTER 5

DISCUSSION

5.1 Principal Findings

This 12-week prospective study demonstrates that Time-Restricted Eating (TRE) is an effective, safe, and feasible intervention for improving multiple health outcomes in patients with chronic plaque-type Psoriasis. The intervention resulted in:

1. Substantial reduction in psoriasis severity: Mean PASI reduction of 3.21 points (34.85%) ($p = 0.002$), with 8 out of 18 participants achieving PASI-50 response ($p < 0.001$)
2. Significant weight loss and metabolic improvements: Mean reductions of 4.57 kg in body weight, 1.62 kg/m² in BMI, and 4.36 cm in waist circumference (all $p < 0.001$)
3. Marked improvement in sleep quality: Mean PSQI reduction of 2.11 points (29.89%), with 13 participants achieving good sleep quality post-intervention ($p < 0.001$)
4. Enhanced quality of life: Mean DLQI reduction of 1.67 points (23.29%), with a four-fold increase in participants experiencing no disease impact on quality of life ($p = 0.005$)

These findings provide compelling evidence that TRE represents a promising adjunctive therapeutic approach for psoriasis management, particularly for patients with metabolic comorbidities or those seeking non-pharmacological treatment options.

5.2 Clinical Significance of Anthropometric Changes

The observed mean weight loss of 4.57 kg (5.63%) over 12 weeks is clinically significant and compares favorably with other dietary interventions in psoriasis populations. Non-surgical lifestyle weight loss interventions combining diet and

physical activity generally result in weight reductions of around 2.6 to 2.7 kg in less than 13 weeks; therefore, 4.57 kg weight loss in this study represents a favorable response within this context.¹⁹⁵

In 2022, a retrospective cohort analysis found that patients who were overweight, obese class 1, 2, and 3 had considerably greater chances of getting psoriasis than patients with a BMI < 25.0.¹² The aforementioned assertion is consistent with this TRE trial, where all psoriatic individuals had a baseline mean BMI of 28.86 ± 3.63 , indicating the overweight to obese class 1 status. Following the TRE intervention, that number decreased to 27.24 ± 3.66 , along with an improvement in PASI scores.

In a different study, 29.8% of the dietary intervention group of overweight or obese individuals with moderate-to-severe psoriasis achieved the goal of $\geq 5\%$ weight loss, which corresponded with a significant improvement in Psoriasis severity after a 20-week intervention combining diet and exercise.¹⁹⁶

The American Heart Association defines clinically significant weight loss as $\geq 5\%$ of initial body weight,¹⁹⁷ a threshold met by the majority (n=11) of participants in this study. Importantly, the weight loss was progressive and sustained throughout the 12 weeks, with no evidence of weight regain, suggesting that longer-term interventions could yield even greater benefits. The progressive nature of weight loss across all four time points (baseline, weeks 4, 8, and 12) suggests good adherence and sustainability of the TRE protocol. The study by Jensen et al. (2013) demonstrated that a low-calorie diet resulted in a 15% weight loss and improved PASI scores by approximately 50%,¹⁹⁸ suggesting that greater weight loss may produce more substantial disease improvement.

Numerous studies have demonstrated that treating obese patients by weight loss may significantly improve the pathophysiology of psoriasis. Moreover, the effects of diet management on obese individuals with moderate-to-severe psoriasis similarly showed that the diet-controlling group's mean weight was much lower than the control group's.⁸⁶

The mechanism underlying TRE-induced weight loss likely involves multiple pathways. By restricting the eating window (typically to 8-10 hours), TRE naturally reduces overall caloric intake without explicit calorie counting, which may improve dietary adherence compared to traditional calorie-restriction diets.^{199,200} Additionally, TRE synchronizes food consumption with circadian cycles, potentially enhancing

metabolic efficiency and fat oxidation during the fasting period.^{201,202} A change in metabolism from glucose to ketones produced from fatty acids is encouraged by the extended fasting period (14–16 hours), which may have additional anti-inflammatory advantages related to the pathogenesis of psoriasis.²⁰³

The reduction in waist circumference (4.36 cm or 4.65%) is particularly noteworthy, as it demonstrated the strongest statistical effect among anthropometric measures [$F(3, 51) = 51.727, p < 0.001$]. Insulin resistance is intimately associated with abdominal adiposity, particularly visceral fat, which also secretes pro-inflammatory adipokines like TNF- α , IL-6, and leptin, which are major contributors to metabolic syndrome, type 2 diabetes, and cardiovascular disease.^{204,205} Because visceral fat has a pro-inflammatory effect, it has been associated with increased disease severity, decreased responsiveness to treatment, and a higher prevalence of metabolic comorbidities in psoriasis patients.¹⁹⁸ The targeted reduction in visceral fat through TRE may underlie observed improvements in PASI scores by decreasing systemic inflammation and improving insulin sensitivity.²⁰⁶ Thus, the shrinking of the waist size can lead to less inflammatory process and alleviate the severity of Psoriasis as found in this study.

5.3 Clinical Relevance of PASI Improvement

The mean PASI reduction of 3.21 points (34.85%) represents a clinically meaningful improvement in Psoriasis severity. The achievement of PASI-50, the threshold commonly used to define treatment success in psoriasis trials, in 44.4% of participants is clinically relevant and compares favorably with other lifestyle interventions reported in the literature.^{207,208} Recent studies by Adawi et al. (2019) and Damiani et al. (2019) found that one month of Ramadan fasting (one form of TRE) was associated with reduced Psoriasis severity in some patients showing a decline from 7.46 ± 2.43 to 5.86 ± 2.37 (mean difference: $-1.59, p < 0.0001$) and a drop from 3.54 ± 2.43 to 2.65 ± 2.03 (mean difference: $-0.89 \pm 1.21, p < 0.0001$) respectively.^{7,162} The longer duration of intervention, which lasted 12 weeks, resulted in a higher mean difference between pre- and post-TRE PASI score of 3.21 ± 2.097 in this study.

The improvement trajectory showed the greatest change occurring between baseline and week 8 (30.94% reduction), with a plateau thereafter, suggesting that the major anti-inflammatory effects of TRE may manifest within the first 8 weeks of intervention. This aligns with observed trajectories showing about a 30% reduction in inflammatory markers during this time frame, indicating that the major therapeutic benefits of TRE may occur early in the course of treatment.^{209,210}

A 24-week randomized controlled trial found that obese patients with moderate to severe psoriasis response better to low-dose cyclosporine if a calorie-restricted diet is included in the treatment regimen. The diet intervention group experienced a significantly higher percentage of subjects achieving PASI-75 and 50 at week 24, with the mean weight loss and reduction in waist circumference being 7.0 ± 3.5 kg and 3.5 ± 2.7 cm.¹⁴ According to another study, only about 29% of patients in the control group achieved PASI-75, while approximately 66.7% of obese patients in the diet-controlling group saw a 75% decrease in their PASI score.⁸⁶

Conversely, the absence of PASI-75 or PASI-90 responders in this 12-week study indicates that TRE, as a monotherapy, may not achieve the profound disease clearance seen with biologic agents or systemic immunosuppressants. This suggests that TRE may be most appropriately positioned as an adjunctive lifestyle intervention to enhance the efficacy of conventional therapies, or as a primary intervention for patients with mild to moderate disease who prefer non-pharmacological approaches.^{209,210}

Several mechanisms may explain the observed improvement in psoriasis severity:

1. Reduction in systemic inflammation: Studies have demonstrated that even modest weight loss (5-10%) can significantly reduce inflammatory markers in obese psoriatic patients.^{196,211} In psoriasis specifically, elevated disease-specific cytokines such as TNF, IL-17, and IL-1 β are strongly linked to disease severity and systemic inflammation, and these cytokines correlate with obesity indices including BMI and waist circumference, indicating that adiposity directly modulates systemic inflammation, driving psoriatic plaque formation.²¹² As such, modest weight loss (~5-10%) in obese psoriasis patients can reduce circulating levels of these pro-inflammatory cytokines, thereby improving psoriasis severity. The inflammatory cytokines IL-17 and

TNF- α play key roles not only in psoriatic skin inflammation but also in related systemic comorbidities and are modulated by obesity and weight status.²¹³ Thus, reduction in adiposity decreases the systemic inflammatory burden that drives Psoriatic plaque formation and comorbidities, supporting weight loss as an important intervention in managing psoriasis severity.^{211,214}

2. Metabolic switching and autophagy: The extended fasting periods in TRE induce metabolic switching to ketone body production and activate autophagy, cellular processes that have been shown to reduce inflammation and promote cellular repair.^{215,216} Psoriasis's hyperproliferative keratinocyte phenotype may be normalized with the use of autophagy, which is particularly important in controlling immunological responses.²¹⁷

3. Improvement in insulin sensitivity: Insulin resistance and compensatory hyperinsulinemia, hallmarks of visceral obesity, directly contribute to Psoriatic pathophysiology. Increased levels of insulin as well as insulin-like growth factor-1 (IGF-1) stimulate keratinocyte proliferation, inhibit terminal differentiation, and activate mammalian target of rapamycin (mTOR) signaling—a pathway implicated in psoriatic epidermal hyperplasia.^{218,219} Insulin sensitivity and glucose metabolism have been demonstrated to be improved by TRE, which may help psoriasis indirectly by lowering inflammatory signals.^{220,221}

4. Gut microbiome modulation: Emerging evidence suggests that TRE can beneficially alter the gut microbiome composition, diversity, and functionality, and lead to additional reductions in weight.^{222,223} TRE significantly increased the abundance of probiotic species, including *E. coli*, and species that synthesize short-chain fatty acids, according to a recent randomized controlled trial.²²³ Given the growing recognition of the pathophysiology of psoriasis and the gut-skin axis, microbiome-mediated effects may contribute to disease improvement.^{224,225}

These findings are particularly noteworthy given that obesity and elevated BMI are frequently observed comorbidities in patients with plaque-type psoriasis, potentially exacerbating disease severity and treatment resistance.¹⁹⁴ The parallel improvements in both body weight and PASI scores in this study indicate a synergistic effect of TRE, where weight loss likely contributes to reduced systemic inflammation, which in turn leads to a decrease in psoriasis severity. This observed trend of decreasing

anthropometric parameters and PASI scores is consistent with other studies on TRE, which have similarly reported significant reductions in body weight, BMI, and waist circumference in diverse cohorts.^{162,226} Such outcomes are particularly relevant given the established link between obesity and Psoriasis, where interventions for weight loss have been established to reduce the severity of illness and enhance quality of life.^{208,227} These results suggest that TRE represents a viable and effective non-pharmacological approach for addressing both weight management and disease severity in Psoriasis patients.

5.4 Sleep Quality Improvements and Circadian Biology

The improvement in sleep quality represents one of the most striking findings of this study, with a large effect size (Cohen's $d = 1.126$) and near-universal benefit (94.4% of participants improved). The proportion of participants with good sleep quality increasing from 27.8% to 72.2% post-intervention represents a substantial clinical benefit.

The significant improvement in sleep quality (29.89% reduction in PSQI score) is a notable finding with multiple implications. First, it demonstrates that TRE can effectively realign circadian rhythms in psoriatic patients, who often experience sleep disturbances due to nocturnal pruritus, inflammation, and psychological distress. According to a systematic review done in 2017, the prevalence of sleep disorders in psoriatic patients ranges from 56.6% to 67.4%.²²⁸ Our baseline data showing 72.2% of participants with sleep difficulties (PSQI >5) is consistent with this literature. Furthermore, according to a meta-analysis of 15 studies, psoriatic patients had a higher PSQI score and a higher risk of sleep disturbance when compared to controls.¹⁰⁷

This dramatic improvement in sleep quality may be attributed to several mechanisms:

1. Circadian rhythm alignment: TRE synchronizes food intake with endogenous circadian rhythms, which may strengthen circadian clock function and improve sleep-wake regulation.²²⁹ Feeding-fasting cycles have a significant impact on the peripheral circadian clocks in metabolic tissues, and TRE may make it possible for

these clocks to properly synchronize with the central circadian pacemaker located in the suprachiasmatic nucleus.²³⁰ TRE increases the expression of circadian clock genes in peripheral tissues, such as skin, where local circadian control affects the production of cytokines, keratinocyte proliferation, and immune cell infiltration. Psoriatic skin cells and immune cells may gradually re-synchronize their disturbed circadian clock, as seen by the study's linear trajectory of PASI improvement. By gradually reducing keratinocyte hyperproliferation and immune cell infiltration, this entrainment may eventually lessen skin inflammation.²³¹

2. Reduced inflammation: Both Psoriasis and poor sleep are characterized by elevated systemic inflammation.²³² Zaky et al. (2023) found that 50% of patients with severe psoriasis had bad sleeping habits. Sleep disruptions, length, and quality were all substantially linked with PASI scores ($p < 0.001$). Significant correlations were also found between the global PSQI and PASI ($p = 0.004$).¹¹² There is evidence that pruritus and pain are direct mediators of insomnia in psoriasis. Sleeplessness was successfully reduced by psoriasis treatments that reduce cutaneous symptoms.¹⁰¹ The anti-inflammatory effects of TRE may improve sleep quality, together with PASI by reducing pro-inflammatory cytokines (IL-6, TNF- α) that interfere with sleep architecture.²³² A 12-week single-arm 10-hour TRE intervention,²⁰⁰ led to a notable improvement in the quality of sleep (23%). while Gill and Panda (2015) found that a 16-week TRE intervention resulted in a 4% reduction in weight and an improvement in sleep duration.²³³

3. Metabolic improvements: Weight loss and improved metabolic health may reduce sleep-disordered breathing (such as obstructive sleep apnea), which is highly prevalent (36% - 81.8%) in psoriatic patients.¹⁰¹ Even modest weight loss has been shown to improve sleep apnea severity and overall sleep quality.²³⁴

4. Reduced nocturnal eating: By limiting eating to daytime hours, TRE eliminates late-night eating and snacking, which can cause circadian misalignment to interfere with sleep, affecting hormonal and metabolic processes and aggravating mood instability. Thus, TRE can align mealtimes with the circadian rhythm and can improve sleep quality.²³⁵

The improvement in sleep quality may also contribute to psoriasis improvement through a bidirectional relationship. Sleep disorders act as both a mediator and an effect

of Psoriasis, meaning poor sleep exacerbates symptoms, while severe symptoms disrupt sleep. Poor sleep quality has been associated with increased Psoriasis severity, likely mediated through dysregulated immune function, increased stress hormones, and impaired skin barrier repair.^{101,107} Conversely, improved sleep may support immune regulation, reduce stress, and enhance skin healing, establishing a beneficial feedback loop that increases TRE's advantages. While some research indicates no discernible increase in sleep impairment following TRE practice,^{177,199} Some other studies have revealed a decrease in inflammatory markers associated with sleep quality.^{232,236,237}

5.5 Quality of Life Enhancement

The significant improvement in DLQI scores (1.67-point reduction, 23.29% decrease) indicates that TRE enhanced multiple dimensions of quality of life in psoriasis patients. The six domains that make up the DLQI are: treatment burden, daily activities, leisure, work/school, personal connections, and symptoms and feelings. The reduction in DLQI scores suggests that TRE has positively impacted these diverse aspects of patients' lives.

There was a direct and moderate correlation between increases in PASI scores and improvements in DLQI domain scores. Patients' quality of life is likely to increase when their skin severity improves. Similarly, quality of life is likely to stay steady if skin severity stops improving.¹²² In our study, the four-fold increase in participants experiencing no effect of Psoriasis on quality of life (from 5.6% to 27.8%) is particularly meaningful, as it indicates that a substantial proportion of participants achieved a state where their skin disease no longer significantly interfered with their daily functioning and well-being. This level of improvement is comparable to that seen with effective pharmacological treatments and underscores the potential of lifestyle interventions to meaningfully improve patient outcomes.

