Educational and self-management interventions for patients with psoriasis in the context of climate/heliotherapy

Marie Hamilton Larsen

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Department of Health Sciences

Institute of Health and Society

Faculty of Medicine

University of Oslo, Norway

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Acknowledgements

LIST OF PAPERS

This thesis is based on the following papers:

Larsen MH, Hagen KB, Krogstad AL, Aas E, Wahl AK. Limited evidence of the effects of patient education and self-management interventions in psoriasis patients: A systematic review. *Patient Education and Counseling* 2014 Feb; 94(2):158−69. doi: 0.1016/j.pec.2013.10.005. Epub 2013 Oct 14.

Larsen MH, Krogstad AL, Aas E, Moum T, Wahl AK: A telephone based motivational interviewing intervention has positive effects on psoriasis severity and self-management − A randomized controlled trial. *Br J Dermatol 2014,* Dec; 171(6):1458-69.

Larsen MH, Wahl AK, Krogstad AL, Aas E: Cost−utility analysis of supported self-management with Motivational Interviewing for patients with psoriasis. Submitted.

Abbreviations

AUC	Area under the curve
BIPQ	Brief Illness Perception Questionnaire
BMI	Body mass index
CBT	Cognitive behavioural therapy
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness acceptability curves
CHT	Climate/heliotherapy
CI	Confidence interval
CLCI	Cumulative Life Course Impairment
COPD	Chronic obstructive pulmonary disease
CUA	Cost–utility analysis
CVD	Cardio-vascular disease
DLQI	Dermatological Life Quality Index
GLM	General linear model
HeiQ	Health Education Impact Questionnaire
HRQoL	Health-related quality of life
ICER	Incremental cost-effectiveness ratio
MI	Motivational interviewing
MIC lab	Motivational Interviewing Coding Laboratory
MITI	Motivational Interviewing Treatment Integrity
NICE	National Institute for Clinical Excellence
PASI	Psoriasis Area and Severity Index
PKQ	Psoriasis Knowledge Questionnaire
QALY	Quality-adjusted life year
QoL	Quality of life
RCT	Randomized controlled trial
ROB	Risk of systematic bias
SAPASI	Self-administered Psoriasis Area and Severity Index
SD	Standard deviation
SMS	Self-management support
SPSS	Statistical Package for the Social Sciences
TAU	Treatment as usual
TTM	Transtheoretical Model of Change
VAS	Visual analogue scale

Summary

Background: Achronic inflammatory immune-mediated skin disorder such as psoriasis require a high level of self-management to acquire the skills, knowledge, self-efficacy and expertise to make constructive choices about treatment and potentially desirable lifestyle changes. However, patients with psoriasis have not been included in research into the effectiveness of educational and self-management interventions for patients living with long-term conditions. Furthermore, there appears to have been limited research interest in developing tailored self-management support (SMS) interventions to improve clinical symptoms, quality of life and self-management for patients with psoriasis.

Aim: The overall aim of this study was to investigate the effects and effectiveness of self-management interventions for patients with psoriasis. Through a systematic review, we described the content and investigated the effects of educational and self-management interventions for this population (paper 1). Second, in a randomized controlled trial (RCT), the effects of an SMS method, i.e., motivational interviewing (MI), were evaluated following 3 weeks of climate/heliotherapy (CHT) (paper 2). The aim was to determine whether motivational interviews by telephone could increase the effect of CHT on outcomes such as disease severity (Self-administered Psoriasis Area Severity Index, SAPASI), self-management (Health Education Impact Questionnaire, HeiQ), knowledge (Psoriasis Knowledge Questionnaire, PKQ) and changes in lifestyle. Finally, a cost–utility analysis assessed the health economic benefits of the MI intervention compared with treatment as usual following CHT (paper 3).

Method: The following designs were employed: a systematic review (paper 1) and an RCT (papers 2 and 3). Nine studies (RCTs, quasi–randomized trials and controlled clinical trials) were included in the systematic review. Methodological quality (risk of bias) was assessed according to the Cochrane Handbook. The main sample comprised 169 patients with psoriasis, who received 3 weeks of CHT in Gran Canaria. The participants were assigned randomly to control (83 patients) or study (86 patients) groups. The MI intervention comprised one mapping talk and six follow-up telephone calls during the 12 weeks following CHT. Four self-management domains were discussed during the calls – diet, physical activity, stress management and psoriasis treatment – but the latter was the only mandatory topic in all of the calls. The main outcome measures were SAPASI and HeiQ. The secondary outcome measures were illness perception (B-IPQ), psoriasis knowledge (PKQ), self -efficacy and

lifestyle change assessments. In the economic evaluation, we assessed health-related quality of life (HRQoL) as quality-adjusted life years (QALYs) based on the generic measure 15D and the disease-specific Dermatological Life Quality Index (DLQI). In addition, we estimated health care utilization, productivity losses and the cost of psoriasis treatment.

Outcomes were measured at baseline, after 3 weeks of CHT (before randomization), and 3 months and 6 months later. In total, 135 patients (80%) reached the third measurement point, and 125 (74%) reached the fourth after 6 months.

Results: The quality evaluation of the reviewed studies revealed a high overall risk of bias, where this deficiency affected the reliability of making strong conclusions regarding the impact and efficacy of educational and self-management interventions for patients with psoriasis. It was noted that there was a lack of self-management focus. In the RCT study, there were significant overall treatment effects in the study group in terms of the SAPASI score after 3 months ($p < 0.001$) and 6 months ($p = 0.011$), in some self-management domains of HeiQ and in the self-efficacy scores ($p = 0.002$ and $p = 0.024$) compared with treatment as usual. The lifestyle change parameters related to skin care were significantly better in the study group after 3 months ($p = 0.045$) and 6 months ($p = 0.048$). In the study group, illness perception (Brief Illness Perception Questionnaire summed score) was significantly lower after 3 months ($p = 0.014$), and psoriasis knowledge (PKQ) was significantly better after 6 months ($p = 0.017$) compared with the controls. In the economic evaluation, MI was shown to provide equivalent quality of life and utility compared with treatment as usual but at a lower cost. Thus, the MI intervention was cost-effective. This result seemed more obvious when using the DLQI as the outcome measure compared with 15D.

Conclusions: The systematic review indicates that there is limited knowledge of educational and self-management interventions for patients with psoriasis and that few effective and customized interventions are available. In this study, we showed that MI is a suitable way of providing SMS to patients with psoriasis, which seems to be beneficial from a clinical perspective and to a certain extent from a health economic perspective.

1 INTRODUCTION

Psoriasis is a chronic inflammatory immune-mediated skin disease, which typically follows a relapsing and remitting course. The disease is associated with psychological distress, reduced quality of life (QoL)(1;2) and stigmatization (3). Furthermore, lifestyle-related concurrent disorders, including hypertension (4), obesity (5;6) and cardio-vascular disease (CVD) (7), have recently been recognized as negatively influenced by psoriasis severity (8;9). This new insight appears to have led to a gradual shift towards more comprehensive disease management (10;11), including an increased focus on treatment strategies (12;13), as well as the need to develop efficient behavioural and educational interventions to support patient self-management (14;15).

At present, there is no cure for psoriasis, but multiple treatment options are available aiming to relieve the symptoms (16), including a wide spectrum ranging from topical treatment and phototherapy to systemic treatment and newer biological agents. Climate/heliotherapy (CHT) is a treatment method with a long tradition in the Nordic countries (17). In Norway, CHT has been officially funded since the beginning of the 1970s. The Norwegian CHT programme is situated on Gran Canaria. The CHT programme has a duration of 3 weeks, which includes tailored sunlight UVB radiation, physical exercise, group discussions and comprehensive education. Previous research has shown that this treatment is effective in terms of multiple outcomes that are important for psoriasis, such as psoriasis severity (18), QoL (18-20) and illness perception (21). Furthermore, parameters such as "sense of coherence" (22), psoriasis knowledge (23) and self-management (18;23) appear to be positively changed after CHT participation. Although the results suggest that this CHT programme may provide a range of benefits, the long-term effects appear to be limited, and most of the results are only sustained for 3 to 4 months (18;19;24). Thus, a remaining challenge seems to be how to achieve long-term benefits and develop proficient methods that provide self-management support (SMS) to these patients.

There are no previous reports about whether the limited long-term effect of CHT might be negatively influenced by low treatment adherence, unhealthy lifestyle choices or a lack of follow-up. However, research has shown that people with psoriasis find successful self-management challenging (10;25;26). Indeed, the need for continuous, sometimes unsatisfactory treatment may cause frustration, dissatisfaction and poor treatment adherence

(27-30), which in turn might negatively influence the disease course (31;32). In addition, the importance of healthy lifestyle behaviours has become a more important topic in psoriasis, and the relationships between disease severity, co-morbidities and lifestyle parameters such as smoking, stress, body mass index (BMI) and physical activity have been identified as key issues in psoriasis self-management in addition to skin treatment (13;33).

The Norwegian Directorate of Health's status report on the Coordination Reform (from August 2013) (34) stresses the importance of developing services for people with chronic diseases. The report notes that non-communicable chronic diseases require monitoring over time with regular controls as well as during peaceful phases of the disease, including more user involvement in the form of patient education and self-management. Thus, the Norwegian government health policy promotes multidisciplinary SMS in long-term conditions. However, to the best of our knowledge, at present, there is no possibility of patients with psoriasis receiving systematic individualized follow-up or tailored self-management programmes. Participation in SMS programmes that aim to develop the attitudes and skills necessary for successful self-management may be beneficial (35;36). Indeed, condition-specific, health professional-led educational and self-management programmes have been used widely in diabetes, asthma and arthritis (37-40). The aim of SMS programmes is often to reduce the disease severity and to increase the patients' skills and self-efficacy in managing their health problems. This includes regular progress assessments and goal setting, as well as problem-solving support (41).

Throughout my clinical nursing career, I have been interested in different methods of patient education and SMS. Working with people with long-term diseases in the context of CHT has further increased my curiosity about whether aspects of the professional–patient collaboration might potentially impact patient outcomes. When communicating with patients with psoriasis, I have often been struck by the profound impact that the disease appears to have on numerous aspects of their lives. In particular, I am interested in the components that influence the extent to which the disease affects and limits the lives of individuals. Patients and health care professionals differ in their beliefs and attitudes regarding psoriasis. Qualitative studies show that health care professionals often view the impact of psoriasis as less serious than their patients do (42;43). A recent qualitative study of the perspectives of general practitioners (GPs) and patients regarding psoriasis found that practitioners recognized the physical, emotional and social impacts of psoriasis, but they avoided discussing these aspects during

consultations with patients. By contrast, patients described their disappointment that their GPs did not address the wider impact of psoriasis, which they found disabling (25). Thus, it seems to be important to bridge this information gap and to form an alliance between the patient and health care professionals.

Health care providers are traditionally trained in a direct style of communication (44). This implies that professionals take charge, which seems appropriate in many health care situations where the patient depends on the professionals' expertise for decisions, action or advice. However, dermatology health care professionals appear to have received limited training, focus and preparation in how to promote health behaviour change (45). Knowledge of the disease and specific lifestyle guidelines appears to be necessary for psoriasis care, but previous studies indicate that the provision of advice, information and recommendations alone is not sufficiently effective in facilitating the appropriate health behaviour changes required for chronic disease management (35;46;47). Thus, self-management depends not only on the technical skills needed to perform routine behaviours but also on an individual's level of motivation to engage in, and to maintain, the self-management of their disease (48). This appears to be especially important regarding health behaviour change, where recognizing and respecting the patient's autonomy to decide seems to be a key element for success (44). In addition, a positive change in different health behaviours may also positively impact psoriasis severity, as advocated by recent studies (33;49-51).

Motivational interviewing (MI) is a collaborative, communication method for strengthening a personal motivation and commitment to behaviour change, and it can be viewed as an SMS method that advocates active patient participation (52;53). MI is evidence-supported (54-56) and it has been applied to chronic diseases that demand daily treatment decisions, as well as to the adoption and maintenance of healthy behaviours by patients, such as those with asthma and diabetes (57-59). However, to the best of our knowledge, MI has never been studied in patients with psoriasis.

In this study, to address the "knowledge gap" between CHT and SMS follow-up, we developed a telephone-based individualized SMS programme, which comprised tailored MI by telephone following CHT treatment. The study was designed as a randomized controlled trial (RCT) to investigate the effects of MI by focusing on psoriasis treatment and desirable behavioural change in the 12 weeks following CHT. An efficient SMS intervention could potentially have positive impacts on disease severity and could also strengthen the patient's

self-management, and increase self-efficacy and health-related quality of life (HRQoL). This thesis reviews previous studies of patient education and self-management in psoriasis, and also describes our evaluation of the effects, effectiveness and cost utility of a novel MI intervention. Previous research in this area for patients with psoriasis is scarce, so these results might provide valuable insights into the provision of effective SMS.

2 BACKGROUND

2.1 Psoriasis

2.1.1 Epidemiology and clinical features

The precise aetiology of psoriasis remains poorly understood, but psoriasis is considered to be a multifactorial disorder that results from a complex interplay between genetics, environment, skin barrier disruption and immune dysfunction (60;61). The most common clinical variant is psoriasis vulgaris or plaque psoriasis, which affects 85–90% of people with psoriasis (62). Psoriasis vulgaris is characterized by well delineated red plaques with adherent silvery scales (63;64). Commonly affected areas include the scalp, knees, elbows and torso. Other locations include the feet, hands, nails and more "difficult to treat" areas such as the face, flexures, axilla, umbilicus and genitalia (13). The characteristic symptoms of psoriasis include itching, scaling and bleeding (29;65;66). In addition to skin-associated pain (67) and the effects of living with a visibly disfiguring skin disease, relationship difficulties, stigma and low self-esteem are potentially negative impacts (3;68).

Approximately one-third of patients with psoriasis have a first-degree relative with the diagnosis (64), and the disease is equally common in males and females (61). Throughout the world, psoriasis has a prevalence of 0–11.8%, (61;69). A recent population-based Norwegian study described an increasing prevalence of self-reported psoriasis in the north of Norway; i.e., from 4.8% in 1979–1980 to 11.4% in 2007–2008 (70). In terms of the type of onset, patients with psoriasis can be classified into two types: type I (early onset or before 40 years) and type II (late onset or after 40 years). Type I psoriasis accounts for more than 75% of cases (71). Early-onset psoriasis is also associated with greater genetic susceptibility, a more severe course and greater psychosocial impact (72).

Psoriasis can be mild, moderate or severe, although the classification of severity lacks standardization (73;74). Body surface area, Physician Global Assessment (PGA) and the Psoriasis Severity Index Score (PASI) are three widely used assessment tools for expressing the severity of psoriasis and for measuring the progress of treatment during research (75;76). However, none of these instruments satisfies all of the validity criteria (75). In addition, they do not appear to be optimal for defining the severity of psoriasis because the experience of the

impact of the lesions varies among different patients (76;77). However, in recent treatment goals, the QoL impact measured by the Dermatological Life Quality Index (DLQI) was also included for defining the severity of psoriasis (78).

Hence, all of the clinical characteristics of psoriasis may result in functional impairment and social limitations. Overall, 65% of psoriasis patients are considered to have mild psoriasis according to the National Psoriasis Foundation (http://www.psoriasis.org). In this thesis, the main focus is patients with moderate or severe psoriasis measured by a PASI score > 7 because this is the qualification measure used for CHT participation.

2.1.2 Pathogenesis

Most previous studies of psoriasis have focused on immune system elements and the role of inflammation in the pathogenesis (79). The inflammation is distinguished by the release of a specific pattern of cytokines in the lesions of affected patients (80). Psoriasis is characterized by an elevated turn-over rate of keratinocytes and a shortened cell cycle. In addition, the desquamation process is altered. Scaling characterizes the clinical features associated with hyperkeratosis, pruritus, inflammation and stratum corneum dryness (60;63). Hyper-proliferation and the abnormal differentiation of keratinocytes are the two critical outcomes of the underlying pathophysiological dysregulation in psoriasis (60), where T-cell activation occurs secondary to dermal inflammation and abnormal keratinocyte proliferation. This constant inflammatory cell chemotaxis and cytokine release leads to a chronic clinical course with recurring lesions. The effective treatment of severe psoriasis is thought to be important for avoiding co-morbidities related to this systemic inflammatory response, although not determined precisely (79).

2.1.3 Co-morbidities

The co-morbidities for psoriasis are listed as CVDs, autoimmune diseases, cancer, psychiatric diseases, sleep apnoea, chronic obstructive pulmonary disease (COPD) and non-alcoholic steatohepatitis (79;81). Approximately 25–34% of psoriasis patients also suffer from psoriatic arthritis, and the cutaneous symptoms is present before the joint symptoms in more than 80% (82). Another important co-morbidity is metabolic syndrome, which includes a cluster of cardio-vascular risk factors (83). Metabolic syndrome is diagnosed if three or more of the following factors are present: abdominal obesity, elevated fasting glucose level, decreased

HDL-cholesterol, hypertriglyceridaemia and hypertension (82). Obesity and metabolic syndrome are both correlated with an increased risk of coronary heart disease (6;84). In earlier studies of psoriasis, the obvious increased risk of CVDs was acknowledged to be an indication of the increased prevalence of risk factors (85), such as obesity and smoking, which were thought to be motivated by the psychosocial burden of the disease (86-88). However, more recent studies have advanced this understanding. A large population-based study demonstrated an increased risk of myocardial infarction in patients with psoriasis (particularly those with severe disease) even when accounting for major cardio-vascular risk factors such as obesity, smoking, diabetes and hypertension (89). A recent UK study including 4065 patients with psoriasis and 40,650 controls detected a significant association between psoriasis and metabolic syndrome (90). The risk of developing metabolic syndrome increases with the severity of psoriasis, and this dose–response relationship suggests that moderate to severe psoriasis may itself be an independent risk factor (91). Studies of insulin resistance and its relationship to the severity of psoriasis have shown that there is a positive correlation between high PASI scores (i.e., more difficult psoriasis), reduced insulin secretion and an increased serum concentration of resistin, which is an adipokine that is elevated during insulin resistance (92;93).

In general, co-morbidities and cardio-vascular risk factors appear to be under-diagnosed and under-treated in patients with psoriasis (94;95). A study of 2899 participants from a clinical trial population found that approximately 20% of the patients had undiagnosed diabetes, hypertension or hypercholesterolemia, and these co-morbidities were not optimally medically managed in 40–60% of the patients (96). However, the impact of aggressively treating psoriasis on these co-morbidities remains unclear, and so is their ultimate effect on mortality (85). Death directly due to psoriasis is rare, but the chronic and incurable nature of psoriasis suggests that concomitant morbidity may be significant (13;97).

2.1.4 Environmental triggers and lifestyle

Psoriasis may be provoked or exacerbated by a variety of different environmental factors, particularly life crisis, infections and drugs. Streptococcal infection is strongly associated with guttate psoriasis debut (98), and the use of medications, such as β-blockers, antimalarial agents, lithium and interferon-α, is associated with induction or deterioration in psoriasis

severity (99). Severe mental stress and life crisis often precede the debut of psoriasis (31;100), and patients frequently indicate mental stressors as reasons for exacerbation (32;101).

Extensive evidence demonstrates a link between excessive alcohol consumption and psoriasis (102-104). The association is described as complex because epidemiological evidence suggests that patients with more severe psoriasis also have an increased incidence of alcohol-related diseases and mortality (105). Moreover, this seems to be unique to psoriasis compared with other autoimmune diseases (105). In addition, the misuse of alcohol in patients with psoriasis has been shown to be associated with decreased response to treatment (106;107).

Studies have shown that on average, patients with psoriasis are more obese than the general population (5;6;108). Recent reports also indicate that the severity of psoriasis is correlated to BMI (109;110). Furthermore, this correlation was recently confirmed in paediatric patients (111;112). However, a Danish study (113) of whether severe psoriasis in adulthood is preceded by a high BMI in childhood found a significant association only for adolescent girls and not for boys. Previous studies indicate that obesity generally precedes the development of psoriasis (109;114), but to the best of our knowledge, the question of whether obesity precedes psoriasis or whether psoriasis leads to obesity has not been fully addressed. However, in a prospective study in the United States, 78,626 nurses were followed from 1991 to 2000, which showed that obesity, weight gain and an increased waist:hip ratio were clearly associated with an augmented risk of developing psoriasis. The results also indicated that a higher BMI resulted in a greater risk of psoriasis development, whereas a BMI below 21.0 was associated with a reduced risk (115).

Several studies have shown that patients with psoriasis also smoke to a greater extent than the normal population, and it has been argued that smoking is a risk factor for psoriasis (86;87;103). A recent systematic review found a possible dose effect of smoking intensity and duration on psoriasis incidence. It was also concluded that smoking is an independent risk factor for the development of psoriasis and that patients with established psoriasis continue to smoke more than patients without psoriasis (50).

Thus, it is increasingly being recognized that the management of psoriasis should involve medication and topical therapy, but there also needs to be a focus on desirable lifestyle changes (13). In particular, some of the risk factors associated with psoriasis, which are

responsible for some of the increased cardio-vascular risk, are known to be amenable to lifestyle changes (79).

2.1.5 The burden of psoriasis

Much evidence supports the negative impact of psoriasis on a person's QoL (1;116;117). The draining physical effects of the skin condition are often correlated with psychosocial effects, such as problems with body image, self-esteem and feelings of stigmatization, shame and embarrassment due to appearance (2;118;119). In addition, depression, high stress levels and employment problems are common, all of which may have a substantial effect on well-being (1;118). A systematic review (117) of QoL in patients with psoriasis found that patients reported physical discomfort and reduced emotional functioning. Negative body and self-image typically limit daily activities, especially in situations that involve skin-exposing events.

According to the National Institute for Health and Clinical Excellence (NICE) clinical guidelines, one-third of people with psoriasis experience major psychological distress, and the extent to which they feel socially stigmatized and excluded is substantial (13). Patients with strongly held beliefs about the negative consequences of psoriasis and those who experience more worry about the disease report poorer QoL (21). Several studies have also found a relationship between treatment adherence and QoL, with most indicating that an increase in HRQoL favours adherence, thereby contributing to an affirmative self-promoting process (120;121). The fact that even psoriasis patients with mild disease activity claim that psoriasis has a major effect on their lives indicates the disease's potential for causing profound changes and interfering with an individual's life (1;28;65). Indeed, lesion severity accounts for less than half of the impact of psoriasis on patients' HRQoL (122). However, psoriasis lesions located on visible locations are significantly correlated with aspects of QoL, particularly mental health (123).

Kimball et al. (124) introduced the concept of Cumulative Life Course Impairment (CLCI) in relation to psoriasis (Fig. 1). The model represents the cumulative lifelong effects of physical co-morbidities, stigma and psychological co-morbidities, as well as their economic and social consequences, which have the potential to place patients with psoriasis at risk of not living their life to their full potential. In summary, CLCI describes the balance between: (A) the burden of the physical and psychological co-morbidities and stigma associated with psoriasis,

and (B) the external factors and coping strategies modulated by the patient's personality (124;125). The relative weight of each component for each person explains the difference in the patient's individual experience of the disease, even with similar disease severity. The negative impact of CLCI may influence major life-changing decisions, which in turn may affect personal, professional, social and family development to alter the course of patients' lives substantially (126). Thus, the application of the CLCI model to psoriasis provides a holistic view of important factors that may impact patients during their lifetime (125). Hence, understanding the key risk factors for CLCI may help health care professionals to identify patients who are more vulnerable to the cumulative impact of psoriasis, which may hopefully result in more appropriate treatment decisions and SMS earlier during the disease course.
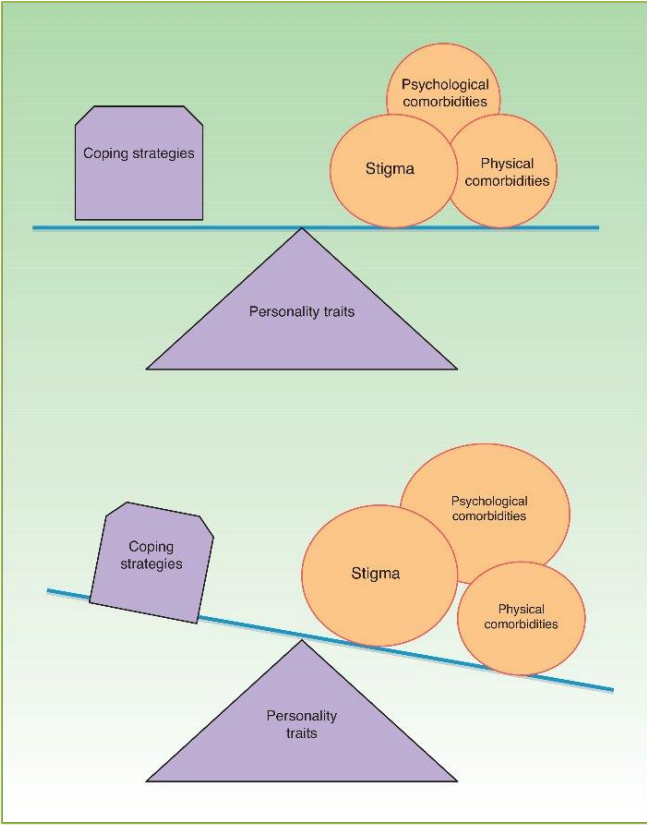
Fig. 1.   Cumulative Life Course Impairment model (124;125). Reprinted with permission from John Wiley and Sons.

2.2 Management recommendations and treatment challenges

The combination of targeted treatment, early intervention and the use of treatment goals is a new approach in medicine, which has been implemented in several disciplines (e.g., diabetes, pulmonary arterial hypertension and rheumatoid arthritis) over the last 5–10 years (127;128). A European Consensus group from 19 European countries have for the first time developed individual treatment goals in psoriasis to promote the consistent use of available therapies to improve patient care (129). Until recently, there was also a lack of consensus on the best practice for management of psoriasis in the Nordic region (130), but in 2014, based on a Delphi approach, a Nordic group of dermatologists agreed on the individualization of treatment goals using PASI and DLQI to guide clinical decision-making. Thus, patients' perception of the effect of treatment will be increasingly incorporated in their treatment, and dermatologists will become more experienced to recognize the psychological aspects of psoriasis (130).

Neither of these fairly recent consensus groups of dermatologists considers lifestyle recommendations. In contrast, the National Psoriasis Foundation clinical consensus recommends that lifestyle modifications such as smoking cessation, altering lifestyle to achieve an ideal BMI, exercising three times a week for 30 minutes, monitoring and modifying cholesterol levels within recommended ranges and taking measures to control depression should be implemented in psoriasis care (85). In addition, the recent NICE guidelines for the assessment and management of psoriasis state that health professionals should provide healthy lifestyle information and support for behavioural change tailored to meet the needs of the individual (13). However, a recent content analysis of post-qualification curricula for health professionals in general practice and dermatology found very little focus on behavioural change skills. In addition, there was no evidence of post-qualification training competencies related to the provision of long-term support of lifestyle behaviour change and little or no reference to evidence-based approaches (45).

Furthermore, there seems to be a gap in perceptions regarding whether dermatologists or primary care providers are responsible for screening/counselling with respect to issues such as alcohol, tobacco and obesity. In a qualitative study in the UK, dermatology specialists and GPs perceived their roles in facilitating and supporting lifestyle change in psoriasis patients as very insignificant (131). They indicated that they possessed limited knowledge and skills in

behavioural change principles, and they also indicated the presence of personal and organizational barriers to the implementation of lifestyle support in their practices. Another study of 171 US academic dermatologists showed that nearly all of the respondents believed that primary care providers should be responsible for both screening (94.2%) and counselling (98.2%). By contrast, dermatologists generally also considered themselves to be responsible for screening (87.1%), but only around half (55.6%) believed the same about counselling (132).

Previous studies suggest that health care providers are crucial for psoriasis management by providing support for comprehensive and persistent treatment, but this relationship may be problematic (43;65;133). In terms of their relationships with GPs and dermatologists, patients emphasize the importance of professionals' providing comfort and of feeling that sufficient time is taken to discuss their issues (65). However, studies show that practitioners were perceived as lacking knowledge, confidence and expertise in the management of psoriasis, as well as lacking empathy with the effects of psoriasis and failing to manage it as a long-term systemic condition (10;25). Nelson et al. (26) stressed that for some participants, this perceived lack of support resulted in withdrawal from conventional health services, increased hopelessness and a quest for alternative sources of help.

In a systematic review that examined the views of health care professionals on barriers and support for implementing shared decision-making, lack of time was the most cited barrier (134), followed by the professionals' perception that the patients did not want this approach and then a lack of applicability due to the clinical situation. The two most often reported facilitators were the motivation of health professionals and the perception that shared decision-making will lead to a positive impact on the clinical process.

Existing office practices are usually designed to provide episodic care, generally by a physician. These practices are often part of larger care systems, which are designed to support treatment for acute rather than chronic illnesses. In current practices, other health care professionals needed to provide effective self-management education and support, seems often not available, not prepared or not fully utilized (135). Nurses administer phototherapy in most dermatology departments, but very few of the Norwegian centres currently have an organized system that allows patients to consult nurses directly. In addition, the dermatologist may be the only health care specialist seen, and one study suggested that patients seen in a

dermatology clinic have unmet preventive health care needs (136). Again, this emphasizes a possible mismatch between the impact of psoriasis on daily living for patients and the failure of practitioners to engage in its management.

2.2.1 Pharmacological treatment

The pharmacological treatment options for psoriasis seem extensive and multimodal, and they have the capacity to reduce symptoms substantially (137;138). The aim of treatment is decreasing or achieving the remission of symptoms such as inflammation, scaling, itching, burning and dryness (80;139). The treatment options belong to three categories. In mild psoriasis, topical treatment with creams and ointments (containing cortisone and vitamin D) is prescribed as a rule (140). Most of this "day to day" and often time-consuming treatment is performed by the patients themselves, who must make informed decisions about whether to lubricate the skin, whether to remove scales, and which creams or emollients to apply, as well as their volume and frequency. With more distinct ailments, phototherapy with certain types of ultraviolet light, possibly in combination with 8-methoxypsoralen tablets, can be beneficial. Systemic treatments using oral and injected medications containing methotrexate, acitretin and cyclosporine are given to treat moderate to severe psoriasis. Patients who receive systematic treatments may also use topical agents (120), therapeutic moisturizers (141) and biologics (138) as adjuvant therapies.

In recent years, patients with unsatisfactory treatment outcomes using conventional treatment have been candidates for biologic treatment. Biologic therapies comprise a series of antibodies and fusion proteins, which target specific molecules and receptors involved in the pathogenesis of psoriasis (142). Biologic agents have also revolutionized the treatment of several other chronic inflammatory diseases such as arthritis, ankylosing spondylitis and Crohn's disease (143;144). An improved understanding of the involvement of cytokines in the aetiology of psoriasis has led to the development of biologic agents that target tumour necrosis factor-α and interleukins-12/23 (134), and the upcoming promising inhibitor of the cytokine interleukin-17 (145;146). A combination of systemic therapies may optimize the treatment results (138). However, a study of Swedish, Finnish and Danish patients found that patients treated only with biologic drugs for 12 months had the highest treatment satisfaction and the lowest DLQI scores. These patients were compared with patients who only used topical treatment and those who used systemic and or biologics for less than 12 months (147).

National professional guidelines for the indication, monitoring and evaluation of the biologic treatment of psoriasis have been established in Norway (148).

Emollients are agents designed to soften the stratum corneum and to make it more flexible by increasing hydration, thereby helping to relieve the clinical manifestations of dry skin (141). In dermatology, they are the most frequently used products, and their regular application is considered to be important (80). The most important indications for emollients and moisturizing agents are as an adjuvant therapy with classical psoriasis treatment modalities and as supportive treatment during remission phases (149). Emollients can be effective in removing scaling before active treatment and also have anti-inflammatory and anti-keratolytic properties (150). Moisturizers have been shown to improve skin conditions and QoL significantly in psoriasis patients (141). A study showed that an emollient could limit the number of relapses after the end of corticosteroid therapy and could also maintain the improvement induced by the corticosteroid treatment on the clinical state measured by Physician Global Assessment (PGA) and skin dryness (151).

Adherence to pharmacological treatment also appears to be crucial for an effective outcome. Adherence describes the extent to which a treatment-following behaviour coincides with that devised and agreed upon by the patient in cooperation with a clinician during health care decision-making (152). The term "compliance" is associated with the medical model of health care, where the clinician more dictates the treatment and the patient is expected to comply (152). Therefore, "adherence" implies that patients are more actively involved in defining and following their medical treatment. However, adherence to treatment is a difficult issue in psoriasis treatment (30;120) and the adherence rate in psoriasis varies from 50% to 60% (120). Additional factors include the efficacy of treatment, ease of use, convenience of application and the health care professional–patient relationship (65;153;154). In summary, this problem is multidimensional, where prescriptions are not collected by patients (primary adherence) and topical medications are not used as recommended (secondary adherence).

2.2.2 Non-pharmacological treatments

To relieve the symptom burden in psoriasis, various non-invasive and non-pharmacological treatment approaches are commonly used (155). This thesis is restricted to SMS in the context of climate therapy, and therefore lifestyle-related and psychological interventions are the elaborated approaches, in addition to climate therapy.

Climate/heliotherapy (CHT)

Heliotherapy traditionally refers to treatments that use natural sunlight. In Greek mythology, Helios was the god of the Sun, the charioteer who drove the chariot of the Sun across the sky each day.

Climatotherapy is the use of climatic factors for therapy (156). The medical area of health resort medicine includes core elements such as balneotherapy, hydrotherapy and climatotherapy. According to Kazandjieva et al. (157), climatotherapy comprises alternative treatment methods that utilize the healing capacities of natural resources, including air, temperature, barometric pressure and light. Thus, it represents a safe and efficient alternative to conventional therapeutic modalities. Climatotherapy includes the planned medical application of climatic factors that can be used for health promotion, prevention, treatment and in rehabilitation (156).

Climate and heliotherapy for the treatment of psoriasis has a long tradition in various locations such as the Dead Sea, Iceland, the Canary Islands and the Black Sea, where research indicates that good clinical results are obtained (157-162). UVB radiation in sunlight is of central importance for the treatment of psoriasis. UVB rays reduce the immunological activity of the psoriasis patches, decrease increased cell division in the epidermis and stimulate vitamin D production (160;161;163).

In the management of psoriasis in Scandinavia, CHT is a well-documented treatment option (158;164;165). For Norwegian patients this is a treatment for patients with moderate to severe psoriasis (PASI > 7 by application). To be considered for CHT, the patient and dermatologist or GP separately complete standardized application schemes, which include PASI, self-administered PASI (SAPASI), the individual goals of CHT treatment, co-morbidities, anti-psoriatic medications and details of the potential failure of other therapies. Applications from all over Norway are then evaluated at the Department of Climate Therapy (Oslo University Hospital, OUS), which is responsible for all CHT organized abroad and allocations are based on priority. Groups of 30–60 patients travel to the Norwegian CHT treatment centre on Gran Canaria (located in the Atlantic Ocean at 28°N, 16°W). At the CHT centre, they are accommodated in small apartments, and they are served three meals a day. Each patient pays 2142 NOK (in 2012) for the treatment, travel and accommodation.

The patients recruited to the RCT described in this thesis were all participants in the CHT programme prior to the intervention. CHT includes individualized sun exposure to increasing doses as the main treatment, and on average, patients receive 80 hours of sun therapy during their 3 week stay (166). The treatment is individually scheduled with gradual sun exposure, dependent on the skin type and current UV index. The beneficial effect of CHT is based on the exposure of the skin to a unique combination of climatic factors: sunlight, seawater and allergen-free air. A good therapeutic response to CHT is accomplished through normalization of keratopoesis, reduction of the inflammatory infiltrate and improvements in the blood circulation and capillary permeability of the skin. Several previous studies have demonstrated positive effects on psoriasis lesions measured by PASI and SAPASI (19;20;23). The programme has also been evaluated as positive based on a number of outcomes, as described in the introduction to this thesis.

The Norwegian CHT programme is unique compared with other climatotherapy programmes because it includes much more than sun treatment. The programme emphasizes daily physical training, tailored education, group discussions and individual consultations, with supervision by nurses and dermatologists. Thus, the 3-week CHT programme comprises both sun treatment and patient education. The educational focus has shifted from mostly didactic teaching to more dialogue-based methods, where the patients are invited to play a more active role. During their first visit, it is mandatory for patients to attend most of the educational classes. Patients who attend repeatedly may select which of the lectures they want to attend, depending on their perceived need, such as sessions that focus on sun and climate treatment, emollients and skin therapy, or healthy eating habits. The teaching sessions presented by the dermatologist are obligatory for everyone, and they provide information/dialogues about psoriasis pathogenesis, manifestations, co-morbidity and treatment options. The importance of lifestyle choices is stressed, with a special focus on the importance of physical activity and healthy eating. Discussions in smaller groups focus on finding tools for managing psoriasis in daily life, relieving stress and quitting smoking. The programme also includes 30 minutes of obligatory physical activity five times a week, and many physical activities are offered as possible leisure activities. An overview of the programme is presented in paper 2.