The improvement in quality of life likely reflects the combined effects of multiple factors:

1. Reduced disease severity: The improvement in PASI scores directly translates to reduced visible skin lesions, itching, and discomfort, which are primary

drivers of quality-of-life impairment in psoriasis.¹¹² In addition, A cross-sectional worldwide healthcare study on psoriasis conducted in 2024 found that PASI and DLQI correlate across geographic regions, and that patients from Europe and those whose quality of life is already severely harmed are more negatively impacted by an increase in PASI.²³⁸

2. Enhanced sleep quality: The dramatic improvement in sleep quality likely contributed to better daytime functioning, mood, and overall well-being.¹¹¹

3. Weight loss and improved body image: The significant weight loss may have improved self-esteem and body image, which are often impaired in overweight Psoriasis patients. In one study, people in the 18–45 age range had difficulties with daily activities, employment, financial and, social relationships, and appearance acceptance.^{239,240} It results in a poorer quality of life and more stress, which is a well-known element that both causes and exacerbates psoriatic skin lesions.²⁴¹

It is noteworthy that some participants showed improvements in objective measures (PASI, weight) without corresponding improvements in DLQI. Prior research has demonstrated that although there is a moderate correlation between changes in PASI and DLQI, enhancements in quality of life are not consistently reflected by the PASI response alone.^{238,242} This discordance highlights the multidimensional nature of quality of life in Psoriasis, which is influenced not only by disease severity but also by psychological factors, social support, coping strategies, and individual expectation.^{243,244} The most noticeable improvements in quality of life are shown in individuals who obtained near-complete skin clearing, which is represented by a clinical indicator improvement range of 76–100%. Interestingly, a $\geq 90\%$ decrease in DLQI was more than six times more likely to occur in patients who achieved a PASI improvement of 75%.²⁴⁵

5.6 Side Effect Burden and Safety Profile

The side effect profile documented in this TRE intervention study demonstrates a favorable safety profile characterized by early-onset, transient adverse events. The predominance of gastrointestinal and sleep-related complaints during the initial weeks

of treatment is consistent with the physiological adaptation phase associated with dietary intervention implementation. The substantial reduction in adverse event reporting after Week 6, coupled with the progressive increase in asymptomatic participants, suggests successful physiological adaptation to the TRE regimen.

Almutairi et al. (2022) found that only minor adverse events occurred during the course of a prospective Ramadan research. In particular, in the early days of fasting, out of 121 psoriasis subjects, 21 patients reported feeling hungry, and 7 patients occasionally experienced weariness throughout the fasting days. Eleven patients complained of constipation.¹⁶¹ In a mixed-methods systematic review, 315 participants from 16 studies—44 of whom contributed qualitative data—were included. Overall, the results imply that TRE does not cause significant increases in hunger or other appetite-related metrics, nor does it cause binge or uncontrolled eating.²⁴⁶ Minimal side effects such as headache (61.3%), fatigue (68%), mood fluctuations (57.8%), high urine output and dizziness (46.2% and 55.8%, respectively) were found during intermittent fasting, being of different intensities, which did not need surgical or medical treatment.¹⁹⁴

During the first three to four weeks, the most frequent early adverse reactions, which were modest and self-limiting, predominated. Most individuals' hunger and food cravings subsided by Week 5, demonstrating effective appetite management adaptation.²⁴⁶ Conversely, the persistence of constipation reports in weeks 10-12, despite resolution in the intervening weeks, may warrant investigation into dietary fiber supplementation or fluid intake management to optimize the long-term tolerability of TRE protocols.

Sleep-related disruptions represented approximately 36.4% of total side effect reports, with insomnia affecting up to 3 participants (16.7% of the cohort) in Week 1. The rapid resolution of these sleep disturbances by Week 6 suggests that temporal adjustment of eating windows may facilitate normalization of circadian sleep patterns. This finding aligns with the principle of circadian meal timing optimization inherent in TRE interventions. Current evidence indicates that short to mid-term TRE does not typically worsen sleep metrics. Nevertheless, although certain populations might have fewer sleep interruptions, others might have fewer sleep efficiency issues.²⁴⁷

The low incidence of concentration difficulties (1 report) and fatigue (2 reports) is noteworthy, as these complications frequently occur in restrictive dietary

interventions and energy-deficit protocols. This suggests that TRE, particularly when implemented with adequate nutrient density during eating windows, may preserve cognitive and metabolic function better than continuous caloric restriction approaches. The relationship between TRE and cognitive status in a sample of senior Italian people over 50 ($n = 916$) was examined in a recent cross-sectional study by Currenti et al. 2021. Compared to ad libitum consumption, TRE (less than a 10-hour eating window) was linked to lower rates of cognitive impairment in older persons [odds ratio (OR) = 0.28; 95% CI: 0.07–0.90].²⁴⁸

The substantial improvement in side effect burden by Week 7, with 18 out of 18 participants achieving asymptomatic status from Week 7 onward, provides encouraging evidence for sustained TRE adherence in this population.

In summary, TRE was well-tolerated in adults with chronic plaque-type psoriasis, with the majority of side effects being mild, transient, and resolving as the early adaptation phase ended. Notably, the decrease in reported adverse effects by more than 70% from week 1 to week 12 is consistent with studies of intermittent fasting in other populations, suggesting high safety and feasibility for longer-term adherence. Importantly, no severe or treatment-limiting adverse events were observed.

5.7 Patients' Satisfactory Grading and Willingness to Continue TRE in the Future

Five out of 18 participants were very satisfied with significant improvements, while 12 others had visible improvements with moderate satisfaction. There was 1 participant who had experienced only a small positive change. Convenience is a secondary factor in psoriasis patients' satisfaction ratings, which mostly reflect their perceptions of treatment efficacy. Nonetheless, individuals who reported feeling anxious or having a reduced quality of life scored lower on satisfaction surveys.²⁴⁹ Treatment satisfaction was high among patients whose skin and quality of life issues were under control.²⁵⁰

Even after accomplishing the 12-week study period of TRE 94.4% of participants are happy to continue TRE practice. Strategies that encourage long-term

habit building are necessary to develop sustainable and healthful eating habits. It has been demonstrated that strategies like goal-setting, self-monitoring, and reinforcement have a good effect on eating habits by encouraging responsibility and giving a sense of achievement.²⁵¹ Additionally, patient preferences are crucial for better treatment outcomes and adherence to treatment. Finding the best course of action for patients may be facilitated by offering a framework that enables both the patient and the healthcare provider to make well-informed decisions, according to a study on patient opinions regarding treatment choices for obesity. Enhancing individuals' health literacy, expanding access to affordable therapy, and enhancing healthcare providers' expertise and assistance can all help solve these issues.²⁵²

5.8 Strengths and Limitations

5.8.1 Strengths

This study has several notable strengths:

1. Prospective design with multiple time points: The 12-week intervention with assessments at multiple time points (weeks 4, 8, and 12) allowed characterization of temporal patterns and sustainability of treatment effects.
2. Comprehensive outcome assessment: This study assessed multiple clinically relevant outcomes, including disease severity, metabolic parameters, sleep quality, quality of life, side effect profile, and patient satisfaction score, providing a holistic view of TRE's effects in psoriasis patients.
3. Rigorous statistical analysis: The use of repeated measures ANOVA for 4-point outcomes and paired t-tests for 2-point outcomes with appropriate effect size calculations strengthens the validity of findings.
4. High completion rate: 18 out of 22 participants completed the 12-week intervention, suggesting good acceptability and feasibility of the TRE protocol.
5. Validated instruments: All outcome measures (PASI, Body weight, BMI, Waist Circumference, PSQI, DLQI) are validated, widely used instruments with established reliability and clinical relevance.

5.8.2 Limitations

Some limitations should be acknowledged:

1. Absence of mechanistic biomarkers: While the study provides clinical outcome data, it did not include mechanistic investigations such as inflammatory markers, metabolic parameters, or circadian biomarkers that could elucidate the mechanisms underlying the observed improvements.
2. Self-report for all sleep metrics: To give more objective evaluations of rest-activity patterns, this study might have benefited from the use of wrist actigraphy.
3. Study population limited to adult plaque-type psoriasis patients: The effect of TRE on juvenile cases and other types of psoriasis cannot be assessed.
4. Potential confounding: Participants may have made other lifestyle changes during the study period (e.g., increased physical activity, stress reduction) that could contribute to the observed benefits. Moreover, there might be natural disease fluctuations, continued use of topical medications and phototherapy, and behavioral modifications due to the sense of being observed, all of which could act as confounding factors.

5.9 Conclusion

This study suggests that Time-Restricted Eating (TRE) may be a practical and safe strategy for improving certain health outcomes in individuals with chronic plaque-type psoriasis. Following a 12-week TRE intervention, participants showed improvements in body weight, BMI, waist circumference, Psoriasis Area and Severity Index (PASI) scores, sleep quality (PSQI), and quality of life (DLQI).

The findings imply that improvements in psoriasis severity and sleep quality also occurred, indicating additional therapeutic mechanisms of TRE beyond simple weight loss. Consequently, TRE could be considered as a supplemental intervention for weight management in patients living with chronic plaque-type psoriasis.

Integrating TRE into a multidisciplinary care plan has the potential to support better patient outcomes and address metabolic factors associated with the disease. As research into the links between metabolism, circadian rhythms, and immune function

progresses, chronobiological interventions like TRE may become useful tools in comprehensive psoriasis management.

5.10 Future Research Directions

The recommendations and suggestions for future studies are as follows:

1. Large-scale randomized controlled trials to confirm efficacy and establish clinical guidelines
2. Studies to elucidate the metabolic parameters underlying TRE's therapeutic effects, such as insulin sensitivity, lipid profiles, etc.
3. Optimization of TRE protocols for different patient subgroups, such as different meal timings and eating windows
4. Long-term studies to assess sustainability and effects on comorbidities
5. Development of predictive models to personalize TRE combination interventions (TRE + exercise training, TRE + specific diet patterns)

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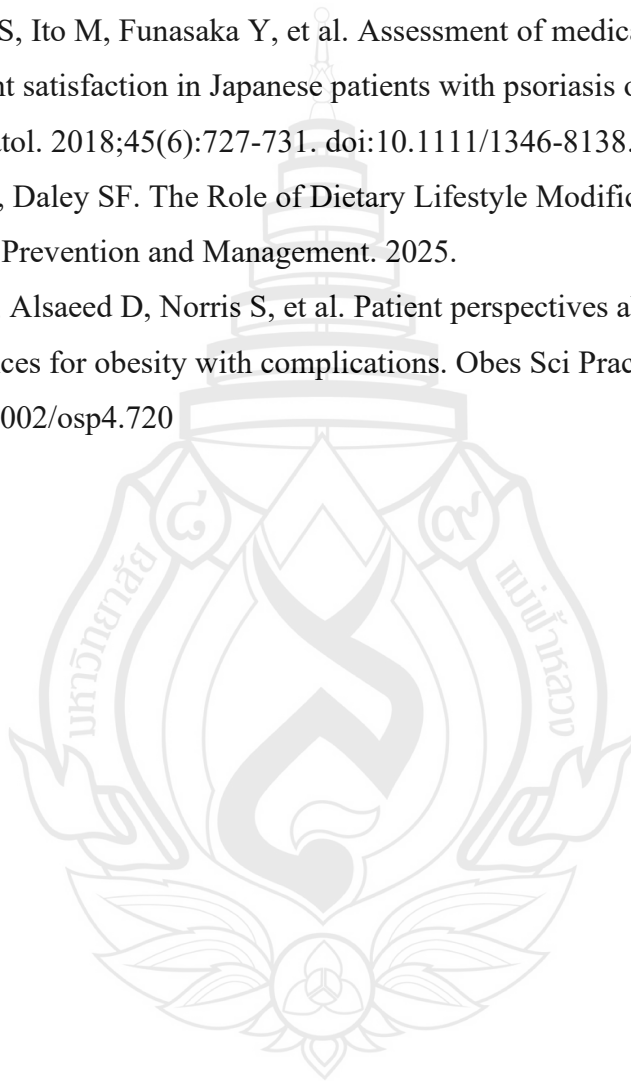
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APPENDIX A

INFORMATION SHEET AND INFORMED CONSENT (ENGLISH)

Research Project Title: The Efficacy of Time-Restricted Eating (TRE) in improving the disease Severity, Weight loss, Sleep quality, and Quality of life in Chronic Plaque-Type Psoriasis

Principal investigator: Dr. Hsu Pyay Zaw

Affiliation: School of Anti-aging and Regenerative Medicine, Mae Fah Luang University

Advisor: Arjan Tanomkit Pawcsuntorn, MD

Source of Research Funding/Sponsor: Self-funding, combined with Mae Fah Luang University's allowed funding

1. Introduction and Project Summary

Time-restricted eating (TRE) is a dietary approach that keeps food consumption within an 8-hour window each day, without needing to limit the amount or type of food eaten. The only restriction of TRE is the length of time for eating. Regular switching back and forth between the fed and fasted metabolic states helps to reduce inflammation, boost stress tolerance, regulate blood sugar, and lose weight. Psoriasis is an immune-mediated inflammatory disease that is persistent and recurrent, and obesity may be a risk factor for it because adipose-related inflammation is further associated with low-grade chronic systemic inflammation, which triggers the immune cascade of Psoriasis. These kinds of inflammation can be decelerated by practicing 16 hours of continuous fasting per day. Although there can be unfavorable effects of fasting such as hunger, fatigue, insomnia, irritability, decreased concentration, nausea, constipation, and headaches, especially during the first month, most of them are only short-lived, non-severe, and reversible.

This is the research project to study the effectiveness (evaluated by the PASI scoring system), and associated benefits including weight loss (examined by body weight,

BMI, and waist circumference), pleasant sleep and enhanced life quality, satisfactory evaluation, and safety (assessed through questionnaires) of restricting eating window to only 8 hours daily without limiting calorie intake as a lifestyle modification therapy in overweight to obese patients with chronic plaque-type Psoriasis. Twenty-two voluntary subjects of any gender with chronic plaque-type Psoriasis, aged between 30-60 years, with a BMI of 25-35 kg/m² will be enrolled and they will need to sign informed consent, follow the instructions for TRE and make regular follow-up visits. As there will be photo recordings of the skin lesions of the participants, the photos will be labeled only with the picture codes instead of the participants' names. If the skin lesions are involved in the readily recognizable areas, such as the face and scalp, a black strip will be used to conceal both eyes in each participant's photograph.

The findings of this research can determine whether daytime TRE could be a therapeutic lifestyle intervention that is safe, effective, feasible, and affordable for patients with chronic plaque-type Psoriasis and serve as a stepping stone in establishing the dietary guidelines for Psoriasis patients.

2. A statement indicating that this is a research project and that participation in this research is voluntary

You are invited to participate in this research. Please take time to read this document as it provides information about your involvement in the research. The decision to participate is entirely voluntary. If you choose not to participate, your healthcare and rights that you are entitled to will not be changed. Your participation in this research is based on your voluntary decision.

- You have the freedom to decide whether to participate in this research or not.
 - You can consult with your family or your physician before making the decision.
- You may also ask any questions; the researcher will provide explanations and answers until you have a clear understanding.
- After deciding to participate in this research, you still have the right to withdraw at any time.