Lifestyle change interventions

Many unanswered questions remain concerning the potential links between lifestyle factors and psoriasis. However, in recent years, there has been an increased interest in determining how lifestyle choices may affect the lives of patients with psoriasis (167;168).

As stated previously, several studies have found that overweight or obese patients have more severe psoriasis (51;109). Furthermore, obesity may reduce the effectiveness of treatment and increase the likelihood of adverse effects (6). In addition, a low-calorie diet with moderate weight loss (i.e., 5–10% of body weight) increases the responsiveness of obese patients to systemic treatment (49;81;169). However, the question of whether weight loss may decrease the disease severity seems less clear. Some studies have shown positive results on disease severity after diet and exercise (49) or after adherence to the Mediterranean diet (170). A recent review addressed the effects of different weight loss interventions on psoriasis severity (51), where a number of studies suggested that weight loss may lead to psoriasis improvement and that such interventions may serve as a preventative and adjunctive therapy. Furthermore, this review revealed that gastric by-pass operations appear to be beneficial in some patients but that larger prospective studies are necessary to explain further the efficacy of these interventions.

There may be a negative link between obesity and exercise activity. Patients with psoriasis exhibit decreased levels of physical activity, possibly because of physical and psychological factors (171). A previous study found that only 13.6% of the overweight patients exercised (172). However, few studies have assessed the effects of exercise on psoriasis severity. By contrast, some studies have considered patients with other chronic conditions, which indicate that exercise programmes are effective in reducing the prevalence of metabolic syndrome and its components (173;174). A recent RCT study by Naldi et al. (49) assessed the impact of a dietary intervention combined with physical exercise in people with psoriasis, where this 20-week intervention reduced the severity of psoriasis in systemically treated overweight or obese patients with active psoriasis.

Abstinence or moderation may help to reduce the effects of smoking and alcohol consumption, but evidence of the effects of such interventions is generally lacking in psoriasis, although studies of women with palmo-plantar psoriasis have demonstrated the effects of smoking cessation (175;176). By contrast, smoking did not affect the response to

systemic treatment in patients with psoriasis vulgaris (177). To establish the most appropriate psychological intervention for alcohol dependence, further studies seems needed to consider this at-risk patient population (105).

Psychological interventions

Given the high levels of distress, the reduced QoL and the proposed interaction between psychological factors and disease processes in psoriasis, it seems necessary to establish whether psychological interventions and specific stress reduction interventions might be helpful additions to standard pharmacological therapy (101;178).

A review of the effects of stress reduction interventions on psoriasis severity (101) found more non-significant than significant differences in psoriasis outcomes (7/10). A similar result was obtained in terms of psychological distress (4/7 non-significant results), but too few of the studies measured QoL to make any conclusions about this effect. This review suggested that arousal reduction interventions are more effective in changing physical rather than psychological outcomes, whereas cognitive behavioural therapy (CBT) is more effective in improving psychological outcomes. However, this review provided no conclusions regarding the effectiveness of these interventions because of the poor quality of the design and reporting in the reviewed studies. Another systematic review also reported a lack of evidence for the effect of psychosocial interventions in individuals with visible differences, including psoriasis (179). By contrast, a narrative review of the effects of psychological and educational interventions reported overall positive effectiveness, especially in terms of psychological and QoL outcomes, although this review also concluded that there is a need for additional RCT studies to address methodological weaknesses (180).

One case-control study evaluating a 6-week multidisciplinary CBT programme demonstrated improvements in distress, depression and psoriasis severity (181;182). A recent study tested a web-based psoriasis-specific CBT treatment programme for patients with mild-to-moderate plaque psoriasis with associated emotional or psychological problems (183), where the intervention obtained improvements in anxiety and QoL, but the results were limited because of a large amount of missing data and an attrition rate of 32%. A pilot RCT study investigated the effects of mindfulness-based cognitive therapy (MBCT) in groups (184), where the participants who completed the MBCT intervention reported a significant improvement in their psoriasis symptoms and less impairment of their QoL compared with a treatment as

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usual (TAU) waiting list control group. However, the small sample size and 45% attrition rate in this study also limited the possible conclusions. In a qualitative follow-up study (185), nine participants were interviewed, and they reported feeling calmer, more confident and sociable after the MBCT intervention. This may suggest improved self-efficacy in dealing with social interactions, but there was no agreement about whether the intervention influenced psoriasis symptoms. Some participants also found that the MBCT was less helpful and socially challenging, thereby suggesting that this intervention is not suitable for all.

In summary, non-pharmacological interventions such as diet, smoking cessation, physical exercise, cognitive therapy and CHT may all have the potential to improve the response to conventional pharmacological treatment for psoriasis, as well as to affect disease severity and possibly to reduce the risk of cardio-vascular disease (109). However, more research seems necessary to establish the intervention methods that are most effective for specific subpopulations. Thus, this thesis aims to contribute to the development of this knowledge base by describing the evaluation of a novel MI intervention following CHT.

2.3 Self-management and self-management support

Self-management is a concept that has evolved enormously in the past two decades, especially in the field of chronic disease (186;187). This evolution has accompanied the tendency to move away from a paternalistic model of care, with a change in focus from the health care professional as an expert and the patient as a passive recipient of care, to more collaborative care. This means that expertise is shared between the patient and the professional, and both parties work together to achieve the best possible management (35;47). There has also been a tremendous shift in the approach to treating chronic diseases, which now emphasizes patients' central role in managing their illness (38;46). In addition, professionals use their expertise to inform, activate and assist the patients in the self-management of the disease. Thus, in both self-management education and collaborative care, the emphasis has shifted towards the patient as the principal caregiver. A rapid literature review of more than 550 studies showed that effective self-management may positively influence QoL, improve confidence to self-manage and reduce the use of health care services (188). However the evidence of the latter is more varied than for clinical outcomes. In contrast to SMS, patient education is a broader and older term, which is often associated with didactic, knowledge-based interventions for a specific condition (189). Traditional patient education emphasizes knowledge acquisition and

didactic counselling, but it has achieved limited success in changing behaviour or enhancing disease control, even if patients' knowledge is increased (190). Imparting factual information alone often does not result in the maintenance of long-term behaviour change (191;192). Especially the work by Kate Lorig et al (39;46) has been essential to raise awareness of the fact that information alone has a limited influence on behavioural change in chronic conditions.

In this thesis, self-management is defined as: "The tasks that an individual must undertake to live well with one or more chronic conditions. These tasks include gaining confidence to deal with medical management, role management, and emotional management" (41 ,s.57). This definition considers self-management as behaviour, but it includes both the notion of "confidence" and the importance of medical management, which appear to be important in the treatment of psoriasis. In addition, this definition encompasses the role and importance of emotional management by the individual patient. Lorig and Holman (46) introduced the catch phrase "Once a chronic disease is present, one cannot NOT manage, the only question is how". They referred to the study by Paterson (193), who suggested that patients with chronic illness sometimes have illness in their psychological foreground and sometimes wellness. Thus, it is claimed that self-management programmes should aim to help patients to maintain "wellness in their foreground perspective" and that six self-management skills should be included in self-management programmes to facilitate this aim; i.e., problem solving, decision-making, resource utilization, the formation of a patient–provider partnership, action planning and self-tailoring (46).

In practice and in peer-reviewed studies, the term self-management is often used interchangeably with the concepts of self-care, patient education, empowerment, health coaching and others (194;195). In particular, the concept of self-care is closely connected to self-management (195-197), and these terms are often used interchangeably (196). Self-management has also been conceptualized as a subset of self-care (198). A thematic analysis of the conceptualization of self-care, self-management and SMS concluded that all three terms are complex and multidimensional (199). It was also stressed that many of the earlier definitions of self-care may be more relevant to the current conceptualizations of self-management, which also seems congruent within the psoriasis literature. However, in this thesis, self-management and self-care are used in somewhat different senses; i.e., self-management in the context of long-term health conditions, and self-care in the management of

everyday basic lifestyle behaviours or preventive strategies that are performed to promote or maintain health (200;201). Some of the interventions described in chapter 2.2.2 regarding "Non-pharmacological treatments" may be considered as self-management interventions.

An important recognized mediator of self-management is self-efficacy. Bodenheimer et al. (47) defined self-efficacy as having the confidence to carry out a behaviour necessary to reach a desired goal. According to Bandura (202), self-efficacy determines whether or not knowledge and skills are actually employed to execute a course of action successfully. Thus, self-efficacy influences whether a patient considers changing his/her health behaviour, his/her motivation to succeed and his/her perseverance after deciding on a course of action. Self-efficacy is enhanced when patients succeed in solving patient-identified problems (203). Self-efficacy also impacts resilience after setbacks and the probability of maintaining a change over time (204). Thus, self-efficacy may be a key element in successful self-management because it is one of several factors that might positively affect the healthy behaviour of patients (203;205). Higher levels of self-efficacy are also associated with more optimal self-management behaviours in chronic conditions other than psoriasis (206-208).

SMS interventions are becoming more common as structured approaches to helping patients learn how to manage a chronic disease such as psoriasis effectively (194). Thus, SMS includes a portfolio of techniques and tools, which help patients to choose healthy behaviours. However, it also encompasses a fundamental transformation in the patient–health care practitioner relationship into a collaborative partnership (209). In this thesis, SMS is defined as: "The systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support" (41 ,s.57). This definition highlights the fact that SMS is more than just education, and the concept means more than simply telling patients what to do. The definition also stresses that the goal of SMS programmes is a positive change in self-efficacy. Coleman and Newton (210) also stressed that SMS expands the role of health care professionals from only delivering information to include processes that develop patient problem-solving skills, improve self-efficacy and support the application of knowledge in real-life situations that matter to patients. Thus, patients work towards their self-selected goals and not those selected by the health professional (47). Hence, SMS means that the patient participates in his/her self-management plan, thereby acknowledging his/her crucial role in maintaining his/her own health (47;135).

Consequently, information about a disease such as psoriasis is presented in response to questions from the participants rather than in lectures. This may increase the possibility of reducing frustration with psoriasis care for both patients and professionals because this model matches the reality of care better, and hopefully it empowers patients to find their own solutions and motivation to care for their psoriasis.

In the model shown in Fig. 2, the strategies for supporting self-management comprise several different approaches categorized along a continuum. Passive information provision about a patient's condition and "technical skills" are placed at one end of the scale, whereas initiatives that more actively seek to support behavioural change and increase self-efficacy are located at the other end of the continuum (188). MI, which is the SMS method tested in this thesis, is located at the right-hand side of the continuum model with a high focus on both self-efficacy and behavioural change. Different conditions and illnesses may require different methods to support self-management. According to a systematic review by Barlow et al., diversity in self-management interventions is advisable because no approach will meet the needs of all
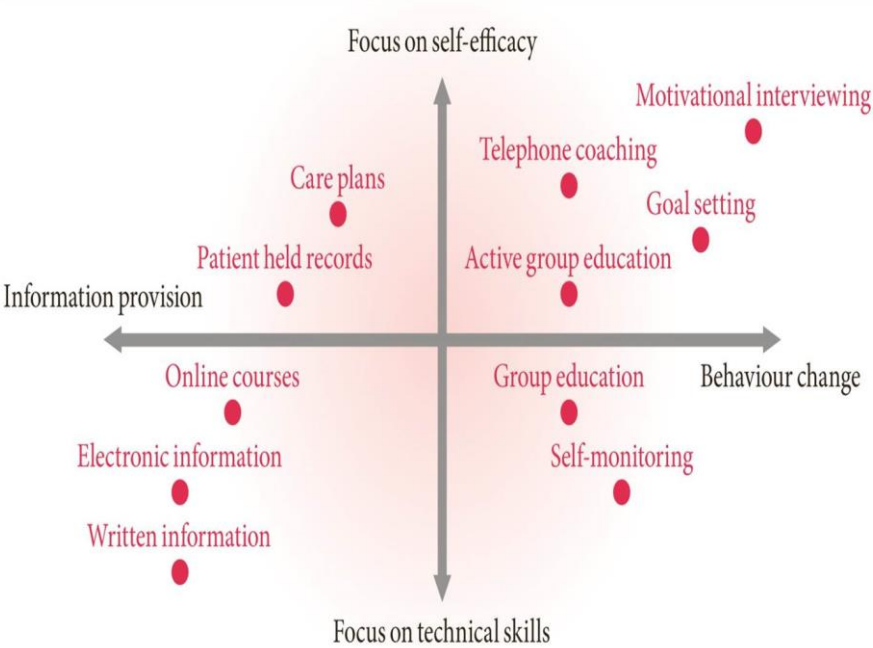
Fig. 2.   Continuum of strategies for supporting self-management given by DeSilva in "Helping people help themselves" (2011, www.health.org.uk). Reprinted with the permission from The Health Foundation, UK.

participants at all points in time (35). In psoriasis, there may be a need for patient education focused on issues such as pathogenesis, co-morbidities, treatment choices, diet and exercise, and stress management. In addition, these patients may also have equal needs for cognitive and behavioural interventions in order to self-manage their psoriasis efficiently.

Individual behaviours influence one's health (211). Many people with chronic conditions can positively affect their chronic disease by managing specific health behaviours and regularly engaging in health-promoting activities. However, both processes may require behavioural change, and successful changes in habitual lifestyle behaviours can be difficult to achieve (212). According to the "continuum of strategies for supporting self-management" model shown in Fig. 2 (188), behavioural change is an important outcome of SMS interventions.

However, many healthy behaviours seems required to manage chronic conditions, and they depend on multiple factors (192;213). An essential element that may be appropriate in many chronic conditions is the need to initiate and also maintain some changes in different behaviours to make the impact of the disease as minor as possible. However, the healthy behaviours of a person living with COPD will vary from those of a patient with psoriasis or multiple sclerosis, although many chronic diseases also share behaviours that are commonly recognized as having positive effects on health, such as exercise, good nutrition, stress management, limited alcohol consumption and smoking cessation (207;212;214). Studies of health behaviour change have shown that this is a more complex process than originally envisioned and that maintaining new health behaviours is particularly challenging (192).

Figure 3 presents a model of behaviour called "The Integrative Model of Behaviour" that includes the common determinants of behaviour (215), which is derived from different behaviour theories, such as The Health Belief Model, Social Cognitive Theory and the Theory of Reasoned Action. According to this model, any given behaviour is most likely to occur if one has the necessary skills and abilities, a strong intention to perform this behaviour and there are no environmental constraints that might prevent the performance of the behaviour (216). According to this model, more traditional demographic, personality, attitudinal and individual difference variables have more indirect roles in influencing behaviour. Intentions comprise a person's motivation towards a goal in terms of direction and intensity, and thus they are a necessary requirement for lifestyle changes (217). Three important determinants of intentions are advocated in the model: attitude, perceived norms and self-efficacy when performing the behaviour. Consequently, when developing SMS interventions, one must first

understand the behaviour from the perspective of the population for whom the interventions are being developed (215).
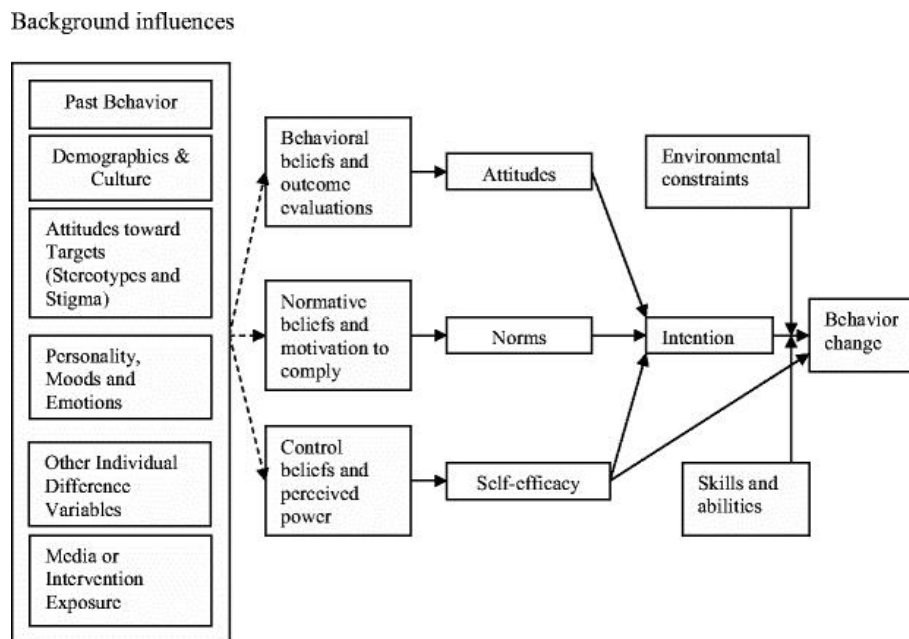
Fig. 3.   The Integrative Model of Behaviour (204). Reprinted with permission from Springer Publishing.

This model proposes that intentions are the most proximal and powerful predictors of following behaviour (215;218). However, good intentions do not necessarily guarantee that the corresponding actions will occur. Indeed, there may be a missing link in terms of understanding health behaviour; i.e., a "gap" between intentions and actions (219). This indicates that intention formulation and intention implementation are different processes (220). Thus, performing MI according to Prochaska and DiClementes' stages of change model (221), as applied in this thesis, may be a concept that addresses this gap. This is partly due to the focus on preparing patients for behaviour change but also helping patients to explore and resolve ambivalence. Furthermore, the MI method may facilitate the continuous tailoring of communication according to the patient's responses, which may positively influence the transition from intention to action. MI and the stages of change model are described in chapter 2.4.

2.3.1 Telephone coaching

Telephone follow-up is a well-established educational tool, which is often used in the context of self-management (222;223). Various types of telephone-based support and coaching have been tested to promote self-management in chronic diseases (208;224-226). MI has also been provided by telephone consultation (227;228), and a number of studies have obtained promising results in terms of the promotion of self-monitoring and self-management (54;229-231). A recent systematic review of telephone-based MI for medication adherence in chronic diseases such as ulcerative colitis, multiple sclerosis and CVD showed that promising results have been obtained (232). A study in the US found that MI primarily by telephone helped to improve patient activation, self-efficacy, perceived health status and promoted lifestyle changes (233). Some evidence even suggests that telephone support may be as successful as face-to-face supported self-management (234;235). However, in psoriasis care, previous telephone interventions were based mostly on medical compliance and disease severity, such as monitoring rashes (236;237).

2.3.2 Self-management and self-management support in psoriasis

Because of obvious complexities, psoriasis patients have to take responsibility for a large number of behavioural choices and activities to manage their condition, predominantly outside the health-care setting. Patients have to monitor their psoriasis lesions and adapt the treatment depending on factors such as body location, level of scaling, itching and the effect of previous treatment (16;120). Symptom management also requires patients to be alert to symptoms of co-morbidity, such as metabolic syndrome and arthritis (79;238). On a behavioural level, adherence to prescribed systematic and topical treatment regimes (121;239), healthy diet and sufficient physical activity (168;240) appears as important self-management behaviours. In addition, smoking cessation (13;50) and modest alcohol consumption are strongly advocated (105). The management of psychological concerns seems also important; e.g., depression, worry, low self-esteem and stress management (118;241). Furthermore, patients should deal effectively with their social and family settings. Obtaining social support, avoiding stigmatization and finding good ways to communicate and collaborate with health care professionals may be important components of psoriasis self-management (3;10;68).

Another key issue seems to be the need for self-efficacy and confidence in order to take the role of a decision-maker, and actually to take responsibility for personal psoriasis care. Furthermore, it may take a considerable amount of time for patients and families to understand fully the implications of psoriasis when they receive a diagnosis (12), thereby suggesting that some patients might not be ready to process complex information or acquire the necessary skills and behaviours required to manage their psoriasis. Hence, the strain of daily self-management has been described as demanding and difficult, and several studies have shown that patients fail to adhere to both their treatments and customized lifestyles (10;65;120).

Psoriasis seems to have been regarded as a less severe condition compared with other chronic conditions such as diabetes, COPD and hypertension, and thus it has received little attention in descriptions and evaluations of educational and self-management programmes for chronic illnesses (35;242;243). Indeed, in other chronic conditions, such as asthma (244), COPD (245;246), arthritis (243) and type 2 diabetes (37;247), the focus on self-management is more apparent, and SMS interventions have been proven to be effective (244;248;249).

As a consequence, there have been few studies of self-management interventions in psoriasis, although a few educational studies that included self-management elements have obtained promising results, as demonstrated by our systematic review. In particular, Bostoen (250) reported a reduction in disease severity and QoL improvements after a comprehensive 12-week educational intervention. This study also included weekly physical training, yoga and mindfulness meditation, as well as stress reduction techniques. Fortune et al. (181) reported similar results for a cognitive behaviour symptom programme that also included stress reduction techniques and homework with individualized goals.

Ersser et al. (251) suggested that tailored education could improve adherence and self-management after a pilot RCT study, where different intervention methods involving group learning, action planning, supporting materials and follow-up telephone consultations were rated highly by patients, but the study lacked sufficient power to find significant group differences in disease severity or QoL. Gradwell et al. (252) evaluated the effect of an additional follow-up by a nurse specialist after visiting the dermatologist. After adding support and education as part of the initial consultation process, 33% of the follow-up appointments with dermatologists were cancelled in the nurse intervention group. A recent educational and motivational pilot study by Balato et al. (253) using text messages with

reminders and educational tools also achieved promising results based on SAPASI. In addition, a disease management programme tested in four European countries that focused on disease education, patient skills training and psychological support reported improvements in disease severity, adherence to treatment and QoL (254). Overall, these results indicate that educational and self-management interventions may have positive effects on disease severity and that they could have important roles in future psoriasis management.

2.4 Motivational Interviewing (MI)

The theoretical approach that underlies our intervention is based on self-efficacy theory (255) and the MI spirit and method (52). According to the "continuum of strategies for support self-management" model in Fig. 2, MI is positioned as a method with a high focus on strengthening self-efficacy and on behavioural change. MI advocates active patient participation, and it may be a valuable tool for facilitating shared decision-making. The MI concept evolved from experience with problem drinking, and it was first described by Miller in 1983 as a conceptual model with some clinical guidelines (256). This early understanding developed into the elaboration of a conceptual model and a detailed description of clinical procedures by Miller and Rollnick in 1991,(257) which were revised twice subsequently (2002 and 2013) (52). MI is defined as: "A collaborative, conversation style for strengthening a person's own motivation and commitment to change" (52 s.12). Hence, MI focuses on assisting patients to identify their problems and also to overcome ambivalence and resistance to behavioural change. Thus, it involves exploring ambivalence in an empathic manner (52). A key goal is to increase the importance of change from the client's perspective. For example, this may be achieved by using specific types of open-ended questions, selective reflections and reflective listening (258), as illustrated in Fig. 4.

The MI Process

```
                              Establish Rapport
                                     ↓
                               Set the Agenda
                                     ↓
                        Assess importance and confidence
                                     ↓
                     Explore Importance/Values and Build
                                  Confidence
                            Open Questions
                            Affirmation
                            Reflective Listening
                            Summarizing
                            Encourage Change Talk
                     Enhance Motivation to Change – Move on to
                          Part 2, Creating a Change Plan
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Exchange Information

Reduce Resistance
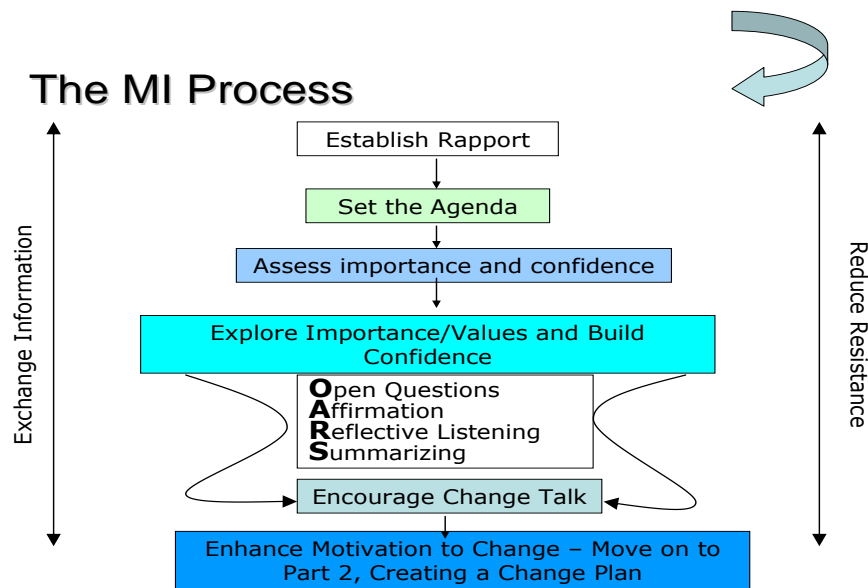
Fig. 4.   Elements of the MI process.

The "spirit" of MI is an important aspect in MI (52). Miller and Rollnick emphasized the importance of MI as being more than a "clever" technique for manipulating patients into making the behavioural changes that are seen to be fit by the counsellor. Therefore, this "spirit" appears to be essential to comprehend and incorporate when working with patients with psoriasis because these patients may have several behavioural problems from the supervisor's perspective. Partnership is one of four vital aspects of this MI spirit, which involves active collaboration between two experts (the counsellor and the patient).

Acceptance is the second aspect of MI, which includes features such as affirmation, autonomy support, absolute worth and accurate empathy. Thus, accurate empathy requires active effort and an interest in actually understanding the other person's perspective on life, while affirmation involves seeking and recognizing the strengths of others as well as their effort (52). Both may be crucial in trying to understand how and why a patient with psoriasis makes particular treatment and behaviour choices, thereby leading to self-management in a satisfactory or unsatisfactory manner. Compassion and evocation are the two last aspects, where evocation is based on the premise that people already have within them much of what is needed for motivation and the resources to change (52). It is possible for a therapist to apply the techniques of MI without abiding by the "spirit" of MI (e.g., the therapist's aim is to manipulate the client into agreeing to change). However, this approach would not be MI, and

it is likely to elicit resistance and thus to lead to reduced efficacy according to Miller and Rollnick.

MI as a method of communication

Consequently, the essence of MI lies in its spirit, where specific techniques and strategies, when used effectively, help to ensure that the spirit is evoked. To achieve this, MI counsellors rely heavily on core communication skills such as open-ended questions, reflective listening, affirmations, summarizing and eliciting change talk (Fig. 4).

The counsellor seeks to evoke this important "change talk", which is defined as expressions of the client's desire, capacity and reasons for change, and they respond by reflective listening. Furthermore, the counsellor offers periodic summaries of the change talk given by the client. Thus, patients hear themselves explaining their own motivations for change in terms of behaviours such as skin care, and they hear them reflected back again by the counsellor (259). However, motivation is multidimensional and not easily assessed. In addition to readiness to change, the MI counsellor also assesses the key factors of "importance" and "self-efficacy" (52;260;261). Importance is determined by the value that a person places on making the change, which is often presented as a visual analogue scale (VAS) ranging from 0 to 10; i.e., from not important at all to very important. Self-efficacy is assessed on the same scale because individuals who think that change is beyond their ability might not even try. For example, patients with psoriasis who rate highly in terms of importance regarding changing their skin care regime or smoking cessation, but low on confidence, need encouragement that change is possible. They may also need specific ideas about how to achieve change. This approach promotes engagement and encourages self-efficacy, and also helps to identify the patient's most important needs and goals (52). Planning is only applied when the patient's readiness to change indicates that he/she is ready to focus more on when and how to change, and less on whether and why. However, this is often a gradual transition. Planning is also a fluctuating process, and it may need to be revisited several times to allow reprioritizing as an ongoing procedure. Consequently, the MI approach allows health care professionals to have a goal for counselling while acknowledging and exploring the variation in an individual's commitment to, and interest in, changing his/her behaviour.

Prochaska and DiClementes' stages of change model

The Transtheoretical Model of Change (TTM) was developed by the American psychologists James Prochaska and Carlo DiClemente at the University of Rhode Island (221). From the beginning, TTM was associated with MI (262); however, MI can be practised independently of the TTM, but most counsellors use the model as a tool during their communication with patients, which is the case in the present thesis.
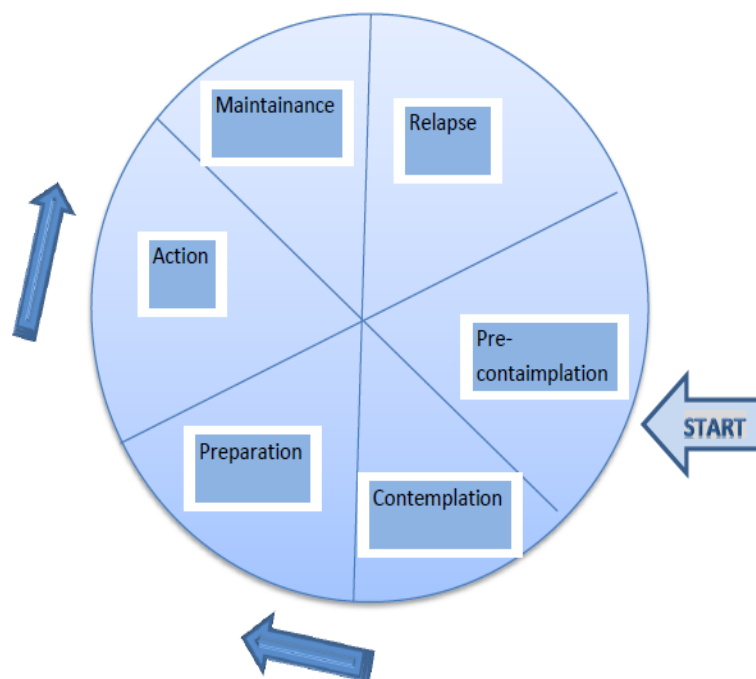
Fig. 5.　　Prochaska and DiClemente: The Transtheoretical Model of Change. Copyright © [1982] by the American Psychological Association, adapted with permission.

The model describes the five stages of readiness through which people pass in the course of changing their behaviour, thereby providing a framework for understanding the change process (Fig. 5). By identifying where a person is located in the change cycle, interventions and communication can be tailored to the individual's "readiness" to progress during the change process. Interventions that do not match the person's readiness stage are less likely to succeed and more likely to create resistance and prevent change. Anything that moves a person through the stages towards a positive outcome should be regarded as a success (221). The first stage is "pre-contemplation", where the subject does not yet acknowledge that there is a problem behaviour requiring change. The next stage is "contemplation", where the subject acknowledges that there is a problem but is not yet ready (or sure of wanting) to make

a change. The third stage is "preparation", where the subject is getting ready to change, which is followed by the "action-face" when the actual change in behaviour occurs. The last two stages are "maintenance" and "relapse", where the former comprises the maintenance of a behavioural change that is now integrated in the subject's life and the latter involves returning to older behaviours and abandoning the new changes (263).

Use of MI in practice and research

The widely distributed clinical method of MI has been elaborated via science and practice throughout the last 30 years (258;264;265). The MI method is applied in health care (44;266), and over 750 clinical trials of MI have been published according to PubMed (June 2015). Over the past 15 years, there have been considerable efforts to adapt and test MI across various chronic disease behaviours (261;267;268), but to the best of our knowledge, MI has not been applied in the context of psoriasis. Several efficacy reviews and meta-analyses have been conducted (53;54;269-271), which have yielded positive results for an array of target problems such as cardio-vascular rehabilitation, diabetes management, dietary change, hypertension, management of chronic mental disorders, problem drinking and substance use disorders. Unexpectedly, these reviews discovered that the specific effect size was larger (270) and more enduring (272) when MI was added to another active treatment. This suggests that there is a synergistic effect of MI with other treatment methods and that MI is more powerful when combined with other active interventions, such as comprehensive CHT, than when it is applied alone. According to a meta-analysis of 72 clinical trials in a range of target problems, the observed effect sizes for MI were larger in ethnic minority populations and when the practice of MI was not manually guided (272).

The main conclusion of a systematic review and meta-analysis by Rubak et al. (55) was that MI in a scientific setting outperformed giving traditional advice during the treatment of a broad range of behavioural problems and diseases. This review showed that MI had a significant and clinically relevant effect in approximately three out of four studies, with effects on physiological (72%) and psychological (75%) diseases. Psychologists and physicians obtained an effect in approximately 80% of the studies reviewed, while other health care providers obtained an effect in 46% of the studies. When using MI in brief

encounters of 15 minutes, 64% of the studies obtained an effect. This review also found that more than one encounter with the patient guaranteed the effectiveness of MI.

Furthermore, MI has been shown to be an efficacious approach for enhancing client engagement and for improving adherence to treatment (273;274), which may be essential in psoriasis care. A recent systematic review of 48 studies in medical settings by Lundahl (53) found that MI had favourable effects in terms of the main outcome in 63% of studies. MI obtained promising results in multiple areas of health care, but it was not particularly effective for eating disorders or self-care behaviours, or in terms of medical outcomes such as heart rate. Appendix 1 provides an summary (untilMay, 2015) of the RCTs included in this review as well as other RCTs within adult chronic disease health care that have implemented MI as an intervention.

In Norway, the use of MI has recently been supported by the state agencies and advocated in various governmental initiatives. The Norwegian Directorate of Health, which is the executive agency and competent authority subordinate to the Norwegian Ministry of Health and Care Services, has encouraged the use of MI in various areas where problematic behavioural change is desirable. They also provide financial support for MI training for health care professionals by hosting a website that includes practice-oriented exercises and interactive training programmes (www.helsedirektoratet.no). The foundation of the Norwegian MI-Analyse lab in 2012 represents another step towards the broader implementation of MI in Norway. This lab is a national advisory centre, which was established at the Bergen Clinics Foundation after being commissioned by the Directorate of Health. The lab provides feedback and guidance based on audio recordings and transcripts of recorded conversations, thereby helping professionals to become good MI practitioners and to maintain their professional competence in MI (http://www.korusbergen.no/mi-mi-analyse/mi-analyse/)

In more recent years, there has been an increased emphasis on studying the MI training process and ensuring the quality of the MI style of counsellors (275-277). For example, several observational measures have been developed to facilitate monitoring, feedback and research into MI skills (275;278), including the approach used in this thesis (279;280).

2.5 Cost–utility analysis (cost-effectiveness)

Economic analyses, including cost–utility, cost-effectiveness, and cost–benefit analyses, can be used to identify the programme or intervention with the greatest effect at the lowest cost (281). Thus, cost-effectiveness analysis (CEA) provides information about the benefits, costs and potential savings of a health product compared with other treatments and/or interventions. A medical treatment or SMS intervention, such as that described in this thesis, is generally considered to be cost-effective under the following conditions: (1) it provides an added health benefit at an equal or lower cost than the alternative treatment, (2) it provides an added health benefit that is worth the additional cost, or (3) it provides a lower health benefit but with a cost saving that is more valuable than the lost health benefit (282).

Utility is a broad measure of the benefits or usefulness of health care programmes, and it is synonymous with preference; thus, a more preferable outcome is associated with greater utility (281). Utility quantifies health outcomes in several dimensions using a health indicator called HRQoL, and it should ideally encapsulate the impact of a treatment on a patient's length of life and the impact on his/her HRQoL, which is recognized as a key indicator of treatment outcomes. Cost–utility analysis (CUA) is a special variant of CEA, which compares different procedures and outcomes relative to a person's HRQoL.

The choice of the effectiveness of an outcome measure is related directly to the method employed for economic evaluation. Disease-specific HRQoL outcomes are often used in evaluations of treatments, as well as self-management and patient education interventions (243;283;284). This is also the case for psoriasis, where HRQoL is recognized as an established outcome measure for monitoring and managing the impact of psoriasis on everyday life (130). However, in many cases, the consequences of an intervention are multidimensional, and it can be difficult to capture these complexities in a single outcome measure (285). Therefore, multiple secondary outcome measures are often used in economic evaluations in addition to the primary outcome measure (281). Furthermore, economists have another concern because the economic valuation should support decision-makers who want to maximize the health care benefits of the available budget across different disease areas. Thus, the health benefit must be expressed using a measure that allows comparisons among different diseases, thereby making the CUAs useful for resource-allocation-related decisions. Therefore, it is usual to employ a generic HRQoL measure. These measures are generally

broader in scope and applicability, thereby facilitating comparisons between different diseases and treatments (286). In the context of quality-adjusted life years (QALYs), the HRQoL must be expressed by a single-index score, where 1 represents full health and 0 represents death. However, some instruments also yield negative scores, which imply health states worse than death (281). Several generic HRQoL measures are used in CUAs, such as the EuroQol (EQ-5D), Short Form 6D (SF-6D), Health Utilities Index (HUI2 and HUI3) and the health state descriptive system 15D. The different properties of these measures are summarized in Table 1.

Table 1. Properties of generic single-index HRQoL instruments

	15D (287;288)	EQ-5D-3L /5L) (289-291)	SF-6D (290;292)	HUI2/HUI3 (281;290;293)
Origin	Finland	Europe	USA	Canada
Items	15	5	11 of 36 *	8
Response levels	5	3/5	2–6	3–6
Range and valuation technique	0 to 1	−0.59 to 1	0.30 to 1	−0.03 to 1/ −0.36 to 1
	Visual analogue scale	Time trade-off method	Standard gamble	Standard gamble
Number of possible health states	$3.1*10^{10}$	243/3125	18.000	24.000/972.000
MIC	0.015	0.05–0.13	0.03−0.04	0.05 (0.03)

* May be calculated from SF-36 or SF-12, MIC: minimum important change.

The HRQoL instruments shown in Table 1 were developed at different times. There has been a tendency for an instrument to be employed most widely in the country where it was developed (294). According to a systematic review of 23 CUAs, EQ-5D is the most commonly used instrument (295). However, this study was published in 2004, so the preference may have changed. In 2011, the EuroQol Group introduced a new version of the EQ-5D instrument. The main differences between the old and new versions are the number of levels in each dimension and the wordings of the previous levels. The number of levels has increased from three to five; i.e., no problems, slight problems, moderate problems, severe problems and extreme problems in each of the existing five EQ-5D dimensions. The new version is called EQ-5D-5L, whereas the old version with three levels was EQ5D-3L (www.euroqol.org). The HUI also has two versions: HUI2 and HUI3, where HUI3 employs a more detailed descriptive system, structural independence and available population norms (281). There is some overlap between HUI2 and HUI3. Yet, in other ways, the two systems complement each other (i.e.; the concepts of emotion differ between the two systems; HUI2

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refers to worry and anxiety while HUI3 to happiness versus depression). HUI2 has some additional features such as self-care and fertility, while dexterity is available only in HUI3.

EQ-5D, SF-6D, HUI and 15D (used in the current study) are standardized and validated generic instruments, which have been used widely and validated in various patient populations and different countries (293;296-298). In addition to 15D, the current study employed a VAS scale for the general health condition as a generic HRQoL measure and DLQI as a disease-specific measure (as described in chapter 4.7.3).

In CUA, the QALY is used as an outcome measure. NICE (299) states that the QALY is now considered to be the most appropriate generic measure of health benefits, where it reflects both life expectancy and HRQoL effects. When calculating QALYs, each of the health states experienced within the time horizon of the model is assigned a utility that reflects the HRQoL associated with the health state (285). When individuals move through health states over time, each health state has an attached value, and the amount of time spent in each health state is multiplied by the utility. The health states are then valued on a scale, where the value of being dead is 0, because the absence of life is considered to be worth 0 QALYs, whereas the upper end of the scale is defined as perfect health, with a value of 1 (296).

QALYs capture the overall effect of a disease on the HRQoL over a given period, where the QALYs combine the quantitative benefit and QoL gained from treatment (300) (as illustrated in Fig. 6). Therefore, QALYs provide a valuation of health benefits, which can be compared among diseases to support resource allocation choices within the overall health care budget. Consequently, QALYs are the preferred outcome measure of many governments and other health authorities when an economic evaluation is required before recommending the implementation of a new intervention or treatment (301). As such, CEAs and QALYs are not designed for use in clinical practice to guide treatment decisions for individual patients but are intended to assess the value of treatment at the population level (301).
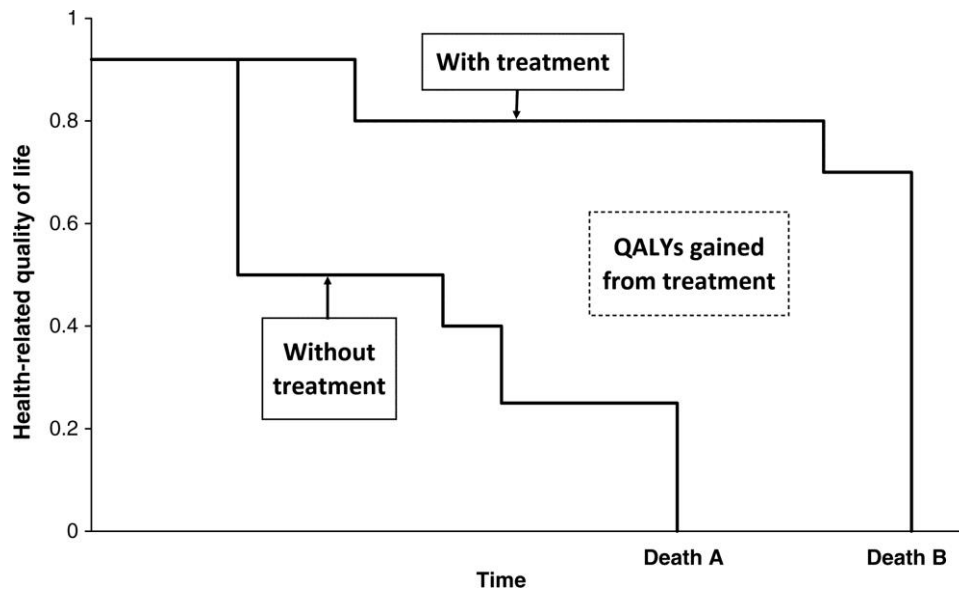
Fig. 6.   QALYs gained from treatment (from Whitehead and Ali, 2010) (285). Reprinted with
            permission from Oxford University Press.

An economic evaluation also needs good-quality evidence of the resources used by the
treatment and control groups. In economic evaluations, costs are often categorized as the
resource usage defined as medical costs; e.g., hospital care, drugs and medical procedures,
and nonmedical costs, such as social services and transportation. In addition, costs arise from
the loss of productivity due to morbidity or mortality (301). Thus, the perspective employed
will determine the costs incurred, which must be appropriate and as comprehensive as
required. Information about the use of health care services and other costs is often collected
by administering questionnaires (repeatedly) to the patients included in a study, as performed
in the current thesis.

However, previous studies have shown that there are wide variations in the estimation of costs
in CUAs (302). Economic evaluations should include all of the costs and all of the benefits,
regardless of who incurs the costs and who gains the benefits, which is known as a societal
perspective (281;301). Thus, when applying a societal perspective, both medical costs and
costs outside the health care sector form part of the analysis. This may be especially important
for chronic conditions such as psoriasis, where most of the costs are often incurred outside the
health care system; i.e., by the general society (e.g., production losses, informal care) or by
the patients themselves. This was also the case in the present study regarding productivity
losses, as described in the results in chapter 5.3. A societal perspective typically includes
productivity costs due to absence from/inability to work, the costs of and for carers and the

additional costs of the illness to patients, but it can also exclude productivity costs (281). Productivity costs can be defined as the costs associated with paid and unpaid production losses and replacement due to illness, disability or death of productive persons (303). The productivity costs can represent a considerable burden on both the individual and society, and they can exceed medical costs (302), but their use in CEAs is an area of controversy (281). This is partly due to methodological uncertainty concerning the appropriate method for measuring productivity losses, especially when significant unemployment is evident (281). Double counting is another issue. If an individual's productivity loss leads to an income loss for the individual, and he/she takes this loss of income into account when valuing health states, this means that part of the productivity loss (the income loss) is already included in the analysis. In this case, separate inclusion of the cost of productivity loss would lead to double counting. Conversely, if individuals do not consider income in their valuation of health states, productivity losses should be included as a cost in the analysis (304). Concern has also been raised regarding the ethical implications of including productivity costs because this may lead to favouring interventions that target the working population (305). Others have argued about equity considerations because including all types of costs (including medical) may be perceived as discriminating between different groups (e.g., old and young) (306). This could then lead to fewer resources being allocated to interventions aimed at unemployed individuals or older individuals, which could be considered to be inequitable. By contrast, when interventions (such as many self-management programmes) require extensive time commitments by productive individuals, the inclusion of productivity costs does not necessarily lower cost-effectiveness estimates or favour interventions for productive individuals. Therefore, the inclusion of productivity costs may cause interventions to become less cost-effective, and thus the treatment of people without paid work would be more cost-effective compared with those in paid work.

Consequently, while the exclusion and inclusion of productivity costs can have distributional consequences, we have chosen to present the CUA in this thesis without including productivity costs in the main analyses.

2.5.1 Incremental analysis of costs and outcomes

A common approach to combining costs and outcomes in health care research is incremental analysis (281), where the additional or incremental costs of the programme are compared with the additional or incremental outcomes. A common question is whether to replace an existing treatment or intervention with another that is more effective but also more expensive. In this case, an estimate is required of the additional resources that need to be spent to obtain the additional benefit. The incremental cost-effectiveness ratio (ICER) is used to answer this key question about whether the intervention provides additional benefits and how much this will cost. The ICER denotes the cost of producing one extra unit of benefit; e.g., a life year saved (281). The ICER is calculated as the ratio between the difference in costs and the difference in the benefits or effects of two interventions or treatments.

In this thesis, the ICER is defined as follows.

$$ICER = \frac{\text{(Cost of MI intervention} - \text{Cost of TAU)}}{\text{(Health effect of MI intervention} - \text{Health effect of TAU)}} = \frac{\Delta C}{\Delta E}$$

In the present study, the total costs and effectiveness differences in the MI and TAU were calculated as the costs of the numerator and the effectiveness of the denominator for each of the two groups 6 months after the CHT by using the area under the curve (AUC) approach to calculate QALYs. This procedure generates the QALYs gained for each patient over this 6-month period. The two groups were then compared to generate an estimate of the mean differential QALY. In our study, the health effects were measured by the 15D QALYs and DLQI QALYs, thereby producing two different ICERs (paper 3).

However, a quick review of an ICER can be misleading because an intervention that is less expensive and more effective will yield a negative ICER, as will an intervention that is more expensive and less effective (282). An important drawback of the ICER is the mathematical difficulty of creating confidence intervals (CIs) for a ratio (307).

Another issue is that ICERs are often published with no accompanying assessment of uncertainty. Recently, several methods have been developed for estimating the uncertainty for the ICER, including techniques such as "bootstrapping" (308). In bootstrapping, the statistical precision is estimated by repetitively generating hypothetical substudies by resampling. The

uncertainty explored via bootstrapping is the heterogeneity in the study population, which can then be represented graphically by plotting each of these replicates in a cost-effectiveness plane (309) (Fig. 7).
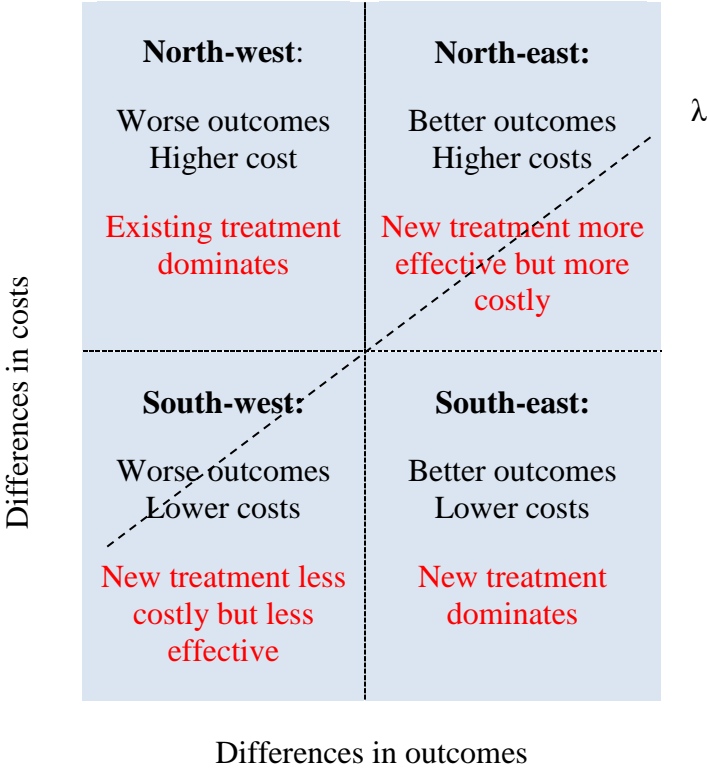
Fig. 7.   Cost-effectiveness plane with threshold cost-effectiveness ratio (λ).

In Fig. 7, the dotted line (λ) represents the "acceptable" cost-effectiveness ratio, which is the maximum or threshold that we are willing to pay for a unit of effect (e.g., a QALY). If a significant proportion (e.g., 95%) falls on, or to the right of, the line representing the selected cost-effectiveness ceiling ratio, then we may have adequate confidence that the new intervention is cost-effective (309). A threshold value is often set by policy makers, who may decide that only interventions with an ICER below this threshold are cost-effective, and thus they are considered to represent good value for money (and they should be funded). If the ICER is above the ceiling ratio, then the new intervention is not considered to be cost-effective. If a treatment is both more effective and less costly, then it is the "dominant" alternative, and the decision is often straightforward. When the choice is between treatments where one is both more costly and more effective, the additional cost of achieving the additional outcome is significant information. Decision-makers can then decide whether to opt for the more costly alternative based on a consideration of whether the extra cost appears

to be justified by the additional advantage gained (301). Finally, the new intervention may cost less than the standard treatment but yield worse outcomes. In this situation, a value decision must be made regarding whether the costs saved justify the poorer outcomes.

In non-dominant situations (i.e., south-west and north-east quadrants), decision-makers need to assess the ICER by considering the difference in costs between the two interventions divided by the differences in outcomes. The ICER can be evaluated against a maximum willingness to pay (λ) for improvements in outcomes.

2.5.2 Cost-effectiveness acceptability curves

The cost-effectiveness acceptability curve (CEAC) is another commonly used method for comparing cost and effectiveness simultaneously (310)(Fig. 8). As described earlier, the new intervention should be implemented if the estimated ICER lies below a threshold level (λ) that defines the maximum that decision-makers are willing to finance to achieve a unit of effectiveness. The CEAC is a method that summarizes uncertainty by considering the proportion of the bootstrap replicates that fall below and to the right of a line with a slope equal to the threshold. This threshold level reflects the maximum that decision-makers are willing to pay to achieve a unit of effectiveness. Thus, the CEAC summarizes the likelihood that the new intervention (MI in the present study) is a cost-effective alternative compared with TAU over a range of threshold values for an additional unit of outcome (e.g., a QALY). Hence, the curve represents much more information about uncertainty than CIs (308). However, if the exact value of λ is unknown, then it must be resolved explicitly or implicitly; thus, a monetary value must be assigned to health outcomes at the time of any decision (308). In our study, the curve represents the probability that MI is cost-effective at 6 months for different threshold values (see Appendix 5 in paper 3).

In CEAC, the *x*-axis represents the amount that the decision-maker is willing to pay for this outcome, and the *y*-axis represents the likelihood that the intervention will be cost-effective at the given threshold (see Fig. 8).

At an ICER Threshold of $15,000, over 85% of simulations will be cost-effective.
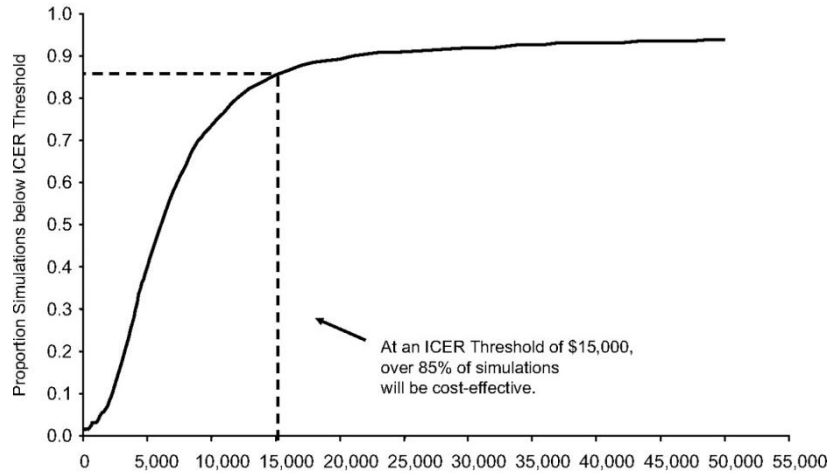
Fig. 8. Example of a cost-effectiveness acceptability curve for two treatments, which represented the willingness to pay for QALYs gained. Reprinted with permission from Wolters Kluwer Health, Inc.

Another way to address the uncertainty of the value of λ is the net health benefit (NHB). This method simplifies the decision-making process by transforming it into a simple maximization problem, which makes the identification of the cost-effective option more straightforward than that using the ICER method, where the decision-maker must identify the greatest ICER with a value below their threshold.

The threshold (λ) is defined as the opportunity cost at which society is indifferent to "trading" costs for effects or vice versa (311). Thus, it is implied that the threshold is independent of the values of costs or effects. In this case, the standard cost-effectiveness decision rule of implementing only if $\Delta C/\Delta E < \lambda$ can be rearranged to obtain two alternative inequalities based on cost or effect scales. Using the opportunity cost (i.e., the threshold) allows us to express the cost of each alternative in a health equivalent, where the effects and costs can be combined in a single outcome measure, NHB:

$$NHB = effect - cost/threshold \text{ (or } NHB = \Delta E - (\Delta C/\lambda)).$$

Analogously, the effect of each alternative can be expressed in a monetary equivalent, thereby yielding the net monetary benefit (NMB):

$$NMB = effect * threshold - cost \text{ (or } NMB = \Delta E * \lambda - \Delta C).$$

Identifying the preferred alternative is now simplified to selecting the alternative with the maximum net benefit (NHB or NMB). If NHB = 0, then the additional health improvement

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exactly offsets the additional resource cost. The decision-maker would (normally) then be indifferent to achieving extra health gains and increasing the expenditure on resources. However, if health gains and costs are both distributed continuously, then so is NHB, and thus there is zero probability that NHB will be exactly zero (312).

2.5.3 Cost-effectiveness studies in psoriasis

In chronic conditions such as psoriasis, the goal of treatment is often preventative in nature; i.e., delaying or avoiding progression to a more severe health state, which is generally associated with higher costs and reduced QoL. However, very few educational and self-management interventions related to psoriasis have included CEA. One RCT that included a CEA for psoriasis involved a 12-week educational programme for patients with psoriasis and atopic dermatitis, showed a lack of cost-effectiveness at 6 months after considering the programme cost per patient and the medical resource use per individual patient (250). To the best of our knowledge, there have been no systematic reviews of cost-effectiveness for educational and self-management interventions in psoriasis care, although recent reviews have considered the cost-effectiveness of different treatment options for psoriasis (313;314). In addition, some studies compared different phototherapy treatments (315;316) and several addressed the economic burden of psoriasis for society in different countries (317;318).

3 AIMS OF THE THESIS

The overall aim of this study was to investigate the effects and effectiveness of self-management interventions for patients with psoriasis. The specific aims were as follows.

- To describe the contents and investigating the effects of patient education and self-management programmes for patients with psoriasis (paper1).

- To evaluate the effects of individualized motivational follow-up calls to support patients with psoriasis in self-management and desired lifestyle change following CHT based on outcomes in terms of disease severity (SAPASI), self-management (Health Education Impact Questionnaire, HeiQ), knowledge (Psoriasis Knowledge Questionnaire, PKQ) and changes in lifestyle (paper 2).

- To assess the cost–utility of MI compared with TAU following CHT (paper 3).

4 MATERIALS AND METHODS

4.1 Study designs

The present study consisted of two designs. To address aim 1, a systematic review was conducted of patient education and self-management interventions for patients with psoriasis (paper 1). To address aims 2 and 3, an RCT was performed to determine the clinical and health economic effects of an MI intervention at follow-up after CHT (papers 2 and 3), where this design was used in the context of CHT treatment on Gran Canaria.

4.2 Study samples and inclusion criteria

4.2.1 Describing the contents and investigating the effects of patient education and self-management programmes for patients with psoriasis (paper 1)

All individual and group-based RCTs, quasi-randomized trials (with inadequate sequence allocation) and controlled clinical trials were considered to be eligible for inclusion. The PICO for the inclusion criteria was as follows. **Population**: Trials involving patients aged over 18 years with a clinical diagnosis of psoriasis, regardless of type or stage, and studies in all settings and where all types of health care professionals provided the intervention. **Interventions**: The programme content had to include at least one "face-to-face" meeting with a health care professional. The intervention had to include psoriasis education or to focus on one or more aspects of living with psoriasis, such as symptom management, cognitive problem solving, communication skills, stress management or lifestyle change. Self-management interventions had to emphasize key elements such as engagement in self-care, self-efficacy strengthening, action planning and problem solving (46) (i.e., education only, self-management only or education and self-management combined). **Comparison:** The educational or self-management intervention should be compared with a different intervention, usual care or waiting list control. **Outcomes** are described in chapter 4.7.

We performed an extensive systematic literature search for articles that contained the terms "patient education", "counselling", "self-management", "intervention" or "programme", which were all combined with psoriasis and/or skin disease and/or chronic illness. The term

"self-care" was also added because of inconsistent terminology usage. The search strategy was organized in collaboration with the librarian at OUS. The following databases were searched up to May 2012: MEDLINE, EMBASE, CINAHL, PubMed, PsycINFO, SweMed and the Cochrane Controlled Trials Register. The initial literature search identified 1404 papers. After removing duplicates, 613 records described potentially relevant studies. However, after reviewing the abstracts, 504 studies were discarded because they clearly did not meet the inclusion criteria. The full texts of the remaining 109 studies were examined in more detail. A check of the database searches in June 2013 identified two additional papers that required full text examination. Finally, 101 of these publications were excluded, and 10 papers (from nine controlled trials) satisfied the inclusion criteria (Fig. 9).
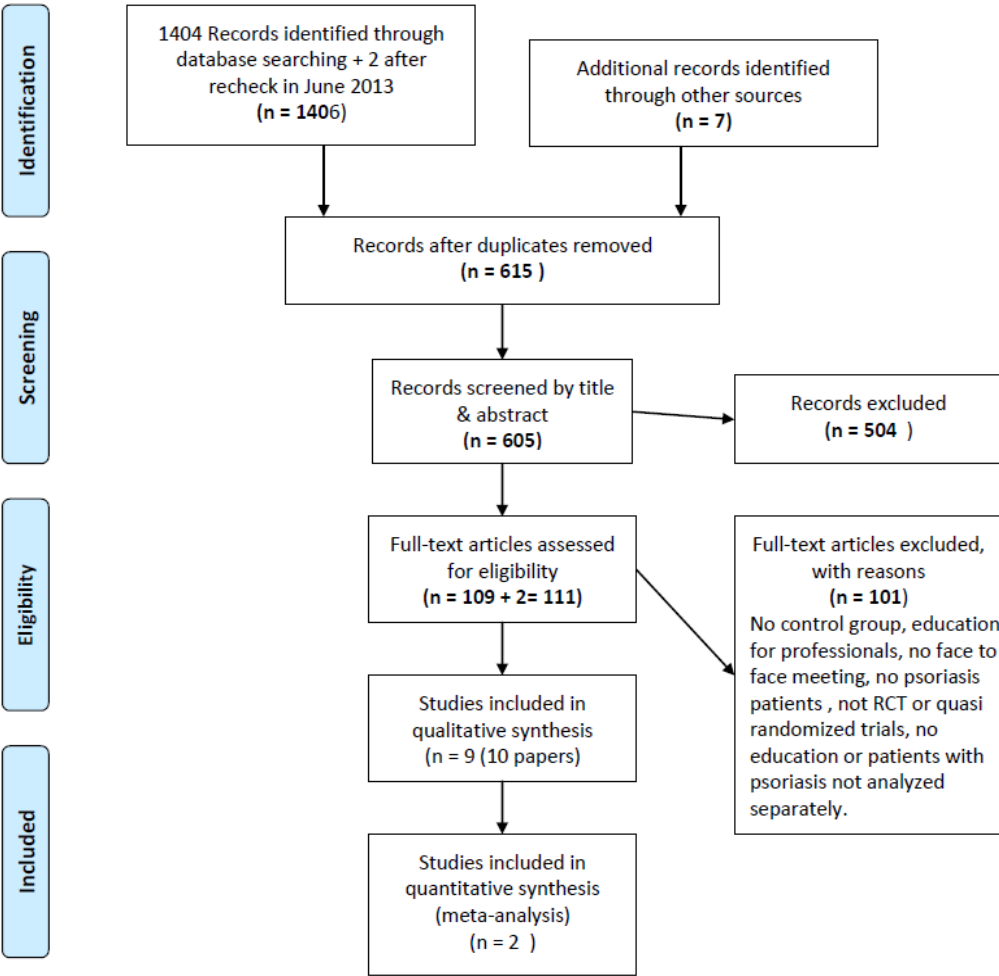
Fig. 9.   Flowchart showing the inclusion procedure (according to PRISMA(319).

4.2.2 Evaluating the clinical and health economic effects of individualized motivational follow-up calls to support patients with psoriasis in self-management and desired lifestyle change following CHT (papers 2 and 3)

For paper 2 and 3, participants in the CHT programme on Gran Canaria were recruited on the first day after attending CHT. The criteria for participation were aged between 20 and 70 years in 2011 (born between 1 January 1941 and 31 December 1991) and diagnosed with psoriasis with PASI > 7.0 when applying for CHT. Participants also had to be capable of answering questionnaires and communicating by telephone. The exclusion criterion was participation in CHT more than eight times during the last 10 years (excluding the current stay). The patients were assessed at four time points: before the start of CHT (T1), after 3 weeks of CHT (T2), 3 months after CHT (T3) and 6 months after CHT (T4). Of the 291 invited patients, 113 (38.8%) decided not to participate for unknown reasons. In total, 178 patients were recruited to the trial between September 2011 and May 2012. Of these, 169 completed both T1 and T2 questionnaires (before CHT and after three weeks of CHT), and they were then allocated randomly to the control (83 patients) or the intervention (86 patients) group. The nine patients who did not reach randomization reported different reasons for leaving the study, such as regret (N = 6) and illness during CHT (N = 3).

Data were obtained for 169 participants at T1 and T2, and 135 participants (79, 9%) reached the third measurement point (T3) after 3 months; i.e., 63 controls and 72 in the study group. Ultimately, 125 (74%) responded to the questionnaires at 6 months; i.e., 60 participants in the control group and 65 in the experimental group (Fig. 10).

Assessed for eligibility (n=342)

Not meeting inclusion criteria (n=51)

Enrollment

Approached for recruitment to study (N = 291). **178 accepted** and completed questionnaire 1 (T1) at arrival CHT.

Declined to participate (n= 113) (38.8%)

9 participants withdrew before the second questionnaire T2 (after 3 weeks of CHT).

Randomized (n=169)

Allocation

Allocated to usual care (n= 83)

Allocated to intervention (n= 86)
* Received allocated intervention (n= 79)
* Did not receive complete allocated intervention for various reasons (n =7)

Follow-Up

* Lost to follow-up T3 questionnaire (3 months after CHT): N=20, **63 participated**
* Lost to follow up T4 questionnaire (6 months after CHT) N=23 **60 participated**

* Lost to follow-up T3 questionnaire (3 months after CHT): (N = 14) **72 participated**
* Lost to follow up 6 months (n=21) **65 participated**

Analysis

Analysed T3 (n=63) =**76%**

Analysed T4 (n= 60)= **72.3%**

Analysed T3 (n=72) = **84%**

Analysed T4 (n= 65)= **76%**

Fig. 10. Flowchart showing the participants in the different stages of the randomized controlled study.

4.3 The pilot study

As part of the planning process, we performed a pilot study where six patients each received four MI calls during June and July in 2011. The aim was to evaluate the workbook and to obtain information about how the patients experienced the motivational calls. We also wanted to test the logistics in relation to the intervention, in terms of both the initial mapping talks in Gran Canaria and the time spent on the calls, and also writing a summary subsequently. In

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addition, we wanted to experience whether the patients prioritized and adhered to the scheduled times. The feedback from pilot study participants allowed us to make some practical changes to the workbook, but no other major changes were necessary.

4.4 Sample size estimation (papers 2 and 3)

The sample size for the RCT study was estimated before inclusion to achieve adequate statistical power for examining the effects of the MI intervention. One of the primary outcomes (HeiQ) was used, and the sample size was determined by a power calculation. Medium effect sizes (Cohen's criteria) (320)) that differed between groups by half a standard deviation (SD), i.e., d = 0.5, were obtained using a test strength of 80 (β) and a significance level of 5% (α) when 64 participants were included in both groups. Thus, a sample of 169 seemed more than sufficient when we also accounted for a possible drop-out rate of 20%.

4.5 The MI intervention – independent variable (papers 2 and 3)
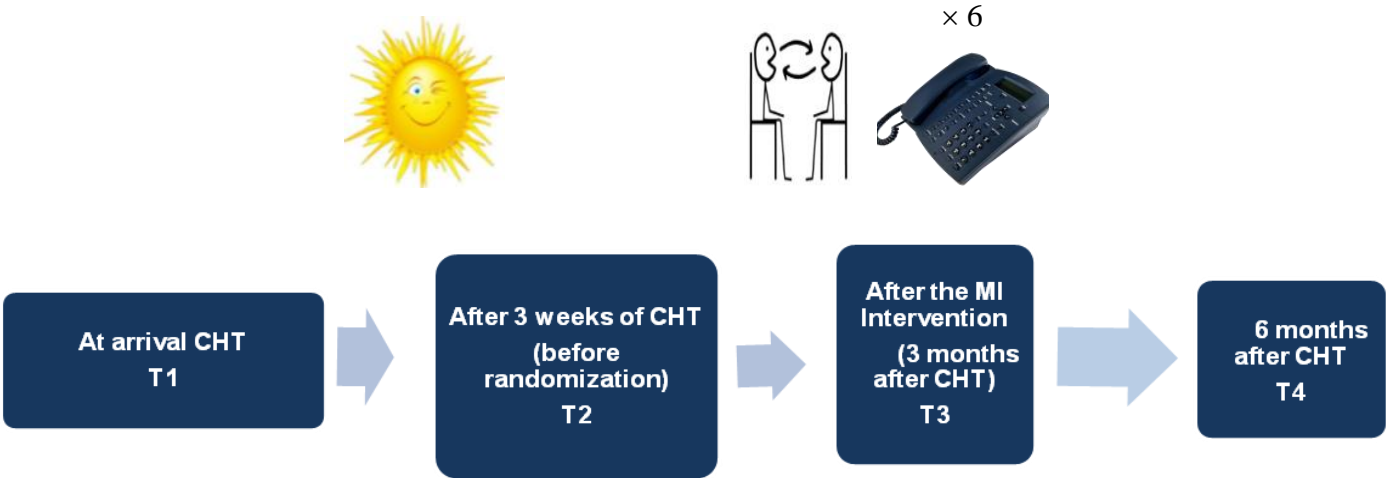
Fig. 11. Overview of the intervention.

4.5.1 Data collection

Data were collected at four time points, as shown in Fig. 11. All of the patients in the CHT programme were informed about the study by the head nurse at the first information meeting after arriving at the CHT centre on Gran Canaria. They also received written information about the study, which highlighted the aims and possible advantages and disadvantages of

participation, and also explained that they could opt out of the study at any time without giving a reason. Two of the CHT nurses implemented the inclusion of patients in the study. They approached all eligible patients after the first medical examination by a dermatologist and nurse, and also provided additional information and answered questions about the study. Patients who consented to participation received a study number, and they then completed the first questionnaire (T1) in a nearby group room. After 3 weeks of CHT and after the final examination by a dermatologist and nurse, they completed questionnaire number two (T2) in the same room, before randomization. After 3 (T3) and 6 (T4) months, the questionnaires were sent by mail with a stamped, addressed return envelope. One reminder was sent to participants each time to request missing questionnaires.

4.5.2 Randomization and blinding (papers 2 and 3)

Randomization was performed in small blocks of six (a series of six envelopes contained three assignments in each group). Permuted blocks were chosen randomly to eliminate deciphering, so a few different block sizes were used (e.g., 4, 6, or 6), but they were selected randomly (321). The person who generated the allocation scheme did not administer the allocation of patients to the two groups and was not part of the research team. Pre-coded, sequentially numbered, sealed, opaque envelopes were used to ensure adequate allocation concealment. The envelope contained a note that assigned the patient to a study group or a control group. The assignment of participants to groups was performed while the patient was present. In total, 86 patients were randomized to the study group and 83 to the control group. Blinding of participants or counsellors is not possible in this type of study. However, all of the outcomes were self-reported, and the data plotters were blinded to group allocation.

4.5.3 The mapping talk

The mapping talk was the first meeting between the patient and the counsellor, other than short pleasantries before randomization. The aim was to allow the patient and the counsellor to become acquainted and to form a collaborative focus (52;258). Thus, all sessions started by asking patients about their motivation for participating in the study and what they knew about MI. Different MI methods were then briefly explained and patients were encouraged to express their thoughts regarding lifestyle choices related to psoriasis. Skin and skin treatment was presented as a standard topic in each follow-up call. Patients were then asked whether

they wanted to focus on particular lifestyle topics in the first talks. A "bubble sheet" for agenda mapping was used to identify a first focusing domain in which to pursue change (Fig. 12) (52), which was presented as: "These are some of the subjects related to psoriasis that we could talk about. Would you like to talk about any of these, or do you have something else (pointing to the blank spaces) that you would prefer to talk about in our first meeting?"