3. Rationale and Significance of the Research

Psoriasis is an immune-mediated inflammatory disease that is persistent and recurrent. The National Psoriasis Foundation estimates that 125 million people worldwide—roughly 2-3 percent of the world's population—have Psoriasis. Due to its chronic nature and tendency to relapse, Psoriasis frequently requires long-term therapy. For Psoriasis, there are numerous therapy choices. They do not, however, come without adverse effects. Unwanted side effects ranging from nausea, vomiting, organ failures, and severe life-threatening infections to malignancy, systemic medications are not the best solutions yet. The high expense of biologic therapy together with the adverse effect profiles, is another major concern. Although there have been major advancements in the treatment of Psoriasis, there is still a need for a more accessible, affordable option. Therefore, currently, medical professionals are focusing on lifestyle modification strategies, particularly the simplest and most affordable dietary interventions. Although there is no scientifically supported dietary guidelines for Psoriasis yet, a growing body of scientific literature regarding the role of diet in the management of Psoriasis has appeared. Of all the methods, Time-Restricted Eating (TRE) is the most natural, safest, economical, and reliable because it does not require calorie restriction during the meal window. Patients can be instructed, "Eat anything as much as you like; all you have to do is stop when the timer sounds."

4. Qualifications and Number of Participants

Volunteers must be in good health and should not have any pre-existing medical conditions that require regular medications before or after meals, as this research involves fasting during certain periods. They should also fulfill the following criteria

- Those between the ages of 30 and 60
- Those who have been clinically diagnosed with Psoriasis by a dermatologist
- Those presenting with active but clinically stable chronic plaque-type Psoriasis, and not taking any oral or injectable medications specific for Psoriasis
- Those with a BMI of 25-35 kg/m²
- Those who can give informed consent to following the procedure and photographing the skin lesions

- Those who can comply with dietary instructions
- Those who are willing to use the Fasting Tracker mobile application to record diet and sleep during the intervention period
- Those who can attend all scheduled visits through the study period
- Those who are willing to provide personal and contact information to communicate with the researcher throughout the study period.
- Those who are willing to apply measures to prevent pregnancy throughout the study period

The number of participants will be 22.

5. Research Objectives

The objective of the research is to examine the effectiveness and safety of Time-Restricted Eating (TRE) for 8 hours per day for a total of 12 weeks on the Psoriasis disease severity, weight loss, sleep quality, and quality of life in overweight and obese patients with chronic plaque-type Psoriasis.

6. Research Design

Twenty-two voluntary subjects of any gender and with chronic plaque-type Psoriasis, aged between 30-60 years, with BMI between 25 and 35 kg/m², who have already been consulted by a dermatologist, have met the inclusion criteria and, are currently residing in Thailand will be enrolled. Those patients will be recruited from Mae Fah Luang University Hospital, Bangkok, Thailand.

7. Research Procedure and Duration of Participation

The researcher will explain the research's objectives, detailed procedures, advantages, and expected side effects of the treatment to the patients. After clearly understanding the rules to follow and the results to expect at the end of the intervention, you must sign a written informed consent form agreeing that you have volunteered to

participate in the research according to your will and that your pre- and post-intervention parameters and photographs can be distributed to the public.

To test the study objectives, a 12-week-long TRE clinical trial will be conducted. During the planned 16-hour fasting window, you will need to refrain from consuming any calories, but during the eating window, you are free to consume as much as you desire. You can select any of the following fasting schedules: 4 p.m. to 8 a.m., 5 p.m. to 9 a.m., 6 p.m. to 10 a.m., or 7 p.m. to 11 a.m.

The first week is a preparatory period, as it will be difficult to restrict the eating window suddenly to only 8 hours per day and the participants will need to practice fasting habits step by step. It will take a week to adapt to the new diet. Lately, the fasting time will be gradually increased up to 16 hours per day. How to initiate the TRE is described in Table 1.

Table 1. Preparation and Adjustment for initiating TRE

Time Frame	Eating Window per day	Fasting Window per day
Day 1 and 2	12 hours	12 hours
Day 3 and 4	11 hours	13 hours
Day 5	10 hours	14 hours
Day 6	9 hours	15 hours
Day 7 and onwards up to Week 12	8 hours	16 hours

When you are fasting, you need to stay hydrated. There will be no dietary limits on the quantity or kinds of food you may eat within the 8 hours. If you have known some particular food that can precipitate your skin lesions, you will need to avoid those. During the fasting period, water and unsweetened teas are allowed to drink, while the following are not allowed to eat or drink any calorie-containing food or drink, such as coffee creamer, sweet teas, alcohol, and snacks.

You will need to download the mobile phone fasting tracker application named “Intermittent Fasting 16:8” which is available on both Android and Apple devices.

After that, you will need to record your time of fasting commencement and ending daily using that app.

You will receive weekly contact from the researcher, who will ask for a weekly report of your fasting progress from that app and also monitor adverse events, encourage adherence, and offer support for any problems encountered during the intervention. During the communications, questions on daily activities, alterations to regular routines, and any changes in health will be asked.

DLQI is a 10-item test that evaluates six distinct factors that could have an impact on your quality of life. These elements include daily activities, recreation, work and academic performance, emotional states, interpersonal interactions, and treatment. You will need to answer these questions 2 times: at the start and at the end of the study.

PSQI is the questionnaire containing 19 items used in clinical populations to assess sleep quality during the month before. You will need to answer these questions 2 times: at the start and at the end of the study, together with the DLQI questionnaires.

After completing the Time-Restricted Eating for 12 weeks, and at your last follow-up visit, you will be asked to fill in the satisfaction score and side effect assessment form.

You will need to come for follow-up visits to Mae Fah Luang University Hospital, Bangkok 4 times in total: at the start, after Week 4, Week 8, and Week 12. At all 4 visits, your skin lesions will be assessed and photographed, and your body weight, height, and waist circumference will be measured by the researcher. You will need to answer the questionnaires 2 times, at the start and at the end of the study. You will be provided with a transportation fee of 200 baht for each in-person visit, which is at the start, at Weeks 4, 8, and 12.

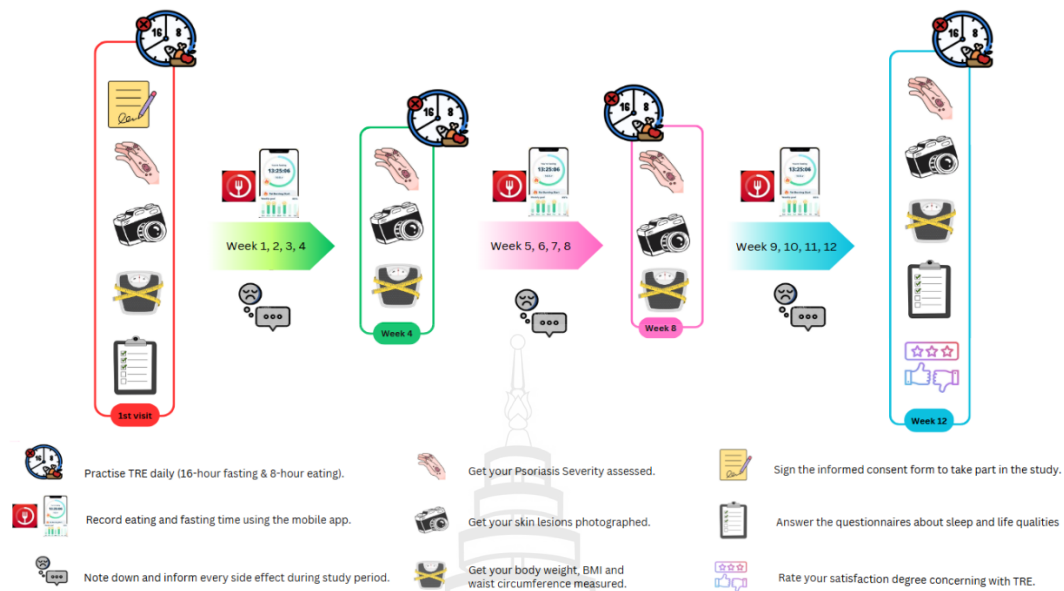


Figure 1: Summary of what you need to do to take part in the research

8. Potential Risks and Discomfort from Participating in the Research

The safety and tolerability of short-term intermittent fasting has been supported by many clinical trials. However, it takes about one to two weeks for most people to acclimate completely to this new eating schedule. Although reports of dizziness and constipation have been made during the first phase, these side effects typically go away by the second week of fasting. During this initial phase, headaches are also commonly observed. Dehydration from inadequate water intake, which can happen when diet is restricted, is typically the cause of headaches. Adding 1.5 L of water to one's daily consumption may aid people with headaches when fasting. Other unfavorable effects such as hunger, fatigue, insomnia, irritability, decreased concentration, nausea, and constipation and unknown risks beyond what is mentioned in this document can occur throughout the TRE period. To ensure your safety, if you experience any side effects, you should promptly inform the researchers and may see your physician before any scheduled appointments.

9. Potential Benefits of Participating in the Research

It is anticipated that TRE has the effects of

- potentially reducing the Psoriasis severity and area involved,
- probably lowering the body weight, BMI, and waist circumference,

- possibly improving sleep quality and quality of life.

Nevertheless, it is not guaranteed that all these expected benefits will be fulfilled certainly.

By conducting this study, it is expected to benefit medical professionals in establishing specific dietary guidelines to help relieve the sufferings of other Psoriasis patients around the world.

10. Alternatives if Choosing NOT to Participate

For those who do not want to participate in the study, you can continue your current medications and continue consulting with your dermatologists for further management. As newer medications are developing nowadays, there are many more ways to improve your disease condition.

11. Guidelines for Managing Situations that May Arise during the Research

Situations	Guidelines
▪ If you decide to withdraw during the research	You will no longer voluntarily participate in the study.
▪ If there is new information regarding the research or your safety	The researcher will inform you promptly and you can decide to remain in the research or not.
▪ If participation in this research is terminated (it will be terminated when the research project does not meet the appropriate criteria.)	The researcher will inform you as soon as possible, and there will be compensation for the waste of time for all the volunteers.

12. Potential Benefits after the Completion of the Research

After the completion of the research, it is expected that the participants will be able to see the improvement in the skin lesions, get a leaner body, sounder sleep and happier life. These results will not only apply to the participants but also to other people with the same disease.

13. Confidentiality of Data and Limitations

As there will be photo recordings of the skin lesions of the participants, the photos will be labeled only with the picture codes instead of the participants' names. If the skin lesions are involved in the readily recognizable areas, such as the face and scalp, a black strip will be used to conceal both eyes in each participant's photograph. The recorded images will be saved in a private, password-protected computer to which only the researcher can get access. However, certain individuals or groups, i.e., the ethics committee, research coordinators, research supervisors, and authorized personnel from governmental institutions or organizations responsible for auditing, may have access to your personal data in order to verify the accuracy of data and research procedures. Even after the research, if the research results are to be presented, it will be without the information that identifies the participants.

14. Reimbursement for Participation

The volunteers will be provided with a transportation fee of 200 baht per in-person visit, with a total of 4 sessions, which are at the start of the study, at Weeks 4, 8, and 12.

15. Expenses that the participants must bear

The participants do not have to pay as all the expenses for this study will be supported by the researcher and the research funding by Mae Fah Luang University.

16. Care and Compensation Guidelines if the participants experience harm or adverse effects from participating in the research

TRE might have some foreseeable side effects such as hunger, cravings, headaches, fatigue, insomnia, irritability, decreased concentration, nausea, constipation, etc. If a patient experiences any negative symptoms during the study period, he/she needs to inform the researcher about the symptoms and the researcher will assess through a video call or in-person consultation and if the condition of the patient is out of the scope of the researcher, the participant will be referred to the Specialists available at Mae Fah Luang Hospital for further appropriate management. If there is any side effect that has happened to the participants, the researcher will take full responsibility for taking care of

the patient until the patient's condition is recovered back to the previous normal condition. If the patient has to take off days from work, the researcher will cover the minimum wages per day of off work for him/her.

17. Contact Person in Case of Questions or Concerns

If you have any questions or concerns regarding the research or safety during participation, you can directly ask the researcher, Dr. Hsu Pyay Zaw, telephone number being 0840457902, or the advisor of this study, Prof. Tanomkit Pawcsuntorn, telephone number being 0816146816.

If you have questions regarding your rights, you can contact the Mae Fah Luang University Ethics Committee on Human Research at the Academic Service building (AS), 4th floor, tel. (053) 917-170 to 1 or (053) 916-551, fax. (053) 917-170, or e-mail: rec.human@mfu.ac.th to ensure that your rights, your safety, and your well-being are protected under the international standards of human-research ethics.



Informed Consent Form

I, _____, have decided to participate in the research project named, “The Efficacy of Time-Restricted Eating (TRE) in improving the disease Severity, Weight loss, Sleep quality, and Quality of life in Chronic Plaque-Type Psoriasis”. I have received information and explanations about this research, and I have had the opportunity to ask questions and receive satisfactory answers. I have had sufficient time to read and understand the information provided in the documents thoroughly and have decided to participate in this research.

I understand that I have the freedom to choose not to participate in this research, and I can withdraw from this research at any time without any impact on my care or rights that I am entitled to.

By signing this document, I do not waive any rights that I am entitled to under the law, and after signing, I will receive a copy of the information sheet and the informed consent.

Participant’s Signature _____ Date _____
(_____)

..... (For illiterate participants who can understand through listening)

I cannot read, but the researcher has read this information sheet and informed consent form to me, and I understand it well. Therefore, I voluntarily sign or place my fingerprint.

Participant’s signature/fingerprint _____ Date _____
(_____)

Testimony of a witness who is not a stakeholder in the research (If the participant cannot read but can understand through listening)

I have been present during the consent request process and confirm that the person requesting consent has read / explained the information sheet to _____. The aforementioned person had the opportunity to ask questions and decided to participate voluntarily after understanding the information in this document.

Witness’s signature _____ Date _____
(_____)

If the participant is a minor, under the age of 18, or with mental or intellectual disabilities, special protections must be provided.

I, as[relationship to the participant]..... have read the information above and fully understand the content. I agree to let Mr. / Mrs. / Miss _____ participate in the research voluntarily. Therefore, I sign this informed consent form.