Hence, the focused topic could be one or more of the topics presented in the bubble sheet or additional topics that patients felt were more important. The patient's own preferences varied among behavioural topics, such as smoking cessation, weight reduction or alcohol abuse, to domains of life that caused stress or concern, such as demanding work situations, personality traits or traumatic life events. Some participants chose one topic, but others selected more, and they were then asked to rate the topic that mattered to them most at that time.
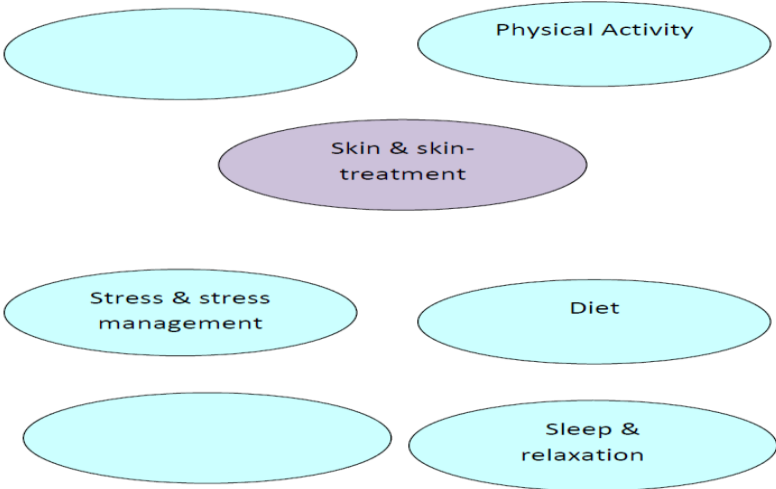
Fig. 12.   Bubble sheet for agenda mapping.

The TTM (described in chapter 2.4) was briefly reviewed, and those who selected a focus for change were asked to consider their current stage according to the theory in relation to their desired lifestyle topic. The patients were also provided with a workbook partly adapted from Farbring (322), which outlined some key MI principles and also presented some open-ended questions, the TTM and practical exercises. An example of the latter was the "decisional balance sheet", which simply comprised four squares that asked about the advantages and disadvantages of changing behaviour or continuing as before (52). Some of the exercises considered specific phases of change in terms of the TTM, and were therefore not suitable for all of the participants.

Towards the end of the session, all of the participants were asked to perform a colouring task. They were presented with a drawing shaped like a shoe, which described 13 different areas of life (Fig. 13). The task was to colour each area in relation to their own life situation based on their feelings about each specific area. Areas that were going smoothly were coloured in green, yellow indicated slightly challenging areas of life and problematic areas were coloured red. I coloured my own copy for future reference and noted the reasons for colour choices given by the patients. As a counsellor, this exercise provided me with an insight into each individual's life and the areas that they felt were problematic or fine. In addition, it appeared that this exercise allowed many of the participants to clarify the areas of their current life that were NOT problematic, as well as the areas in need of attention. Many spoke of the "shoe" exercise again in subsequent calls, and they were eager to report a "change of colour" based on their efforts to change behaviour.
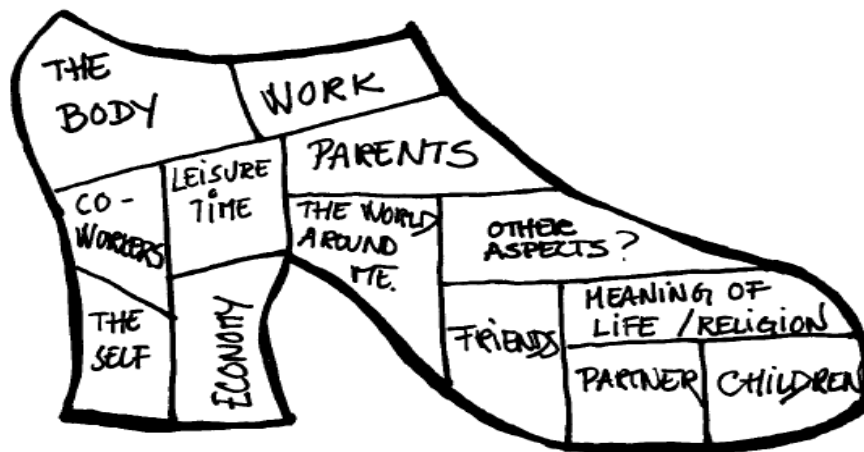
Fig. 13.   The shoe exercise.

4.5.4 Content of the follow-up calls

The first telephone appointment was arranged for approximately 2 weeks after returning home from the CHT at a time that suited the patient. The patients were encouraged to choose the time and place so that they could talk without interruptions and be as open as they wished, without having to consider other people who might be present. The conversations comprised four continuous processes, where the last depended on the patient's degree of readiness to change: 1) creating a good and confident relationship, 2) finding a useful focus for each talk in collaboration with the patient, 3) exploring the patient's motivation for change and 4)

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assisting with creating a plan for facilitating change. A special interview format was not applied because it has been shown (as mentioned previously) that a structural approach limits the effects of the method (272). Some of the exercises in the workbook were often used in the course of the calls, but they did not give a structure to the counselling process. As mentioned earlier, some of the exercises were dependent on a specific stage of change, and thus they were not used with all of the patients.

All of the telephone sessions started by asking the patient about their patches of psoriasis and individual skin treatment. The patient also shared his/her thoughts, experiences and knowledge about his/her choice of treatment or no treatment. The topic(s) that the patient perceived as important was then discussed, and any changes from the last session regarding personal goals for change were assessed, where different MI tools were applied depending on the patient's readiness to change. All of the calls had a maximum duration of one hour. A short summary was written following each call.

4.5.5 Motivational Interviewing Treatment Integrity (MITI) code

A random sample of calls was recorded, which was then evaluated and rated by the Motivational Interviewing Coding Laboratory (MIC lab) at The Karolinska Institute in Sweden using MITI code 3.0 (MITI 3.0). At the beginning of the telephone conversation, patients were asked if the following session could be recorded. All of the patients included in the study from 1 January 2012 also gave their written consent to this possibility. We did not know of the possibility that the MIC lab might assess the Norwegian MI talks when the patients were included during the autumn of 2011. Originally, it was planned that the taped calls would be randomized at approximately 1:5, but this procedure was not feasible because of shared office space, and the recording option was only available on a fixed telephone. Thus, some calls were made using a hands-free telephone in a vacant office nearby. However, the recorded calls were still selected randomly, depending on the availability of the fixed telephone.

MITI is a coding manual for assessing how well a counsellor uses MI (279). MITI is focused solely on the counsellor's behaviour during calls, and it contains a system for encoding the degree to which the counsellor uses attitudes, principles and communication skills in MI. Thus, the counsellor's behaviour was assessed in terms of global empathy and MI spirit levels, reflection to question ratios, proportion of complex reflections to total reflections,

percentage of open-ended questions and percentage of MI adherence. The behaviours during MIs were then compared with the MI proficiency levels (280). All of the coded calls were assessed by two Swedish MI assessors at the MIC lab because of language variations and because some of the calls involved different Norwegian dialects. The results obtained from the MIC lab are presented in paper 2, which shows that all of the threshold criteria were satisfied.

4.5.6 MI education and training

In the first planning phase, it was intended that the intervention with the MI follow-up calls would be performed by nurses from the CHT centre who knew the patients from their 3-week stay in Gran Canaria. However, this was too difficult to achieve because of limited CHT staffing and the expensive telephone charges from Spain to Norway. Instead, as a PhD candidate, I performed the follow-up calls and met all of the study participants in mapping conversations every 3 weeks on Gran Canaria. In total, the MI intervention comprised 86 mapping conversations and 507 motivational telephone calls between September 2011 and August 2012. Adequate theoretical and practical knowledge, and competence in MI, were crucial for performing the MI intervention, so after theoretical MI studies, I attended a 3-day workshop in spring 2011, which was provided by a trainer experienced in MI education, as well as a 2-day theoretical course. In addition, I completed a postgraduate course in MI at Oslo and Akershus University College for health care professionals. The teacher was highly experienced in MI methods and a member of the Motivational Interviewing Network of Trainers. This course outlined the key MI principles, strategies and techniques, and it comprised didactic teaching, modelling by the trainer, video-taped demonstrations and role-playing with feedback using adult education principles. It also involved a large amount of hands-on practice, as well as more theoretical analysis of various aspects of the method. The course also comprised 20 hours of MI training in small groups between meetings, where audio and video were used as learning tools.

4.6 Treatment as usual (TAU)

The participants in the control and study groups received their usual psoriasis treatment after returning to Norway. TAU may include consultations with a dermatologist or GP, UV light treatment and/or self-management in terms of topical treatment, exercise and stress

management. Norwegians with psoriasis are usually treated by their GPs in primary care. In addition, they are usually referred to a dermatologist if the disease is of a moderate or severe nature, but there are no systematic follow-up procedures for patients with psoriasis, as described in chapter 2.2.

4.7 Outcome measures

4.7.1 Outcomes in the systematic review (paper 1)

To measure the effects of education and self-management interventions for patients with psoriasis, we decided to use a comprehensive approach where we considered parameters such as disease severity, symptom relief, illness perception, QoL, self-efficacy and psychological status. We also decided to include studies that measured knowledge, regardless of the type of questionnaire, as well as interventions with self-customized questionnaires, provided that they referred to any of the topics of interest.

4.7.2 Instruments used in papers 2 and 3

Papers 2 and 3 are based on data obtained from the RCT study. The patients completed a series of self-administered questionnaires at four time points, as described in chapter 4.2.2. Additional clinical parameters such as PASI at CHT arrival/departure and BMI were collected from the CHT medical records at OUS. At baseline (arrival at the CHT), a questionnaire was used to collect socio-demographic data, including personal factors such as age, sex, height, weight, educational level and cohabitation status. The standardized clinical instruments are presented in Table 2 (see also papers 2 and 3). In paper 2, the primary outcomes were SAPASI and HeiQ, while the secondary outcomes were PKQ and the Brief Illness Perception Questionnaire (BIPQ). In paper 3, the primary outcomes were QALYs assessed by 15D and the DLQI, while secondary outcomes were health care utilization, psoriasis medication, cost to participants and productivity losses.

Table 2.Overview of data collection and assessments (papers 2 and 3)

Concept	Instrument	Paper 2	Paper 3
Socio-demographic characteristics	Age (years)	X	X
	Gender (male/female)	X	X
	Education (years)	X	X
	Employment/work status	X	X
	Productivity loss		X
	Disease duration	X	
Self-management, psoriasis perception, knowledge and severity	Self-administered psoriasis area and severity index (SAPASI)	X	
	Health Education Impact Questionnaire (HeiQ)	X	
	Self-efficacy on desired behaviour change Self-Administered	X	
	Co-morbidity Questionnaire (SCQ-18)	X	
	Psoriasis Knowledge Questionnaire (PKQ)	X	
	Brief Illness Perception Questionnaire (BIPQ)	X	
Quality of life	Health state descriptive system (15D)		X
	Dermatological Life Quality Index (DLQI)	X	X
	General health assessments on VAS scale	X	
	General health status assessment (1–5 = poor–excellent)	X	X
Lifestyle and lifestyle change	Plans for lifestyle change	X	
	Willingness to change to self-management of psoriasis	X	
	Self-efficacy regarding lifestyle change (VAS scale)	X	
Health-care utilization	Health care utilization		X
	Anti-psoriasis medication		X
	Self-care and consumption of over-the-counter products		X

4.7.3 Questionnaires

Questionnaire packages were used at all four time points (see Fig. 11). Most of the questionnaire packages were identical at T1, T3 and T4, but the package at T2 (after CHT) was more limited because of the possibility of biased results caused by CHT and being away from home. For example, DLQI and 15D were not assessed at T2.

SAPASI

SAPASI is a structured instrument that allows subjects to assess accurately the severity of their psoriasis. The questionnaire is self-assessed using the same criteria as the PASI, but it is presented with non-professional terminology (323). SAPASI scores range from 0 to 72, and studies have shown that SAPASI can detect changes in disease severity during clinical trials (324). SAPASI scores are also correlated with PASI scores according to several studies (75;325;326). Cronbach's alpha for SAPASI was 0.69 in the present study.

HeiQ

HeiQ provides a broad evaluation of proximal outcomes for patient education and self-management interventions among patients with chronic conditions (327;328). The

questionnaire comprises 40 items across eight independent scales, which cover areas such as behaviours, skills, attitudes, self-monitoring, health service navigation and emotional well-being. The domains are: positive and active engagement in life, emotional well-being, self-monitoring and insight, constructive attitudes and approaches, skill and technique acquisition, social integration, and support and health service navigation (327;329). Each of the eight scales has 4–7 items, which are rated on a four-point Likert scale (1 = strongly disagree to 4 = strongly agree). The items in each scale are summed, and the sum is divided by the actual number of items in each scale; thus, the scale scores range between 1 and 4. A higher score indicates better self-management related to the specific scale, and a lower score indicates inferior self-management, except for the emotional distress scale, which is reversed. Results of psychometric studies using the HeiQ show that adequate results can be obtained in diverse settings (327;328;330). In the present study, Cronbach's alpha for the HeiQ domains ranged from 0.65 to 0.89.

Self-efficacy was measured by a VAS using ratings of 0–10 based on perceived self-efficacy related to possibly desirable behaviour change, where 0 = "Absolutely certain that I will NOT manage to do it" and 10 = "Absolutely certain that I will manage to do it" with respect to the possibility of the desirable change.

The Self-administered Co-morbidity Questionnaire (SCQ-18) evaluates disease presence and severity by asking whether the disease is being treated and whether it limits activities (Yes = 1, No = 0). The Norwegian version has 18 predefined and two optional conditions (e.g., diabetes, headache and depression, rheumatoid arthritis, cancer and heart disease). The total score ranges from 0–54, where higher scores indicate a more severe co-morbidity profile. Previous research suggests that the SCQ is a valid and reliable measure (331), and it has been used in previous studies for patients with psoriasis (332).

The PKQ assesses psoriasis knowledge using 49 statements about psoriasis, where the response to each statement is reported as valid, uncertain or invalid. Based on the number of valid answers, a total score is calculated with a possible range from 0–49. Higher scores indicate higher levels of knowledge (23). The PKQ has been used previously in the context of CHT (23).

The BIPQ comprises eight items where each assesses one dimension of illness perception. The instrument uses an ordinal scale (0–10) to measure a patient's cognitive perception of

their illness. Eight areas are examined: consequences (item 1), timeline (item 2), personal control (item 3), treatment control (item 4), descriptions of the condition and symptoms (item 5), coherence (item 7) and concern and emotions (items 6 and 8). Items 3, 4 and 7 are reversed items (333;334). Item 9 is a causal item where patients are asked to list the three main factors that cause their disease. The overall summed score for BIPQ was computed as described on the BIPQ website http://www.uib.no/ipq/index.html. This was mainly because of the scope of paper two, where this outcome was only secondary, thereby making it impossible to present a more comprehensive analysis of the results. The maximum score is 80 on the BIPQ, where higher scores reflect a more negative perception of psoriasis. In this study, all eight dimensions of the BIPQ had relatively high internal consistency, and Cronbach's alpha was 0.70.

The Health State Descriptive System (15D) is a comprehensive standardized self-administrated measure, which can be used as both a profile and a single-index score measure. It has 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress vitality and sexual activity. The valuation system employed by the questionnaire is based on the application of multi-attribute utility theory. The single index (15D score) on a 0–1 scale that represents the overall HRQoL is calculated from the health state descriptive system using a set of population-based preference or utility weights (288;335) (0 = being dead, 0.0162 = being unconscious or comatose, 1 = no problem on any dimension = full HRQoL). The weight for each item is obtained by multiplying the level value by the importance weight of the dimension at that level. Recently, a difference of 0.015 was stated to be the minimum important change in 15D scores (287). This questionnaire is well validated and easy to use (288;335). The Cronbach's alpha was 0.81 for this study.

The DLQI contains 10 questions concerning symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment (336), and it is the most frequently used QoL instrument in RCTs related to dermatology (336). Each question is scored on a four-point Likert scale: not at all/not relevant = 0, a little = 1, a lot = 2 and very much = 3. The scores for individual items (0–3) are added to yield a total score (0–30), where higher scores indicate greater impairment of a patient's QoL. The reliability and validity of the DLQI is well established (336;337). In this study, Cronbach's alpha was 0.90.

General health status was estimated using a VAS scale of 0–100, which ranged from "worst imaginable health state" to "best imaginable health state". We also measured self-assessed health status on a Likert scale of 1 to 5 = poor to excellent.

Lifestyle change assessments included study-adapted readiness to change questions related to skin treatment and desirable lifestyle change. These questions had response alternatives according to the different stages in the TTM (221). Thus, for the question: "Are you prepared to give priority to spend the time that it takes to treat your psoriasis symptoms?", the response option: "No, and I have no plans to do so within the next 6 months" reflected the pre-contemplation phase, and the option: "Currently, I do not treat my psoriasis symptoms, but I have specific plans to begin within the next month" reflected the preparation stage. Views on lifestyle change due to psoriasis were also assessed by five questions, such as: "I am aware of the importance of lifestyle change when one has psoriasis, but I cannot do it now" or "I've set up a plan for how I will change my lifestyle". Patients were requested to answer how much they agreed with each of these items on a five-point Likert scale, where 1 = strongly agree and 5 = strongly disagree.

Health care utilization, productivity loss and costs of psoriasis treatment were assessed according to three different cost groups. The first cost group covered the costs for primary and secondary health care services. This health care utilization assessment required patients to recall the use of hospital services (i.e., out and inpatient consultations, and UVB treatment), specialist medical care (GP, dermatologist, rheumatologist and internal medicine experts), allied health care (e.g., physiotherapist, manual therapist, chiropractor and psychologist) and the use of alternative medicine care (e.g., healer, acupuncture and homeopath). We assessed the costs according to the charge per treatment or diagnosis-related group (DRG) codes for 2012. This international coding system aims to measure hospital productivity and resource consumption (338). The cost was estimated by multiplying the cost weight for the specific DRG group by the cost of one DRG in 2012 (€ 5112). We also added the estimated travel costs to consultations with specialists and psychologist, and for hospital visits. Appointments at GP offices and with physiotherapists, chiropractors, etc. were estimated without travel costs because these services are often provided close to the patient's home. Travel costs to UVB treatment varied depending on the patient's home location, and thus we used the travel expenses reported in the questionnaires. The unit costs of the resources used are presented in Table 1 in paper 3.

The second cost group included pharmaceuticals, use of prescribed psoriasis medication, over-the-counter (OTC) products and other self-care products related to skin care. These assessments also included systematic treatment prescriptions for psoriasis, as well as the volumes applied of topical treatments and OTC moisturizing creams and emollients. To estimate the cost, we calculated all of the concomitant medications registered by start and stop dates, where we used the prices from a local pharmacy and The Norwegian Pharmaceutical Product Compendium. For the moisturizers bought on Gran Canaria, we used the price at the local pharmacy in Patalavaca, where most of the patients purchased these products (all based on the prices in 2012). We also used the DRG codes for biologic medicines from 2012.

The final cost group covered the cost of productivity losses for employed patients. To estimate these costs, each patient was asked about his/her work status according to four categories: (i) fully employed (100%), (ii) working part-time, (iii) full-time housework or (iv) not working. Patients in the latter category were asked to state whether this status was caused by: (a) unemployment, (b) disability pension or rehabilitation benefits, (c) sick leave, (d) retirement due to age or contractual early retirement pension or (e) others (including students and military service). Changes in work status over time were recorded in the follow-up questionnaires at 3 and 6 months. The cost of sick leave (for those who were employed) was estimated as the number of days that each patient spent out of work because of psoriasis. This cost was estimated as equal to the average income, inclusive of social costs, where we used the median income in Norway during 2012 (446,200 Norwegian krone = € 59,732 per year) (Statistics Norway 2012, http://www.ssb.no/ inntekt). The human capital approach was used to estimate the costs (281), which is one of the most frequently used methods for estimating indirect costs due to the loss of working time, where it is assumed that the time that one person is absent from work is lost, thereby constituting a cost for society. For the patients who were able to work part-time, this productivity cost was reduced in proportion to the time worked. The appendix provides an example from the questionnaires regarding assessment of health-care utilization and topical psoriasis treatment.

4.8 Analyses

In this chapter, we describe the analytic processes employed in the three studies. We briefly present the analysis employed in paper 1, followed by those in papers 2 and 3.

4.8.1 Literature analysis (paper 1)

In the systematic literature review (paper 1), two researchers (MHL and AKW) independently assessed the list of titles and abstracts for full text review and thereby determined their eligibility. Full text articles were obtained for all potentially relevant studies, and complete articles were also retrieved if there was any doubt regarding the fulfilment of criteria. All of the full text articles were again assessed independently and evaluated to determine their relevance by the same two reviewers. Any disagreements were resolved by discussions. Next, one reviewer (MHL) extracted the data from the included studies, and another reviewer (AKW) ensured that all of the relevant information included was accurate. The methodological quality of each study and the risk of systematic bias (ROB) were assessed independently by the same two authors according to the approach described in the Cochrane Handbook for Systematic Reviews of Interventions (339). The ROB assessment included evaluations of the procedures used for generating random sequences, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other potential sources of bias. Every entry was rated as either "low risk of bias", "high risk of bias" or "unclear risk of bias". The conclusions were checked by a third assessor, and the ROB scores for each study were then updated. Full agreement on all criteria was reached in a consensus meeting attended by all of the authors. We used Review Manager 5.1 to calculate the weighted mean difference and 95% CI for each comparison.

4.8.2 Statistical analysis (papers 2 and 3)

Statistical analyses were performed using SPSS (Statistical Package for Social Sciences, program version 21), STATA and Microsoft Excel 2010.

In all analyses, we compared two groups and all of the results represent between-group differences. Continuous data were expressed as the mean (SD) and 95% CIs, or median and min-max values. For normally distributed data, we determined the mean differences, and we performed paired samples t-tests and independent samples t-tests. For categorical data, we

used Pearson's chi-squared test and Fisher's exact test if the expected frequency was below five in more than 25% of the cells. To analyse continuous data, we used the independent samples t-test for observations with normal distributions, and the results were presented for "equal variances not assumed" if the significance value according to Levene's test for equality of variances was less than or equal to 0.05. The Mann–Whitney U-test was performed if the continuous observations did not follow a normal distribution. When the median or median differences were obtained, Wilcoxon's signed rank test or the Mann–Whitney U-test was used for between-group analyses. The number of patients and the percentage of the total number were used as categorical data.

Furthermore, in the statistical analyses of differences between two groups, we used ANCOVA (SPSS general linear models (GLM), UNIANOVA), which is a form of regression analysis, and we adjusted for the baseline or T2 (after CHT/before randomization) scores. In the analyses, the differences between the groups from baseline to T2 (after CHT, before randomization), and from T2 to T3 (3 months) and T4 (6 months) according to PASI, HeiQ and secondary outcomes were used as the dependent variable, while the grouping variable was a fixed factor, and the score at baseline or T2 was the covariate. By controlling for the baseline/T2 scores in this RCT, we adjusted for any heterogeneity that might have occurred by chance during the randomization procedure. GLM was conducted for each outcome. However, some clinical and socio-demographic variables might have confounded the effect of the MI intervention in the intervention and control groups, so gender, age, HRQoL, education level, duration of disease as and health status were treated as covariates in the ANCOVA analysis one at a time to adjust for the effects of these variables.

In paper 2, responses to "daily skin treatment" and "plans for lifestyle change" were dichotomized from the five phases of readiness and changed into "risk behaviour " (pre-contemplation, contemplation and preparation) or "no risk behaviour" (action and maintenance). We also dichotomized the answers to views on lifestyle change as a result of psoriasis disease; e.g., for the statement: "I already changed my lifestyle after I got psoriasis", YES = strongly agree and agree, and NO = indefinite, disagree and strongly disagree.

In paper 2, we also calculated the effect sizes (Cohen's d) for between-group differences in order to achieve a standardized measure of the amount of change. Cohen defined d as the difference between the means (M1 − M2) divided by the SD of either group (when the

variance of the two groups is homogeneous) (320). Effect sizes are generally defined as small (d = 0.2), medium (d = 0.5) and large (d = 0.8).

Cronbach's alpha was used to determine the internal consistency or reliability of the multi-item scales in terms of both the total score and the subscales. Cronbach's alpha measures how closely a set of items "hang together"; i.e., the degree to which items that comprise a scale measure the same underlying construct. Cronbach's alpha values ≥ 0.7 are considered to indicate good internal validity, and ≥ 0.9 is excellent (340).

In paper 3, the resource utilization and cost data were highly skewed, so we present the total consumption volumes with both the median (with min-max) and means (SD) (Appendix 4, paper 3). The 95% CI around the mean cost per patient and the between-group differences in mean total costs were estimated. We calculated QALYs by plotting utilities against time using the AUC. This represents a time-integrated summary score of the change from baseline, which was calculated by the trapezium rule standardized using the study duration (341). We also controlled for imbalance in baseline utility when estimating the mean differential QALYs by regression analysis, as recommended by Manca et al.(342) because a patient's baseline utility is likely to be strongly correlated with his/her QALYs in the follow-up period. Thus, the baseline utility values are likely to be predictive of the follow-up utility. We employed an approach based on the AUC using the baseline utility measure, which may create misleading results if this unbalance is not handled explicitly. According to Manca et al. (342), the ICER can be very sensitive to quite small changes in its denominator. The control group had a significantly better 15D score at baseline, so it was particularly important to ensure that the correct conclusions were obtained from the analysis.

Using the patient level estimates of costs and effects, it is possible to determine the joint density of costs and effects by resampling (the non-parametric bootstrap). In bootstrapping, the statistical precision is estimated by repetitively generating hypothetical substudies via resampling, which involves the random selection of data from the original data set with replacement, thereby allowing each original patient to be sampled more than once. In our study, we used bootstrapping with 1000 replicates with Excel and STATA 13 (StataCorp, College Station, TX, USA). A scatter plot of 1000 bootstrapped ICERs was created by repeatedly drawing a random sample with replacement using parameters estimated from the study. Individual values were used for the QALY gained, and the mean values were used as

the costs related to the intervention (MI or TAU) incurred by the participants. In this manner, we calculated the likelihood that the intervention was cost-effective using several thresholds of willingness to pay for a QALY. CEAC, which represents the probability that either MI or TAU is cost-effective, was also calculated using Excel.

4.9 Ethical issues

The present RCT study was recommended by the Regional Committee for Medical Research Ethics for Southern Norway 29.6.2011 (ID: 2011/1019) and registered on: http://www.clinical trials.gov (ID: NCT01352780). This study was also approved by the research manager, the administrative leader of the related OUS clinic and the Centre for Privacy and Information Security, all at OUS. We also got a project amendment by the Regional Committee for Medical Research Ethics for Southern Norway regarding the external assessment of the MI talks at the MIC lab. A valid data processing agreement between OUS and the MIC lab was created and authorized by the Regional Committee for Medical Ethics before the audio files were transmitted. The project was performed in accordance with the principles of the Declaration of Helsinki (343). The three core principles of the Belmont Report, which aims to protect participants, were also followed: respect for persons, beneficence and justice (344).

Respect for persons assumes that individuals should be treated as autonomous agents. Patients who attended the CHT received verbal and written information about the study after their arrival on Gran Canaria, which stated the purpose, nature, risks and benefits of the study. They were briefly informed about the study in the first information meeting with the CHT head nurse. Before their medical examination, they were approached by one of the two CHT study nurses, who gave them more information about the study, the questionnaires and the possibility of being randomized to receive motivational telephone calls. They were also told that participation was voluntary, that their data would be treated confidentially and that the findings could not be traced back to specific individuals. Furthermore, they were informed that they could withdraw from the study at any time without reasons or negative consequences for their future CHT treatment.

Patients may feel uncomfortable declining if the researcher is present, so all of the inclusion procedures were executed solely by the CHT nurses. However, patients may also feel obliged to participate in a study when recruited by a familiar clinical nurse, which may have been the

case for recurrently participating CHT patients, but it may also be easier to decline to a familiar nurse from previous stays. Both study nurses were instructed to give oral and written factual information about the study but not to attempt to influence the patient's decision because of his/her personal preferences or motivation. All of the participants gave their written informed consent to participate in the study. Patients also consented to the potential recording of the MI talks. They retained a copy of the consent form, which included the phone number of PhD students in case they had any additional questions and concerns. There were no costs to the patients, and they were not paid for their participation.

Beneficence, as described in the Belmont Report (344), obligates the investigator to follow two general rules. The first is to "do no harm", and the second is to "maximize possible benefits and minimize possible harms". There were no anticipated physical risks for any of the data collection procedures. Participants gave their written consent to registration of data from their medical journal at OUS. The values registered from this journal were generated during routine clinical consultations with a dermatologist and nurse at CHT, and they did not involve any extra measurements. The possible psychological risks were restricted to the extent to which the study focused the attention of patients on their potentially serious health condition(s). To the best of our knowledge, there have been no previous reports of negative harm when using MI (52;345). Indeed, the major role of MI in supporting the value of patient autonomy without losing the value of beneficence has been suggested (346). The patients were also informed about the expected time frame for completing the questionnaires (i.e., 15–20 minutes) and that the duration of the mapping talk was 45 minutes. Patients whom the CHT nurses assumed might suffer emotionally (i.e., those with evident psychiatric diagnoses or cognitive impairment) were excluded from study participation.

An investigator's ethical obligation to treat subjects justly is achieved primarily during the subject selection process and when defining a protocol's inclusion and exclusion criteria. However, this initial concept of justice has evolved to include the concept of fair access (344). Fair access requires that individuals (a class of patients who receive an innovative therapy or procedure) should have an equal opportunity to receive the possible benefits of these. The present study aimed to recruit all of the consecutive patients who participated in CHT and who satisfied the inclusion criteria. However, because of unforeseen events and limited staff capacity, some patients might not have been asked about participation, although we added a study nurse on the examination days. It might also be viewed as a violation of justice that

study participation was excluded for patients who had attended the CHT more than eight times within the last 10 years. This based on a clinical judgment by the staff and the research group that the most "experienced" patients were less motivated towards behavioural change, but this should possibly have been the individual patient's decision.

The principle of confidentiality was adhered to throughout the study. To safeguard confidentiality, patients were assigned a sequential record number at the time of enrolment. This number replaced personal identification in all datasets, and no names appeared on any of the data collection forms. All personal identification was separated from the dataset, except for the coding list with identification numbers. The handwritten list describing the personal identification codes has been kept separate from the questionnaires in a private locked filing cabinet at OUS, and it will be destroyed at the end of the study.

5 MAIN RESULTS

5.1 Limited evidence of the effects of patient education and self-management interventions in psoriasis patients: A systematic review (paper 1)

The objective of this study was to describe the contents and to investigate the effects of patient education and self-management programmes in patients with psoriasis. The systematic literature search and review identified 10 papers from nine studies; i.e., five RCTs (three pilot studies) and four controlled clinical studies. The number of study participants ranged from 42 to 402, and the median age was 47.9 years.

Three studies focused exclusively on education about various aspects of psoriasis, where two were group based and the third was individualized. The contents were described as empowerment-based education, a psycho-educational programme and an evaluation of a "decision board" that aimed to facilitate the provision of information regarding treatment. Six studies focused on education and practical self-management. Two interventions were individualized, whereas four were group based with meetings 1–2 times per week (total of 15–48 hours). All studies varied in terms of their focus, content and intensity. The main measures of efficacy were related to disease severity, knowledge and QoL, as well as different aspects of the psychological impact of psoriasis. Many of the outcome instruments were developed by the authors themselves, and assessments of validity were rarely described.

We assessed ROB using the six-item quality appraisal list recommended by the Cochrane Handbook (339). Each entry was assessed as either "low risk of bias", "high risk of bias" or "unclear risk of bias". Overall, the methodological assessment scores were poor. The three teaching interventions were generally considered to have very low methodological quality. Two of the studies that focused on both teaching and self-management used the patient's preferences to determine the group distribution during random sequence allocation, thereby resulting in a high risk of bias for the two items in terms of randomization. Only four of the studies had low ROB scores for the quality criterion "random sequence allocation", and thus they were considered to be suitable for effect analyses. A meta-analysis of the two studies that compared patient education and self-management education with standard follow-up detected no significant differences in DLQI.

In conclusion, there was a significant absence of self-management focus in these interventions and compared with other chronic diseases there seem to be few effective disease-specific and customized educational programmes. In addition, this review showed that has been a significant lack of focus on lifestyle choices and behavioural changes such as exercise, diet or smoking habits.

5.2 A telephone-based motivational interviewing intervention has positive effects on psoriasis severity and self-management - A randomized controlled trial (paper 2)

The baseline sample included 169 patients. The main personal and disease characteristics of the subjects included in this study are presented in Table 3. The majority of the participants were middle-aged (46 years), and 44% were female. Most were working and cohabiting, and 42% had more than 13 years of education. At arrival, they had a mean PASI score of 8.1, which decreased to 2.1 after 3 weeks of CHT. Among those who were not working, 43% reported work disability as the main reason. At arrival, 33% were smokers, and they had a mean BMI of 28.8. No statistical differences were found in the baseline demographics and clinical characteristics between the follow-up study sample (T3) and drop-outs at 3 months (N = 34), except that the drop-outs were more often men, younger and living alone (Table 3).

The objective was to evaluate the effects of individualized motivational follow-up calls to support patients with psoriasis self-management and desired lifestyle change following CHT based on outcomes that comprised disease severity (SAPASI), self-management (HeiQ), knowledge (PKQ) and changes in lifestyle (paper 2).

Table 3. Demographics and clinical characteristics of the baseline sample, the follow-up sample and drop-outs.

Variables	Baseline sample (N = 169 Mean (SD) N (%),)	Completers (N = 135) Mean(SD) N (%)	Drop-outs (N = 34) Mean (SD) N (%)	Between-group difference (95% confidence interval), p-value (a, b)
SAPASI 1 (arrival)	8.59 (5.06)	8.24 (4.72)	10.03 (6.16)	−1.79(−4.11, 0.14),p = 0.13 (a)
SAPASI 2 (departure)	1.84 (2.85)	1.61(2.50)	2.74 (3.84)	−1.1 (−2.5, 0.27), p = 0.11(a)
Duration of disease years	22.9 (13.93)	24.1 (13.51)	21.7 (12.0)	2.39 (−2.62, 7.41), p = 0.35 (a)
Age (in 2012)	46.3 (12.8)	48.0 (11.9)	39.7 (14.5)	8.34 (3.63, 13.04), **p = 0.001** (a)
DLQI at CHT arrival	11.2 (5.89)	11.43 (5.94)	10.09 (5.64)	1.34 (−0.93, 3.61), p = 0.24 (a)
BMI at arrival	28.78 (5.51)	28.63 (4.61)	29.39 (7.18)	−0.76 (−3.37, 1.86), p = 0.56 (a)
Male % (N)	95 (56·2%)	69 (51.2%)	26 (76.5%)	χ^2 = 6.1, **p = 0.013** (b)
Current smoker: Yes	56 (33.3%)	47 (34.8%)	9 (27.3%)	χ^2 = 0.38, p = 0.54 (b)
Self-assessed health (1–5: poor–excellent)	3.10 (0.92)	3.08 (0.87)	3.21 (1.08)	−1.70 (−8.34, 4.93), p = 0.61 (a)
Married/cohabiting	106 (64.2%)	93 (71%)	13 (38.2%)	χ^2 = 28.3, **p < 0.001** (b)
Level of education	N = 161			
Primary/secondary school 7–10 years	22 (13.7%)	17 (13.3%)	5 (15.2%)	χ^2 = 0.94, p = 0.93 (b)
High school ≤ 13 years	74 (46%)	58 (45.3%)	16 (48.5%)	
College /university < 4 years	30 (18.6%)	25 (19.5%)	5 (15.2%)	
College/university ≥4 years	35 (21.7%)	28 (21.9%)	7 (21.2%)	

PASI: Psoriasis Severity and Area Index, CHT: Climate/heliotherapy, DLQI: Dermatological Life Quality Index, BMI: Body Mass Index. The values are means (± SD) unless indicated otherwise. SD: standard deviation. Difference between groups: (a) independent samples *t*-tests of means, (b) Pearson's Chi-squared (χ^2) tests of proportions. N differs among individual analyses because of missing values. Drop-outs: Did not answer the questionnaire at 3 months.

The main finding was that compared with the control group, patients with psoriasis who received the MI intervention following CHT had significantly reduced disease severity measured by the SAPASI score after 3 and 6 months. The differential change between groups was −2.47 (95% CI: −3.94 to −1.00, p < 0.001) at 3 months, and −2.45 (95% CI: −4.33 to −0.56, p = 0.011) at 6 months (Fig. 14).

Two of the eight domains comprising the HeiQ scores had significantly better results after 3 months: "skill and technique acquisition" = 0.17 (95% CI: 0.019, to 0.32, p = 0.028) and "constructive attitudes and approaches" = 0.15 (95% CI: 0.004 to 0.29, p = 0.044). After 6 months, the domain "self-monitoring and insight" had a significantly higher score in the study group: 0.12 (95% CI: 0.019 to 0.22, p = 0.020).

In terms of the secondary outcomes, there was no significant difference between groups for psoriasis knowledge measured by the PKQ after 3 months. However, the study group had higher scores after 6 months: 1.70 (95% CI: 0.31 to 3.09, p = 0.017). We detected significant treatment effects with respect to illness perception after 3 months because the BIPQ score was significantly lower at 3 months in the

study group: −3.75 (95% CI: −6.73 to −0.77, p = 0.014), although this between-group difference was not significant at 6 months: −1.89 (95% CI: −5.18 to 1.40, p = 0.26).
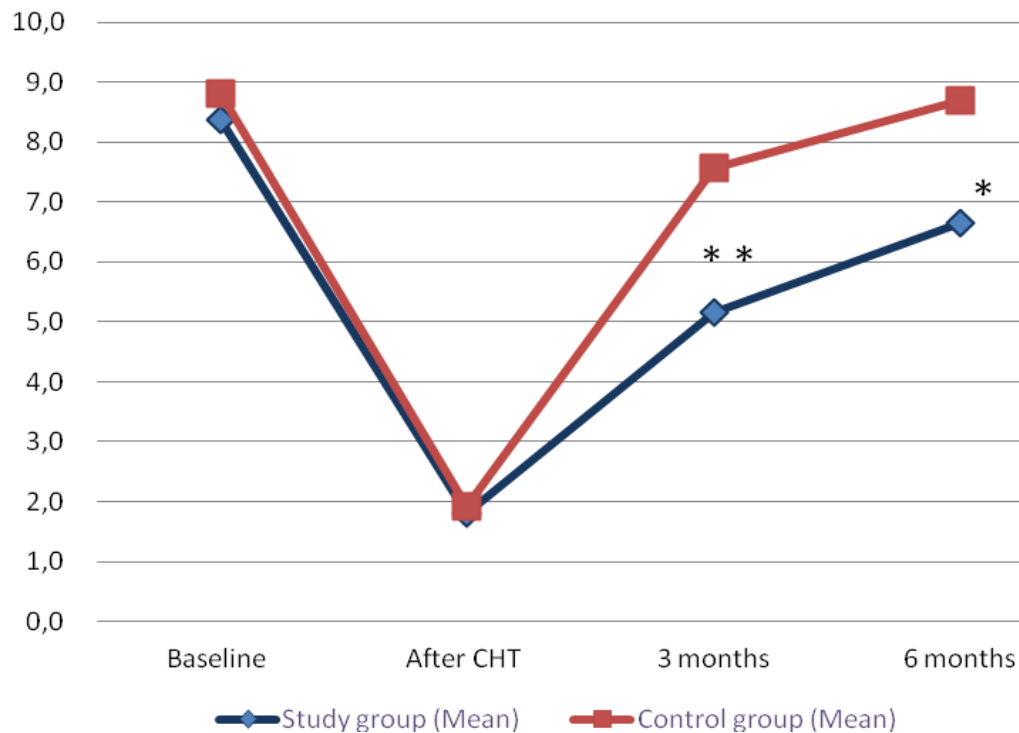
Fig. 14. Group differences in mean SAPASI scores throughout the trial.

The self-efficacy scores measured on a VAS scale related to desired lifestyle change showed that the study group had significantly higher scores at 3 months after CHT compared with the control group (i.e., 0.91, 95% CI: 0.33 to1.50, p = 0.002), as well as at 6 months (0.71, 95% CI: 0.096 to1.33, p = 0.024). For planned lifestyle change, the study group exhibited a more positive response after 3 months (p = 0.001), but this was not significant at 6 months (p = 0.059). Significantly more members of the study group agreed that they had already implemented lifestyle change following their psoriasis diagnosis at 6 months after CHT (p = 0.035). According to the previously described TTM regarding skin care, significantly more members of the study group changed their position from "risk" (pre-contemplation, contemplation and preparation stages) to "no risk" (action and maintenance stages) during the intervention (p = 0.045). This difference was maintained at 6 months after CHT (p = 0.048). Significantly more participants in the study group also remained in the "no risk" stage during the intervention regarding planned lifestyle change (p = 0.06), whereas a significantly higher percentage of the controls remained in the "risk" group (p = 0.04).

In summary, the MI intervention led to positive changes in multiple outcomes, and it appears to be a promising method for providing SMS to patients with psoriasis.

5.3 Cost–utility analysis of supported self-management with motivational interviewing for patients with psoriasis (paper 3)

The aim of this study was to assess the health economic benefits of the MI intervention using CUA. The HRQoL measures both indicated some positive effects after the MI intervention. The DLQI scores at 3 months were significantly better in the study group −2.81, (95% CI: −4.76 to −0.85), p = 0.005. However, this difference was not significant after 6 months −1.39, (95% CI: −3.59 to 0.81), p = 0.21. The incremental effect after adjusting for baseline (342) showed no significant differences in QALYs for the DLQI after 6 months between the groups, -0.62 QALYs (95% CI,0.41 to -1.65), p= 0.24.

The summed score for the generic instrument 15D increased from 0.86 to 0.88 at 3 months in the study group and to 0.87 at 6 months, whereas the control group had a higher summed score at baseline (0.90), and this remained unchanged throughout the study period. Thus, the results showed that only the study group reported improvements in their health condition according to 15D at 3 months. After adjusting the QALYs for the baseline 15D scores, the mean incremental effect for the six-month –long study period showed no significant differences, between groups, 0.0022, (95% CI: = −0.02 to 0.01), p = 0.77.

We assessed costs using three different cost groups and found no significant differences among these groups at baseline. One cost group reflected the costs of primary and secondary health care services, where the analysis detected only small differences in the total cost at all three of the data collection points. However, there were significant decreases in the mean costs of primary and secondary health care services in both groups at 3 and 6 months after CHT treatment compared with the 3 months before CHT. The study group consulted the dermatologist significantly less frequently than the controls during the 6 months after CHT, indicating less costs: €−105 (95% CI: −189 to −20), p = 0.016. The same trend was found with UVB treatment, but the difference was not significant €−104, (95% CI: −216 to 8), p = 0.068.

The second cost group included pharmaceuticals, prescribed psoriasis medications, and OTC and self-care products. There were only small differences between the groups during the 6 months after CHT. However, the control group had significantly higher costs for systemic and biologic treatments (€−799,

95% CI: −1499 to −101, p = 0.025). Both groups used more body lotion and emollients during the 3 months after CHT compared with the period before CHT.

The final cost group comprised the costs for productivity losses in employed patients. In terms of productivity losses due to sick leave, the study group had €1048 less productivity losses during the 6 months after CHT, but the difference was not significant compared with the control group (p = 0.46). Productivity losses accounted for 70.4% of the total costs in the 6 months following CHT. In the 3 months prior to the CHT, 77% of the patients stated that they had productivity losses of € 0. In the following two 3-month periods, 60% reported no productivity losses, and there were no significant differences between the groups.

The cost of delivering the MI intervention comprised the working hours required by the counsellor to prepare and write summaries of calls, a minimum of 3 days at a course to master the MI techniques and the cost of mapping talks for 60 min for each patient, with a total cost of €101. In addition, the wage costs were €142 for the time spent making counselling calls (paper 3). We based our estimate on the minimum wage on 6 June, 2012 according to the Norwegian Nurses' Association for a registered nurse with 10 years of experience. The estimated mean cost per participant for the delivery of the MI intervention was €243.

After calculating the cost for all three cost groups and the MI intervention, a mean cost difference of €1780 in favour of the MI intervention appeared. When productivity losses were not included in the calculation, the between group difference post-CHT was €−1103 (95% CI: −2293 to 87, p = 0.058).

The ICER for the MI group tended to be more dominant when using DLQI as an outcome measure because the ICER was negative (= both more effective and cheaper). A figure in paper 3 shows the incremental cost and QALYs (15D) for MI compared with TAU based on the bootstrapped costs and effects using the QALYs obtained from 15D. The points are mainly below the *x*-axis and fairly evenly distributed on either side of the *y*-axis; i.e., the cost of the intervention was lower, but the results provided limited evidence of improved HRQoL.

There were no statistically significant differences in costs and effects between MI and TAU, which was confirmed by the 15D cost-effectiveness plane for this comparison. The CEAC showed that at a ceiling ratio of zero, there was still a 95% probability that MI was cost-effective. The CEAC indicated that the intervention was likely to be more cost-effective only with a lower willingness to pay for improvements in 15D (see paper 3, Appendix). For example, when we set a cost ceiling of €55.000, the intervention had an 88% probability of being cost-effective.

In conclusion, compared with TAU, MI by phone was shown to provide at least equivalent QoL and utility at lower costs. The discrepancy in the economic evaluation based on QALYs (obtained using 15D and DLQI) and the ICER suggests that further research is required to determine the validity of using 15D in psoriasis cost–utility studies. Overall, the costs were lower for the MI intervention compared with TAU, which suggests that it is the preferred treatment option from a societal perspective.

6 DISCUSSION

The discussion in this chapter is organized according to three main issues. First, the main results are discussed in the light of relevant research findings and the specific aims of the thesis to complement the discussions in papers 1–3. Second, the methodological aspects are discussed based on the selection of study samples, the study design and data analysis. Third, the possible implications of the results are also discussed.

6.1 Discussion of the main findings

6.1.1 Effects of educational and self-management interventions in psoriasis

There has been little previous research in this area regarding psoriasis, and the systematic review provided limited evidence for the effects of patient education and self-management interventions in patients with psoriasis. However, this was mainly because of the low methodological quality of many of the studies reviewed. In addition, there was a noticeable lack of disease-customized programmes, the virtual absence of self-management focus in the interventions, and a dearth of lifestyle or positive health behaviour initiatives. However, the most recent studies have exhibited more positive methodological trends with a more obvious self-management rationale (250;251). Psoriasis is now classified as an immune-mediated inflammatory disease of the skin (347), and the potential for systemic co-morbidity (79) may have induced this new self-management focus because it has become clear that these patients require comprehensive health care in a similar manner to other chronic diseases such as diabetes, arthritis and COPD (10;11), and that self-management may be a crucial element (198). However, few new studies have focused on patient education and self-management within psoriasis care in the period since we concluded our literature search. Indeed, only one new RCT within the scope of the review has been published, where patients were provided with daily text messages, including treatment reminders and educational tools for 12 weeks (253). This study reported positive effects on disease severity (SAPASI, PASI), QoL (DLQI) and treatment adherence. Several qualitative studies of self-management have also been published during this period. These studies focused mainly on health care professionals within dermatology to address the lack of knowledge and skills required to implement self-management objectives such as behavioural change, lifestyle counselling and shared decision-making in practice (25;26;45;131). These barriers are also important to address if SMS is to be implemented in routine health care for psoriasis management.

Although there were some variations, the patients in the studies addressed by the systematic review were surprisingly similar. In general, they were aged above 40, had mild to medium disease severity and a long history of living with psoriasis. These interventions did not consider the disease onset time or life phases, which may require different educational or self-management interventions. These findings are supported by a previous integrative review that aimed to identify and describe the needs of patients in terms of education to support self-management of psoriasis in daily life (11). This review concluded that when evaluating the general needs for patient education, health care professionals must consider the various life phases when psoriasis emerges. In our RCT study, the population was also similar, where the patients had a long mean disease duration of nearly 23 years and a mean age of 46.3 years. This suggests that an important question for future research is to determine whether the provision of SMS and education during the early phase of the disease may have a preventative effect.

To the best of our knowledge, the RCT described in this thesis is the first study to evaluate the effects of telephone-based MI for supporting patients with psoriasis in self-management and desirable lifestyle changes. The main finding was a significant improvement in the primary outcome disease severity measured by SAPASI in the study group at both 3 and 6 months. This positive difference is promising because the intervention only comprised verbal support. It is not clear whether this difference was caused by increased adherence to skin treatment, increased self-efficacy and problem solving regarding treatment choices and goals, or whether the psychological impact of discussing symptoms and treatment choices was the crucial component. Furthermore, it is not known whether the attention of the interventionist alone contributed mostly to these results, or whether the effect was due to the MI methods employed. The lack of a sham control group is discussed further in section 6.2.1. However, our findings are similar to those reported in the previously described new RCT that provided educational text messages (253), thereby indicating that an increased focus on symptoms and treatment may have a positive influence on outcomes such as SAPASI, PASI, QoL and adherence. Some results from the systematic review also indicate that educational and self-management interventions have the potential to reduce disease severity in patients with psoriasis, as described by Bostoen et al. (250) and Ersser (251).

Studies have shown that the application of MI in other chronic conditions was effective in reducing health-related clinical parameters such as blood pressure, the glycosylated haemoglobin test (HbA1c), BMI, BP and cholesterol (56;231;348;349). Inflammation is recognized as the main driver of the disease process in psoriasis, and it increases the risk of co-morbidities such as CVD (350). Thus, it is important to achieve symptom control and to maintain the reduced level of disease severity obtained during CHT for as long as possible. The inflammation process and the elevated immune responses may

be decreased as a consequence, thereby reducing the impact of a negative co-morbidity profile (97). Several studies have indicated that there is a dose–response effect where people with severe psoriasis have a higher risk of myocardial infarction than people with mild psoriasis (7;9;89), which also highlights the importance of controlling systemic inflammation. In addition, a milder burden of disease may be beneficial in reducing the psychological impact of psoriasis (25) in terms of social stigma and QoL (118;351), which may then positively influence self-management and reduce the potentially negative impact of CLCI (124).

Other self-management issues incorporated in MI are a focus on problem solving, increasing self-efficacy and lifestyle changes (52). The HeiQ can be used to evaluate the proximal outcomes of patient education and self-management interventions for people with chronic conditions (327). We found that the HeiQ scores in the study group were significantly higher in two of eight domains at 3 months after CHT; i.e., "skill and technique acquisition" and "constructive attitudes and approaches". At 6 months after CHT, only the "self-monitoring and insight" domain had significantly higher scores. It may be discouraging that none of the other domains was positively influenced by the intervention, but it is not clear whether all of the self-management areas reflected in the HeiQ scales are equally important or relevant for measuring the outcomes of MI interventions. Both of the domains that were positively influenced by the intervention at 3 months include important self-management issues, which agree with the aims of MI. One domain includes improvement in knowledge-based skills and techniques for managing personal health, while the other is based on the attitude that individuals are not going to let health problems control their life, thereby indicating a shift in how the study group participants viewed the impact of their condition on their life. A previous study within the CHT context detected statistically significant improvements in all of the HeiQ scales after 3 weeks of CHT (18). However, only the "emotional distress" scale was still improved significantly 3 months later, which indicates that CHT provides a range of self-management benefits for people with psoriasis, but they are mostly short term. In contrast to our findings, a mobile health intervention that tested a mobile app for type 2 diabetes found no differences between the groups in terms of the HeiQ scores after one year. In that study, one group received usual care, and a second group received a diabetes diary app with multiple functions, which aimed to increase self-management. The third group received the app and monthly health counselling sessions (four) by a diabetes specialist nurse. The importance of a personal relationship between the patient and the health care provider was demonstrated in the latter group, where the patients exhibited a greater increase in self-management domain skills and technique acquisition compared with the groups without personal follow-up (352).

Studies of other chronic conditions have detected HeiQ changes in several or single domains at 3 or 6 months follow-up after self-management interventions, which agree with our findings (353;354). It is important that the self-monitoring domain, which focuses on the level of insight into living with a health problem, differed significantly between groups after 6 months in our study. This domain captures how individuals engage in the self-monitoring of their health problems. It also includes individuals' acknowledgement of realistic illness-related limitations, and their ability and confidence to adhere to these limitations. A particular focus of the MI intervention was to enhance goal-setting skills by planning manageable steps to improve psoriasis self-management, establishing reasonable goals and managing barriers to goal attainment. This approach builds the capacity for problem-solving and has the potential for wider applicability to other health goals (52).

The MI intervention targeted multiple areas of behavioural change in addition to skin care; i.e., diet, physical activity, stress management and sleep. These behaviours were all affected positively after MI interventions in other studies (355-358). By contrast, we found no significant differences between the groups in terms of the different outcomes that targeted these different behaviours (data not shown), although there were significant improvements at 6 months in the study group in terms of their responses to whether they had already changed their lifestyle after psoriasis diagnosis. This inconsistency may be due to the fact that some patients chose one behavioural change topic, whereas others selected several. Many of the patients chose to discuss other behaviour-related topics that they perceived to be more important for them, rather than those suggested on the "bubble sheet" for agenda mapping (Fig. 11). This may also be consistent with the findings of Hettema et al.(272), who showed that the effect of MI may be delayed for behaviours such as diet and exercise as "sleeper effects" (i.e., effects that accumulate and take time to produce measurable change), and thus our follow-up period of 6 months may have been too short. It is possible that targeting only one topic such as physical activity or weight loss would have made it easier to measure the effects of MI, but the autonomy of the intervention could have been compromised. The effect of MI may be larger when a single outcome is targeted, as demonstrated by the results of the systematic review reported by Armstrong et al. (345).

Consequently only the focus on skin care was mutual for all of the study group participants, and this focus seems related to the significant differences between the groups in terms of the SAPASI score. A sustained change in skin care behaviour was supported by the fact that compared with the controls, more study group participants moved from "risk" (pre-contemplation, contemplation and preparation stages) at baseline to "no risk" (action and maintenance stages) in the TTM of change regarding skin care at both 3 and 6 months (as described in paper 2). It is also possible that by targeting multiple aspects, the MI group may have been more confident in the likelihood of overall behaviour change.

However, previous studies differ on this possibility, where some studies advocate that changing multiple behaviours is more challenging, whereas others suggest that changing one behaviour may facilitate change in other behaviours (359;360) because of a ripple effect.

Another MI component that might have a positive effect on self-management is the level of self-efficacy (46;47). Self-efficacy refers to the confidence in one's ability to take action and to persist in that action despite obstacles or challenges (361). Thus, a person's perception of self-efficacy evolves as he/she becomes more experienced and more knowledgeable. This shift in perception also influences the likelihood of a given behaviour's being adopted (47). Self-efficacy was used as main outcome in the majority of the studies included in a systematic review of patient self-management outcomes (242). However, rather surprisingly, self-efficacy assessments were completely lacking in the studies that focused on self-management and education in our systematic review. In our trial, the sustained improvements in self-efficacy scores related to desirable behaviour change in the intervention group at 6 months suggest a lasting benefit of the MI intervention. A high level of self-efficacy is necessary to achieve the goals of self-management, and it is also a crucial factor for switching to healthy lifestyles and maintaining health (47;362). Other studies that used MI have also reported benefits in terms of self-efficacy similar to those found in our study (363;364).

In the present study, the decreased concern about the seriousness of psoriasis according to BIPQ after the MI intervention may have been due to the participants' successfully attempting to change their psoriasis self-management procedures, thereby making them less concerned about the current seriousness of their psoriasis, its possible future complications and its effects on their life. Further research may explore these findings more deeply.

We also found that the study group participants reported significantly better psoriasis knowledge (PKQ) after 6 months, but is not clear whether this difference has any practical meaning because both groups had significantly increased psoriasis knowledge after CHT participation, which agrees with previous research in this context (23). Both groups also had significantly improved knowledge scores compared with those before CHT at 6 months, thereby indicating the persistence of the knowledge acquired during CHT, regardless of the MI intervention. Six months after CHT (T4), the average score of the study group increased by 1.7 points in the 49 questions when we controlled for T2 values, which appears to be a minor difference. However, the study group obtained their best knowledge score at 6 months, whereas the control group had their best score immediately after CHT. A systematic review by Barlow stressed that increased knowledge is an important benefit of self-management approaches for people with chronic conditions (35). According to a study by Renzi (365) that was included in our

review, reported patients who had good knowledge more frequently complete satisfaction with care than did patients who had poor knowledge; hence, awareness about psoriasis and its treatment may be important in learning how to live with chronic symptoms. Thus, increased knowledge may improve self-management and QoL in patients with psoriasis, even if other factors are needed to achieve long-term behavioural change (46;366). Overall, the scores obtained on the knowledge, illness perception and self-efficacy scales indicated that although there was limited HeiQ change, the MI participants still achieved self-management benefits.

In the RCT study, there was also a significant improvement in the QoL score measured by the DLQI in the MI group at 3 months, but this difference was not significant at 6 months. This agrees with the results of an educational and self-management study by Bostoen, which we included in our systematic review (250). Other studies using MI have also reported increased HRQoL as a result of the intervention (261;358;367), while others have found no effect on HRQoL (368;369). The 15D scores also improved significantly in the study group after the intervention, where the values exceeded the minimum important change (287). It is interesting but also confusing that the controls reported better HRQoL scores according to the 15D throughout the study. This is a "mixed message" because in addition to reporting better QoL, they reported more sick-leave, greater disease severity according to SAPASI and more need for a dermatologist in the 6 months after the intervention. Thus, the DLQI scores appear to agree better with the other results obtained by the intervention because the study group still had better DLQI scores at 6 months than the control group at 3 months. The methodological implications of using multiple HRQoL measures are discussed further in chapter 6.2.1, particularly in terms of their internal validity.

The cost differences favoured the intervention, although most were not statistically significant. Both groups reported similar costs for different contacts with health care professionals during the 6 months after the CHT, except dermatologist visits and alternative treatment, where the costs were significantly higher in the control group in both cases. The same trend was seen in UVB treatment, but the difference was not significant. Interestingly, the control group also reported significantly higher costs for systemic and biologic treatment. This difference occurred mostly because a few of the control patients had started expensive treatment with biologics during the 6 months following CHT. It might be a coincidence that none of the study group members had been prescribed biologics. By contrast, it may be argued that MI has the potential to impact disease severity, thereby reducing health care costs, as well as maybe postpone the need to initiate treatment with biologics. A similar trend was also obvious when the productivity losses were calculated, but there were no significant differences between the groups. Productivity losses were not part of the CUA analyses, but these work-related

costs far exceeded the medical costs and treatment costs, where they comprised approximately 70% of the total costs. A recent systematic review of the economic burden of psoriasis showed that productivity losses are the key driver of indirect costs, and it was concluded that the costs associated with psoriasis are comparable to, or higher than, those in other serious illnesses, such as pancreatic cancer, melanoma, prostate cancer and asthma, in various countries (370).

Cost-effectiveness studies combined with clinical RCTs are considered by many to be the "gold standard" for health economic evaluations when introducing a new treatment option (281). In this study, we present results on acceptable cost-effectiveness, which should be sufficient for making decisions about whether a method should be used as a clinical standard. In addition, a preventative effect may be important for positive changes in lifestyle or reduced medical risk markers among participants due to reduced disease severity (9;51). Hence, our study may have underestimated the total health gains expected from the intervention, while our limited follow-up period makes our conclusions somewhat ambiguous.

We found that the 11 patients in the intervention group who did not complete their questionnaires at 3 months after CHT (T3) did not have significantly different scores for any of the primary outcomes (SAPASI, HeiQ and DLQI) at baseline or after CHT compared with those who completed the questionnaires. However, some patients may have felt discomfort because of the intrusive nature of the intervention based on MI, but these issues are not clear because of the lack of a qualitative assessment in the study. This hypothesis may be supported by the fact that the drop-outs received significantly less MI counselling relative to the total duration of the calls compared with the responders. Furthermore, interventions that focus on skin care and lifestyle might make patients resistant to changing their behaviour, possibly because of feelings of failure if they do not succeed in behavioural change. Qualitative studies of diabetes have shown that some patients found it difficult to meet the requirements for behavioural change in accordance with the disease regime (371;372). This may also be the case for patients with psoriasis. By contrast, MI techniques may be less useful, contraindicated or counterproductive if the responder has already decided to make a behavioural change (272;360). This occurs because of a mismatch in the stages of change; i.e., the counsellor's work may be related to earlier stages such as pre-contemplation or contemplation, whereas the patient is already clearly committed to change and ready for action, and thus he/she may feel that there is no need to discuss his/her motivation or ambivalence to change. Therefore, the study group drop-outs may also have started their behavioural change, so they had no need of MI techniques following CHT.

In this study, we detected several positive effects of the MI intervention following CHT. These promising results indicate that health behaviour change counselling has the potential to increase self-management in patients with psoriasis. This was supported by the results of our CUA analysis, which suggested that MI interventions are potentially cost-effective, although the differences in the QALY measurements obtained using 15D were insignificant throughout the study period. To the best of our knowledge, no other studies of lifestyle interventions in psoriasis have reported immediate cost reductions as a consequence of an educational or self-management intervention in the absence of health effects; however, this has been reported in lifestyle interventions for other chronic diseases (373). MI is an SMS method within psoriasis care, which needs to be investigated further in a larger RCT study by focusing on a more recently diagnosed psoriasis population. More research is also required to determine the clinical significance and persistence of the self-management effects observed in the present study.

6.2 Methodological considerations

This research process was guided by methodological and theoretical reflections, which affected the perspectives and empirical data on which this thesis is based. The strengths and limitations of the approaches employed are discussed in the following chapters in terms of their internal and external validity.

The rationale for conducting this thesis was a perceived lack of tailored SMS interventions for patients with psoriasis, despite a major requirement for self-management to cope with this condition. The motivation for conducting a systematic review was to assess the evidence for self-management and patient education in psoriasis care before conducting new research as an RCT. The importance of this practice is strongly advocated in evidence-based research, and is recommended by Nylenna and Chalmers in an article in the Lancet in 2014 (374). A recent review of previous research also stated that an assessment of the existing evidence is crucial for providing the ethical, scientific and environmental justification required for proposed new trials (375). Thus, the implementation of a systematic review is a methodological strength of this thesis. Furthermore, paper 2 received a positive editorial comment in the British Journal of Dermatology, which stated that the strength of our RCT study was its originality, thereby strengthening the study's importance (376). This comment also recognized that the description of the MI intervention made it easy to replicate, thereby facilitating larger-scale RCTs in this area of psoriasis care.

6.2.1 Internal validity

The results of a study must be internally valid (i.e., the design and conduct must minimize the possibility of bias) (377). Thus, the internal validity is the extent to which the results of a study are true. Research has shown that the systematic review process reduces systematic error, thereby ensuring high internal validity (378). Systematic reviews aim to minimize bias when locating, selecting, coding and aggregating individual studies, but the design may also create bias. Like all research, the value of a systematic review depends on what was done, what was found and the clarity of reporting; thus, we only included RCTs and quasi-controlled trials in the systematic review to increase the comparability between studies. In terms of possible threats to internal validity, most of the studies included in our review did not report all of the possible sources of bias, as indicated in the ROB figure in paper 1, and selection bias limitations (especially patient randomization) led to limited reporting of such effects in these studies. However, the ROB estimates in each study also had some limitations according to the scope of this review. To avoid unintended differences in the intervention and control groups, the blinding of participants and/or personnel (performance bias) is usually a quality criterion (379). However, this is difficult to achieve in educational and self-management interventions, and we only scored "high risk of bias" when PASI was the outcome measure with no description of the blinding of the personnel involved in the assessment. Furthermore, performance bias did not restrict our report of interventional effects.

During the review process, two researchers read the same body of literature in order to reach a consensus about which studies to include in the review. Ideally, reporting the inter-rater reliability of this assessment should comprise as part of the systematic review process (380), but we did not score the consensus for the ratings given by the two authors. However, there was very little disagreement about which studies to include in the review and how to categorize the interventions as educational, or educational and self-management. Despite this, we cannot exclude the effect of the inherent subjectivity of each author's evaluation on the quality of our study. When categorizing the interventions, one of the issues is that we relied on the accuracy of the study descriptions.

The second design described in this thesis is an RCT. The objective of the RCT design was to determine how a single factor influenced the results of an intervention; i.e., showing that the MI intervention caused behavioural change and elucidating whether the change was due to other extraneous factors, such as differences in the assessment procedures between the intervention and control participants (381). First, we conducted a pilot study to examine the key uncertainties in the development of the MI intervention. Most of the questionnaires had been tested on the same

population in previous studies (18;19;23), so we only performed a qualitative assessment of the participants' experiences of the MI calls and the perceived usefulness of the workbook. Therefore, one weakness of this study may be the pragmatic approach employed when designing the pilot test because the number of participants and the number of MI calls were based primarily on a clinical judgment. However, previous research indicates that pilot studies do not need to be a scale model provided that important concerns are addressed (382). One of our main concerns was whether the patients would prioritize the calls because adherence to treatment seems to be an issue in the psoriasis population (120), but this was not a problem during pilot testing. The feedback from the participants was mostly positive, which agrees with other pilot testing studies using MI (383;384). We also prepared a thorough and detailed description of all the components of the intervention in paper 2, and the bubble sheet and the VAS scale for self-efficacy are provided as appendices to paper 1, to facilitate replication of the study.

The participants were randomized to MI or TAU. Randomization is the most robust method for preventing selection bias (382), and we obtained very similar groups in terms of most of the outcomes at baseline, as described previously. Randomization also eliminated any allocation bias to minimize the possibility of confounding. Allocation bias refers to the systematic difference between participants in how they are allocated to treatment (385). For example, if the participants had a preference for a treatment, it might have threatened the internal validity of the trial. Those who had a preference for MI might have been more motivated and exhibited greater adherence to the treatment if they had been allocated to the intervention. By contrast, the participants who did not receive their preferred treatment might have exhibited resentful demoralization, with poor compliance and possible withdrawal from the trial (381).

Blinding is difficult to achieve in lifestyle and educational interventions but not impossible. In the current study, both the participants and the counsellor were aware of who received the additional intervention. Therefore, the participants who received the motivational calls may have reported better outcomes simply because of the extra attention or because they believed that the intervention would be beneficial, and thus post-randomization bias might have compromised the internal validity of this RCT (386).

The fact that our MI intervention only had one MI counsellor could be both a positive and a negative feature. Behavioural change communication is a complex skill, which requires practice, feedback and coaching over time in order to be successful. Forsberg et al. (280) suggested that the complexity of developing sufficient competence in conducting MI counselling is an important barrier to the transfer

of training into practice. Several studies have demonstrated that a few days of MI training is insufficient (277;387;388), whereas others suggest that it may be difficult to suppress prior counselling habits, including practices that may be inconsistent with MI (280). However, systematic reviews of MI have reported positive changes in communication skills related to behavioural change after only a limited training period (275;276).

The MI training that I received before the intervention was extensive, and it included various practical and theoretical elements over a fairly long period, as described earlier. However, there was limited feedback on my MI competency during the last phase of the intervention. Consequently, follow-up training sessions with feedback would have been desirable to ensure that I had acquired sufficient MI skills throughout the study period. The fact that MI competence tends to decay quickly unless there is some systematic post-training support, supervision or training (276) emphasizes this weakness of the study design. However, a significant strength of this study was the application of a validated and reliable assessment tool to assess the competence of the counsellor who delivered the intervention. In particular, since a random set of the calls made in the last phase of the study were rated by the MIC lab, which indicated that my MI skills were sufficient. My competence and practice seems safeguarded by conducting over 500 MI talks, but any weaknesses in my MI guidance could potentially have negatively compromised all of the talks.

Other studies have assessed training outcomes at a single point in time (276), which yields low internal validity. We could possibly have increased the number of interviews coded by the MIC lab, but they represented all of the groups from January to May 2012, including calls from the beginning, middle and end of the six calls. The financial cost that this incurred meant that we chose not to send more interviews for coding. Furthermore, the coded calls represented half of the study period, and the results indicated that they conformed to the satisfactory levels of the thresholds for proficiency (279) (paper 2).

It should be noted that participants in the TAU control group did not receive individual contact time with a therapist that was equivalent to the MI group. Thus, it is impossible to know whether the increased effect on the clinical outcomes was associated with the unique components of MI specifically or whether it can simply be attributed to the opportunity for clients to talk with a supportive person after comprehensive CHT treatment. Another factor that might have influenced the internal validity was my double role as both a researcher and the MI interventionist. The attention from a researcher with a great interest in demonstrating the effect of the MI intervention may have biased the results because of the patients' eagerness to please. However, when I conducted the MI talks, I

talked very little about the study and concentrated my attention on fulfilling my role as an MI counsellor by adhering to the core communication skills, such as open-ended questioning, reflective listening, making affirmations, and summarizing and eliciting change talk related to the behavioural themes presented by the patients. The evaluation of the recorded calls by the MIC lab supported this proficiency. However, in my opinion, future RCTs should compare the effects and cost-effectiveness of MI with other active non-pharmacologic control conditions, which are equivalent to the MI intervention in terms of therapy time and therapist allegiance. Indeed, I think that the lack of control over therapist allegiance is one of the main flaws of the current RCT. In contrast to our study, in a the MI study by Ang et al. (356) with fibromyalgia patients, the control group received equal numbers of fibromyalgia self-management lessons instead of MI to control for time and therapist attention.

Good internal validity of a study also requires valid and reliable measurements. In this study, questionnaires were used at all four time points to collect self-reported data. Established and validated questionnaires were used in order to obtain systematic information related to multiple outcome measures and to ensure their internal validity. The Cronbach's alpha scores for internal consistency were acceptable for all of the measures, which indicates that these questionnaires generated trustworthy results (340). However, a general consideration with self-reported questionnaires is that the internal validity may be compromised because their validity may be affected by recall bias. This may be particularly relevant for paper 3 when we asked for details of health care utilization, medicines and skin-care products in the previous 3 months. Thus, caution is required when interpreting these results given the considerable uncertainty surrounding the cost estimates. One weakness was that only direct medical costs were available for patients, and other costs were not included, such as costs related to informal care at home, co-morbidities or lost productivity for the family and caregiver. This may have led to an underestimation of the costs (281). In addition, we do not know whether the amounts for utility use, medication and OTC products were reported correctly in the questionnaires by the patients. More sophisticated adherence measures (389;390) or simply providing a weekly journal to record the use of emollients, topical therapy and other therapeutic self-care products might yield a more exact estimate given the likelihood of forgetting specific details during the 3-month period between assessments. The skewed nature of the cost data may indicate that the study lacked sufficient powered to detect statistical differences in costs, but this is the case for most economic evaluations conducted alongside an RCT (391). Finally, as mentioned previously, the time horizon of 6 months was too short to observe further developments in psoriasis severity and co-morbidities such as CVD, as well as to measure the changes associated with QALYs gained.

Furthermore, it is questionable whether the preferences of 15D accurately reflected the preferences of the patients with psoriasis. Nevertheless, the strength of including a generic instrument for the HRQoL assessment is that the total scores represent a weighted average across dimensions, where the weightings are based on the preferences of patients. Therefore, these evaluations represent a valuable tool for decision-makers and also make an important contribution to the optimization of resource allocation across different patient groups (392). However, the baseline health utilities were already high because both the study and control groups scored relatively highly on 15D at baseline (mean score study group = 0.86 and control group = 0.90), and none of the patients had a score lower than 0.53. This implies that there was little room for improvement in the QALYs gained. These mean scores are similar to the scores obtained in a large Finnish study that included patients with psoriasis (mean score = 0.89) (298) and also agree with a study of arthritis patients (393), which may indicate a possible ceiling effect (394). However, previous research has also shown that 15D is sensitive to detecting deviations from full health (395;396). Other outcome measures could have been more relevant for evaluating cost-effectiveness. QALYs are the most commonly used measure, but QALY weights can be obtained by different methods, such as the recently developed EQ-5D-5L or SF36. Various instruments have been shown to yield different weights. In one study, the EQ-5D detected greater differences in the HRQoL scores compared with 15D (297), whereas another study found that 15D was more sensitive, especially in terms of the responsiveness to clinically important change (397). Further research seems required to clarify the instrument that is most sensitive to psoriasis HRQoL.