Legal representative/guardian's signature _____ Date _____
(_____)



APPENDIX B

INFORMATION SHEET AND INFORMED CONSENT (THAI)

เอกสารข้อมูลและขอความยินยอมเข้าร่วมการวิจัย

ชื่อโครงการวิจัย: ประสิทธิภาพของการกินอาหารแบบจำกัดช่วงเวลา (Time-Restricted Eating: TRE) ในการปรับปรุงความรุนแรงของโรค การลดน้ำหนัก คุณภาพการนอนหลับ และคุณภาพชีวิตในผู้ป่วยโรคสะเก็ดเงินชนิดผื่นหนาเรื้อรัง

ผู้วิจัยหลัก : พญ. Hsu Pyay Zaw

สังกัด : สำนักวิชาเวชศาสตร์ชะลอวัยและเวชศาสตร์ฟื้นฟู มหาวิทยาลัยแม่ฟ้าหลวง

แหล่งทุนวิจัย/ผู้สนับสนุนการวิจัย : ทุนส่วนตัวและ เงินทุนจากมหาวิทยาลัยแม่ฟ้าหลวง

1. บทนำและสรุปโครงการวิจัย

การกินอาหารแบบจำกัดช่วงเวลา (Time-Restricted Eating: TRE) เป็นวิธีการรับประทานอาหารที่จำกัดเวลาการบริโภคอาหารให้อยู่ภายใน 8 ชั่วโมงต่อวัน โดยไม่จำเป็นต้องจำกัดปริมาณหรือประเภทของอาหารที่รับประทาน ข้อจำกัดเดียวของ TRE คือระยะเวลาที่สามารถรับประทานอาหารได้ การสลับไปมาระหว่างสภาวะเผาผลาญอาหารของการรับประทานและการอดอาหารเป็นประจำสามารถช่วยลดการอักเสบของร่างกาย เพิ่มความทนทานต่อความเครียด ควบคุมระดับน้ำตาลในเลือด และช่วยลดน้ำหนัก

โรคสะเก็ดเงิน (Psoriasis) เป็นโรคอักเสบเรื้อรังที่เกิดจากระบบภูมิคุ้มกันและสามารถกลับเป็นซ้ำได้บ่อยครั้ง ความอ้วนถือว่าเป็นปัจจัยเสี่ยงของโรคนี้ เนื่องจากการอักเสบที่เกี่ยวข้องกับเนื้อเยื่อไขมันสัมพันธ์กับการอักเสบเรื้อรังในระดับต่ำของระบบ ซึ่งจะไปกระตุ้นกระบวนการตอบสนองของระบบภูมิคุ้มกันในโรคสะเก็ดเงิน การอักเสบลักษณะนี้สามารถลดลงได้ด้วยการอดอาหารติดต่อกัน 16 ชั่วโมงต่อวัน

แม้ว่าการอดอาหารอาจส่งผลกระทบต่อไม่พึงประสงค์ เช่น ความหิว อ่อนเพลีย นอนไม่หลับ หงุดหงิด ขาดสมาธิ คลื่นไส้ ท้องผูก และปวดศีรษะ โดยเฉพาะในช่วงเดือนแรก แต่ผลข้างเคียงเหล่านี้มักเกิดขึ้นชั่วคราว ไม่รุนแรง และสามารถกลับคืนสู่สภาวะปกติได้เอง

โครงการวิจัยนี้มีเป้าหมาย เพื่อศึกษาประสิทธิภาพ (วัดโดยระบบการให้คะแนน PASI) และประโยชน์ที่เกี่ยวข้อง เช่น การลดน้ำหนัก (ตรวจวัดจากน้ำหนักตัว ดัชนีมวลกาย และเส้นรอบเอว) คุณภาพการนอนหลับที่ดีขึ้น คุณภาพชีวิตที่เพิ่มขึ้น ความพึงพอใจ และความปลอดภัยในการรักษา

(ประเมินผ่านแบบสอบถาม) ของการจำกัดช่วงเวลาการรับประทานอาหารเหลือเพียง 8 ชั่วโมงต่อวัน โดยไม่จำกัดปริมาณแคลอรี เพื่อเป็นการปรับเปลี่ยนวิถีชีวิตในผู้ป่วยโรคสะเก็ดเงินชนิดเรื้อรังแบบปื้น ที่มีน้ำหนักเกินถึงอ้วน

โครงการนี้จะรับอาสาสมัครจำนวน 22 คน ที่มีเพศใดก็ได้ และ อายุระหว่าง 30-60 ปี และมี BMI ระหว่าง 25-35 กก./ม² ผู้เข้าร่วมจะต้องลงนามในแบบฟอร์มยินยอมรับการวิจัย ปฏิบัติตามคำแนะนำการทำการกินอาหารแบบจำกัดช่วงเวลา(TRE) และเข้ารับการติดตามผลตามกำหนดเวลา ในการบันทึกภาพรอยโรคผิวหนังของผู้เข้าร่วม ภาพจะถูกระบุด้วยรหัสภาพแทนชื่อผู้เข้าร่วม หาก รอยโรคปรากฏในบริเวณที่สามารถระบุบุคคลได้ เช่น ใบหน้าและหนังศีรษะ จะมีการใช้แถบสีดำ ปิดบังบริเวณดวงตาในภาพถ่ายของผู้เข้าร่วมแต่ละคน

ผลการวิจัยนี้ อาจช่วยยืนยันว่าการกินอาหารแบบจำกัดช่วงเวลา(TRE) ในช่วงกลางวันเป็น วิธีการปรับเปลี่ยนวิถีชีวิตที่ปลอดภัย มีประสิทธิภาพ สามารถปฏิบัติได้ง่าย และมีต้นทุนต่ำสำหรับ ผู้ป่วยโรคสะเก็ดเงินชนิดเรื้อรังแบบปื้น อีกทั้งยังเป็นพื้นฐานสำคัญในการกำหนดแนวทางการบริโภค อาหารสำหรับผู้ป่วยโรคสะเก็ดเงินต่อไป

2. คำชี้แจงว่าเป็นโครงการวิจัยและการเข้าร่วมเป็นไปโดยสมัครใจ

ท่านได้รับเชิญให้เข้าร่วมในโครงการวิจัยนี้ โปรดใช้เวลาอ่านเอกสารนี้อย่างละเอียด เนื่องจากมีข้อมูลเกี่ยวกับการเข้าร่วมของท่านในงานวิจัย การตัดสินใจเข้าร่วมโครงการเป็นไปโดยสมัครใจทั้งหมด หากท่านเลือกที่จะไม่เข้าร่วม สิทธิในการได้รับการดูแลทางการแพทย์และสิทธิอื่น ๆ ที่ท่านพึงมีจะไม่ได้รับผลกระทบใด ๆ

การเข้าร่วมโครงการวิจัยนี้ขึ้นอยู่กับความสมัครใจของท่าน

- ท่านมีอิสระในการตัดสินใจว่าจะเข้าร่วมในโครงการวิจัยนี้หรือไม่
- ท่านสามารถปรึกษากับครอบครัวหรือแพทย์ของท่านก่อนตัดสินใจเข้าร่วมโครงการได้ ท่านยังสามารถสอบถามคำถามเพิ่มเติม โดยนักวิจัยจะให้คำอธิบายและตอบคำถามจนกว่าท่าน จะมีความเข้าใจอย่างชัดเจน
- หลังจากตัดสินใจเข้าร่วม โครงการวิจัยแล้วท่านยังคงมีสิทธิ์ที่จะถอนตัวออกจากโครงการ ได้ตลอดเวลา

3. เหตุผลและความสำคัญของงานวิจัย

โรคสะเก็ดเงิน (Psoriasis) เป็นโรคอักเสบเรื้อรังที่เกิดจากระบบภูมิคุ้มกันและมีลักษณะเป็นโรคเรื้อรัง ที่กลับเป็นซ้ำได้ง่าย จากข้อมูลของมูลนิธิโรคสะเก็ดเงินแห่งชาติ (National Psoriasis Foundation) มีการประมาณว่ามีผู้ป่วยโรคสะเก็ดเงินทั่วโลกประมาณ 125 ล้านคน หรือประมาณ 2-3% ของ

ประชากรโลก เนื่องจากลักษณะเรื้อรังและการกลับเป็นซ้ำของโรค ผู้ป่วยมักต้องการการรักษาในระยะยาว

แม้ว่าปัจจุบันจะมีทางเลือกในการรักษาโรคสะเก็ดเงินหลายวิธี แต่วิธีเหล่านี้มักมาพร้อมกับผลข้างเคียงที่ไม่พึงประสงค์ เช่น คลื่นไส้ อาเจียน อ่อนเพลียต่ออวัยวะภายใน การติดเชื้อที่รุนแรงถึงขั้นคุกคามชีวิต และแม้แต่ความเสี่ยงต่อการเกิดมะเร็ง ยาในรูปแบบระบบ (Systemic Medications) ยังไม่ใช่วิธีการแก้ปัญหาที่ดีที่สุด นอกจากนี้ ค่าใช้จ่ายสูงของการรักษาทางการแพทย์ที่ใช้สารชีวภาพ (Biologic Therapy) และผลข้างเคียงที่พบได้ยังเป็นปัญหาสำคัญ แม้จะมีความก้าวหน้าทางการรักษาโรคสะเก็ดเงินอย่างมากในปัจจุบัน แต่ยังคงมีความต้องการทางเลือกการรักษาที่เข้าถึงได้ง่ายกว่าและมีค่าใช้จ่ายต่ำกว่า

ในปัจจุบัน ผู้เชี่ยวชาญทางการแพทย์ได้หันมาให้ความสำคัญกับกลยุทธ์การปรับเปลี่ยนวิถีชีวิต โดยเฉพาะการปรับปรุงด้านโภชนาการเป็นวิธีการที่ง่ายที่สุดและประหยัดที่สุด แม้ว่าจะไม่มีแนวทางการปรับปรุงด้านโภชนาการที่ได้รับการสนับสนุนทางวิทยาศาสตร์สำหรับโรคสะเก็ดเงิน แต่ก็มีงานวิจัยทางวิทยาศาสตร์ที่เพิ่มขึ้นเกี่ยวกับบทบาทของอาหารในการดูแลโรคสะเก็ดเงิน

จากแนวทางทั้งหมด การกินอาหารแบบจำกัดช่วงเวลา (Time-Restricted Eating: TRE) ถือเป็นวิธีที่เป็นธรรมชาติที่สุด ปลอดภัยที่สุด ประหยัดที่สุด และน่าเชื่อถือที่สุด เนื่องจากไม่จำเป็นต้องจำกัดแคลอรีในช่วงเวลาที่รับประทานอาหาร ผู้ป่วยสามารถได้รับคำแนะนำง่าย ๆ ว่า "กินอะไรก็ได้เท่าที่ต้องการ แต่เพียงแค่อยุ่ในเวลาที่กำหนดไว้หมดลง"

4. คุณสมบัติและจำนวนผู้เข้าร่วมการวิจัย

คุณสมบัติของอาสาสมัคร

อาสาสมัครต้องมีสุขภาพดีและไม่มีโรคประจำตัวที่จำเป็นต้องรับประทานยา ก่อนหรือหลังมื้ออาหาร เนื่องจากการวิจัยนี้มีการอดอาหารในช่วงเวลาที่กำหนด และต้องมีคุณสมบัติดังต่อไปนี้:

- มีอายุระหว่าง 30 ถึง 60 ปี
- ได้รับการวินิจฉัยทางคลินิกว่าเป็นโรคสะเก็ดเงินโดยแพทย์ผิวหนัง
- มีอาการโรคสะเก็ดเงินชนิดเรื้อรังแบบหนาเรื้อรังที่ยังคงอยู่ในสภาวะคงที่ทางคลินิก และไม่ได้รับยาชนิดรับประทานหรือฉีดที่เฉพาะเจาะจงสำหรับโรคสะเก็ดเงิน
- มีค่า BMI อยู่ระหว่าง 25-35 กก./ม²
- สามารถให้ความยินยอมอย่างเป็นลายลักษณ์อักษรสำหรับการปฏิบัติตามขั้นตอนการวิจัย และการถ่ายภาพรอยโรคผิวหนัง
- สามารถปฏิบัติตามคำแนะนำด้านอาหารได้

- ยินยอมใช้แอปพลิเคชัน Fasting Tracker เพื่อติดตามการรับประทานอาหารและการนอนหลับในช่วงระยะเวลาของการทดลอง
- สามารถเข้าร่วมการนัดหมายทั้งหมดในช่วงระยะเวลาของการศึกษา
- ยินยอมให้ข้อมูลส่วนตัวและข้อมูลติดต่อเพื่อการสื่อสารกับนักวิจัยตลอดระยะเวลาของการศึกษา
- ยินดีใช้มาตรการป้องกันการตั้งครรภ์ตลอดระยะเวลาของการศึกษา

จำนวนผู้เข้าร่วมการวิจัย

จำนวนผู้เข้าร่วมการวิจัยทั้งหมดคือ 22 คน

5. วัตถุประสงค์ของการวิจัย

วัตถุประสงค์ของการวิจัยนี้คือการศึกษาศรีประสิทธิภาพและความปลอดภัยของการกินอาหารแบบจำกัดช่วงเวลา (Time-Restricted Eating: TRE) เป็นเวลา 8 ชั่วโมงต่อวัน เป็นระยะเวลา 12 สัปดาห์ ในการลดความรุนแรงของโรคสะกดเงิน การลดน้ำหนัก คุณภาพการนอนหลับ และคุณภาพชีวิตของผู้ป่วยโรคสะกดเงินชนิดเรื้อรังแบบปิ่นที่มีน้ำหนักเกินและโรคอ้วน

6. รูปแบบการวิจัย

อาสาสมัครจำนวน 22 คนที่สมัครใจเข้าร่วมการวิจัย โดยสามารถเป็นเพศใดก็ได้ และ ซึ่งเป็นผู้ป่วยโรคสะกดเงินชนิดเรื้อรังแบบปิ่น อายุระหว่าง 30-60 ปี และมีค่า BMI ระหว่าง 25-35 กก./ม² โดยต้องได้รับการรักษาจากแพทย์ผิวหนังแล้ว และมีคุณสมบัติตรงตามเกณฑ์การคัดเลือก ทั้งยังพำนักอาศัยอยู่ในประเทศไทย

ผู้ป่วยกลุ่มนี้จะได้รับการคัดเลือกจากโรงพยาบาลมหาวิทยาลัยแม่ฟ้าหลวง กรุงเทพฯ ประเทศไทย

7. ขั้นตอนการวิจัยและระยะเวลาการเข้าร่วม

นักวิจัยจะอธิบายวัตถุประสงค์ ขั้นตอนโดยละเอียด ประโยชน์ และผลข้างเคียงที่คาดว่าจะเกิดจากการรักษาให้ผู้เข้าร่วมทราบ หลังจากที่คุณเข้าร่วมเข้าใจถึงกฎเกณฑ์ที่ต้องปฏิบัติและผลลัพธ์ที่คาดหวังได้อย่างชัดเจนแล้ว ผู้เข้าร่วมจะต้องลงนามในแบบฟอร์มยินยอมที่เป็นลายลักษณ์อักษร โดยแสดงความสมัครใจที่จะเข้าร่วมการวิจัยตามความประสงค์ของตนเองและยินยอมให้ใช้ข้อมูลก่อนและหลังการทดลอง รวมถึงภาพถ่ายในการเผยแพร่สู่สาธารณะ

การทดลองทางคลินิกการกินอาหารแบบจำกัดช่วงเวลา(TRE) จะดำเนินการเป็นระยะเวลา 12 สัปดาห์ เพื่อทดสอบวัตถุประสงค์ของการศึกษา ในช่วงที่อดอาหาร 16 ชั่วโมงต่อวัน ผู้เข้าร่วม

จะต้องงดการบริโภคแคลอรี แต่ในช่วงเวลาที่รับประทานอาหารสามารถรับประทานได้ตามต้องการ ผู้เข้าร่วมสามารถเลือกตารางเวลาการอดอาหารจากตัวเลือกดังต่อไปนี้:

- 16:00 - 08:00 น.
- 17:00 - 09:00 น.
- 18:00 - 10:00 น.
- 19:00 - 11:00 น.