An extensive range of scoring systems can be used to assess disease severity in psoriasis, but no objective measure is available at present (75;398). PASI is the most extensively studied clinical severity score for psoriasis, and it is the most thoroughly validated (75). However, the PASI score also requires a subjective judgment by a physician, whereas SAPASI is self-reported and scored directly by the patient, and thus it may be perceived as subjective and less stringent. However, it may be claimed that a patient-oriented outcome must truly measure what is important for the patient. Therefore, SAPASI may be preferred because it better reflects the patient's perspective on his/her disease, at least in studies (such as the present study) based on "at-distance" follow-ups that focus on self-management. The PASI and SAPASI scores were strongly correlated in our study at baseline and after CHT, which agrees with the results of other studies (399), although a systematic review study found only a moderate correlation between these two measurements (75).

Overall, I consider that the designs described in this thesis were appropriate for answering the different research questions. The implementation of a systematic review, successful randomization and the assessment of the MI counsellor's competence by the MIC lab are all elements that support the validity

of this study. However, it is not clear whether the lack of blinding, the choice of 15D as a QALY measure and the absence of a sham intervention influenced the results described in papers 2 and 3.

Statistical validity

Statistical validity refers to whether a study can obtain conclusions that are in agreement with statistical and scientific laws (400). In the following, the main threats to the validity of the statistical analyses described in this thesis will be discussed.

An SMS intervention such as MI is multimodal and multifaceted, and many factors might influence the results obtained even with a strong research design, such as an RCT. Therefore, we aimed to include all of the potentially important confounders and to adjust for these in the analyses. None of the variables considered had any impact on the results, but it might be debated whether we included all of the potentially important confounders. One potential confounder was the summed 15D score at baseline. This variable had not been analysed when we wrote paper 2, and thus it was not included as a confounder, although significant differences at baseline between the groups were detected subsequently. However, we adjusted for this utility imbalance in the regression analysis to estimate QALYs (342), and we adjusted for the baseline differences in general health in the ANCOVA analysis in paper 2, which appeared to agree with the 15D scores. Our primary aim was to evaluate the effect of the MI intervention, so the RCT design should have balanced known and unknown potentially confounding factors between the groups compared.

At the fourth measurement point after 6 months in the RCT study, the drop-out rate from baseline was 26%. According to the guidelines for assessing the methodological quality of studies, drop-out rates exceeding 20% may cause serious bias (401). Thus, the high drop-out rate and the unknown reasons for drop-outs should be considered to be limitations on the representativeness of the sample. The relatively high number of losses to follow-up after 3 and 6 months might have weakened the statistical validity, thereby highlighting the vulnerability of sending follow-up questionnaires by post. The drop-out rate made it necessary to perform an additional analysis of the differences between the completers and non-completers in terms of sex, age and education. The analyses showed that significantly more of the drop-outs were male, younger and unmarried, and more patients dropped out of the control group than the study group, as might be expected, especially at 3 months. Losing more males in the standard treatment group is unlikely to have resulted in clinically important effects. The drop-outs in the study group received significantly less MI consultation time, which might indicate that the MI intervention is not suitable for all patients with psoriasis, as discussed in section 6.1. "Discussion of the main findings".

In addition, the high drop-out rate may have reduced the study's power at 6 months (T4). The power calculation was based on one of the primary outcomes, HeiQ, which indicated a need for 64 participants in each group in order to draw conclusions and to avoid accepting the wrong null hypothesis (Type 2 error). At 3 months, there were 72 participants in the study group and 63 in the control group, but the total number of participants was sufficient. After 6 months, 60 remained in the control group and 65 in the study group, where the total sample size was 125, which was slightly below the requisite number of 128. However, there were still significant differences in multiple outcomes in favour of the study group at a significance level of $p < 0.05$. Further studies in the psoriasis population that require individual data about health care use may have to rely on self-reported data because it is not feasible to collect these data from other sources. Nevertheless, methods should be developed for improving the data completeness in studies with many self-reported costs and effect measurements to increase the internal validity of these studies.

A method that can correct for differential drop-out rates between patients in one arm of a study involves analysing data based on the intent to treat; i.e., the data are analysed based on the manner in which the patients were randomized, regardless of whether they received the intended intervention (402). This intent to treat correction is a form of protection against bias that strengthens the conclusions of a study. It enhances the internal validity because it ensures that the treatment groups retain similar baseline characteristics, thereby minimizing confounding (403;404). After a discussion in the research group, we decided not to perform an intention to treat analysis, such as "last observation carried forward" (LOCF) or multiple imputations, to obtain a full dataset (405). We had complete samples at T1 and T2, but it might have created bias if we had used the T2 scores at T3 and T4 because of the major positive effect of the CHT on multiple outcomes as previously described. However, we did perform an intention to treat analysis to check for possible changes using the baseline scores with the LOCF approach. These analyses obtained the same results as the per-protocol analysis but with greater significance. We decided to report the per-protocol results because all measures for the same patients were often missing at both T3 and T4 because they did not return their questionnaires. When questionnaires were completed, there were almost no missing answers.

 Finally, there is no perfect imputation approach if missing data are too frequent (405-407). However, we tried to follow the intention-to-treat principle by keeping the missing data to a minimum by sending out a reminder questionnaire when the participants failed to answer. The trial was conducted with high fidelity to the study protocol, where only one reminder was sent and the participants were not contacted by telephone or mail. Another principle was treating participants according to their

allocation group; thus, two patients who answered T3 and T4 questionnaires although they did not receive all of the MI follow-up calls were treated as study group participants in all of the analyses.

Despite these threats to statistical validity, we were able to draw conclusions that were in agreement with statistical and scientific laws.

6.2.2 External validity

To be clinically useful, a result must also be relevant for a definable group of patients in a particular clinical setting, which is generally known as external validity, applicability or generalizability (408). Thus, external validity is the extent to which the results of an experiment or study can be extrapolated to different situations, and whether a comparison and a translation of the studies to a new policy and practice context are possible (381). Therefore, a possible threat to external validity comprises the characteristics of the input (409). For example, our review had linguistic constraints because our eligibility criteria comprised English, German or Scandinavian languages. If we had only utilized published studies according to the language constraints (e.g., English) employed by certain electronic databases, as is the case with many published meta-analyses, a large number of eligible studies would have been missed, thereby resulting in substantial bias.

Possible publication bias cannot be discounted completely in the review. An inappropriate or non-comprehensive search strategy and only including publications with full text are other common errors that can reduce the representativeness of the studies included (410). These biases were minimized with the help of an experienced librarian and by obtaining full text copies of all possible papers. However, a comprehensive search could also have included "grey literature", such as papers, reports, technical notes or other documents that are not distributed or indexed by commercial publishers. A systematic review of the extent of bias in systematic reviews suggested that grey literature, especially conference abstracts, should be included (410). However, the "positive" trials presented as abstracts or oral presentations based on RCT design have a greater likelihood of being published, and thus systematic reviews of only published material may have exaggerated the effect sizes. In addition, self-selection bias may arise when researchers choose not to publish some of their primary studies for various reasons.

Another possible bias is that we did not include an outcome-level assessment, which involves evaluating the reliability and validity of the data for each important outcome by determining the methods used to assess them in each individual study (411). The "Grading of Recommendations

Assessment, Development and Evaluation" (GRADE) system provides an explicit, comprehensive and pragmatic system for rating the quality of evidence and strength of recommendations. According to the GRADE system, "quality" means more than ROB, and it may also be compromised by the imprecision, inconsistency and indirectness of study results, as well as publication bias. In addition, several factors can increase our confidence when estimating effects. GRADE provides a systematic approach for considering and reporting each of these factors (412). Thus, by using GRADE, we could have evaluated the overall quality of the body of evidence from our systematic review and produced a summary of findings in a table to present to decision-makers.

RCTs and systematic reviews are the most reliable methods for determining the effects of treatments (413). Thus, conducting an RCT yields the strongest evidence of whether an observed difference is a causal effect of the intervention (404), and RCTs are often considered to be the gold standard design. However, many challenges remain when testing a self-management intervention even when using the RCT design. The Consolidated Standards of Reporting Trials (CONSORT) statement (http://www.consort-statement.org/) is an evidence-based minimum set of recommendations for reporting randomized trials, which provides a standard method for authors to prepare reports of trial findings, thereby facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation (413). When we considered the current study based on CONSORT, 21 out of 22 potential items were found to be reported in the published paper because our RCT study lacked information about whether the full trial protocols could be accessed. Thus, despite its strengths, our study also had a number of limitations.

External validity may also be threatened by the selection of patients. The subjects who are included as willing participants may differ from those who do not want to participate in the study. Thus, an appropriate question is to the degree to which our results might be representative for all patients with psoriasis in Norway. We do not know whether the patients with psoriasis who applied for CHT differed from the overall psoriasis population in Norway in terms of their motivation to change, treatment adherence and choices of lifestyle, but we do know that CHT is a treatment option for patients with moderate to severe psoriasis (PASI > 7 by application). Furthermore, 39.2% of the eligible patients declined to participate for unknown reasons, and we do not know whether they differed from the population included. Psychological and physical stresses related to the 3 weeks of CHT, participation in previous studies or uncertainty related to motivational talks could all be factors that prevented participation. An important question is also whether the patients who refused to participate did not believe that they were in need of SMS after CHT because they had already taken necessary steps to change their lifestyle, or because they did not believe in the motivational talks as an

efficient SMS method. Thus, it is not clear whether the sample was representative of the population. However, the participants in CHT were recruited from all over Norway, and thus they were more likely to represent the psoriasis population than if they had been recruited from one region by convenience sampling.

Vulnerability in the recruitment situation may be another weakness in terms of external validity. The nursing staff at the CHT centre were limited in numbers, so busy days with many other assignments might have made it challenging to inform all of the patients properly before they were enrolled in the CHT, as discussed previously in section 4.9 ("Ethical issues"). However, this was probably a random occurrence and would not have caused any selection bias.

The external validity of an RCT also depends on whether the outcomes are clinically relevant. Deciding the type of questionnaire employed to measure the effects of a complex intervention is an important process. Thus, several clinical instruments were assessed and discussed by the research team. It was essential to consider the availability of previously tested and validated instruments (414), as well as to identify the most appropriate outcomes for the MI intervention. Hence, prior to data collection, we prepared the questionnaires for the study and included standardized questionnaires on psoriasis severity, co-morbidities (baseline only), impact of health education, self-management, knowledge, lifestyle parameters, health status and illness perception.

Another limitation on the external validity was the limited time frame of 6 months follow-up after CHT because we know that behavioural and lifestyle changes may take a long time to incorporate into everyday life, as described by the TTM of behavioural change (221). This may also have affected the CUA because more significant changes between groups could potentially have occurred after our cost and effect estimates were obtained. The 6-month follow-up period was a pragmatic decision based on the possibility of the patients' applying for new CHT treatment, thereby leading to confounding bias. Patients may be allocated to CHT once every calendar year, and it would have been unethical to refuse their application because of study participation.

In addition, the long-term sustainability of lifestyle and behavioural change interventions may be limited by the uncontrollable surrounding environment, personal situation and loss of interest by the participant over time (415). Other limitations include the influence of confounding factors such as changes in therapy. The treatment interventions were not restricted in either of the groups. Most of the patients received topical treatment, but some also received systematic medications, and others had started UV treatment or biologics post-CHT.

Despite these weaknesses in the external validity of this study, our findings agree with some comparable findings from other studies in psoriasis care. Overall, the knowledge and results described in this thesis may be transferable to patients with moderate to severe psoriasis.

7 CONCLUSION

The present study provides novel and comprehensive information about the effects and effectiveness of self-management interventions for patients with psoriasis, as well as the significance of self-management for psoriasis care.

The main conclusions of this study are as follows.

- The systematic review provided limited evidence of the effectiveness of patient education and self-management interventions for patients with psoriasis. There was uncertainty and inconsistency regarding the most effective approaches, and the educational content that produces the best effects.

- The quality evaluation of the reviewed studies indicated their poor methodological quality with an overall high risk of bias. There also appeared to be a lack of focus on lifestyle change and self-management. However, the most recent studies had a more obvious focus on self-management and better methodological quality.

- In the RCT study, the patients with psoriasis who received the MI intervention had a significantly reduced disease severity measured by SAPASI after 3 and 6 months compared with the control group.

- The study group had significantly better self-management scores in two of the eight HeiQ domains at 3 months, but at 6 months, only the "self-monitoring and insight" domain scored significantly better in the study group.

- In terms of secondary outcomes, we found that the study group had significantly better psoriasis knowledge (PKQ) at 6 months and better illness perception at 3 months, and the study group participants exhibited a healthier pattern of behavioural change related to skin treatment throughout the study period compared with the controls. The study group had significantly higher self-efficacy scores related to desirable lifestyle change at both 3 and 6 months.

- The CUAs showed that the intervention group tended to have better patient outcomes at lower costs. However, this result was more evident when the DLQI was used as the utility outcome measure compared with the 15D.

- Compared with TAU, MI by phone provided at least equivalent QoL and utility, with a tendency to reduce the costs.

8 CLINICAL IMPLICATIONS AND FUTURE RESEARCH

This is the first study to evaluate an MI intervention in the context of psoriasis. Future research could build on the results described in this thesis and address their limitations. The results described in this thesis suggest the following implications for psoriasis care and future research.

This study adds to the growing knowledge of the process of self-management and lifestyle change in psoriasis care. The individual factors need to be explored further in order to determine how lifestyle changes are achieved and maintained within psoriasis care, as well as the possible implications for disease severity and co-morbidity profile. Autonomous motivation and self-efficacy are important motivational factors, but we still need more research to understand how this knowledge can be used in clinical work. More large multicentre multidisciplinary RCTs with long follow-up periods, sufficient sample size and validated outcome measures, which should focus on self-management and lifestyle, are necessary before firm conclusions can be reached.

It is evident that people with psoriasis have specific needs to support their daily requirements for skin care management, medication and co-morbidity prevention, such as diet and exercise. Therefore, we recommend that treatment providers should be aware of the difficulties that some vulnerable patients face when coping with the responsibility of self-management. A good understanding of how to meet the needs of individuals in terms of SMS is necessary in the development of psoriasis treatment strategies to ensure sustainable treatment.

Individual counselling based on MI appeared to maintain the patient's level of insight into living with a health problem such as psoriasis. Supporting autonomy and self-efficacy by phone or other "at-a-distance follow-up methods" are promising interventional strategies for improving the long-term maintenance of treatment adherence and lifestyle changes. Testing this MI intervention style in another psoriasis population setting, preferably with a "sham" control group, would provide important and clinically relevant information.

Thus, MI intervention has the potential to be an important SMS method that may be implemented in primary health care. Future psoriasis care will have to shift from a focus on acute episodes of physical exacerbations to meeting the demands of patients with a combination of long-term physical, social and psychological needs. In fact, whenever possible, patients need to be involved in the decision-making process concerning their pathway of care and also to be supported in how to self-manage their

disease(s), thereby helping them to continue living their daily life. However, this need to focus on health promotion and illness prevention may challenge the culture and mindset of existing health care, thereby highlighting the need for new ways of working that also address social and psychological determinants of health. Thus, MI provides a means of developing a collaborative relationship between individuals with psoriasis and their health practitioner, which includes an exploration of the individual's beliefs about psoriasis, and the importance of behavioural change and treatment adherence. MI also provides a means of working with individuals who know what is required in terms of psoriasis self-management but who struggle with implementing and maintaining the necessary behavioural change(s).

This type of follow-up seems to be in line with the Norwegian Ministry of Health and Care Services' plans for the co-ordinated reform (416) of future health care, where it has been stated that the implemented reform will provide more assistance to people who want to change their lifestyles, which may lead to illness. In addition, the reform aims to ensure that people with chronic conditions will receive better follow-up with the right to managed and co-ordinated care, and will be involved in planning their health and social services.

The quality of psoriasis care in Norway following CHT may suffer from a lack of systemic multidisciplinary health care, customized monitoring and competence in methods for supporting behavioural change and self-management such as MI. However, the often longitudinal nature of the relationship between patients with psoriasis and their local health care providers in Norway may provide multiple opportunities for clinicians, physiotherapists and nurses to provide tailored patient education and SMS over long periods. In particular, nurses appear to be in a unique position to undertake this interaction and communication with patients because they already work in close co-operation with the patients and their families. Counselling is an important role in nursing, and an increased co-operation between dermatology nurse counsellors and physicians may relieve the physician of the responsibility of promoting healthy behavioural interventions to psoriasis patients in busy dermatology outpatient clinics. For example, the possibility of patients receiving tailored follow-up sessions with skilled nurses on subjects such as skin care and lifestyle change is important, including self-management principles like problem-solving skills, goal setting and self-efficacy support. According to the association between SMS and health outcomes found in our study, it may be important to offer tailored follow-ups to patients with psoriasis over an extended period following other treatments such as CHT.

In order for future research to be able to recommend guidelines about how to use SMS methods such as MI in dermatology practice, it is imperative that efforts be made to describe exactly how the counsellors are educated and trained, the methods employed and the ways in which they can be applied in counselling; e.g., MI. We also need to know whether the self-management of behavioural change can be maintained after the intervention is complete or whether a more permanent SMS regime is necessary for maintaining self-management skills, treatment adherence and lifestyle changes in psoriasis.

More and larger studies need to be conducted with a long follow-up period to obtain further insights into the effects of SMS intervention over time. Furthermore, the present study did not determine the long-term effects of MI in psoriasis care. MI appears to initiate a process of change in patients, so there is a need for long-term follow-ups of the intervention programme to elucidate the full details of its effects.

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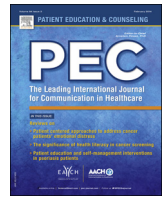
Review

Limited evidence of the effects of patient education and self-management interventions in psoriasis patients: A systematic review

Marie Hamilton Larsen [a,b,*], Kåre Birger Hagen [a,e], Anne-Lene Krogstad [b,d], Eline Aas [c], Astrid Klopstad Wahl [a]

[a] Medical Faculty, Department of Health Sciences, Institute of Health and Society, University of Oslo, Norway
[b] Section for Climate Therapy, Integration and International Collaboration, Oslo University Hospital, Norway
[c] Medical Faculty, Department of Health Management and Health Economics, Institute of Health and Society, University of Oslo, Norway
[d] The Department of Dermatology, Oslo University Hospital, Norway
[e] National Resource Centre for Rehabilitation in Rheumatology, Department of Rheumatology, Diakonhjemmet Hospital, Norway

A B S T R A C T

Objective: To describe the contents of educational and self-management programmes for patients with psoriasis, and to evaluate their effects.
Methods: A systematic review of randomized controlled trials (RCTs), quasi-randomized trials and controlled clinical trials identified by a systematic literature search. Risk of bias was assessed by two independent reviewers and interventional effects were summarized descriptively and by meta-analysis.
Results: Nine studies were included, which ranged from single brief interventions to long complex multidisciplinary programmes. Four RCTs with adequate sequence allocation were included to analyze interventional effects. One RCT compared two different educational programmes and found no differences between groups. The results of three trials that focused on combinations of education and self-management were heterogeneous. One RCT based on a 12-week comprehensive programme reported statistically significant effects ($p < 0.05$) on disease severity and health-related quality of life. Two RCTs with less comprehensive programmes reported no effects on HRQoL.
Conclusion: This review showed that little evidence is available to support the effects of educational and self-management interventions in patients with psoriasis that are studied in RCTs. There is a significant lack of focused self-management and, compared with other chronic conditions, there appear to be few effective disease-specific tailored educational programmes for psoriasis.

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* Corresponding author at: Department of Health Sciences, Institute of Health and Society, University of Oslo, Norway. Tel.: +47 41268988; fax: +47 22067861.
   E-mail addresses: m.h.larsen@medisin.uio.no (M.H. Larsen), k.b.hagen@medisin.uio.no (K.B. Hagen), a.l.krogstad@ous-hf.no (A.-L. Krogstad), eline.aas@medisin.uio.no (E. Aas), a.k.wahl@medisin.uio.no (A.K. Wahl).

1. Introduction

Psoriasis is a chronic recurrent immune-mediated inflammatory skin disease with fluctuating disease severity. It has a prevalence of 2–4% in the Scandinavian population [1,2] and clinical symptoms often include thick and scaly plaques, which can cause pain, ache and itching of the skin [3,4]. There is no difference between men and women in relation to the number of people affected and the disease may debut in all ages [2,5]. Factors such as stressful life events and psychological distress appear to have significant effects on the onset or exacerbation of the disease [6–8]. Psoriasis patients often have a lower quality of life than the general population and an increased risk of concurrent disorders [9–12]. Many suffer from extensive psychological difficulties such as anxiety, depression and pathological worry [13–16]. Patients appear to lack knowledge about the disease [17], are often dissatisfied with their care [18,19] and exhibit low adherence to medical treatments [20,21]. In recent years, the relationships between disease activity and lifestyle parameters such as smoking, stress, body mass index and physical activity have been identified as areas where psoriasis patients can influence their illness in a positive or negative direction [22–24]. Thus, the need for patient education and self-management interventions appear to be particularly important for patients with psoriasis.

Patients with chronic conditions, such as psoriasis, make day-to-day decisions about how to self-manage their illness, individual lifestyles and adherence to often time-consuming treatments are largely the patient's choice. Thus, coping with chronic illness to fulfil your life's potential may require extensive effort and commitment. Self-management has been defined as the patient's ability to deal with all the problems that chronic illness entails, including symptoms, treatment, physical and social consequences and lifestyle changes [25]. Patients can however experience barriers to active self-management [26] making patient and self-management education cornerstones of treatment. They are however two different educational concepts. Traditional patient education imparts often disease-specific information and technical skills [27]. In theory, education will increase a patient's knowledge about their disease, which may motivate them to make behavioural changes that help to improve their clinical outcomes [28]. The content and focus is to a large degree decided by health care professionals [27]. Self-management education is different as patients themselves identify relevant problems. By providing a collaborative partnership with health care providers the programmes aim to increase problem solving skills, action planning and increase self-efficacy [27,29].

Hence, patient education, self-management programmes and counselling all help to ensure that patients with chronic diseases have sufficient knowledge and understanding so they can participate actively in making informed choices regarding their own health care.

Previous systematic reviews in the fields of patient education and self-management interventions related to chronic diseases have assessed interventions for chronic diagnoses other than psoriasis [30–32]. To the best of our knowledge, the only systematic review that included psoriasis used quality of life as the sole outcome measure [33]. One reason for this lack of research may be that psoriasis has mainly been considered as a difficult cosmetic skin disease, so there was no apparent need to evaluate specific educational programmes in this area. However, the current status of psoriasis as an autoimmune disease with high co-morbidity risks [10] has changed this viewpoint and there is a need for a more holistic educational focus, particularly tailored educational and self-management interventions. To provide a better basis for future research and clinical practice, the present systematic review aimed to describe the contents of educational and self-management programmes for patients with psoriasis and to evaluate their effects, with a broader outcome focus than quality of life alone.

2. Methods

2.1. Study characteristics

Individual and group based randomized controlled trials (RCTs), quasi-randomized controlled trials (with inadequate sequence allocation) and controlled clinical trials were considered eligible for inclusion.

The PICO (Population, Interventions, Comparison and Outcomes) used for inclusion is given in Table 1.

2.2. Search strategy

We performed a broad systematic literature search for articles that contained the terms 'patient education', 'counselling', 'self-management', 'intervention' or 'program', which were all combined with psoriasis and/or skin disease and/or chronic illness. The term 'self-care' was also added because of inconsistent terminology usage. The search strategy was organized in collaboration with the librarian at Oslo University Hospital.

The following databases were searched up to May 2012: MEDLINE, EMBASE, CINAHL, PubMed, PsycINFO, SweMed and the Cochrane Controlled Trials Register. The reference lists of relevant studies and systematic reviews were also investigated. We also reviewed the reference lists of all the articles identified and subscribed to notifications of new publications. The databases were investigated again in November 2012 using the same search

Table 1
Inclusion criteria.

Population: We included trials that included patients aged over 18 years with a clinical diagnosis of psoriasis, regardless of the type or stage. We included studies from all settings where all types of health-care professionals could provide the interventions.

Interventions: The programme content had to include at least one face-to-face meeting with a health-care professional. The intervention had to include psoriasis education, or focus on one or more aspects of living with psoriasis, such as symptom management, cognitive problem solving, communication skills, stress management or lifestyle change. Self-management interventions had to emphasize key elements such as engagement in self-care, self-efficacy strengthening, action planning and problem solving [31] (i.e., education only, self-management only or education and self-management combined).

Comparison: The educational or self-management intervention should have been compared with a different intervention, usual care or a waiting list control.

Outcomes: To measure the effects of education and self-management interventions, we decided to use a holistic approach and considered all relevant parameters such as disease severity, symptom relief, illness perception, quality of life, self-efficacy and psychological status. We also decided to include studies that measured knowledge, regardless of the type of questionnaire, as well as interventions with self-customized questionnaires, provided they referred to any of the topics mentioned above.

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strategy to ensure that the review was up to date and that all relevant interventions were included. We also searched for possible new publications in June 2013.

2.3. Study selection

Two reviewers (MHL and AKW) independently reviewed all of the titles and abstracts and determined their eligibility. Full text versions were obtained for all potentially relevant studies and complete articles were retrieved if there was any doubt regarding the fulfilment of criteria. All of the full text articles were assessed independently and evaluated to determine their relevance by the same two reviewers. Any disagreements were resolved by discussions.

2.4. Data extraction and management

Next, one reviewer (MHL) extracted the data from the included studies and another reviewer (AKW) ensured that all of the relevant information included was correct. The following parameters were described for each study.

1. Study reference (author, year of publication, country)
2. Study design
3. Participants (numbers of participants, mean age, setting)
4. Intervention(s) (focus, duration and frequency, hours of teaching)
5. Whether the intervention was based on a theoretical model
6. Control group and comparison
7. Outcome measures and effects
8. Follow-up
9. Contribution of health-care provider alone or in combination

The findings are summarized in Tables 2 and 3 (effects).

2.5. Quality assessment

The methodological quality of each study and an evaluation of the risk of systematic bias (ROB) were assessed independently by the same two authors in accordance with the approach described in the Cochrane Handbook for Systematic Reviews of Interventions [34]. A third person (ALK) was involved if there were disagreements.

2.6. Quantitative data synthesis

Only trials considered to have a low ROB related to 'random sequence allocation' were considered for the quantitative data synthesis. Separate comparisons were made, which depended on the type of intervention and the type of control group. Attempts were made to pool trials when more than one trial was available for a specific comparison and outcome. Two trials were considered sufficiently similar in terms of their comparisons

and outcomes to pool the data. We calculated the weighted mean difference (WMD) and 95% confidence interval (95% CI) for one comparison using Review Manager 5.1. Qualitative summaries were prepared for the other comparisons.

3. Results

3.1. Study selection

The initial literature search identified 1404 papers (Fig. 1 shows a flowchart of the inclusion procedure). After removing the duplicates, 613 records described potentially relevant studies. Of these, 504 studies were discarded after reviewing the abstracts because they clearly did not meet the inclusion criteria. The full texts of the remaining 109 studies were examined in more detail. The check of the database searches in June 2013 identified two further papers that required full text examination. Finally, 101 of these publications were excluded and 10 papers satisfied the inclusion criteria for this review. However, two publications reported different aspects of the same trial [35,36]. The reasons for exclusion included: case studies, inadequate descriptions of the educational or self-management intervention, or the psoriasis results were not analyzed separately when multiple diagnoses were included. Interventions without control groups, 'face to face' meetings and solely pharmaceutical clinical interventions were excluded. We chose to exclude articles that described and evaluated psychological interventions because these studies were focused on the treatments. Studies of psoriatic arthritis patients in arthritis self-management programmes were excluded because their main focus was on managing arthritis.

3.2. Study characteristics

The nine studies described trials that varied in terms of their content, duration and focus. Five were RCTs (three pilot studies) and four were controlled clinical studies (three with patient preference procedures related to group allocation). The studies were published between 1980 and 2012, with four published in the last six years (2007 onwards). Eight of the trials were conducted in Europe, i.e., England [35–38], Italy [39–41], Belgium [42] and the Netherlands [43], with one in Canada [44].

3.3. Participants

The number of participants in the studies ranged from 42 to 402, with a total of 1076 subjects. The median age was 47.9 years and the subjects were recruited from a range of settings, as shown in Table 1. The disease duration was reported as a baseline characteristic in six papers, i.e., a mean of 20.2 years with psoriasis [35,36,40,42,44,45]. The age at onset, which ranged from 20 to 34.3 years [39,42], was only reported in two studies.

Table 2

Characteristics of the studies included in the review.

Study/reference/country	Study design	Theoretical background of the intervention	Participants' mean age	Setting provider of intervention duration	Intervention and comparison	Outcome measures: domain (instrument) follow-up
Educational focus Lora et al. [39] Italy	Pilot RCT	No theory presented	123 adults with mild to moderate psoriasis *Mean age*: 55 years	*Setting*: Comano Spa for skin diseases/Trentino *Provider*: Dermatologist and psychologist *Duration*: 2 h × 1	*Group intervention*: 2-h psycho-educational programme provided by a dermatologist and a psychologist where the psychologist participated in discussions to manage negative emotions and offer coping strategies *Control group*: 2-h educational programme conducted by a dermatologist	*Disease severity*: (Previous treatment + visual analogue scale of itching at baseline) *Quality of life*: (Skindex 29 at baseline) *Knowledge*: (Study-specific questionnaire related to psoriasis and treatments before and after the intervention) *Psychological status*: (Study-specific questionnaire) *Coping*: (Study-specific questionnaire) + attitudes towards therapy and physicians and reason for choosing spa treatment *Follow-up*: After intervention + telephone interview at six months
Pagliarello et al. [40] Italy	Controlled trial (patient preference)	No theory related to the basis of the intervention	136 spa patients with psoriasis, aged >18 years *Mean age*: 52 years	*Setting*: Comano Spa health facility for skin diseases *Provider*: Not described *Duration*: 2 h × 1	*Group intervention*: Empowerment-based educational intervention (EBEI) in addition to spa treatment *Control group*: Spa treatment	*Disease severity*: Self-administered Psoriasis Area and Severity Index (SAPASI) *Quality of life*: (Skindex-17) *Empowerment*: (Psoriasis Empowerment Enquiry in Routine practice (PEER)) *Follow-up*: After intervention + 12 daily baths in calcium magnesium oligomineral Comano spring water
Renzi et al. [18] Italy	Controlled trial with two consecutive phases–control phase: September 2003–January 2004; study phase: January–April 2004.	Limited theoretical presentation of differences between the paternalistic and shared model (partnership) with respect to patient involvement and treatment decisions	402 adults aged <18 years, inpatients and outpatients *Mean age*: 56 years	*Setting*: Dermatological treatment and research hospital, Rome *Provider*: Dermatologists *Duration*: Time frame not described (20 min?)	*Individual intervention*: Use of a decision board as an aid for discussing treatment options *Control group*: Routine medical treatment	*Disease severity*: (Assessed by a dermatologist on a five-point scale: "how severe is the patient's condition?") *Knowledge*: Identifying nine correct statements from 12 options *Patient satisfaction*: Study-specific questionnaire with 25 questions related to attitude/satisfaction with the decision-making process *Follow-up*: After intervention
Educational and self-management focus						

Table 2 (*Continued*)

Study/reference/country	Study design	Theoretical background of the intervention	Participants' mean age	Setting provider of intervention duration	Intervention and comparison	Outcome measures: domain (instrument) follow-up
Bostoen et al. [42] Belgium	RCT	No theory (only a previously described group-based educational programme, Lambert et.a,2011)	59 adults with psoriasis or atopic dermatitis aged 21–63 (29 psoriasis patients) *Mean age*: 39.6 years	*Setting*: Ghent University Hospital *Provider*: Dermatologists, dermatological nurse, pharmacist, dietician, training expert, psychiatrist, psychologist and philosopher, sports, yoga and mindfulness trainer *Duration*: Twelve-week educational programme, 2-h sessions twice each week	*Group intervention*: 1. Education on skin diseases 2. Education on healthy lifestyles 3. Weekly physical training, yoga and mindfulness meditation, and stress reduction techniques Two feedback sessions with a dermatologist The study group received the educational programme + medical therapy + monthly telephone calls *Control group*: Medical therapy only	*Disease severity*: (Psoriasis Area and Severity Index (PASI), Scoring Atopic Dermatitis (SCORAD), Eczema Area and Severity Index (EASI)) *Quality of life*: (Dermatology Life Quality Index (DLQI), Skindex 29, Psoriasis Disability Index (PDI), Quality of life Index for Atopic Dermatitis (QoLIAD)) *Psychological status/stress*: (Beck Depression Inventory (BDI), Everyday Problem Checklist) *Lifestyle*: (smoking behaviour, physical activity) *Health economy*: (EQ5D, medical consumption) *Follow-up*: Three, six and nine months
Gradwell et al. [38] UK	RCT	No theory base	66 newly referred patients with psoriasis or eczema ≥14 years *Mean age*: 39.4 years	*Setting*: Dermatology outpatient clinic, Nottingham *Provider*: Dermatology nurse specialist *Duration*: 20 min × 1	*Individual intervention*: Additional session with a dermatology nurse specialist after a dermatologist. A nurse assessed the patient's understanding of their skin condition, provided practical demonstrations of treatment applications and gave details of further sources of support, with a written treatment plan. *Control group*: Dermatologist only + normal care	*Quality of life*: (DLQI) *Knowledge*: (study-specific questionnaire) *Health economy*: Numbers of consultations with secondary and primary care *Follow-up*: Six weeks
Rothman et al. [44] Canada	RCT	No theoretical basis (only a superficial presentation of PERC's educational philosophy)	91 patients with psoriasis *Mean age*: 40.5 years	*Setting*: The Psoriasis Education and Research Centre (PERC), Toronto *Provider*: PERC staff (not specified, other than a nurse who charted the functional history) *Duration*: Three weeks of day care (not described further)	Individual intervention Three-week PERC educational programme (day hospital) on self-care for psoriasis and coping strategies. The contents of the individualized programme were not described. *Control group*: Normal hospitalization for three weeks (content not described)	Disease severity (skin assessment) *Knowledge*: (Functional history obtained by a nurse) *Self-care*: (Functional history obtained by a nurse) *Coping*: (Functional history obtained by a nurse) *Follow-up*: Three weeks, six months and one year (results not presented)

Ersser et al. [37] UK	Pilot RCT with cluster randomization	Social Learning Theory (SLT) and the central concept of self-efficacy (+ feedback on key factors related to self-management based on a qualitative study conducted by the same research team)	64 adults with mild-moderate psoriasis *Mean age*: 58 years	*Setting*: Eight primary health care centres *Provider*: Specialist dermatology nurse and research nurse *Duration*: 2 h × 1 + 20-min follow-up consultation	*Group Intervention*: Theory-based educational intervention with three components: structured 2-h nurse-led sessions in groups, including practical elements and individual action planning; support with written and audiovisual material; follow-up telephone consultation (20 min × 1 after 1 month) *Control group*: Usual treatment + access to primary care	*Quality of life*: (DLQI) *Disease severity*: (PASI) Plus qualitative feedback about the feasibility of the intervention *Follow-up*: Six weeks
Fortune et al. [35,36] UK	Controlled trial with a patient preference randomization procedure	Modelled on biopsychosocial pain management programmes + combined aspects of the psychology of disfigurement, social anxiety and stigma	93 with dermatologist-confirmed psoriasis (age 18–65) *Mean age*: 43 years	*Setting*: Specialist psoriasis clinic at Hope Hospital, Manchester *Provider*: A clinical psychologist and a team of nursing staff *Duration*: 2.5 h × 6 (15 h) for six weeks	*Group intervention*: CBT and didactic teaching of the medical and biological basis of psoriasis: treatments and effects, stress reduction techniques and cognitive techniques + homework with individualized model-centred goals *Control group*: Standard medical treatment	Article 1 (2002): *Disease severity*: (PASI) Psychological status/stress: (Toronto Alexithymia scale (TAS-20), Hospital and Anxiety scale (HADS), PDI, Psoriasis Life Stress Inventory (PLSI) *Coping*: (COPE, Illness Perception Questionnaire (IPQ)) Article 2 (2004): Psychological status/stress: (COPE, IPQ, TAS-20) *Follow-up*: Six weeks and six months
Schulte et al. [43] The Netherlands	Controlled trial	Study based on a pyramid of previous studies and the equilibrium model (described elsewhere)	42 adults, aged <70 years with psoriasis vulgaris *Mean age*: Not stated	*Setting*: Dermatological departments in four hospitals *Provider*: *Dual trainers*: a fellow sufferer and a physician *Duration*: 2 h × 10 weeks (20 h) over a period of three months	*Group intervention*: Duo formula group treatment (DFGT) support group (seven patients in each group), who discussed the somatic and emotional aspects of psoriasis. Information about psoriasis treatment options, diets, self-care techniques, etc. Relaxation and respiratory exercises, which were practiced during each session and as home tasks between the sessions with partners at home. *Control*: No treatment, waiting list. (A high number of drop-outs led to the use of equal data from the PERC study in Toronto)	*Disease severity*: Assessment of the severity at baseline by a dermatologist (1, 2 or 3) Study-specific questionnaire, i.e., the equilibrium assessment: 46 questions related to illness behaviour, shame, social directness, problem solving in groups and personal growth *Follow-up*: After intervention + three months (two-year data not shown)

Table 3
The interventions conducted in the four trials with adequate random sequence allocation procedures.

Focus: Educational interventions	
(Lora et al., 2009)	No statistically significant differences between the two programmes, but between-group differences according to two questions related to systemic therapies, which indicated that the patients who attended the patient education session were more inclined to systemic treatment ($p=0.0001/p=0.003$).
"Efficacy of a single educative intervention in patients with chronic plaque psoriasis"	
Focus: Patient education and self-management	
(Bostoen et al., 2012)	Psoriasis Area Severity Index (PASI): the intervention group had a significantly greater reduction in the mean PASI score at three months ($p=0.036$) and at six months ($p=0.017$) compared with the control group.
"An educational programme for patients with psoriasis and atopic dermatitis: a prospective randomized controlled trial"	Dermatology Life Quality Index (DLQI): there was a significant reduction in the mean DLQI ($p=0.019$) of the intervention group at three months and a non-significant reduction at six months.
(Ghent)	The Psoriasis Disability Index (PDI) was reduced significantly ($p=0.015$) at three months in the intervention group compared with the controls, which persisted at six and nine months. The intervention group had significantly higher physical activity levels ($p=0.035$) than the controls throughout the entire study. There were no differences between groups in terms of stress, consumption of medical resources and cost-effectiveness at six months.
(Gradwell et al., 2002)	No change in the DLQI between groups, but improvements in both groups. The patients who visited the nurse had greater knowledge of the duration of treatment ($p=0.05$) and where to obtain more support ($p<0.001$). In the intervention group, 33% of follow-up appointments with doctors were cancelled.
"A randomized controlled trial of nurse follow-up clinics: do they help patients and do they free up consultants' time?"	
(Ersser et al. 2011)	No statistically significant differences in the baseline and follow-up PASI or DLQI scores in the intervention or control groups. Insufficient power to detect changes in scores.
"A pilot randomized controlled trial to examine the feasibility and efficacy of an educational nursing intervention to improve self-management practices in patients with mild-moderate psoriasis"	Modest reduction in PASI in the intervention group for patients with a PASI or DLQI score > 6, but not statistically significant.

3.4. Content of interventions and comparisons

The studies were categorized into two groups, depending on the focus and content of the intervention: education only and a combination of education and self-management.

Three studies [18,39,40] focused solely on education in different aspects of psoriasis, with three comparisons. Two were group-based and lasted for 2 h, whereas the other was individualized [18] and did not provide details of the duration. Comparisons were made between an educational programme provided by a dermatologist alone [39], spa treatment [40] or routine treatment [18]. The contents were described as empowerment-based education [40] or a psycho-educational programme, which provided information on psoriasis and its treatment [39]. The third intervention evaluated the use of a decision board to facilitate the presentation of information on treatment options [18]. A dermatologist provided two of the educational interventions, one in co-operation with a psychologist [39], while the third study did not describe the provider [40].

Six studies focused on education and practical self-management or self-care, which included two comparisons. Five studies were compared with normal medical care [35–38,42,43] and one made a comparison with hospitalization in a dermatology ward [44]. Two were individualized sessions of 20 min [38] and 2.5 h [37], where the latter included an additional follow-up telephone call after one month. The other four were group-based interventions, which comprised weekly or twice-weekly meetings of two or 2.5 h duration for 10–24 sessions, i.e., 15-, 20- or 48-h programmes. Several focused on improving the quality of life [35–37,42,43] and reducing the disease severity [35–37,42]. One was aimed specifically at increasing self-management skills [37], whereas the others focused on changing coping strategies [35,36,43,44], illness perception [35,36] or offered practical demonstrations of treatment applications [38]. Some interventions included stress reduction techniques [35,36,43] and one study (two publications) used a cognitive behavioural therapy programme [35,36]. One study provided weekly physical training, as well as yoga and mindfulness meditation [42], while two interventions included homework, using self-management tools as individualized goals [35,36], and relaxation exercises [36,43]. With respect to the health professionals who provided the interventions, two studies were nurse-led [37,38], one was led by a fellow patient and a physician [43] and three studies were multidisciplinary [35,42,44].

Three of the studies presented theory to support the components of the intervention [36,37,18] (Table 2). Most self-management and educational programmes for people with chronic diseases tend to be based on what health-care professionals consider to be important educational topics and self-management requirements for patients. Thus, only one of the nine studies reported a structured intervention based on feedback from psoriasis patients. This study, which was conducted by Ersser et al. [37], based their intervention on the findings of earlier focus group interviews [45], where participants identified key factors that might enhance their poor self-management capacities.

3.5. Outcomes

Several outcomes were used in the studies (see Table 2), although it was surprising that six studies did not define what they regarded as primary and secondary outcome measures. The follow-up time varied. Of the studies focused on patient education, one conducted phone interviews after six months to determine whether the patients had retained the knowledge that was imparted [39], whereas the others performed evaluations before and after the intervention [18,40]. In the studies that focused on both patient education and self-management, the follow-up time varied from six weeks [37,38] to three [43], six [35,36], nine [42] or 12 months [44].

3.5.1. Disease severity

Disease severity was included as an outcome in eight of the studies. The Psoriasis Area and Severity Index (PASI) was used in three studies, being defined as the primary outcome in one study [42], as a secondary outcome in another [37] and as one measure among many outcomes in the third [35,36]. One study used the Self-administered PASI (SAPASI) and another used a visual analogue scale of itching [39]. The study-specific assessments of disease severity used in the other three studies appeared to be simple, with coarse classifications and a lack of validation [18,43,44].

Fig. 1. Flowchart showing the inclusion procedure.

Fig. 2. Risk of bias summary: review of the authors' judgements of the risk of bias for each item included in each study.

outcome in one of these three studies [42], and it was also used in three other studies [35,39,40]. One study used Skindex 17 [40] and another also used EQ-5D [42]. Two studies (three publications) [35,36,42] used the 15-item psoriasis-specific Psoriasis Disability Index (PDI) questionnaire, which is a commonly used measure of the impact of psoriasis [46].

3.5.3. Knowledge

Four studies included knowledge as an outcome, although the studies did not use the same questionnaire to measure the impact of the intervention on knowledge of psoriasis. Three studies employed study-specific questionnaires [18,38,39] and one study described knowledge based on an assessment made by a nurse using a functional history record after interviewing the patient [44]. Only one study provided details of the actual questions or statements presented to the patients [39].
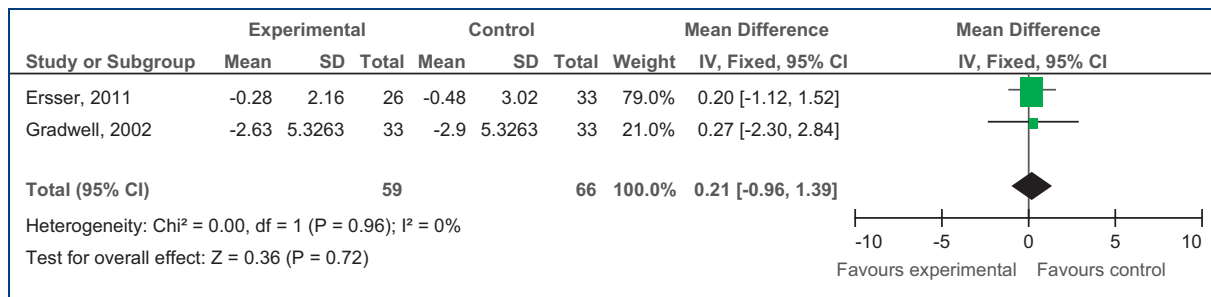
3.5.2. Quality of life

Six studies measured the quality of life. The Dermatology Life Quality Index (DLQI) was defined as a primary outcome in three studies [37,38,42]. Skindex 29 was also defined as a primary

Study or Subgroup	Experimental			Control			Weight	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Ersser, 2011	-0.28	2.16	26	-0.48	3.02	33	79.0%	0.20 [-1.12, 1.52]	
Gradwell, 2002	-2.63	5.3263	33	-2.9	5.3263	33	21.0%	0.27 [-2.30, 2.84]	
Total (95% CI)			59			66	100.0%	0.21 [-0.96, 1.39]	
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.96); I² = 0%									
Test for overall effect: Z = 0.36 (P = 0.72)									

Fig. 3. Forest plot of the Dermatology Life Quality Index scores for education and self-management interventions.

3.5.4. Illness perception and coping

Four studies considered coping and two addressed illness perception. The study with two publications used the COPE Inventory and the Illness Perception Questionnaire (IPQ) [35,36]. In another study, nurses assessed coping based on the functional histories of patients [44], while two studies used self-prepared questionnaires that contained questions related to coping [39,44]. The study-specific questionnaires also aimed at measuring related topics such as illness behaviour [43], empowerment [40], patient satisfaction [18] and decision making [18].

3.5.5. Psychological status/stress

Three studies measured the effects of the educational interventions on the psychological status of patients. The outcomes used were the Hospital Anxiety and Depression Scale (HADS) [35,36,42], the Everyday Problem Checklist [42], the Beck Depression Inventory (BDI) [42] and the Toronto Alexithymia scale (TAS-20) [35,36].

3.5.6. Lifestyle and health-care consumption

Bostoen et al. [42] was the only study that considered lifestyle changes as outcome measures. This study queried participants at monthly intervals to determine changes in their smoking behaviour and the quantity and intensity of physical activity. They also measured the use of medical treatments including topical and systemic therapies, as well as assessing the costs of medication and doctor visits. In addition, Gradwell et al. [38] assessed the number of consultations with secondary and primary care during a six-week follow-up period.

3.6. Quality assessment

We assessed Risk of bias (ROB) using the six-item quality appraisal list recommended by the Cochrane Handbook [34]. This included evaluations of the procedures used for generating random sequences, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other potential sources of bias. Each entry was rated as either 'low risk of bias', 'high risk of bias' or 'unclear risk of bias'. Full agreement on all criteria was reached in a consensus meeting. The conclusions were checked by a third assessor and the ROB scores for one study were upgraded. We assessed studies as having a high risk of detection bias when they used PASI as the outcome measure without addressing the blinding of personnel. We also rated studies as high risk when the outcome assessment involved interviewing participants without addressing the blinding of group allocations. Outcome assessments based only on questionnaires were rated as having a low ROB, even when insufficient information about blinding was included in the article.

The three studies that focused on educational interventions were generally rated as very low in terms of methodological

quality. Only the study by Lora et al. [39] had a 'low risk of bias' for the item 'random sequence allocation' (see Fig. 2).

Three of the studies that focused on both self-management and educational interventions had low ROB scores for the item 'random sequence allocation'. The two studies that used patient preference randomization had lower ROB scores [35,36], which was also the case for the older studies because of incomplete reporting and their low methodological quality. Incomplete outcome data were methodological flaws in all but one of the studies [42]. The drop-out rates were generally quite high, with several above 20% [36,42,44], and intention-to-treat analyses were only conducted in two trials [35,36,38]. Thus, four trials had low ROB scores for the item 'random sequence allocation' and were considered eligible for the effect analyses (see Fig. 2).

3.7. Reported effects of interventions

Given the poor methodological quality of the three studies that focused on patient education, there is very little evidence of the effects of educational interventions in psoriasis patients. The study of Lora et al. [39] compared two different types of educational interventions, so the absolute effect of patient education could not be evaluated. There were no statistically significant differences between the two programmes, but there was a between-group preference for the programme conducted by the dermatologist and psychologist together according to two questions related to systematic therapies (Table 3).

Only three of the six studies that focused on a combination of educational and self-management interventions were considered to be of sufficient methodological quality [37,38,42] to reach any conclusions regarding their effects. In the most comprehensive intervention, which was conducted by Bostoen et al. [42], the intervention group had a significantly different mean PASI compared with the control group at three ($p = 0.036$) and six months ($p = 0.017$), but not at nine months. There was a significant difference in the DLQI score at three months ($p = 0.019$), but not at the six- and nine-month follow-ups. This was the only study that measured the quality of life based on multiple outcomes, while it also used PDI, EQ-5D and Skindex 29. There was a significantly higher reduction in the PDI score in the intervention group compared with the controls at three ($p = 0.015$), six ($p = 0.020$) and nine months ($p = 0.021$), but no significant differences in the Skindex scores. The severity of depression was measured using the BDI and the scores were significantly better for the intervention group on all three follow-up dates ($p < 0.05$). There were no between-group differences in the stress levels, but the intervention group had higher physical activity levels throughout the nine-month intervention period ($p = 0.035$). The smoking behaviour also changed in the intervention group, whereas there were no changes in smoking behaviour in the control group. There were no significant differences in the medical treatments received and no differences in the EQ-5D values.

The two less extensive interventions reported a lack of difference between groups in terms of the primary outcome effects. The pilot study conducted by Ersser et al. [37] lacked sufficient power to detect clinically relevant differences in the PASI and DLQI.

Gradwell et al. [38] reported that there was no difference in the DLQI between groups, although both groups had improved quality of life (DLQI) by approximately three points after six weeks. However, the group followed up by nurses had greater knowledge of some areas, such as the duration of treatment ($p = 0.005$), how to obtain a repeat prescription ($p = 0.01$) and where to obtain additional support ($p < 0.001$). In the intervention group, 33% of the follow-up appointments with doctors were cancelled, whereas no follow-up consultations were cancelled in the normal care group.

Thus, the pooled result of the two less extensive interventions conducted by Gradwell et al. [38] and Ersser et al. [37], which compared education and self-management education with standard care, reported no significant differences in the DLQI (Fig. 3).

4. Discussion and conclusion

4.1. Discussion

This systematic review aimed to describe the contents of patient education and self-management interventions provided to patients with psoriasis, and to evaluate their effects. Unfortunately, we did not reach any strong conclusions because of weaknesses in the methodological quality and the small effect sizes in several studies [18,37–39]. Most of the studies included were not of high quality and many suffered from major methodological flaws [18,35,36,40,43,44]. Some of the studies included would have benefited from clearer reporting of the trial procedures [39,40,44]. Different measures were used to evaluate the effectiveness of the interventions and some studies lacked rigorous established outcome measures [18,39,43,44]. Overall, these studies indicate that there is insufficient evidence to identify the best approach. Of course, single and double blinding is challenging in these types of interventions, where the participants and/or staff would have to be unaware of the intervention. However, it may be possible to ensure the blind allocation of participants to treatment groups and at least to ensure the blinding of a clinical outcome assessment, such as PASI.

The main objectives of the interventions were related to the effects on disease severity [35–37,42], knowledge [18,38,39,44] and quality of life [37–40,42], as well as different aspects of the psychological impacts of psoriasis. PASI was the only objective measure reported, which suggests that there are limited options for measuring the objective effects of educational interventions in psoriasis. Bostoen et al. [42] reported a significant change in the PASI score, whereas Ersser et al. [37] found no significant changes. The PASI scores were very low at baseline in these studies, which suggests that mild disease activity appears to be important because a small group with moderate severity (PASI > 6) experienced a stronger effect on the PASI score, although it was not significant. This lack of effect may be attributable to the PASI score's lack of sensitivity to body surface area changes of less than 10% [5].

The different assessment tools used to measure psoriasis knowledge made it difficult to compare the studies. Most of the instruments were developed by the investigators themselves [18,38,39,44] and validity assessments were only provided in one study [18]. There is still a gap in our knowledge of the educational needs of psoriasis patients, and there seems to be a need for new validated measurements to assess knowledge based on more objective measures. The fluctuation of disease severity, together with the new co morbidity consequences seems likely to enhance patients' needs for tailored knowledge as a necessary precondition to become empowered self-managers.

Several studies focused on the psychological impacts of psoriasis interventions [35,36,42,43]. Three studies taught relaxation and stress reduction techniques [35,36,42,43], and the most recent study had a practical component based on yoga and mindfulness [42]. Most patients report that stress is the main trigger that exacerbates the onset of psoriasis [47,48], so it seems to be important to offer methods that help patients to reduce stress, thereby giving them some degree of symptom control.

There appeared to be a significant lack of focus on lifestyle and behaviour changes such as exercise, diet or smoking in the studies, with the exception of the study conducted by Bostoen et al. [42]. This may reflect how these aspects have recently become more significant from the perspectives of co-morbidity and self-management in relation to psoriasis.

The studies were conducted over a period of 32 years, during which time the treatment options, educational content and modes of teaching have probably changed considerably. In recent years, self-management support and behavioural change have become increasingly important issues in the treatment of chronic disease, so it is slightly surprising that no interventions focused solely on self-management in this review. Self-efficacy, which was used as a main outcome by most of the studies included in a systematic review of self-management outcomes by Du and Yuan [32], was completely lacking in the studies of psoriasis we reviewed. The core skills of self-management, such as strengthening self-efficacy, goal setting, action planning and problem solving were discussed little in these studies. Only two of the studies aimed to improve education by targeting changes in the dissemination methods used by health workers [18,36]. In other chronic conditions such as asthma [49], COPD [50,51] arthritis [52] and type 2 diabetes [53,54] self-management focus seems more apparent and self-management programmes have proven to be effective.

Although there were some variations, the patients included in these studies were surprisingly similar. In general, they were aged above 40, had a mild to medium disease severity and a long history of living with psoriasis. The debut of psoriasis has two peaks: one at the age of 16–22 years and a second at the age of 57–60 years [55]. Psoriasis often follows an irregular course in early-onset patients, in whom it tends to become more severe and extensive with greater psychosocial impacts [56]. The elderly onset group have milder disease courses and a lower likelihood of a family history [57]. This may mean that the different life phases require different educational interventions because younger patients are more vulnerable to co-morbidity risks and cumulative life course impairment. The biopsychosocial consequences of psoriasis include the cumulative life-long effects of physical and psychological co-morbidities, stigma and economic and social consequences, which may prevent some patients from fulfilling their full life potential [58]. Thus, the provision of self-management support and education during the early phase of the disease may have a preventative effect in this group as concluded in a recent integrative review [59]. By comprising seven qualitiative and 12 quantitative papers this review aimed to identify psoriasis patients need for education to support self-management in daily life. They concluded that onset time, illness perception and how the visibility influences on the psychological and social burden of the disease all were important factors to consider, when designing educational programmes for psoriasis patients.

None of the educational interventions included in this review addressed these topics or described the tailoring of these types of interventions.

The requisite durations of the interventions were also unclear in this review. A review by de Bes et al. [33] of educational programmes provided to patients with chronic skin diseases showed that the provision of intensive interventions for a long period of time (>3 months) was the most successful approach. Coster and Norman [31] analyzed Cochrane reviews of educational and self-management interventions, which showed that more intensive interventions for longer time periods (>3 months) were generally more successful. This also seemed to apply to the studies in the present review, although the heterogeneity and the lack of an additional meta-analysis mean that this conclusion is limited. Thus, a more comprehensive course seems appropriate and necessary if the intervention has a more holistic objective and a behavioural change is desirable. However, the drop-out rates in some of these trials suggest that patients did not want to attend scheduled sessions for an extended period [35,36,43].

4.2. Conclusions

The conclusions of this review are limited. Any suggestions that educational and self-management interventions have the potential to change the illness severity in psoriasis, increase knowledge and improve the quality of life were contaminated by methodological shortcomings and poor reporting. There was a significant lack of self-management focus and, compared with other chronic conditions, there appear to be few effective disease-specific tailored educational psoriasis programmes. Psoriasis treatment also appears to lack guidelines, and there is no clear understanding of the concepts and educational content that characterize an effective approach. The most recent study by Bostoen et al. [42] was characterized by its improved design, execution and more holistic focus, but the challenge is to expand further upon this knowledge to develop effective interventions in the short and long term.

4.3. Further research

Evidently, it will be necessary to conduct more large, multi-centre, multidisciplinary RCTs with long follow-up periods, sufficient sample sizes and validated outcome measures, which should focus on self-management and lifestyle changes, before further conclusions can be reached. Cost-effectiveness analyses should also be performed in future RCTs. The Consolidated Standards of Reporting Trials (CONSORT) checklist should be used for non-pharmacological treatments, which would facilitate transparent reporting, assessments of validity, and evaluations of the effects as measured outcomes. An extended follow-up period will probably be necessary if the objective is behavioural change and increased adherence to treatments and lifestyle patterns. The durations of interventions should be adjusted so they are not overly time-consuming, which may motivate patients to attend and complete the programmes. Convenient follow-ups via telephone or email may prevent drop-outs, as well as providing efficient self-management support.

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A telephone-based motivational interviewing intervention has positive effects on psoriasis severity and self-management: a randomized controlled trial

M.H. Larsen,[1,2] A.L. Krogstad,[2,3] E. Aas,[4] T. Moum[5] and A.K. Wahl[1]

[1]Department of Health Sciences and [4]The Department of Health Management and Health Economics, Institute of Health and Society, The Medical Faculty, University of Oslo, P.O. Box 1089 Blindern, N-0317 Oslo, Norway

[2]Section for Climate Therapy and [3]The Department of Dermatology, Oslo University Hospital, Oslo, Norway

[5]Department of Behavioural Sciences in Medicine, The Medical Faculty, University of Oslo, Oslo, Norway

Summary

Background Psoriasis is a common skin disease with extensive comorbidity risks, which may affect multiple aspects of life. Self-management is essential for skin treatment and lifestyle choices, but few disease-specific tailored self-management and educational programmes appear to be available.

Objectives To evaluate the effects of a 3-month individual motivational interviewing intervention in patients with psoriasis (with a total follow-up of 6 months) after climate therapy/heliotherapy (CHT).

Methods A randomized controlled trial with 169 patients with psoriasis was conducted in the context of CHT at Gran Canaria, Spain. The main outcome measures were Self-Administered Psoriasis Area and Severity Index (SAPASI) and Health Education Impact Questionnaire (heiQ), and the secondary outcomes were illness perception, psoriasis knowledge and lifestyle change assessments. Outcomes were measured at baseline, after 3 weeks of CHT, and 3 months and 6 months later.

Results There were significant overall treatment effects in the study group in terms of the SAPASI score, three self-management domains of heiQ and the self-efficacy scores ($P < 0.05$). The lifestyle change parameters were significantly better in the study group. Illness perception differed between the groups at 3 months ($P = 0.014$), and psoriasis knowledge was significantly better in the study group at 6 months ($P = 0.017$).

Conclusions A 3-month motivational interviewing intervention following CHT had positive overall effects on disease severity, self-efficacy, psoriasis knowledge and health behaviour change. This approach has the potential to be an important complement to medical management, self-management and education in patients with psoriasis.

What's already known about this topic?

- Psoriasis requires extensive self-management with respect to skin treatment and lifestyle choices.
- Motivational interviewing is a form of patient-centred counselling that aims to facilitate change and increase self-efficacy.

What does this study add?

- The first evaluation of motivational interviewing in patients with psoriasis.
- Motivational interviewing could be an important self-management support method in psoriasis, leading to reduced disease severity, increased self-efficacy and psoriasis knowledge, and better lifestyle patterns.

Living with psoriasis may be a challenge for individuals, not only in terms of physical and mental ailments, but also in terms of satisfaction with life.[1–3] Treatments are often time consuming,[4] and patients report limited effects,[5] while the nonadherence rates are high.[6,7] Recent studies show that patients with psoriasis have an increased risk of lifestyle-related concurrent disorders, including hypertension, obesity, diabetes and cardiovascular disease.[8,9] A certain level of knowledge and technical skills related to psoriasis may be required to become an effective and proactive self-manager. However, core skills in self-management education and support also appear to be essential for achieving sustained health-related behavioural change and making choices that improve psoriasis-related outcomes.[10,11]

The aim of self-management support for patients is to enhance problem-solving skills, action planning and self-efficacy.[12,13] However, core self-management skills have received little attention in previous psoriasis research.[14,15] There is a lack of well-designed studies, and methodological weaknesses are apparent.[15]

Motivational interviewing (MI) is a self-management support method.[16] MI is a well-known, scientifically tested[17–20] collaborative communication method for strengthening a person's own motivation and commitment for behaviour change[21] and treatment adherence.[22,23] MI hypothesizes that persons considering behaviour change always experience ambivalence related to the pros and cons of change.[21] The conversation style seeks to evoke the client's own motivation for change, develop commitment to change, and eventually verbalize concrete plans for behaviour change. Affirmations, reflections, summarizing and open-ended questions are all approaches that can empower patients to make desirable health-related changes.[21]

MI has been applied to various health problems and settings,[24–26] including chronic diseases that demand daily treatment decisions by patients, such as chronic obstructive pulmonary disease and diabetes.[27–29] However, to the best of our knowledge, MI has never been tested in patients with psoriasis. A recent systematic review[24] concluded that MI appears to be useful in various clinical settings, and that only one MI session may be effective in enhancing readiness to change and action directed towards reaching health behaviour change goals.

Climate therapy/heliotherapy (CHT) is one of the therapeutic options available to Norwegian patients with moderate-to-severe psoriasis. A 3-week multidisciplinary programme is provided in the Canary Islands (located in the Atlantic Ocean at 28°N, 16°W), which includes tailored sunlight ultraviolet (UV)B radiation,[30] physical exercise, group discussions and comprehensive education (Table 1).

Previous studies have reported that CHT has positive effects on disease severity,[31–34] mental health,[35] level of knowledge[36] and health-related quality of life.[31,32] However, most of these positive changes last for only 2–3 months.[31,32] There are no previous reports about whether this effect might be negatively influenced by low treatment adherence, unhealthy lifestyle choices or lack of follow-up after CHT. However, tailored patient education and self-management interventions appear to be important for successful psoriasis treatment because they can enhance treatment behaviour and lifestyle choices, as well as prolonging the positive effects on clinical outcomes.[37–39]

Thus, we developed a telephone-based individualized self-management support programme, which comprised an extended follow-up with tailored MI following CHT treatment. The focus of the programme was daily psoriasis treatment and desirable behavioural change. Our hypothesis was

Table 1 Aims and content of the 3-week climate therapy/heliotherapy programme in Gran Canaria

Aim
Reduce disease severity
Increase knowledge and insight about the disease, treatment and symptom management
Increase awareness about how to reduce deteriorating risk factors such as smoking, stress and overweight
Discuss recent knowledge about psoriasis comorbidity, how to reduce risk profiles and motivate positive lifestyle changes

Content
Examination by the dermatologist and nurse at three time points (on arrival, after 1 week and after 3 weeks) and follow-ups when needed
A combination of tailored sun treatment (on average 250 standard erythemal doses)[30] and salt-water bathing. Exposure according to skin type and current ultraviolet index
Physical activities: morning 'workout' and voluntary participation in other physical activities such as water aerobics, walking/running, swimming, muscular training and relaxation techniques
Interactive educational sessions conducted by a dermatologist, nurses and physiotherapist about psoriasis pathogenesis, manifestations, comorbidity, quality of life and treatment options and the importance of a healthy lifestyle focusing on physical activity, stress reduction and healthy eating. Educational sessions: creams and ointments (2 h), sun treatment (1 h), nutrition (2 h), physical activity (1 h), education about psoriasis (2 h), comorbidity related to the disease (1 h), medical treatment (2 h) and research (1 h)
Group meetings (eight to 12 participants) focused on experiences of living with psoriasis, coping with stress, nutrition in daily life and self-management (1–3 h)
Smoking cessation course (4–6 h)
Interaction with others with similar health challenges in formal and informal settings

that this intervention would provide significant clinical benefits, enhance disease knowledge and improve self-management in patients with psoriasis.

Patients and methods

Study design and participants

The present study was a randomized controlled trial that included 169 Norwegian patients with psoriasis who received CHT in Gran Canaria, Spain. The sample was recruited between September 2011 and June 2012, and data collection was completed in December 2012. The inclusion and exclusion criteria are shown in Table 2. The participants signed an informed consent form and were informed according to the Declaration of Helsinki.[40] The study was approved by the research director and by the Centre for Privacy and Information Security at Oslo University Hospital. The study was recommended by the Regional Committee for Medical Research Ethics for Southern Norway (ID 2011/1019) and registered on ClinicalTrials.gov (NCT01352780).

CHT nurses invited eligible patients to participate when they arrived. Overall 113 of the 291 invited patients (38·8%) decided not to participate for unknown reasons. In total, 178 patients were recruited to the trial. Of these, 169 completed both T1 and T2 questionnaires (before CHT and after 3 weeks of CHT) and were then allocated randomly to the control (83 patients) or intervention (86 patients) group. The nine patients not reaching randomization reported different reasons for abandoning the study (Fig. 1) The patients were assessed at four time points: before the start of CHT (T1), after 3 weeks of CHT (T2), 3 months after CHT (T3) and 6 months after CHT (T4). After 3 and 6 months, questionnaires were sent by mail with a stamped, addressed return envelope. One reminder was sent to participants each time to request missing questionnaires. Data were obtained for T1 (169 participants), T2 (169), T3 (135, 80%) and T4 (125, 74%). Significantly more of the dropouts were male, younger and unmarried. The participant flow throughout the trial is shown in Figure 1.

Sample size

The sample sizes were calculated based on the primary outcome (Health Education Impact Questionnaire, heiQ) and determined by a power calculation. Medium effect sizes

(Cohen's criteria,[41] which differed between overall groups by half an SD, $d = 0.5$) were obtained using a test strength of 80 (β) and a significance level of 5% (α) when 64 participants were included in each group. Thus, a sample of 169 was more than sufficient.

Randomization

The participants were assigned randomly (1 : 1) to normal care in Norway or normal care with the additional MI intervention. This procedure involved the use of sequentially numbered, sealed, opaque envelopes to ensure adequate allocation concealment. The envelopes were stored in a locked cabinet. The study nurse at the CHT centre opened the next consecutively numbered envelope in the presence of the participant after they completed the second questionnaire (T2). Randomly permuted small blocks were used to ensure equal-sized treatment groups while eliminating deciphering. The person who generated the allocation scheme did not allocate the patients to the two groups and was not part of the research team. Blinding of patients and the MI counsellor was not possible in this type of study. However, all of the outcomes were self-reported questionnaires and the data plotters were blinded to the group allocations.

Motivational interviewing intervention

The intervention comprised one motivational mapping session (45–60 min) with the MI nurse counsellor just before returning home, followed by six follow-up telephone calls during the next 12 weeks. The main author (M.H.L.), who was formally educated in MI counselling, conducted these mapping talks, as well as the telephone calls with participants. The motivational calls lasted 15–60 min. The mean conversation time was 32.5 ± 12.7 min and each participant received an average of 3.3 ± 1.3 h of phone counselling.

An important aspect of the mapping session was to develop a collaborative relationship between the counsellor and the participant, this being their first encounter. The counsellor encouraged participants to tell how psoriasis affected their everyday life (colouring exercise) and share their thoughts regarding lifestyle choices related to psoriasis. By letting patients 'tell their stories' and describe their own motivation and potential thoughts on change, the patient-centred approach of MI was ensured.[21,42] Skin and skin treatment was presented as a mandatory topic in each follow-up call.

Table 2 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age 20–70 years (born 1 January 1941 to 31 December 1991)	Participated in CHT more than eight times during the last 10 years (excluding the current stay)
Diagnosed with psoriasis with PASI > 7·0 when applying CHT	
Capable of answering questionnaires and communicating by telephone	

PASI, Psoriasis Area and Severity Index; CHT, climate therapy/heliotherapy.
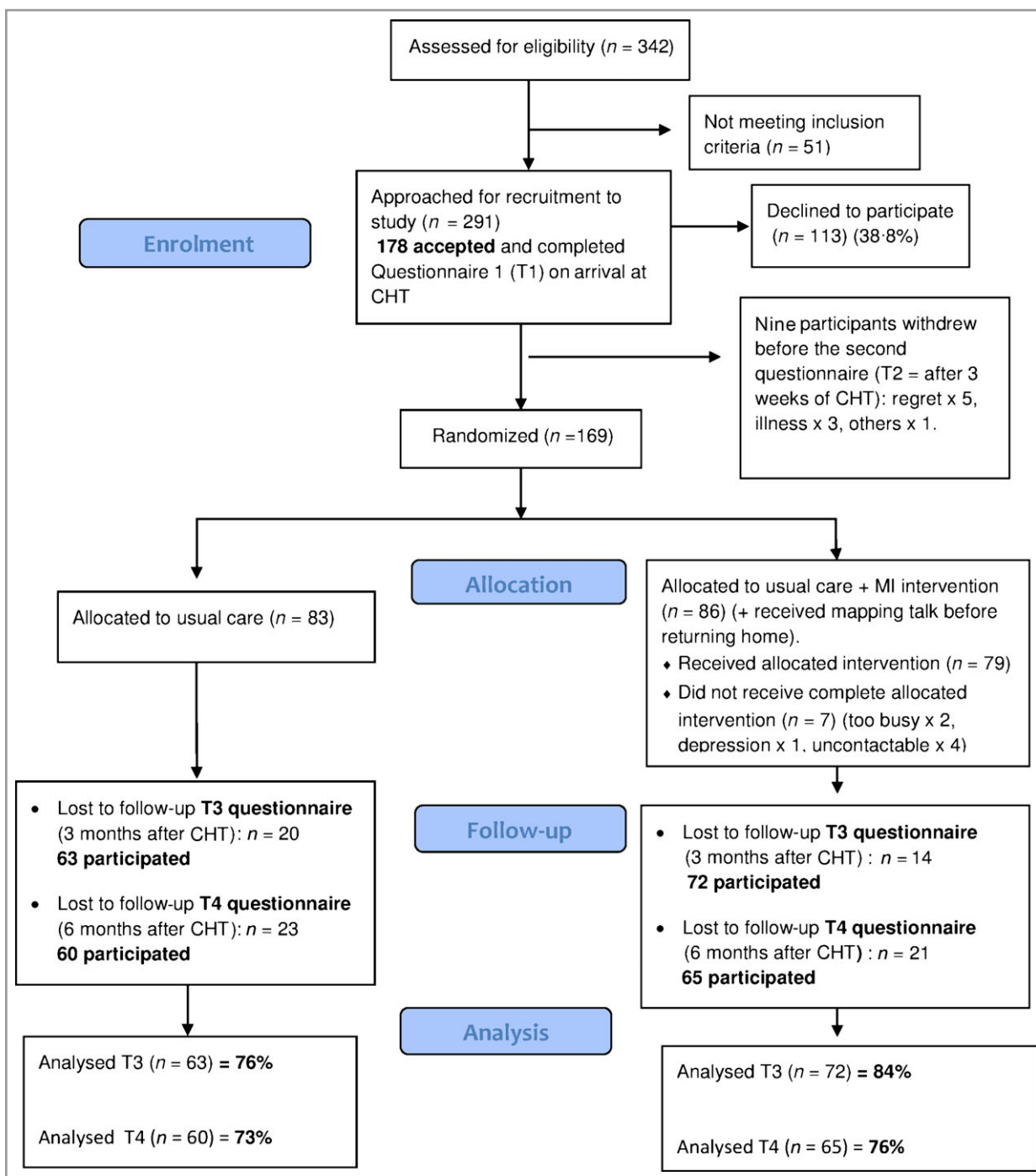
Fig 1. Flowchart of the inclusion procedure. CHT, climate therapy/heliotherapy; MI, motivational interviewing.

Additional key areas for the follow-up calls were presented on a 'bubble sheet' (Figure S1; see Supporting Information), representing three psoriasis-tailored self-management domains: diet, physical activity and stress management. The agenda mapping was introduced as, 'These are some of the subjects which we could talk about. Would you like to talk about any of these, or do you have something else (pointing to the blank spaces) you would prefer to talk about?'[21] The patient's own focuses varied from behavioural topics such as smoking

cessation, weight reduction or alcohol abuse to domains of life causing stress or concern, such as demanding work situations, personality traits or traumatic life events.

Prochaska and Di Clemente's transtheoretical model of change (TTM)[43,44] was briefly described and, if applicable, participants assessed their current stage of change related to their desired topic. The stages are precontemplation (not intending to change soon), contemplation (change is being considered but not definitely planned), preparation (behaviour