ช่วงสัปดาห์แรก จะเป็นระยะเตรียมความพร้อม เนื่องจากการปรับลดระยะเวลารับประทาน อาหารเหลือเพียง 8 ชั่วโมงต่อวันอาจทำได้ยากในทันที ผู้เข้าร่วมจะต้องค่อย ๆ ฝึกปรับนิสัยการอด อาหารทีละขั้นตอน โดยใช้เวลาหนึ่งสัปดาห์เพื่อปรับตัวให้เข้ากับรูปแบบการรับประทานอาหารใหม่ หลังจากนั้นระยะเวลาในการอดอาหารจะเพิ่มขึ้นอย่างค่อยเป็นค่อยไปจนถึง 16 ชั่วโมงต่อวัน รายละเอียดการเริ่มต้นการทำ TRE ระบุไว้ในตารางที่ 1

ตารางที่ 1 การเตรียมตัวและการปรับตัวเพื่อเริ่มต้นการทำ TRE

กรอบเวลา	ช่วงเวลารับประทานอาหารต่อวัน	ช่วงเวลาอดอาหารต่อวัน
วันที่ 1 และ 2	12 ชั่วโมง	12 ชั่วโมง
วันที่ 3 และ 4	11 ชั่วโมง	13 ชั่วโมง
วันที่ 5	10 ชั่วโมง	14 ชั่วโมง
วันที่ 6	9 ชั่วโมง	15 ชั่วโมง
วันที่ 7 จนถึงสัปดาห์ที่ 12	8 ชั่วโมง	16 ชั่วโมง

รายละเอียดเพิ่มเติมเกี่ยวกับขั้นตอนการวิจัยและข้อกำหนดในการเข้าร่วม

การอดอาหาร

ในช่วงเวลาที่อดอาหาร (16 ชั่วโมง) ผู้เข้าร่วมต้องรักษาสุขภาพด้วยการดื่มน้ำอย่างเพียงพอ สามารถดื่มน้ำเปล่า ชาที่ไม่มีน้ำตาล หรือเครื่องดื่มที่ไม่มีแคลอรีได้

ห้ามรับประทานหรือดื่มอาหารและเครื่องดื่มที่มีแคลอรี เช่น ครีมเทียม กาแฟที่มีส่วนผสมของแคลอรี ชาหวาน เครื่องดื่มแอลกอฮอล์ และขนม

การบริโภคอาหารในช่วง 8 ชั่วโมง

ไม่มีข้อจำกัดในปริมาณหรือชนิดของอาหารที่สามารถรับประทานได้

หากทราบว่าอาหารบางชนิดกระตุ้นให้เกิดรอยโรคสะเก็ดเงิน ควรหลีกเลี่ยงอาหารดังกล่าว การใช้งานแอปพลิเคชันติดตามการอดอาหาร

ดาวน์โหลดแอปพลิเคชัน “Intermittent Fasting 16:8” ซึ่งรองรับทั้งระบบ Android และ Apple

บันทึกเวลาเริ่มต้นและสิ้นสุดการอดอาหารในแต่ละวันผ่านแอปพลิเคชัน

การติดตามผลและสนับสนุน

นักวิจัยจะติดต่อผู้เข้าร่วมทุกสัปดาห์เพื่อสอบถามความคืบหน้าในการอดอาหารจากแอปพลิเคชัน

มีการติดตามผลข้างเคียง ให้คำแนะนำ และสนับสนุนผู้เข้าร่วมในกรณีที่พบปัญหา

แบบสอบถามคุณภาพชีวิต (DLQI)

แบบสอบถาม DLQI ประกอบด้วยคำถาม 10 ข้อ ที่ประเมินปัจจัย 6 ด้านที่มีผลต่อคุณภาพชีวิต ได้แก่ กิจกรรมประจำวัน การพักผ่อน การทำงานหรือการเรียน สภาพอารมณ์ ความสัมพันธ์ระหว่างบุคคล และการรักษา

ผู้เข้าร่วมจะตอบแบบสอบถาม DLQI 2 ครั้ง: ช่วงเริ่มต้นและสิ้นสุดการวิจัย

แบบสอบถามคุณภาพการนอนหลับ (PSQI)

แบบสอบถาม PSQI ประกอบด้วยคำถาม 19 ข้อ ที่ใช้ประเมินคุณภาพการนอนหลับในช่วงเดือนก่อนหน้า

ผู้เข้าร่วมจะตอบแบบสอบถาม PSQI พร้อมกับ DLQI ในช่วงเริ่มต้นและสิ้นสุดการวิจัย

การติดตามผลและประเมินผล

หลังจากทำ TRE ครบ 12 สัปดาห์ ผู้เข้าร่วมจะกรอกแบบประเมินความพึงพอใจและผลข้างเคียง

การเยี่ยมติดตามผลที่โรงพยาบาลมหาวิทยาลัยแม่ฟ้าหลวง กรุงเทพฯ

ผู้เข้าร่วมต้องเข้าพบที่โรงพยาบาล 4 ครั้ง:

- ช่วงเริ่มต้นการศึกษา
- สัปดาห์ที่ 4
- สัปดาห์ที่ 8
- สัปดาห์ที่ 12

ในการเยี่ยมแต่ละครั้ง นักวิจัยจะทำการประเมินและถ่ายภาพรอยโรคสะเก็ดเงิน พร้อมวัดน้ำหนัก ส่วนสูง และเส้นรอบเอวของผู้เข้าร่วม

ค่าตอบแทนการเดินทาง

ผู้เข้าร่วมจะได้รับค่าตอบแทนการเดินทางครั้งละ 200 บาท สำหรับการเข้าร่วมในแต่ละครั้ง (เริ่มต้น สัปดาห์ที่ 4, 8 และ 12)

8. ความเสี่ยงและความไม่สบายที่อาจเกิดขึ้นจากการเข้าร่วมการวิจัย

ผลข้างเคียงในช่วงเริ่มต้น

อาการปวดศีรษะพบได้บ่อยในช่วงเริ่มต้น สาเหตุหลักมาจากการขาดน้ำเนื่องจากการดื่ม
น้ำไม่เพียงพอเมื่อจำกัดอาหาร การเพิ่มปริมาณน้ำดื่มอีก 1.5 ลิตรต่อวันอาจช่วยบรรเทาอาการปวด
ศีรษะได้

- ความหิว
- อ่อนเพลีย
- นอนไม่หลับ
- หงุดหงิดง่าย

- สมาชิกดลง
- คลื่นไส้
- ท้องผูก
- เมื่อยล้า
- มองเห็นภาพเบลอ
- พูดไม่ชัด
- สับสน
- ชัก
- สูญเสียสติ

นอกจากนี้ยังอาจมีความเสี่ยงที่ไม่ทราบมาก่อนเกินกว่าที่ระบุไว้ในเอกสารนี้

การดูแลความปลอดภัย

หากคุณประสบกับผลข้างเคียงใด ๆ ควรแจ้งให้นักวิจัยทราบทันที

คุณสามารถปรึกษาแพทย์ก่อนถึงวันนัดหมายหากจำเป็น

การแจ้งผลข้างเคียงและการดูแลจากแพทย์อย่างทันทั่วทั้งที่จะช่วยให้มั่นใจในความปลอดภัยตลอดระยะเวลาของการวิจัย

9. ประโยชน์ที่อาจได้รับการเข้าร่วมการวิจัย

การกินอาหารแบบจำกัดช่วงเวลา TRE คาดว่าจะให้ผลดังนี้:

- อาจช่วยลดความรุนแรงและพื้นที่ที่ได้รับผลกระทบจากโรคสะกดเงิน
- อาจช่วยลดน้ำหนักตัว ค่า BMI และเส้นรอบเอว
- อาจช่วยปรับปรุงคุณภาพการนอนหลับและคุณภาพชีวิต

อย่างไรก็ตาม ไม่สามารถรับประกันได้ว่าผลลัพธ์ที่คาดหวังเหล่านี้จะเกิดขึ้นกับทุกคน

ผลประโยชน์ต่อวงการแพทย์

การศึกษานี้มีเป้าหมายที่จะช่วยให้บุคลากรทางการแพทย์พัฒนาคำแนะนำทางโภชนาการที่เฉพาะเจาะจง เพื่อช่วยบรรเทาความทุกข์ทรมานของผู้ป่วยโรคสะกดเงินรายอื่นทั่วโลก

10. ทางเลือกหากเลือกที่จะไม่เข้าร่วมการศึกษา

สำหรับผู้ที่ไม่ต้องการเข้าร่วมการศึกษา คุณสามารถใช้ยาที่คุณใช้อยู่ในปัจจุบันต่อไปได้ และปรึกษาแพทย์ผิวหนังของคุณต่อไปเพื่อการดูแลเพิ่มเติม ปัจจุบันมียาใหม่ ๆ ที่กำลังพัฒนาอย่างต่อเนื่อง ทำให้มีวิธีการปรับปรุงสภาพโรคของคุณมากยิ่งขึ้นทางเลือกหากไม่ต้องการเข้าร่วมการวิจัย

11. แนวทางการจัดการเมื่อมีสถานการณ์ที่อาจเกิดขึ้นระหว่างการวิจัย

สถานการณ์	แนวทางการปฏิบัติ
■ หากท่านถอนตัวระหว่างการวิจัย	ท่านจะไม่เข้าร่วมการศึกษาโดยสมัครใจอีกต่อไป
■ หากมีข้อมูลใหม่ที่เกี่ยวข้องกับการวิจัย หรือความปลอดภัยของท่าน	นักวิจัยจะแจ้งให้ท่านทราบทันทีและท่านสามารถตัดสินใจว่าจะร่วมในการวิจัยหรือไม่
■ หากการมีส่วนร่วมในการวิจัยนี้ถูกยกเลิก (จะถูกยกเลิกเมื่อโครงการวิจัยไม่เป็นไปตามเกณฑ์ที่เหมาะสม)	นักวิจัยจะแจ้งให้คุณทราบโดยเร็วที่สุด และจะมีการชดเชยค่าเสียเวลาสำหรับอาสาสมัครทั้งหมด

12. ประโยชน์ที่อาจเกิดขึ้นหลังจากเสร็จสิ้นการวิจัย

หลังจากการวิจัยเสร็จสิ้น คาดว่าผู้เข้าร่วมจะเห็นการปรับปรุงของรอยโรคบนผิวหนัง มีรูปร่างที่สมส่วนมากขึ้น นอนหลับได้ดีขึ้น และมีชีวิตที่มีความสุขมากขึ้น ผลลัพธ์เหล่านี้ไม่เพียงแต่ส่งผลต่อผู้เข้าร่วมการวิจัยเท่านั้น แต่ยังเป็นประโยชน์ต่อผู้ที่มีโรคเดียวกันด้วย.

13. การเก็บข้อมูลเป็นความลับและข้อจำกัด

เนื่องจากจะมีการบันทึกภาพรอยโรคบนผิวหนังของผู้เข้าร่วมการวิจัย ภาพเหล่านี้จะติดฉลากด้วยรหัสภาพแทนการใช้ชื่อของผู้เข้าร่วม หากรอยโรคอยู่ในบริเวณที่สามารถจดจำได้ง่าย เช่น ใบหน้าและหนังศีรษะ จะมีการใช้แถบสีดำปิดบริเวณดวงตาในภาพของผู้เข้าร่วมแต่ละคน ภาพที่บันทึกจะถูกเก็บไว้ในคอมพิวเตอร์ส่วนตัวที่มีการป้องกันด้วยรหัสผ่าน ซึ่งมีเพียงนักวิจัยเท่านั้นที่สามารถเข้าถึงได้

อย่างไรก็ตาม บุคคลหรือกลุ่มบางกลุ่ม เช่น คณะกรรมการจริยธรรม ผู้ประสานงานการวิจัย ผู้ดูแลการวิจัย และบุคลากรที่ได้รับอนุญาตจากหน่วยงานหรือองค์กรของรัฐที่มีหน้าที่ตรวจสอบ อาจสามารถเข้าถึงข้อมูลส่วนบุคคลของคุณเพื่อยืนยันความถูกต้องของข้อมูลและขั้นตอนการวิจัย แม้หลังจากการวิจัยเสร็จสิ้น หากมีการนำเสนอผลการวิจัย ข้อมูลจะถูกนำเสนอโดยไม่มีการระบุข้อมูลที่สามารถระบุตัวผู้เข้าร่วมได้.

14. ค่าตอบแทนสำหรับการเข้าร่วม

อาสาสมัครจะได้รับค่าเดินทางจำนวน 200 บาทต่อการเข้าร่วมแต่ละครั้ง รวมทั้งหมด 4 ครั้ง ได้แก่ ครั้งแรกในช่วงเริ่มต้นการศึกษา และในสัปดาห์ที่ 4, 8 และ 12

15. ค่าใช้จ่ายที่ผู้เข้าร่วมต้องรับผิดชอบ

ผู้เข้าร่วมไม่ต้องเสียค่าใช้จ่ายใด ๆ เนื่องจากค่าใช้จ่ายทั้งหมดในการศึกษาครั้งนี้จะได้รับการสนับสนุนจากนักวิจัยและทุนวิจัยที่ได้รับอนุมัติจากมหาวิทยาลัยแม่ฟ้าหลวง

16. แนวทางการดูแลและชดเชยหากผู้เข้าร่วมได้รับอันตรายหรือผลข้างเคียงจากการเข้าร่วมการวิจัย

การวิจัยนี้ (TRE) อาจมีผลข้างเคียงที่คาดการณ์ได้ เช่น ความหิว ความอยากอาหาร ปวดศีรษะ อ่อนเพลีย นอนไม่หลับ หงุดหงิด สมาธิลดลง คลื่นไส้ ท้องผูก เป็นต้น หากผู้เข้าร่วมมีอาการไม่พึงประสงค์ในช่วงระยะเวลาการศึกษา ควรแจ้งให้นักวิจัยทราบ นักวิจัยจะประเมินอาการผ่านวิดีโอคอลหรือการปรึกษาแบบพบหน้ากัน และหากอาการดังกล่าวเกินขอบเขตความสามารถของนักวิจัย ผู้เข้าร่วมจะถูกส่งต่อไปยังผู้เชี่ยวชาญที่โรงพยาบาลมหาวิทยาลัยแม่ฟ้าหลวงเพื่อรับการดูแลที่เหมาะสม

หากเกิดผลข้างเคียงใด ๆ ขึ้นกับผู้เข้าร่วม นักวิจัยจะรับผิดชอบในการดูแลผู้เข้าร่วมจนกว่าอาการจะกลับสู่ภาวะปกติ หากผู้เข้าร่วมต้องหยุดงานเนื่องจากอาการดังกล่าว นักวิจัยจะชดเชยค่าแรงขั้นต่ำต่อวันให้กับผู้เข้าร่วมในช่วงที่ต้องหยุดงาน.

17. บุคคลติดต่อในกรณีมีคำถามหรือข้อกังวล

หากคุณมีคำถามหรือข้อกังวลเกี่ยวกับการวิจัยหรือความปลอดภัยระหว่างการเข้าร่วม สามารถติดต่อสอบถามนักวิจัยโดยตรงได้ที่ ดร. ฮชู พยะ ชอว์ หมายเลขโทรศัพท์ 084-045-7902 หรือที่ปรึกษางานวิจัยนี้ นพ. ฌนอมกิต เพระสุนทร หมายเลขโทรศัพท์ 081-614-6816

หากคุณมีคำถามเกี่ยวกับสิทธิของคุณ สามารถติดต่อ คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยแม่ฟ้าหลวง ได้ที่อาคารบริการวิชาการ (AS) ชั้น 4 หมายเลขโทรศัพท์ (053) 917-170 ถึง 1 หรือ (053) 916-551 โทรสาร (053) 917-170 หรืออีเมล rec.human@mfu.ac.th เพื่อให้มั่นใจว่าสิทธิ ความปลอดภัย และสวัสดิภาพของคุณได้รับการคุ้มครองตามมาตรฐานสากลของจริยธรรมการวิจัยในมนุษย์.

หนังสือแสดงความยินยอมเข้าร่วมการวิจัย

ข้าพเจ้า _____ ตัดสินใจเข้าร่วมการวิจัยเรื่อง

ประสิทธิภาพของการจำกัดระยะเวลารับประทานอาหารในแต่ละวัน (TRE) ในการลดความรุนแรงของโรค, การลดน้ำหนัก, คุณภาพการนอนหลับและคุณภาพชีวิตในโรคสะกดเงินชนิดผื่นหนาเรื้อรัง ซึ่งข้าพเจ้าได้รับข้อมูลและคำอธิบายเกี่ยวกับการวิจัยนี้แล้ว และได้มีโอกาสซักถามและได้รับคำตอบเป็นที่พอใจแล้ว ข้าพเจ้ามีเวลาเพียงพอในการอ่านและทำความเข้าใจข้อมูลในเอกสารให้ข้อมูลสำหรับผู้เข้าร่วมการวิจัยอย่างถี่ถ้วน และได้รับเวลาเพียงพอในการตัดสินใจว่าจะเข้าร่วมการวิจัยนี้

ข้าพเจ้ารับทราบว่าข้าพเจ้าสามารถปฏิเสธการเข้าร่วมการวิจัยนี้ได้โดยอิสระ และระหว่างการเข้าร่วมการวิจัย ข้าพเจ้ายังสามารถถอนตัวออกจากการวิจัยได้ทุกเมื่อ โดยไม่ส่งผลกระทบต่อการศึกษา หรือสิทธิที่ข้าพเจ้าพึงมี

โดยการลงนามนี้ ข้าพเจ้าไม่ได้สละสิทธิใด ๆ ที่ข้าพเจ้าพึงมีตามกฎหมาย และหลังจากลงนามแล้ว ข้าพเจ้าจะได้รับเอกสารข้อมูลและขอความยินยอมไว้จำนวน 1 ชุด

ลายมือชื่อผู้เข้าร่วมการวิจัย _____ วัน-เดือน-ปี _____
(_____)

..... (กรณีที่ผู้เข้าร่วมการวิจัยอ่านหนังสือไม่ออกแต่ฟังเข้าใจ)

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในเอกสารข้อมูลและขอความยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนามหรือพิมพ์ลายนิ้วมือของข้าพเจ้าในหนังสือนี้ด้วยความเต็มใจ

ลงนาม/พิมพ์ลายนิ้วมือผู้เข้าร่วมการวิจัย _____ วัน-เดือน-ปี _____
(_____)

ลายมือชื่อผู้ขอความยินยอม _____ วัน-เดือน-ปี _____
(_____)

คำรับรองของพยานผู้ไม่มีส่วนได้เสียกับการวิจัย (กรณีที่ผู้เข้าร่วมการวิจัยอ่านหนังสือไม่ออกแต่ฟังเข้าใจ)

ข้าพเจ้าได้อยู่ร่วมในกระบวนการขอความยินยอมและยืนยันว่า ผู้ขอความยินยอมได้อ่าน/อธิบายเอกสารข้อมูลให้แก่ _____ ซึ่งผู้มีชื่อข้างต้นมีโอกาสดูถามข้อสงสัยต่าง ๆ และได้ให้ความยินยอมเข้าร่วมการวิจัยโดยอิสระ หลังจากได้รับทราบข้อมูลที่มีอยู่ตรงตามที่ปรากฏในเอกสารนี้แล้ว

ลายมือชื่อพยาน _____ วัน-เดือน-ปี _____
(_____)

กรณี อาสาสมัครที่เป็นเด็ก หรือน้อยกว่า 18 ปี หรือเป็นบุคคลที่มีปัญหาทางจิตหรือสติปัญญา ต้องได้รับการปกป้องคุ้มครองเป็นพิเศษ

ข้าพเจ้าในฐานะ _____ กับผู้เข้าร่วมการวิจัย ได้อ่านข้อความข้างต้นและมีความเข้าใจดีทุกประการแล้ว ยินยอมให้ ด.ช./ด.ญ./นาย/นาง/นางสาว _____ เข้าร่วมการวิจัยด้วยความสมัครใจ จึงได้ลงนามในเอกสารใบยินยอมนี้

ลายมือชื่อผู้แทนโดยชอบธรรม/ผู้ปกครอง _____ วัน-เดือน-ปี _____

(_____)



APPENDIX C

PATIENT'S PROFILE (CONFIDENTIAL)

Patient's Demographic Information (ข้อมูลประชากรของผู้ป่วย)

1. Date of data collection (วันที่เก็บข้อมูล) _____

2. Gender (เพศ):

☐ Male(ชาย)

☐ Female(หญิง)

3. Age(อายุ)_____

4. History of food or drug allergy (ประวัติของการแพ้อาหารหรือการแพ้ยา)

☐ Yes (มี)

☐ No(ไม่มี)

If Yes, please specify (ถ้ามี กรุณาระบุ): _____

5. Any specific food that can induce or precipitate the skin lesions (อาหารชนิดใดที่สามารถกระตุ้นหรือทำให้เกิดผื่นผิวหนัง)

☐ Yes (มี)

☐ No(ไม่มี)

If Yes, please specify (ถ้ามี กรุณาระบุ): _____

6. Psoriasis duration (Months or Years) (ระยะเวลาของโรคสะเก็ดเงิน) (เดือนหรือปี) _____

7. Underlying chronic illnesses or comorbidities if any (โรคเรื้อรังหรือโรคประจำตัวที่มีอยู่ถ้ามี):

.....

8. Regular medications if any (ยาประจำถ้ามี):

.....

.....

.....

.....

.....

.....

.....

9. Family history of Psoriasis (ประวัติครอบครัวเป็นโรคสะเก็ดเงิน)

- ☐ Yes (มี)
- ☐ No (ไม่มี)

10. History of treatment received before for Psoriasis (ประวัติการรักษาที่เคยได้รับสำหรับโรคสะเก็ดเงิน)

- ☐ Yes (มี)
- ☐ No (ไม่มี)

If Yes, please choose one or more of the following options. (ถ้ามี กรุณาเลือกหนึ่งหรือหลายตัวเลือกต่อไป)

- ☐ Cream (ครีม)
- ☐ Laser or Phototherapy (เลเซอร์หรือการบำบัดด้วยแสง)
- ☐ Oral medication (ยารับประทาน)
- ☐ Others, please specify. (อื่น ๆ โปรดระบุ):

.....

11. Currently practicing lifestyle modification measures (ขณะนี้กำลังปฏิบัติตามการปรับเปลี่ยนวิถีชีวิต)

- ☐ Dietary alterations (การเปลี่ยนแปลงอาหาร)
- ☐ Exercise programs (โปรแกรมการออกกำลังกาย)
- ☐ Alcohol abstinence (การงดเครื่องดื่มแอลกอฮอล์)
- ☐ Smoking cessation (การเลิกบุหรี่)

- ☐ Meditation (การทำสมาธิ)
- ☐ Others, please specify. (อื่น ๆ โปรดระบุ):
.....
- ☐ No lifestyle modification currently (ไม่มีการปรับเปลี่ยนวิถีชีวิตในขณะนี้)



Date

Volunteer Number.....

Psoriasis Area and Severity Index (PASI) scoring sheet

Scoring key

Score	0	1	2	3	4	5	6
Erythema Induration Scaling	None	Slight	Moderate	Severe	Very Severe		
Area %	0	<10	10–29	30–49	50–69	70–89	90–100

	Head	Upper limbs	Trunk	Lower limbs
Erythema				
Induration				
Scaling				
Sum (E+I+S)				
Area score				
Sum x Area				
Correction	x 0.1	x 0.2	x 0.3	x 0.4

+ + + =

Height
cm

Weight
kg

Waist circumference
cm

APPENDIX E

DERMATOLOGY LIFE QUALITY INDEX (DLQI) QUESTIONNAIRES IN ENGLISH

The aim of this questionnaire is to measure how much your skin problem has affected your life **OVER THE LAST WEEK**. Please check one box for each question.

1.	Over the last week, how itchy, sore, painful or stinging has your skin been?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	
2.	Over the last week, how embarrassed or self-conscious have you been because of your skin?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	
3.	Over the last week, how much has your skin interfered with you going shopping or looking after your home or yard ?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant ☐
4.	Over the last week, how much has your skin influenced the clothes you wear?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant ☐
5.	Over the last week, how much has your skin affected any social or leisure activities?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant ☐
6.	Over the last week, how much has your skin made it difficult for you to do any sport ?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant ☐

7.	Over the last week, has your skin prevented you from working or studying ?	yes	☐	Not relevant ☐
		no	☐	
	If "No", over the last week how much has your skin been a problem at work or studying ?	A lot	☐	
		A little	☐	
		Not at all	☐	
8.	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives ?	Very much	☐	Not relevant ☐
		A lot	☐	
		A little	☐	
		Not at all	☐	
9.	Over the last week, how much has your skin caused any sexual difficulties ?	Very much	☐	Not relevant ☐
		A lot	☐	
		A little	☐	
		Not at all	☐	
10.	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	Very much	☐	Not relevant ☐
		A lot	☐	
		A little	☐	
		Not at all	☐	

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APPENDIX F

DLQI THAI VERSION

แบบสอบถามวัดคุณภาพชีวิตของผู้ป่วยโรคผิวหนัง

(ข้อมูลของท่านจะเป็นความลับ ไม่ถูกนำไปเปิดเผยเป็นรายบุคคลต่อผู้ใดทั้งสิ้น)

DLQI Score: _____

หมายเลขอาสาสมัคร _____ วันที่ ____ / ____ / ____

จุดประสงค์ของแบบสอบถามนี้เพื่อประเมินว่า ผื่นผิวหนังทำให้เกิดปัญหากับคุณมากน้อยเพียงใดในช่วงหนึ่งสัปดาห์ที่ผ่านมา?		
กรุณาตอบคำถามโดยทำเครื่องหมาย ☐ ลงในช่องทางขวามือ (ขอความกรุณาตอบคำถามทุกข้อ)		
1. ช่วงสัปดาห์ที่ผ่านมา คุณมีอาการคัน, เจ็บ, ปวด, หรือปวดเสียว ที่ผิวหนัง มากน้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	
2. ช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังทำให้คุณรู้สึกอับอาย, ขาดความมั่นใจ มาก น้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	
3. ในช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังทำให้คุณมีปัญหาในการออกจากบ้านไป จ้างยาสีบล้าง, ดูแลบ้าน หรือดูแลสวน มากน้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	☐ ไม่มีความเกี่ยวข้อง
4. ช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังของคุณ มีผลกระทบต่อการเลือกเสื้อผ้าที่จะสวมใส่ มากน้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	☐ ไม่มีความเกี่ยวข้อง

5. ช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังของคุณ มีผลกระทบต่อการ เข้าสังคม หรือ ต่อกิจกรรมในยามว่าง มากน้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	☐ ไม่มีความ เกี่ยวข้อง
6. ช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังมีผลกระทบต่อการเล่นกีฬา การออกกำลังกายของคุณ มากน้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	☐ ไม่มีความ เกี่ยวข้อง
7. ช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังมีผลทำให้คุณขาดงานหรือ ขาดเรียนหรือไม่	☐ มี ☐ ไม่มี	☐ ไม่มีความ เกี่ยวข้อง
ถ้า “ไม่มี” ในช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังทำให้คุณมี ปัญหาในการ ทำงาน หรือการเรียน มากน้อยเพียงใด	☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	
8. ช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังของคุณ ได้สร้างปัญหาให้กับ คู่ครอง หรือญาติหรือเพื่อนสนิท มากน้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	☐ ไม่มีความ เกี่ยวข้อง
9. ช่วงสัปดาห์ที่ผ่านมา ผื่นผิวหนังทำให้คุณมีปัญหาในการมี เพศสัมพันธ์มาก น้อยเพียงใด	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	☐ ไม่มีความ เกี่ยวข้อง
10. ช่วงสัปดาห์ที่ผ่านมาการรักษาผื่นผิวหนังก่อให้เกิดปัญหา แก่คุณ มากน้อย เพียงใด เช่น ทำให้มีการประอะเปื้อนในบ้าน, การรักษาทำให้เสียเวลา เป็นต้น	☐ มาก ☐ ปานกลาง ☐ เล็กน้อย ☐ ไม่มีเลย	☐ ไม่มีความ เกี่ยวข้อง

APPENDIX G

PITTSBURGH SLEEP QUALITY INDEX (PSQI) QUESTIONNAIRES IN ENGLISH

Instructions: The following questions relate to your usual sleep habits during the past month. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night? _____
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night? _____
3. During the past month, what time have you usually gotten up in the morning? _____
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.) _____

Table G1. PSQI questionnaires (continued)

5. During the past month, how often have you had trouble sleeping because you...	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes.				
b. Wake up in the middle of the night or early morning.				
c. Have to get up to use the bathroom.				
d. Cannot breathe comfortably.				
e. Cough or snore loudly.				
f. Feel too cold.				
g. Feel too hot.				
h. Have bad dreams.				
i. Have pain.				
j. Other reason(s), please describe:				

6. During the past month, how often have you taken medicine to help you sleep (prescribed or “over the counter”)?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				
	Very good	Fairly good	Fairly bad	Very bad
9. During the past month, how would you rate your sleep quality overall?				
	No bed partner or roommate	Partner or roommate in another room	Partner in the same room but not the same bed	Partner in the same bed
10. Do you have a bed partner or roommate?				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
If you have a roommate or bed partner, ask him/her how often in the past month you have had:				
a. Loud snoring				

b. Long pauses between breaths while asleep				
c. Legs twitching or jerking while you sleep				
d. Episodes of disorientation or confusion during sleep				
e. Other restlessness while you sleep, please describe:				



APPENDIX H

PITTSBURGH SLEEP QUALITY INDEX (PSQI) QUESTIONNAIRES IN THAI

แบบประเมินคุณภาพการนอนหลับของพิตส์เบิร์กฉบับภาษาไทย

คำแนะนำในการตอบแบบสอบถาม

คำถามต่อไปนี้เกี่ยวข้องกับพฤติกรรมการณ์การนอนของท่านในช่วงระยะเวลา 1 เดือนที่ผ่านมา
คำตอบของท่านควรบ่งบอกสิ่งที่ใกล้เคียงความเป็นจริงมากที่สุด และเป็นสิ่งที่เกิดขึ้นกับตัวท่านเป็น
ส่วนใหญ่ทั้งในเวลา กลางวันและกลางคืน โปรดตอบทุกคำถาม

1. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ส่วนใหญ่ท่านมักเข้านอนเวลากี่โมง
เวลาเข้านอน _____
2. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ส่วนใหญ่ท่านต้องใช้เวลานานเท่าไร(นาที)จึงจะนอนหลับ
จำนวนนาที _____
3. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ส่วนใหญ่ท่านตื่นนอนตอนเช้าเวลากี่โมง
เวลาที่ตื่นนอนตอนเช้า _____
4. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ท่านนอนหลับได้จริงเป็นเวลาที่ชั่วโมงต่อคืน (คำตอบอาจ
แตกต่างจาก
ระยะเวลารวมทั้งหมดตั้งแต่เริ่มเข้านอนจนถึงตื่นนอน)
จำนวนชั่วโมงที่หลับได้จริงต่อคืน _____

โปรดตอบคำถามข้างล่างต่อไปนี้ทุกข้อ โดยแต่ละข้อให้เลือกตอบเพียง 1 คำตอบ

5. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ท่านมีปัญหาการนอนหลับเนื่องจากเหตุผลต่อไปนี้ บ่อยเพียงใด
 - 5.1 นอนไม่หลับหลังจากเข้านอนไปแล้วนานกว่า 30 นาที

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา
 _____ น้อยกว่า 1 ครั้งต่อสัปดาห์
 _____ 1 หรือ 2 ครั้งต่อสัปดาห์
 _____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.2 รู้สึกตัวตื่นขึ้นระหว่างนอนหลับกลางดึก หรือตื่นเช้ากว่าเวลาที่ตั้งใจไว้

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.3 ตื่นเพื่อไปเข้าห้องน้ำ

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.4 หายใจไม่สะดวก

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.5 ไอ หรือ กรน เสียงดัง

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.6 รู้สึกหนาวเกินไป

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.7 รู้สึกร้อนเกินไป

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.8 ฝันร้าย

- _____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา
- _____ น้อยกว่า 1 ครั้งต่อสัปดาห์
- _____ 1 หรือ 2 ครั้งต่อสัปดาห์
- _____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.9 รู้สึกปวด

- _____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา
- _____ น้อยกว่า 1 ครั้งต่อสัปดาห์
- _____ 1 หรือ 2 ครั้งต่อสัปดาห์
- _____ 3 ครั้งต่อสัปดาห์ขึ้นไป

5.10 เหตุผลอื่น ถ้ามี กรุณาระบุ _____

จากเหตุผลในข้อ 5.10 ในช่วงระยะเวลา 1 เดือนที่ผ่านมา เกิดบ่อยเพียงใด

- _____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา
- _____ น้อยกว่า 1 ครั้งต่อสัปดาห์
- _____ 1 หรือ 2 ครั้งต่อสัปดาห์
- _____ 3 ครั้งต่อสัปดาห์ขึ้นไป

6. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ท่านคิดว่าคุณภาพการนอนหลับโดยรวมของท่านเป็นอย่างไร

- _____ ดีมาก
- _____ ค่อนข้างดี
- _____ ค่อนข้างแย่
- _____ แย่มาก

7. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ท่านใช้ยาเพื่อช่วยในการนอนหลับ บ่อยเพียงใด (ไม่ว่าจะตามใบสั่งแพทย์ หรือ หาซื้อเอง)

- _____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา
- _____ น้อยกว่า 1 ครั้งต่อสัปดาห์
- _____ 1 หรือ 2 ครั้งต่อสัปดาห์
- _____ 3 ครั้งต่อสัปดาห์ขึ้นไป

8. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ท่านมีปัญหา่วงนอนหรือเผลอหลับ ขณะขับขียานพาหนะ, ขณะรับประทานอาหาร หรือขณะเข้าร่วมกิจกรรมทางสังคมต่างๆ บ่อยเพียงใด

- _____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา
- _____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

9. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ท่านมีปัญหาเกี่ยวกับความกระตือรือร้นในการทำงานให้สำเร็จ
มากน้อยเพียงใด

_____ ไม่มีปัญหาเลยแม้แต่น้อย

_____ มีปัญหาเพียงเล็กน้อย

_____ ค่อนข้างที่จะเป็นปัญหา

_____ เป็นปัญหาย่างมาก

10. ท่านมีเพื่อน, เพื่อนร่วมห้องหรือผู้อาศัยอยู่ในบ้านหลังเดียวกันหรือไม่

_____ ไม่มีเลย

_____ มี แต่นอนคนละห้อง

_____ มี และนอนในห้องเดียวกัน แต่คนละเตียง

_____ มี และนอนเตียงเดียวกัน

หากท่านตอบว่ามี กรุณาสอบถามจากบุคคลข้างต้นว่า ในช่วงระยะเวลา 1 เดือนที่ผ่านมา ท่านได้เคย
มีอาการดังต่อไปนี้หรือไม่

10.1 กรณเสียงดัง

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

10.2 มีช่วงหยุดหายใจเป็นระยะเวลานาน ขณะหลับ

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

10.3 ขากระตุก ขณะหลับ

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

10.4 สับสนเป็นช่วงๆ ขณะหลับ

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป

10.5 อาการกระสับกระส่ายอื่นๆที่พบขณะหลับ ถ้ามี กรุณาระบุ _____

จากอาการในข้อ 10.5 ในช่วงระยะเวลา 1 เดือนที่ผ่านมา มีอาการบ่อยเพียงใด

_____ ไม่เคยเลยในช่วงระยะเวลา 1 เดือนที่ผ่านมา

_____ น้อยกว่า 1 ครั้งต่อสัปดาห์

_____ 1 หรือ 2 ครั้งต่อสัปดาห์

_____ 3 ครั้งต่อสัปดาห์ขึ้นไป



APPENDIX I

PATIENT'S SATISFACTION SCORE SHEET

Please rate your level of satisfaction with the intervention using the following grading scales (0–3) for all 4 areas:

- ☐ 0 = Unsatisfied, No improvement in disease severity, life quality, sleep quality and weight reduction
- ☐ 1 = Somewhat satisfied, Slight improvement in disease severity, life quality, sleep quality and weight reduction
- ☐ 2 = Moderately satisfied, Visible improvement in disease severity, life quality, sleep quality and weight reduction
- ☐ 3 = Very satisfied, Significant improvement in disease severity, life quality, sleep quality and weight reduction

Would you like to practice TRE again in the future?

- ☐ Yes
- ☐ No

If No, please specify the reason.

APPENDIX J

PATIENT'S SATISFACTION SCORE SHEET IN THAI

แผ่นคะแนนความพึงพอใจของผู้ป่วย

โปรดให้คะแนนระดับความพึงพอใจของคุณกับการแทรกแซงโดยใช้มาตราส่วนการให้คะแนนต่อไปนี้ (0-3) สำหรับทั้ง 4 ด้าน:

- ☐ 0 = ไม่พอใจ ไม่มีการปรับปรุงความรุนแรงของโรค คุณภาพชีวิต คุณภาพการนอนหลับ และการลดน้ำหนัก
- ☐ 1 = ค่อนข้างพอใจ ความรุนแรงของโรคดีขึ้นเล็กน้อย คุณภาพชีวิต คุณภาพการนอนหลับ และการลดน้ำหนัก
- ☐ 2 = พอใจปานกลาง ความรุนแรงของโรค คุณภาพชีวิต คุณภาพการนอนหลับ และการลดน้ำหนักดีขึ้นอย่างเห็นได้ชัด
- ☐ 3 = พอใจมาก การปรับปรุงอย่างมีนัยสำคัญในความรุนแรงของโรค คุณภาพชีวิต คุณภาพการนอนหลับ และการลดน้ำหนัก

คุณต้องการฝึก TRE อีกครั้งในอนาคตหรือไม่?

- ☐ ใช่
- ☐ ไม่

ถ้าไม่ โปรดระบุเหตุผล

APPENDIX K

SIDE EFFECT ASSESSMENT FORM

Did you experience any unintended side effects or symptoms throughout the study period?

☐ Yes

☐ No

If “Yes”, please tick every symptom that you had during each specific week in the following Table 1.

Table 1. Adverse effects experienced by the participants during the study period

Unwanted symptoms	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Hunger												
Craving for food												
Binge eating												
Nausea												
Constipation												
Headache												
Inability to sleep												
Irritability												
Inability to concentrate												
Fatigue												
Blurred vision												
Slurred speech												
Disorientation												
Seizure												
Loss of consciousness												
Others												

If you have chosen “Others”, please specify.

APPENDIX L

SIDE EFFECT ASSESSMENT FORM

แบบฟอร์มการประเมินผลข้างเคียง

คุณมีอาการข้างเคียงหรืออาการไม่พึงประสงค์ใดๆ ในช่วงระยะเวลาการศึกษาหรือไม่?

☐

มี

☐

ไม่มี

ถ้ามี กรุณาช่วยเลือกอาการทั้งหมดที่คุณมีในแต่ละสัปดาห์ตามตารางที่ 1 ด้านล่างนี้

ตารางที่ 1 ผลข้างเคียงที่อาจจะเกิดกับผู้เข้าร่วมงานวิจัยในช่วงระยะเวลาการศึกษา

อาการข้างเคียง	สัปดาห์ ที่ 1	สัปดาห์ ที่ 2	สัปดาห์ ที่ 3	สัปดาห์ ที่ 4	สัปดาห์ ที่ 5	สัปดาห์ ที่ 6	สัปดาห์ ที่ 7	สัปดาห์ ที่ 8	สัปดาห์ ที่ 9	สัปดาห์ ที่ 10	สัปดาห์ ที่ 11	สัปดาห์ ที่ 12
หิวมากตลอดเวลา												
อยากทานอาหาร มาก												
กินแบบไม่ยั้ง												
คลื่นไส้												
ท้องผูก												
ปวดหัว												
นอนไม่หลับ												
หงุดหงิด												
ไม่มีสมาธิ												
เมื่อยล้า												
มองเห็นภาพเบลอ												
พูดไม่ชัด												
สับสน												
ชัก												
สูญเสียสติ												
อาการอื่นๆ												

หากคุณเลือก "อาการอื่นๆ" กรุณาช่วยระบุให้ชัดเจน.....

[illegible][illegible]

Table 3. DLQI scores of the patients at Baseline and Week 12

[illegible]

Table 4. PSQI scores of the patients at Baseline and Week 12

[illegible]

Table 5. Patients' Satisfaction Scores at Week 12

[illegible]

Table 6. Overall Side Effect Profile

[illegible]

APPENDIX N

RESEARCH ADVERTISEMENT (THAI)

Version 2.0 Date 29Nov2024

รับสมัครอาสาสมัครผู้ใหญ่ที่มีภาวะสะเก็ดเงิน (Psoriasis) เพื่อเข้าร่วมการศึกษาทางคลินิกเกี่ยวกับผลกระทบของการอดอาหารแบบ 16 ชั่วโมงต่อวันต่อรอยโรคบนผิวหนัง น้ำหนักตัว การนอนหลับและคุณภาพชีวิต

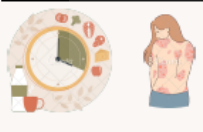
	การศึกษานี้เกี่ยวกับอะไร? การศึกษานี้มีวัตถุประสงค์เพื่อค้นหาว่าการกินอาหารแบบจำกัดเวลา (Time-Restricted Eating หรือ TRE) สามารถเปลี่ยนแปลงให้ความรุนแรงของรอยโรคบนผิวหนัง รวมถึงน้ำหนักตัว การนอนหลับ และคุณภาพชีวิตของผู้ที่มีภาวะสะเก็ดเงินชนิด Plaque-Type ได้หรือไม่
	ผู้เข้าร่วมจะถูกขอให้ทำอะไร? ระหว่างการศึกษา คุณจะถูกขอให้ปฏิบัติตามการรับประทานอาหารแบบจำกัดเวลา (Time-Restricted Eating หรือ TRE) เป็นเวลา 12 สัปดาห์ ซึ่งหมายถึงการรับประทานอาหารเฉพาะในช่วงเวลา 8 ชั่วโมงต่อวัน และงดอาหารในช่วง 16 ชั่วโมงที่เหลือ โดยไม่มีข้อจำกัดเรื่องปริมาณแคลอรีที่บริโภค แต่จะจำกัดเฉพาะช่วงเวลาที่สามารถรับประทานอาหารได้เท่านั้น ในช่วงเริ่มต้นการลงทะเบียน และหลังจากครบ 12 สัปดาห์ คุณจะถูกขอให้ตอบแบบสอบถามเกี่ยวกับการนอนหลับและคุณภาพชีวิตของคุณ ภาพถ่ายของรอยโรคบนผิวหนังและการวัดสัดส่วนร่างกายจะถูกบันทึกในช่วงเริ่มต้น (Baseline) และในสัปดาห์ที่ 4, 8 และ 12 คุณจำเป็นต้องใส่แอปพลิเคชันบนโทรศัพท์มือถือทุกวันเพื่อจดเวลาที่รับประทานอาหารเมื่อแรกและเมื่อสุดท้าย เพื่อให้มั่นใจว่าคุณปฏิบัติตามโปรแกรมการรับประทานอาหาร นอกจากนี้ คุณจะต้องบันทึกผลข้างเคียงใดๆ ที่เกิดขึ้นระหว่างการเข้าร่วมโปรแกรม TRE 12 สัปดาห์นี้ด้วย
	ใครสามารถเข้าร่วมการศึกษานี้ได้บ้าง? ผู้ที่ต้องการเข้าร่วมการศึกษานี้คือผู้มีคุณสมบัติดังนี้: - มีโรคสะเก็ดเงินชนิด Plaque-type Psoriasis และได้รับการรักษาเฉพาะทางยาภายนอกเท่านั้น - มีอายุระหว่าง 30-60 ปี - มีค่าดัชนีมวลกาย (BMI) อยู่ระหว่าง 25-35 กก./ตร.ม. - มีสุขภาพโดยรวมที่ดีและไม่มีโรคประจำตัวที่ต้องใช้ยาประจำตัวก่อนหรือหลังอาหาร เนื่องจากการศึกษาเกี่ยวข้องกับการอดอาหารในบางช่วงเวลา
	ผู้เข้าร่วมสามารถติดต่อผู้วิจัยได้อย่างไร? คุณสามารถติดต่อผู้วิจัยได้ผ่านทาง: อีเมล: 1992happyjoyzaw@gmail.com โทรศัพท์: 080457902 LINE: happyjoyzaw นอกจากนี้ คุณยังสามารถใช้ QR Code ที่สามารถสแกนด้วยสมาร์ตโฟนเพื่อเข้าถึงบัญชี LINE ของผู้วิจัยได้โดยตรง
	สถานที่วิจัยอยู่ที่ไหน? กระบวนการวิจัยจะดำเนินการที่โรงพยาบาลมหาวิทยาลัยแม่ฟ้าหลวง ซึ่งตั้งอยู่ที่ 30/12 ถนนเอ็กมาเนติ แขวงคลองเตยเหนือ เขตวัฒนา กรุงเทพมหานคร 10110

APPENDIX O

RESEARCH ADVERTISEMENT (ENGLISH)

Version 2.0 Date 29Nov2024

We are recruiting adult volunteers with Psoriasis to participate in the clinical study examining the effects of daily 16-hour fasting on the skin lesion, body weight, sleep and life qualities.

	What is the study about? The study is to find out whether time-restricted eating can change not only the severity of skin lesions but also the body weight, sleep and life qualities in people with plaque-type Psoriasis.
	What will participants be asked to do? During the study, you will be asked to practice 12 weeks of time-restricted eating (TRE), i.e, eating only 8 hours a day and for the remaining 16 hours, you need to fast. There will be no limitation of calorie intake, only the time of eating will be restricted. At the time of enrollment, and after 12 weeks, you will be asked to answer the questionnaires related to your sleep and life quality. The photos of your skin lesions and the body measurements will be taken at baseline, week 4, 8 and 12. You need to use a mobile phone application daily to mark the time of first and last meal so that your compliance to the diet is ensured. It is required to note down any side effect that you experience during the whole 12-week-TRE program.
	Who can participate in this study? To take part in the study, you must • have Plaque-type Psoriasis treated topically only • be 30-60 years old with BMI of 25-35kg/m2 and • be in good health and should not have any pre-existing medical conditions that require regular medication before or after meals, as this research study involves fasting during certain periods.
	How can participants contact the researcher? You can contact the researcher by email: 1992hrupayzaw@gmail.com; or by phoning 080457902; or by LINE: hrupayzaw. You may also Choose to use a QR code that can be read by one's smartphone that takes you to the researcher's LINE account.
	Where will be the research location? The research process will take place at Mae Fah Luang University Hospital, which is located at 38/12 Asok Montri Rd, Khlong Toei Nuea, Watthana, Bangkok 10110.

APPENDIX P

DATA VISUALIZATIONS

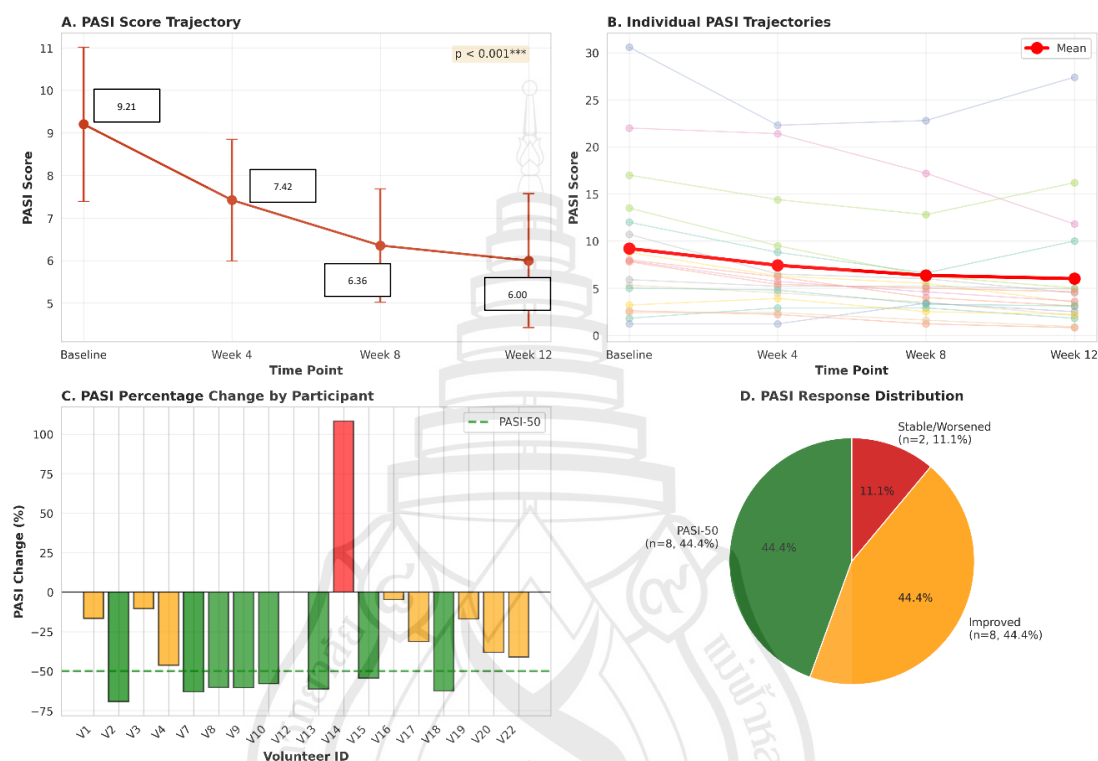


Figure P1 Changes in Psoriasis Disease Severity throughout the study: (A) Mean PASI $\pm$ SD at each visit (B) Individual PASI scores at each visit (C, D) PASI response distributions

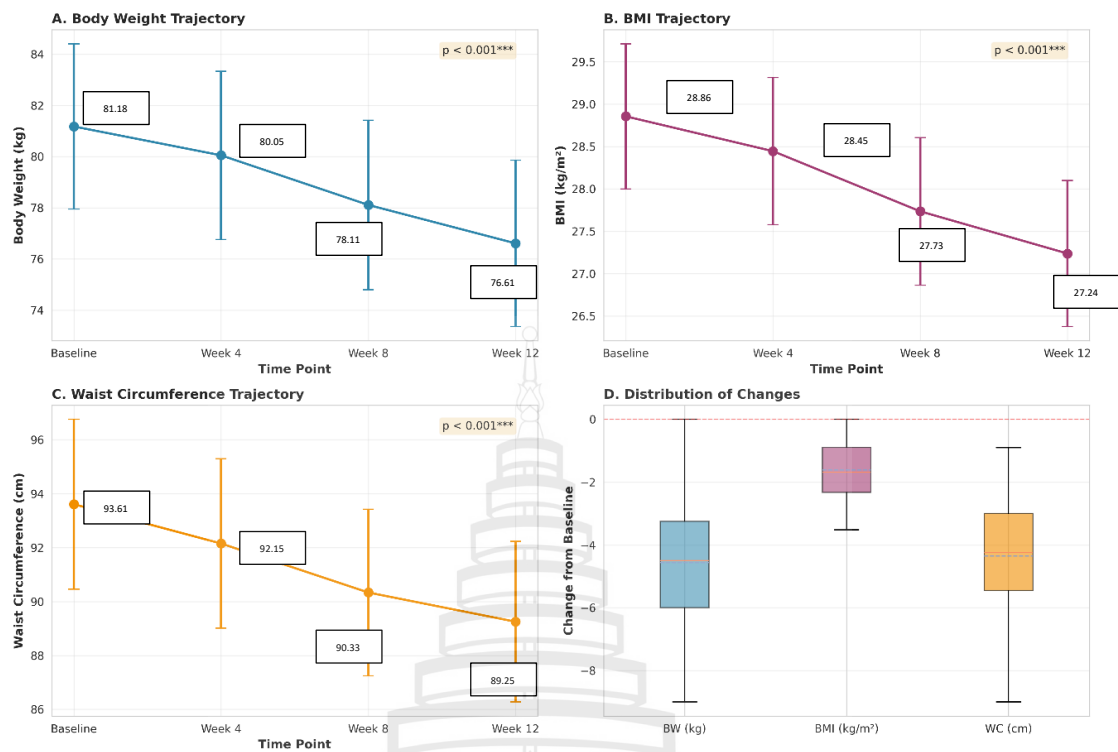


Figure P2 Anthropometric Changes after 12-Week TRE Intervention: (A) Serial Changes in Body Weight (B) Serial Changes in BMI (C) Serial Changes in Waist Circumference (D) Distribution of Changes in all 3 Categories

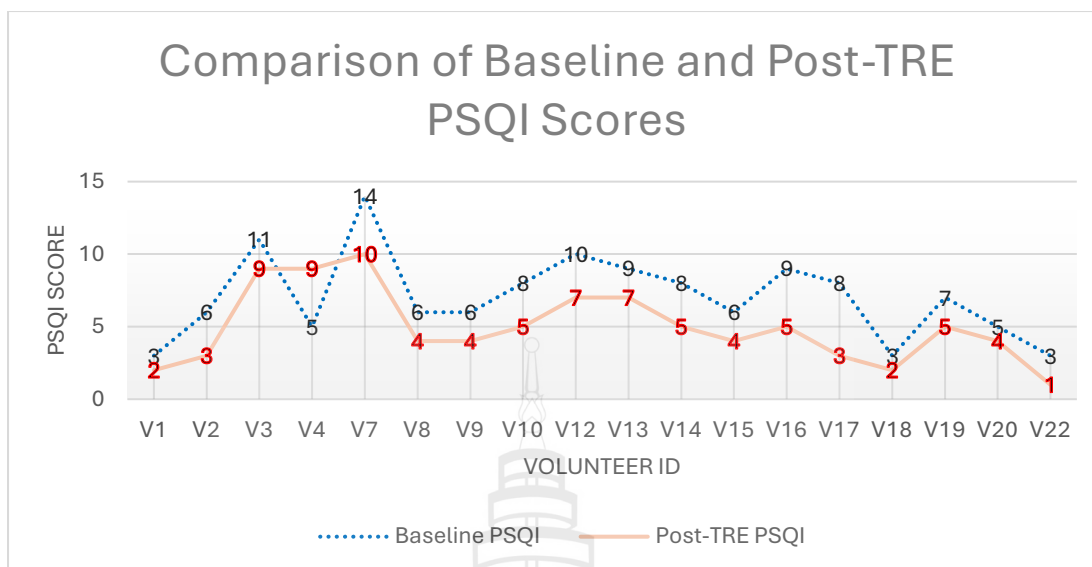


Figure P3 Changes in individual PSQI scores before and after TRE intervention

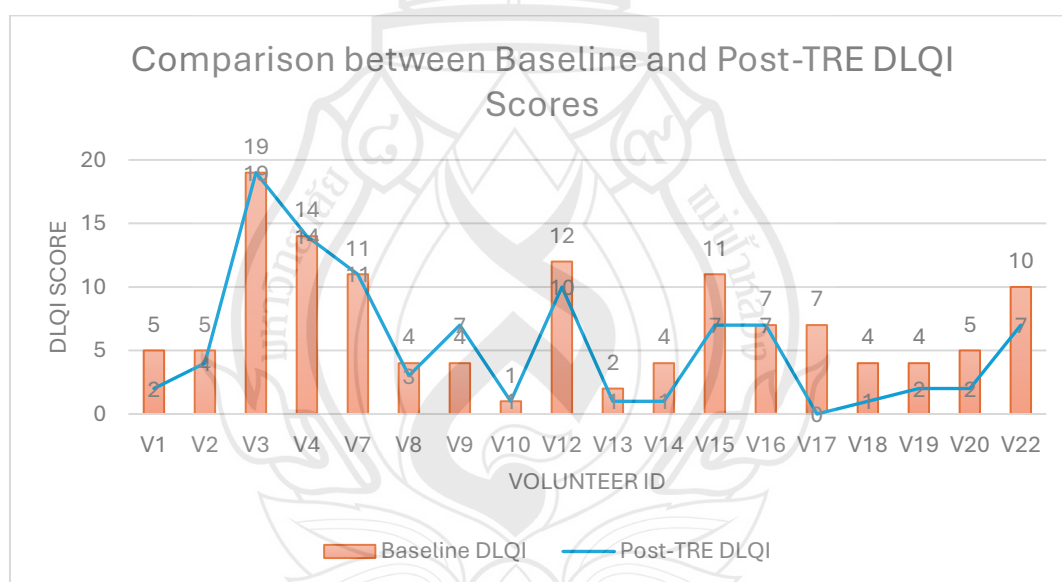


Figure P4 Changes in individual DLQI scores before and after TRE intervention

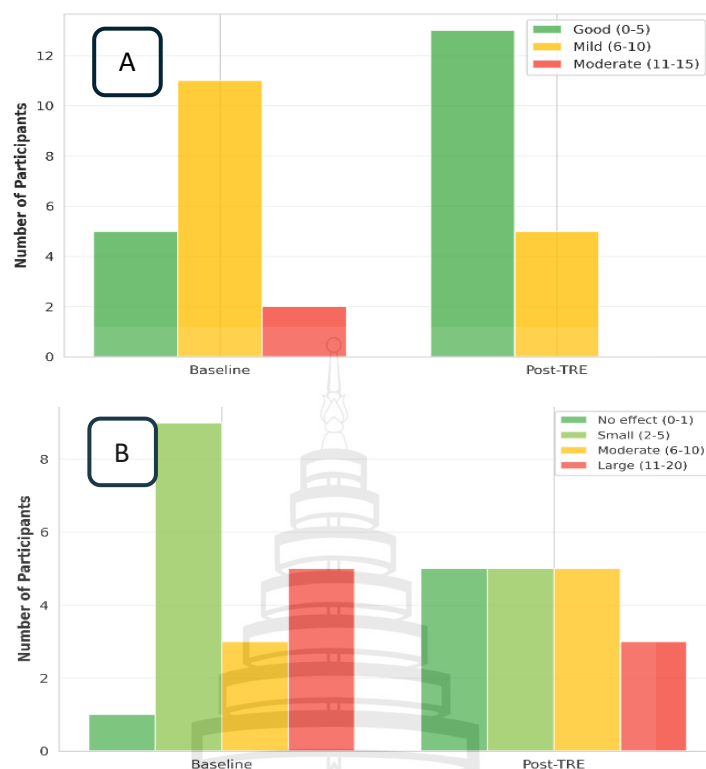


Figure P5 Categorical Changes in PSQI (A) and DLQI (B) Before and After TRE

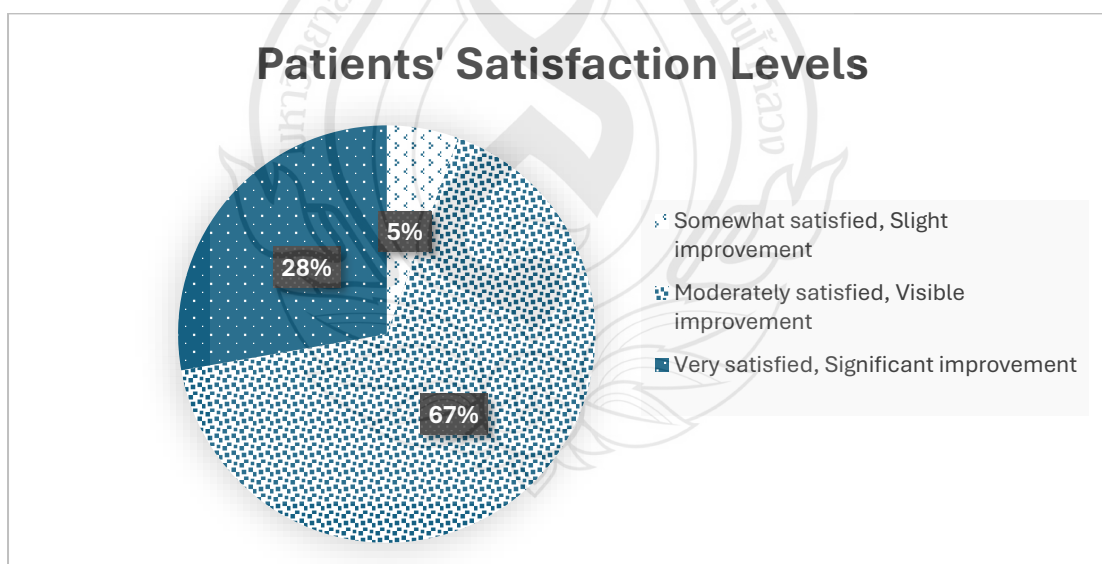


Figure P6 Pie chart showing the participants' satisfaction levels

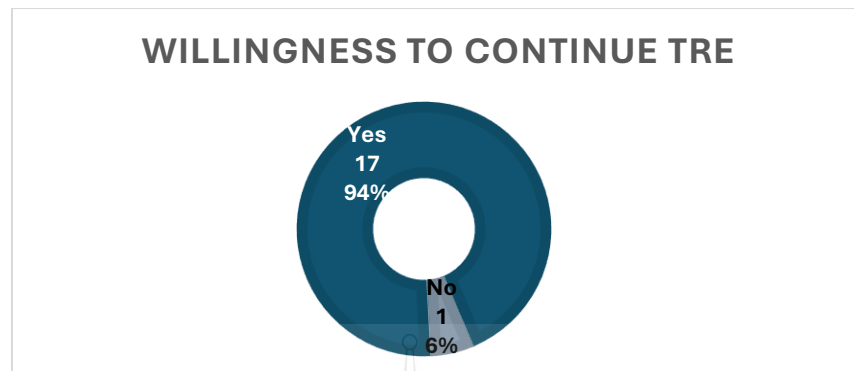


Figure P7 Donut chart showing the proportion of subjects who are willing to continue TRE



CURRICULUM VITAE

NAME Hsu Pyay Zaw

EDUCATIONAL BACKGROUND

2021	Professional Certificate of General Dermatology Healthcare Education, Bond University, Australia
2019	Certificate of Advanced Cardiovascular Life Support (ACLS) American Heart Association
2019	Passed Part 1 Exam for Membership of the Royal College of Physicians of the United Kingdom (MRCP UK) Royal College of Physicians, United Kingdom
2015	Bachelor of Medicine, Bachelor of Surgery (M.B.,B.S) University of Medicine, Mandalay, Myanmar

WORK EXPERIENCE

2021 - 2022	Resident Medical Officer of In-Patient Department (IPD) Pun Hlaing Hospital, Mandalay, Myanmar
2020 - 2021	Emergency Medical Officer City Hospital, Mandalay, Myanmar
2019 – 2020	Medical Site Doctor International SOS Clinic
2017 – 2019	Medical Officer Mandalay Specialist Centre Clinic
2014 – 2015	House Officer (Internship) Institutions: Mandalay General Hospital, 300- bedded Teaching Hospital, 300-bedded Children Hospital, Central Women Hospital, Mandalay, Myanmar

VOLUNTEER WORK

2020

Volunteer Medical Officer

Aung Myay Thar San Fever Clinic during
COVID-19 pandemic, Mandalay, Myanmar

2021

Volunteer Medical Officer

Bramaso Charity Clinic, Mandalay, Myanmar