change is imminent), action (behaviour change is occurring) and maintenance (behaviour change has been consolidated). By identifying where a person is in the change cycle, the MI communication can be tailored to the individual's readiness to progress in the change process.[43] Relevant MI tools were shared, and behavioural focus and the time for the first follow-up call were agreed upon.

Additionally, participants were provided with a personal workbook, which they used to varying degrees, depending on the patient's focus and preference. The workbook outlined some key MI principles and presented a figure and a brief description of the TTM. In addition it contained the 'bubble sheet', some open questions for reflections and some visual MI tools and exercises. Some of these were dependent on specific phases of change and were therefore not applicable to all participants.

A pilot study that included six patients was conducted in June 2011 to evaluate the workbook and to obtain feedback on the relevance of the topics and patient experiences of MI counselling.

Motivational Interviewing Treatment Integrity code

The behaviours of the counsellor during the motivational interventions were compared with the MI proficiency levels.[45] A random sample of calls was recorded, a selection of which were evaluated and rated by the Motivational Interviewing Coding Laboratory at The Karolinska Institute in Sweden (www.miclab.org) using Motivational Interviewing Treatment Integrity (MITI) code 3.0.[39] Table 3 shows that the counsellor exceeded all of the threshold criteria, including global empathy and MI spirit levels, reflection to question ratios, proportion of complex reflections to total reflections, percentage of open-ended questions and percentage MI adherence.

Standard care

The participants in the control and study groups received their usual psoriasis treatment, which could include consultations with a dermatologist or general practitioner, UV radiation treatment and/or self-management in terms of topical treatment, exercise and stress management. However, it is known that there is considerable variation among patients with psoriasis in healthcare uptake and the administration of their own treatment.[4,46]

Measures

The sociodemographic characteristics recorded at baseline included age, sex, marital status and years of education (Table 4). The clinical parameters were collected from the CHT medical records at Oslo University Hospital. Medical comorbidity was measured using the Self-Administered Comorbidity Questionnaire-18,[47] where higher scores indicate a more severe comorbidity profile.

Primary outcomes

The primary outcomes in this trial were disease activity measured by the Self-Administered Psoriasis Area and Severity Index (SAPASI) and self-management measured using the heiQ. The heiQ facilitates comprehensive evaluations of patient education and self-management interventions for people with chronic conditions.[48] The questionnaire comprises 40 items from eight independent domains, which cover areas such as behaviours, skills, attitudes, self-monitoring, health service navigation and emotional well-being (Cronbach's α for the heiQ domains ranged from 0·65 to 0·89).

Table 3 Behaviour of the nurse counsellor in the current study compared with established thresholds for proficiency

MITI 3.1.1 indicator of proficiency	Recommended proficiency threshold[a]	Current study average (n = 8)	Current study range
Global scores (1–5, high = good)			
Global empathy	≥ 4·0	5	5–5
Global MI spirit	≥ 3·5	4·47	4·0–4·67
Global direction (focus on target behaviour)	–	5	5–5
Summary of behaviour counts			
Reflection to question ratio (R:Q) = (SR + CR)/(CQ + OQ)	1 : 1	3·60 : 1	1·60 : 1 to 5·56 : 1
Open-ended questions = OQ/(OQ + CQ)	≥ 50%	58%	50–70%
Complex reflections = CR/(SR + CR)	≥ 40%	56%	46–77%
MI adherence = MiA/(MiA + MiNa)	≥ 90%	93%	87·5–100%

MITI, Motivational Interviewing Treatment Integrity; Global MI spirit, (average of evocation + collaboration + autonomy/support)/3; SR, simple reflection; CR, complex reflections; CQ, closed questions; OQ, open questions; MiA, MI adherent; MiNa, MI nonadherent. [a]According to Forsberg *et al.*[57]

Table 4 Baseline characteristics of participants allocated to the motivational interviewing counselling intervention (study group) or treatment as usual (control group)

Variable	Full sample (n = 169)	Study (n = 86)	Control (n = 83)	Between-group difference (95% CI), P-value
Male, n (%)	95 (56·2)	51 (59)	44 (53)	$\chi^2 = 0.68$, P = 0·41[b]
Female, n (%)	74 (43·8)	35 (41)	39 (47)	
Age (years), mean ± SD	46·31 ± 12·8	46·16 ± 12·71	46·46 ± 13·02	0·30 (−4·2, 3·6), P = 0·88[a]
Duration of disease (years), mean ± SD	22·9 ± 13·93	24·6 ± 14·29	21·2 ± 13·42	3·39 (−0·84, 7·63), P = 0·12[a]
Previous CHT, n (%)	89 (52·7)	47 (55)	42 (51)	$\chi^2 = 0.13$, P = 0·72[b]
Number of previous CHT treatments, median	2·0	2·0	2·0	z = −1·26, P = 0·21[c]
Marital status, n (%)	n = 165	n = 83	n = 82	$\chi^2 = 2.43$, P = 0·49[b]
Married/cohabiting	106 (64·2)	53 (64)	53 (65)	
Unmarried	34 (20·6)	15 (18)	19 (23)	
Divorced/separated/widowed	22 (13·3)	14 (17)	8 (10)	
Other	3 (1·8)	1 (1)	2 (2)	
Level of education, n (%)	n = 161	n = 81	n = 80	$\chi^2 = 0.98$, P = 0·41[b]
Primary/secondary school ≤ 10 years	22 (13·7)	13 (16)	9 (11)	
High school ≤ 13 years	74 (46·0)	37 (46)	37 (46)	
College/university < 4 years	30 (18·6)	15 (19)	15 (19)	
College/university ≥ 4 years	35 (21·7)	16 (20)	19 (24)	
BMI, mean ± SD	n = 168; 28·78 ± 5·51	n = 86; 29·07 ± 4·89	n = 82; 28·48 ± 5·54	0·47 (−1·00, 2·18), P = 0·47[a]
Current smoker on arrival, n (%)	n = 168	n = 85	n = 83	$\chi^2 = 0.19$, P = 0·66[b]
Yes	56 (33·3)	27 (32)	29 (35)	
No	112 (66·7)	58 (68)	54 (65)	
Comorbidity profile (SCQ-18) (range 0–54), median	n = 169; 4·0	n = 86; 4·0	n = 83; 3·0	z = −1·74, P = 0·082[c]
Health condition (VAS 0–100), mean ± SD	n = 166; 65·15 ± 17·24	n = 85; 63·24 ± 17·14	n = 81; 67·16 ± 17·2	−3·93 (−9·19, 1·34), P = 0·14[a]
Self-assessed health status [1 (poor) to 5 excellent)], mean ± SD	2·90 ± 0·92	2·70 ± 0·90	3·10 ± 0·89	−0·40 (−0·67, −0·12), P = 0·005[a]
SAPASI on arrival at CHT, mean ± SD	n = 166; 8·59 ± 5·06	n = 84; 8·38 ± 5·11	n = 82; 8·81 ± 5·05	−0·43 (−1·98, 1·13), P = 0·59[a]
SAPASI on departure from CHT, mean ± SD	1·84 ± 2·85	1·77 ± 2·53	1·91 ± 3·15	−0·14 (−1·01, 0·73), P = 0·75[a]
PASI on arrival at CHT, mean ± SD	8·6 ± 5·1	7·8 ± 4·78	8·4 ± 4·04	−0·63 (−1·98, 0·72), P = 0·36[a]
PASI on departure from CHT, mean ± SD	2·1 ± 1·86	1·9 ± 1·85	2·3 ± 1·87	−0·38 (−0·94, 0·19), P = 0·19[a]
DLQI on arrival at CHT (range 0–30, low = good), mean ± SD	n = 163; 11·2 ± 5·89	n = 82; 11·3 ± 5·71	n = 81; 11·0 ± 6·1	0·34 (−1·49, 2·17), P = 0·71[a]

n differs among individual analyses because of missing values. BIPQ, Brief Illness Perception Questionnaire; BMI, body mass index; CHT, climate therapy/heliotherapy; CI, confidence interval; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; SAPASI, Self-Administered PASI; SCQ-18, Self-administered Comorbidity Questionnaire; VAS, visual analogue scale. Difference between groups: [a]independent-samples t-test of means; [b]Pearson's χ^2-test of proportions; [c]Mann–Whitney U-test of medians.

Secondary outcomes

The Psoriasis Knowledge Questionnaire (PKQ)[36] assesses psoriasis knowledge based on 49 statements about psoriasis. The responses are reported as valid, uncertain or invalid, and the total calculated score range is 0–49, where higher scores indicate higher levels of knowledge (Cronbach's α = 0·87).

The Brief Illness Perception Questionnaire (BIPQ) comprises eight items, each of which assesses one dimension of illness perception. The overall mean summed score for BIPQ was computed as proposed on the BIPQ website (http://www.uib.no/ipq/index.html), where the summed score (range 0–80) represents the degree to which the illness is perceived as threatening (high score) or benign (Cronbach's α = 0·70).

Other assessments

Participants completed visual analogue scale ratings on perceived self-efficacy with respect to desired lifestyle change (Figure S2; see Supporting Information). The stages of change (precontemplation, contemplation, preparation, action and maintenance) described in the 'transtheoretical model of health behaviour change' reported by Prochaska and De Clemente[43] were assessed in the study using questions adapted to lifestyle and psoriasis. These questions had response alternatives according to the different stages: for example the question, 'Do you exercise?' had responses such as 'Currently I do not exercise and I have no plans to start exercising' (precontemplation) or 'Currently I do not exercise, but I have specific plans to begin within the next month' (preparation).

Analyses

SPSS version 19 (IBM, Armonk, NY, U.S.A.) was used for data analysis. Between-group differences were analysed using *t*-tests (for parametric data) and χ^2 statistics, or Mann–Whitney U-tests for nonparametric data. Each outcome measure was estimated separately using multivariate ANOVA (SPSS), a general linear model (ANCOVA) after adjusting for the T2 values (i.e. after CHT, before randomization). For some measures, we used the baseline scores as covariates instead of T2 (as indicated in Table 5). The results are reported as marginal means and their 95% confidence intervals (CIs). Two-sided P-values < 0·05 were considered statistically significant. To assess whether the effect of the intervention might have been confounded by an uneven allocation between the intervention and control groups in terms of sex, age, educational level, health status and disease duration, ANCOVAS were performed that adjusted for the effects of these variables. However, these adjustments did not alter the effects of the grouping variable. To support the data interpretation, we also report Cohen's *d* for effect sizes, where 0·2 is considered a small effect, 0·5 is a medium effect and ≥ 0·8 is a large effect.[49]

Results

At baseline, the two groups were well matched in terms of their disease characteristics and demographics (Table 4). The only significant difference was in health status perception, where the control group rated their health status more favourably than the study group (between-group difference −0·40; 95% CI −0·67 to −0·12, P = 0·005).

Primary outcomes

The between-group difference in SAPASI at 3 months after CHT was −2·47 (95% CI −3·94 to −1·00, P = 0·001). After 6 months, the between-group difference was −2·45 (95% CI −4·33 to −0·56, P = 0·011).

The study group had significantly higher heiQ scores in two of eight domains at 3 months after CHT; these were 'skill

and technique acquisition' (differential change between groups 0·17, 95% CI 0·019–0·32; P = 0·028) and 'constructive attitudes and approaches' (0·15, 95% CI 0·004–0·29; P = 0·044). At 6 months after CHT, only the domain 'self-monitoring and insight' had significantly higher scores (0·12, 95% CI 0·019–0·22; P = 0·020).

Secondary outcomes

Knowledge

There were no significant between-group differences in psoriasis knowledge (PKQ) at 3 months after CHT (0·46, 95% CI −0·81 to 1·74; P = 0·47). However, the study group had a significantly higher score at 6 months after CHT (1·70, 95% CI 0·31–3·09; P = 0·017).

Illness perception

The study group had a significantly lower BIPQ sum score at 3 months after CHT. The between-group difference was −3·75 (95% CI −6·73 to −0·77; P = 0·014), but this difference was not significant at 6 months after CHT (−1·89, 95% CI −5·18 to 1·40; P = 0·26). The effect sizes ranged from small to medium (Table 5; Fig. 2a).

Lifestyle change

The self-efficacy scores related to desired lifestyle change were significantly higher in the study group at 3 months after CHT (0·91, 95% CI 0·33–1·50; P = 0·002) and at 6 months after CHT (0·71, 95% CI 0·096–1·33; P = 0·024). When asked whether they had planned lifestyle changes in advance, significantly more positive responses were obtained from the study group at 3 months after CHT (P = 0·001), although the difference was not significant at 6 months after CHT (P = 0·059). At 6 months after CHT, significantly more members of the study group agreed that they implemented lifestyle changes following their psoriasis diagnosis (P = 0·035) (Fig. 2b–d).

The health behaviour risk change assessment for 'daily skin treatment' showed that significantly more members of the study group changed their scores from 'risk' (precontemplation, contemplation and preparation stages) to 'no risk' (action or maintenance stages) during the intervention (P = 0·045), and this difference was still significant at 6 months after CHT (P = 0·048). Significantly more members of the study group remained in the 'no risk' group during the intervention with respect to planned lifestyle change (P = 0·06), whereas a significantly higher percentage of the controls remained in the risk group (P = 0·04) (Table 6).

Discussion

The main aim of this study was to evaluate the effect of MI as a follow-up intervention after CHT. The results demonstrated that the study group differed from the control at 6 months

Table 5 Baseline and follow-up data for the patients

Measures	MI study group, mean ± SD				Control group, mean ± SD				Differential change between groups, T2[a,b]	Differential change between groups, T3[a,c]	Differential change between groups, T4[a,c]
	T1	T2	T3	T4	T1	T2	T3	T4			
Primary outcomes											
SAPASI (higher score = greater disease severity)	8·38 ± 5·10	1·77 ± 2·53	5·15 ± 4·04	6·65 ± 4·40	8·81 ± 5·04	1·91 ± 3·15	7·57 ± 4·59	8·70 ± 6·07	−0·068, (−0·94, 0·79), $P = 0.88$, $d = -0.08$	−2·47 (−3·94, −1·00), $P = 0.001$, $d = -0.56$	−2·45 (−4·33, −0·56), $P = 0.011$, $d = -0.44$
heiQ (score 1–4, high score = good)											
Dimension 3: skill and technique acquisition (Cronbach's α = 0·77)	2·70 ± 0·51	2·96 ± 0·44	2·98 ± 0·44	2·93 ± 0·35	2·68 ± 0·54	2·97 ± 0·43	2·84 ± 0·50	2·88 ± 0·59	−0·28 (−0·14, 0·87), $P = 0.63$, $d = 0.04$	0·17 (0·019, 0·32), $P = 0.028$, $d = 0.29$	0·11 (−0·025, 0·25), $P = 0.11$, $d = 0.11$
Dimension 4: constructive attitudes and approaches (Cronbach's α = 0·77)	3·11 ± 0·47	3·25 ± 0·44	3·21 ± 0·47	3·20 ± 0·45	3·13 ± 0·55	3·26 ± 0·49	3·10 ± 0·45	3·15 ± 0·53	0·0 (−0·11, 0·11), $P = 1.0$, $d = 0.05$	0·15 (0·004, 0·29), $P = 0.044$, $d = 0.21$	0·07 (−0·080, 0·22), $P = 0.36$, $d = 0.10$
Dimension 5: self-monitoring and insight (Cronbach's α = 0·65)	2·95 ± 0·39	3·15 ± 0·42	3·19 ± 0·40	3·16 ± 0·35	2·92 ± 0·47	3·09 ± 0·36	3·06 ± 0·36	3·02 ± 0·36	0·048 (−0·046, 0·14), $P = 0.32$, $d = 0.15$	0·11 (−0·008, 0·22), $P = 0.068$, $d = 0.34$	0·12 (0·019, 0·22), $P = 0.020$, $d = 0.40$
Secondary outcomes											
Mean BIPQ sum score (range 0–80, low = good)	44·86 ± 9·29	40·63 ± 10·25	40·08 ± 10·95	40·36 ± 10·36	43·33 ± 10·42	40·31 ± 9·49	43·78 ± 9·86	42·28 ± 10·52	−0·59 (−2·90, 1·72), $P = 0.62$, $d = 0.03$	−3·75 (−6·73, −0·77), $P = 0.014$, $d = -0.36$	−1·89 (−5·18, 1·4), $P = 0.26$, $d = -0.18$
PKQ score (range 0–49, higher score = greater level of knowledge)	25·12 ± 8·11	31·62 ± 7·04	31·96 ± 7·00	32·62 ± 6·36	24·60 ± 8·1	31·95 ± 6·14	31·29 ± 6·19	30·53 ± 7·29	−0·60 (−2·05, 0·84), $P = 0.41$, $d = 0.05$	0·46 (−0·81, 1·74), $P = 0.47$, $d = 0.10$	1·70 (0·31, 3·09), $P = 0.017$, $d = 0.30$

BIPQ, Brief Illness Perception Questionaire; CHT, climate therapy/heliotherapy; heiQ, Health Education and Impact Questionnaire; MI, motivational interviewing; PKQ, Psoriasis Knowledge Questionnaire; SAPASI, Self-Administered Psoriasis Area and Severity Index. Assessments: T1, on arrival for CHT; T2, after 3 weeks of CHT, before randomization; T3, at 3 months after CHT, with MI intervention; T4, at 6 months after CHT, with MI. [a]Mean (95% confidence interval). [b]Significant differences were tested using ANCOVA, with the score at T1 as the covariate. [c]Significant differences were tested using ANCOVA, with the score at T2 as the covariate.
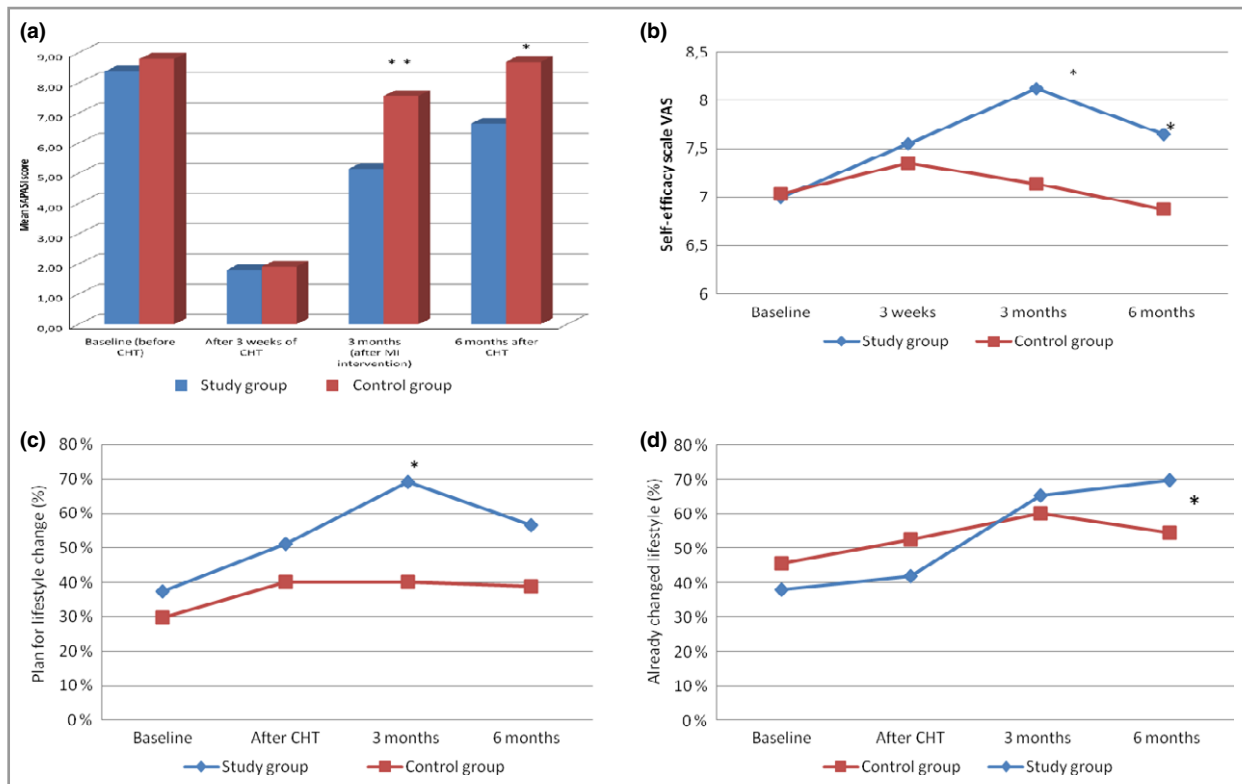
Fig 2. (a) Group differences in the mean Self-Administered Psoriasis Area and Severity Index (SAPASI) scores throughout the trial. Assessments: T1, on arrival for climate therapy/heliotherapy (CHT); T2, after 3 weeks of CHT, before randomization; T3, at 3 months after CHT, with motivational interviewing (MI) intervention; T4, at 6 months after CHT, with MI. *$P < 0.05$, **$P < 0.001$, one-way ANOVA. (b) Group differences in mean self-efficacy scores [(visual analogue scale, VAS): range 0–10, high = good] in terms of desired lifestyle changes at baseline, after 3 weeks of CHT, at 3 months after CHT and at 6 months after CHT. *$P < 0.05$, independent-samples t-test. (c) Group differences in 'Already made plans for lifestyle change' (Yes: strongly agree + agree; No: uncertain + disagree + strongly disagree). *$P < 0.05$, χ^2-test for proportions. (d) Group differences in 'Already changed lifestyle after psoriasis diagnosis' (Yes: strongly agree + agree). *$P < 0.05$, χ^2-test for proportions.

after CHT in terms of disease severity, psoriasis knowledge, self-efficacy and some lifestyle change parameters.

The difference in disease severity appears to be particularly important. Systemic inflammation with abnormal keratinocyte proliferation is recognized as one of the main drivers of the disease process in psoriasis,[50] and increases the risk of comorbidities such as metabolic syndrome and cardiovascular diseases.[8] The apparent dose–response effect indicates that people with severe psoriasis have a higher risk of myocardial infarction than people with mild psoriasis,[51] which highlights the importance of controlling the systemic inflammation.

Bostoen *et al.*[37] reported a reduction in disease severity after a comprehensive educational intervention, while Fortune *et al.*[38] reported similar results with a cognitive behaviour symptom programme. A recent educational and motivational pilot study by Balato *et al.*[52] using text messages with reminders and educational tools also reported promising results based on SAPASI. Overall, these results indicate that educational and self-management interventions may have positive effects on disease severity, and they could have important roles in psoriasis management. Other studies have shown that MI is effective in reducing health-related clinical parameters, such as

blood pressure, the glycosylated haemoglobin test (HbA1c), body mass index and cholesterol.[24,53,54]

In the present study, the MI strategies appeared to have positive effects on the psoriasis self-management levels after CHT. We detected significant between-group differences in three of the eight heiQ domains after the MI intervention. However, these domains encompassed self-management, self-monitoring and insights into living with a health problem, thereby indicating empowerment and that the participants had the attitude that they were not going to let health problems control their lives. Thus, they utilized symptom-relief skills and knowledge-based techniques to manage their own health,[48] which were all consistent with the content of the MI intervention. The change in illness perception may reflect a better perceived control over symptoms, and the study group also increased their level of self-efficacy. An integrative review of psoriasis self-management in daily life stressed that interventions directed at increasing the patient's level of self-efficacy are more likely to produce positive outcomes in terms of behavioural change and health outcomes.[14]

A higher percentage of MI participants had a more health-promoting pattern after the intervention in terms of the phases

Table 6 Health behaviour risk change with respect to motivation to administer daily skin treatment, and planning lifestyle change

Daily skin treatment							
From T2 to T3	Study group (n = 72)	Controls (n = 62)	P-value	From T2 to T4	Study group (n = 65)	Controls (n = 58)	P-value
No risk to no risk	45 (63)	46 (74)	0·21	No risk to no risk	42 (65)	43 (74)	0·29
No risk to risk[a]	4 (6)	2 (3)	0·69	No risk to risk	2 (3)	3 (5)	0·57
Risk to no risk	19 (26)	9 (15)	0·045	Risk to no risk	19 (29)	9 (16)	0·048
Risk to risk	4 (6)	5 (8)	0·74	Risk to risk[a]	2 (3)	3 (5)	0·63
Planning lifestyle change							
From T2 to T3	Study group (n = 68)	Controls (n = 58)	P-value	From T2 to T4	Study group (n = 62)	Controls (n = 53)	P-value
No risk to no risk	32 (47)	15 (26)	0·06	No risk to no risk	24 (39)	11 (21)	0·022
No risk to risk[a]	6 (9)	11 (19)	0·15	No risk to risk	9 (15)	10 (19)	0·66
Risk to no risk	15 (22)	9 (16)	0·21	Risk to no risk	11 (18)	10 (19)	0·96
Risk to risk	15 (22)	23 (40)	0·04	Risk to risk[a]	18 (29)	22 (42)	0·21

Values are n (%), based on the readiness-to-change model. Risk, precontemplation, contemplation and preparation stages; no risk, action and maintenance; T2, after 3 weeks of climate therapy/heliotherapy (CHT), before randomization; T3, at 3 months after CHT, with motivational interviewing intervention; T4, at 6 months after CHT (χ^2-test or [a]Fisher's exact test).

of the TTM of health behaviour change.[43] This implies that they remained in the 'action phase' or moved from 'precontemplation', 'contemplation' or 'preparation' to 'action', thereby indicating that MI positively affects motivation to change. In MI, the patients decide what behaviour, if any, they wish to discuss, and the interactions with the counsellor are collaborative. By articulating their desire to change and estimating the importance of and their personal readiness for change, they strengthen their determination to change and increase self-efficacy. Telephone intervention using MI also has positive effects on lifestyle choices in patient populations other than psoriasis.[25,55]

Timing seems to be important for educational interventions.[56] This MI intervention occurred immediately after 3 weeks of CHT treatment, which promoted a significant decrease in illness severity and an increase in quality of life,[32] and this appeared to be important. The educational programme and peer discussions may have enhanced the knowledge of psoriasis among participants (based on the PKQ scores at T2), as well as showing them how to manage the disease in their everyday lives. The risk of resuming potentially unhealthy lifestyle habits and nonadherence may have been reduced by providing the intervention immediately after CHT. The motivational calls encouraged healthy behaviours and facilitated the development of problem-solving skills, as well as providing emotional support and regular follow-up.

The present study is the first randomized controlled trial of MI in psoriasis and one of the few studies to focus on self-management support in psoriasis. This study confirms the beneficial effects of MI and the potential for prolonging the positive effects of CHT. The reason why 39% of the invited patients declined to participate is unknown. One reason may be lack of motivation to discuss possible lifestyle change; maybe they had already made important changes in lifestyle, or their nonattendance was caused by uncertainty of what the MI intervention actually entailed.

Obvious limitations in the study design are the fact that the MI counsellor (M.H.L.) was also a member of the research team, and that we did not include an 'attention only' or sham control group. Having such a 'placebo' control group might have helped clarify the extent to which the attention from the MI counsellor and thereby the increased therapist time per se contributed to the positive results observed in the study group. However, the application of the MITI code to some of the recorded interviews demonstrated that the study group received MI and that the counsellor used attitudes, principles and communication skills congruent with MI (Table 3). In addition, the participants were not blinded to their treatment allocation. However, the sample was selected randomly and we reduced possible bias due to seasonal variations by recruiting throughout a year of CHT treatment. Another limitation is that the CHT context limits any potential generalizability to the general psoriasis population. In particular, we did not know whether the patients with psoriasis who applied for CHT were different from the overall psoriasis population in Norway in terms of their motivation to change, treatment adherence and lifestyle. Despite these limitations, MI appears to be a promising method for providing self-management support to patients with psoriasis, which affects the disease severity.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Figure S1. 'Bubble sheet' for agenda mapping.

Figure S2. Visual analogue scale for self-efficacy.

Cost-utility analysis of supported self-management with

Motivational Interviewing for patients with psoriasis

M.H. Larsen[1,2], A.K. Wahl[1], AL. Krogstad[2,3] and E. Aas[4]

[1] Department of Health Sciences, Institute of Health and Society, the Medical Faculty, University of Oslo, Norway
[2] Section for climate therapy, Oslo University Hospital, Norway
[3] The Department of Dermatology, Oslo University Hospital, Norway
[4] The Department of Health Management and Health Economics, Institute of Health and Society, the Medical Faculty, University of Oslo, Norway

Short title: Cost- utility of a MI intervention in psoriasis

Corresponding author: Marie Hamilton Larsen

Department of Health Science, University of Oslo

Postboks 1130 Blindern

0318 Oslo

Mail: m.h.larsen@medisin.uio.no

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ABSTRACT

There are few studies evaluating the cost-effectiveness of self-management interventions for patients with psoriasis. Motivational Interviewing (MI) as a telephone follow-up after climate-heliotherapy (CHT) has been shown to be effective on several clinical parameters, but its cost-effectiveness is unknown. A cost-utility analysis (CUA) was conducted alongside a RCT comparing MI to usual care. A total of 169 Norwegian patients were included. A within-trial analysis was conducted comparing the costs and quality-adjusted life years (QALYs). Utilities were measured with the 15D and supplemented with DLQI. A time-integrated summary score defined the clinical effects. QALYs were adjusted for baseline differences. Costs were estimated in Euros (€). MI was shown to provide equivalent quality of life and utility, at lower costs, compared with treatment as usual. The MI intervention was thus cost effective. This result was more evident when using the DLQI as outcome measure compared to 15D.

Key words: psoriasis, motivational interviewing, cost-utility

INTRODUCTION

Psoriasis is a complex, chronic inflammatory skin disease. The disease is associated with psychological distress (1) and physical co-morbidities (2;3), and patients may suffer from disfigurement and social stigmatisation (4). High body mass index and smoking may contribute to an increased risk of developing psoriasis (5), and recent research indicates that such lifestyle factors may also exacerbate the disease (6).

Several measures in addition to traditional treatment have been taken to reduce the burden for these patients, such as stress management (7), cognitive therapy (8), diet (9) and self-management support (10). One important comprehensive treatment for Norwegian patients is three weeks of Climate Heliotherapy (CHT) at Gran Canaria. In order to optimize the benefits of CHT, telephone-based Motivational Interviewing (MI) focusing on daily skin treatment and lifestyle changes following CHT were compared with treatment as usual (TAU). Participants were randomized to TAU or TAU with additional MI, a directive, client-centred counselling style for strengthening a person's motivation and commitment to change (11). Previously, the efficacy of this MI intervention was published (12). Before a new method for self-management support can be implemented, a thorough analysis of both health outcomes and costs must be undertaken. Hence, as literature on the cost-utility of MI is limited, the objective of this paper was to compare the cost-utility of MI to TAU for patients with psoriasis following CHT.

METHODS

Study design and participants

This economic evaluation was designed alongside a randomized controlled trial of 169 Norwegian patients participating in CHT. They were 20 to 70 years old with moderate to severe psoriasis (PASI >7 at application) and needed to be capable of answering questionnaires and communicating by telephone. Full inclusion and exclusion criteria are presented in the original clinical paper (12).

Ethical approval

Throughout the study, the principles outlined in the Declaration of Helsinki were followed (13). The study was approved by the research director and the Centre for Privacy and Information Security at Oslo University Hospital and also by the Regional Committee for Medical Research Ethics for Southern Norway (ID: 2011/1019) and registered at: http://www.clinicaltrials.gov (ID: NCT 01352780).

Climate therapy program

CHT includes individualized sun exposure in increasing doses as the main treatment. Thus, the sun exposure is dependent on skin type and the current UV index. Additionally the program emphasizes daily physical training, tailored education, group discussions and individual consultations and supervision by nurse and dermatologist. Hence, the tree weeks of CHT program consist of both sun treatment and patient education. The CHT program is further presented in Appendix 1.

Motivational Interviewing

Motivational interviewing (MI) is defined as "A collaborative, conversation style for strengthening a person's own motivation and commitment to change" (11, s.12). The MI counsellor focuses on assisting patients to identify their problems and also overcome ambivalence and resistance to behaviour change. A key goal is to increase the importance of change from the client`s perspective. This is accomplished by for example using specific types of open ended questions, selective reflections, summaries and reflective listening (11).

Intervention

Both groups participated in CHT prior to the MI intervention and were randomized to the control or the intervention group after discharge, one to two days before returning to Norway. A more-detailed description of the intervention is published elsewhere (12). Briefly, patients in the study group received one face-to-face mapping conversation (45–60 minutes) with the MI counsellor (main author) before returning home from Gran Canaria and six follow-up calls using the Motivational Interviewing technique during the next 12 weeks. The duration of the calls was between 15 and 60 minutes. The mean (SD) conversation time was 32,5 (SD 12.7) minutes and each participant received an average of 3.3 (SD 1.3) hours of phone counselling. Participants allocated to the control and study groups all received psoriasis treatment as usual (from a dermatologist or a GP) according to the usual clinical practice after they returned to Norway.

Measures

Information about health outcomes and costs are collected from self-reported questionnaires, which were collected at baseline (at arrival for CHT), at three months, and at six months post-randomization (after three weeks of CHT). The baseline questionnaires covered resource use during the three-month period prior to the baseline assessment.

Health outcomes

The health outcomes were measured in quality-adjusted life years (QALYs). QALY is a generic measure that includes both quantity (duration of time in a state of health) and health-related quality of life (HRQoL) generated by health care interventions (14). One year of perfect health equals one QALY (15). We used the 15D instrument, a generic, comprehensive, self-administered measure of HRQoL. It consists of 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress vitality and sexual activity. Each dimension has five levels ranging from "no problems" to "extreme problems" (16). Based on the Finnish valuations, the single index (15D score) was calculated on a scale from zero (equivalent to being dead) to one (equivalent to full health, i.e. no problems on any dimension) (16). A difference of 0.015 was recently stated as the minimum important change in 15D scores (17).

We also investigated the scenarios when QALYs were calculated from the Dermatological Life Quality Index (DLQI-N). DLQI is a well-validated, dermatology-specific, quality-of-life form (18).

Cost

Information on health care utilisation, medication, participants' costs and productivity loss was obtained through the three-month and six-month questionnaires. Information on cost per unit was collected from several sources (Table 1).

The different costs are analysed and presented in three different cost categories. Cost group 1 includes direct costs for primary and secondary health care services. Patients were asked to recall use of hospital services (i.e. out & inpatient consultations, UV light treatment), medical specialists care (e.g. GP, dermatologist and rheumatologist), allied health care (for example physiotherapist and psychologist), as well as use of alternative medicine care (i.e. healer &acupuncture). Here we assessed the costs according to charge per treatment or Diagnose related groups (DRG) codes for 2012. DRG is an international coding system that aims to measure hospital productivity and resource consumption. The cost is estimated by multiplying the cost weight for that specific DRG group by the cost for one DRG (19). In 2012, the cost for one DRG point was €5112. Travel cost was added to consultations with specialists, psychologists and hospital visits. UVB treatment was estimated with reported travel costs from the questionnaires. Appointments at a GP's office and with a physiotherapist, chiropractor, etc. were considered as zero travel costs, as these services are often received close to home.

Cost group 2 contains pharmaceuticals and use of prescribed psoriasis medication (systemic and topical). The impact on cost of "over-the-counter" (OTC) and self-care products that were skin care related was also expected to be relevant. To estimate the cost all concomitant medication registered by start and stop dates were added for each patient and period. The assessments also included volume of applied topical treatment and over the

counter moisturizing creams and emollients'. Here we used the prices (in 2012) from a local pharmacy and The Norwegian Pharmaceutical Product Compendium. Regarding biological medicines we used DRG codes for 2012.

Cost group 3 covered cost for production loss for employed patients. Productivity loss is limited to work absenteeism and defined as productivity loss due to health-related absence from work (20). Changes in work status were recorded on the follow-up questionnaires. Patients that were students, unemployed, retired due to age, or on disability were excluded, as they were presumed to have no productivity losses. The human capital approach was used to estimate the costs of sick leave (21), estimated as the number of days each participant was absent from work due to psoriasis. This cost was estimated to be equal to average income and social costs. Here we used the median income in 2012 in Norway (NOK446 200 = €59732 per year) (Statistics Norway 2012, http://www.ssb.no). For patients who were able to work part time, this productivity cost was reduced in proportion to the time worked.

The cost of delivering the MI intervention and the cost assessments for the three cost groups are respectively presented in Table 1 and Table 2.

Economic evaluation

We calculated QALYs by plotting HRQoL against time and applying the area under the curve approach using the trapezoidal method (22). This procedure generates a QALY gained for each patient over the six-month period of the study. The two trial groups were then compared to generate the estimate of mean differential QALY. The incremental cost-

effectiveness ratio (ICER) was calculated as the mean difference in costs between the two groups divided by their difference in QALYs gained, defined by:

$$\text{ICER} = \frac{\text{(Cost of MI intervention} - \text{Cost of TAU)}}{\text{(Health effect of MI intervention} - \text{Health effect TAU)}} = \frac{\Delta C}{\Delta E}$$

Because a positive outcome is measured by a reduction in DLQI, we adjusted for this by including a negative sign in the definition of the ICER including DLQI. The 95% confidence interval (95% CI) around the mean cost per patient and the between-group differences in mean total costs were estimated with bootstrapping, repeating the analysis 1000 times. Cost-effectiveness acceptability curves (CEACs) were estimated to consider the uncertainty surrounding the cost-effectiveness (in €) of the MI programme by plotting the probability that the MI intervention and TAU is cost-effective according to threshold values, i.e. the decision maker's willingness to pay for an additional QALY (23;24).

Analysis

Normal distributed continuous data are indicated as mean value with standard deviation (SD). Non-normally distributed data are indicated as median value with the minimum and maximum values. To analyse differences between groups, we used independent sample t-tests with corresponding 95% confidence intervals and non-parametric analysis (Mann-Whitney U test) to compare, respectively, normally distributed and non-normally distributed continuous data. Two-sided $p < 0.05$ were regarded as significant.

SPSS version 21 was partially used for the analyses (SPSS Inc., Chicago, IL). We used STATA to estimate uncertainty around the ICER using bootstrapping, generating 1000 replications of each ratio (replicated ICERs). Cost-effectiveness acceptability curves (CEAC) were calculated in Excel. Additionally, we controlled for imbalance in baseline HRQoL in the estimation of mean differential QALYs by regression analysis, as recommended by Manca (25). Missing values on cost items, health care utilisation, psoriasis treatment and self-care products in the questionnaires were consequently set at zero. Costs were calculated in Norwegian kroner (NOK) and presented in Euros (€), using an exchange rate of €1 = NOK7.47 (medium value in 2012). All costs and outcomes fell within a six-month period, and therefore discounting was not appropriate.

RESULTS

Baseline characteristics for each group are described elsewhere (12). For this economic evaluation, no significant differences could be found between the patients at baseline, with the exception of the utility measure 15D and self-assessed health status (1–5 = poor–excellent). In the latter, the members of the control group assessed their health status to be significantly better, with a between-group difference of - 0·40 (95% CI - 0·67, - 0·12), p value = 0·005, (Appendix 2).

Health outcomes

Regarding the 15D results, the control group had a significantly higher 15D sum score at baseline (0·90) than the intervention group (0·86) did, indicating a between-group difference of - 0·32, (95% CI -0·60, -0·003), p value = 0·029. After three months, the 15D score for the MI group increased to 0·88 and then decreased to 0·87 at six months. The controls remained

at 0·90. After adjusting for baseline differences (45), the mean incremental effect for the six-month-long study period showed no significant differences between the groups -0·0022 QALYs (95% CI -0·02, 0·01), p= 0·77.

There were no significant differences in DLQI scores at baseline. A significant difference in DLQI scores was found in favour of the MI group at three months. Between-group differences were -2·81, (-4·76, -0·85), p= 0·005. These differences were not significant at six months. The incremental effect after adjusting for baseline showed no significant differences -0.62 QALYs (95% CI, 0.41, -1.65), p= 0·24, (Table 3).

Costs

Our estimated mean cost per participant for the delivery of the MI intervention was €243 (Table 1). No significant differences were found in either of the cost groups at baseline. Table 2 summarises the mean use of resources at baseline (T1), by the end of the MI intervention (after 3 months, T3) and at 6 months (T4).

Cost group 1 reflects the cost for primary and secondary health care services, and the analysis showed only small differences in total costs at all data collection points. However, there was a significant decrease in the mean cost of both primary and secondary health care services for both groups at three months and six months after CHT treatment, compared to the three months before. The study group consulted the dermatologist significantly less often than the control group subjects during the six months following CHT, indicating less cost €-105 (-189, -20), p= 0·016. The same tendency was seen in UVB treatment; however, it was not significant at €-104 (-216,8), p= 0·068.

Cost group 2 includes pharmaceuticals, use of prescribed psoriasis medications, OTC and self-care products. For the six-month period following CHT, there were only small differences between the groups. The control group, however, had significantly more costs for systemic and biological treatments at €-799 (-1499, -101), p= 0·025, because some patients had started biological treatment. Since the use of biologics is a contraindication for participation in CHT treatment, no one received this treatment at baseline. No study group participants used biological medications. This difference is also indicated in the total cost variances in cost group 2.

Cost group 3 covers costs for production loss for employed patients. The study group had €1048 less in production losses in the six months following CHT, but this difference was not significant (p= 0·46).

When computing all three cost groups in the six months post-CHT, the study group had a lower cost than the TAU group, with a mean difference of €1780. When excluding productivity loss from the calculation, the mean incremental cost was €-1103 (-2293, 87), p= 0·058 (Table 2, Appendix 3).

Incremental cost-effectiveness ratio (ICER)

The ICER (ΔC / ΔE) when using 15D QALYs became € 500909, 1 as there was such a small difference in effect, when using DLQI the ICER was € -1779, 0. Thus the ICER for the MI group shows a tendency to be more dominant when using DLQI as an outcome measure, as the ICER was negative (= more effective and cheaper in this case) (Table 3). Figure 1 displays the ICERs based on the bootstrapped results using QALYS from 15D. The points are predominantly below the x-axis and are quite evenly distributed on either side of the y-axis, i.e. the cost of intervention is lower, but the results show limited evidence in HRQoL. The

distribution is as follows: 1.6 % of the ICERs fall in the upper right-hand quadrant, indicating that better effects are obtained against higher costs; 2% fall in the upper left-hand quadrant, indicating that the MI is inferior; 30·1% fall in the lower left-hand quadrant, indicating that MI has worse clinical outcomes against lower costs; and 66·3 % of the bootstrapped ICERs fall in the lower right-hand quadrant, implying that the MI intervention is dominant because it generates better outcomes against lower costs than the control condition.

We found no statistically significant differences in costs and effects between MI and TAU, and the 15D cost-effectiveness plane for this comparison confirmed this. The CEAC (Appendix 5) showed that at a ceiling ratio of zero, there was still a 95% probability that MI was cost-effective. The acceptability curve indicates that only at a lower willingness to pay for improvements in 15D is the intervention likely to be more cost-effective. For example, if a cost ceiling of €55.000 was set, then the intervention would have an 88% probability of being cost-effective.

DISCUSSION

Our results show that Motivational Interviewing as a follow-up after CHT was less costly than treatment as usual (TAU). MI was at least as effective as TAU and may be preferable from an economic health perspective.

In this study, two different but relevant instruments were applied to illuminate the health effects, and they produced different measures and results. The results indicate that MI provides improvements in subjects' health-related quality of life when the disease-specific DLQI is used; however, there were no significant differences in QALY gained. The MI group also achieved a 0.02 increase in the 15D score just after the intervention, indicating a

significant clinical difference (17); however, there were no significant between group differences.

A complicating factor in the interpretation of the observed equivalent quality of life and utility is that the control-group patients were significantly better off according to 15D at baseline. Such differences were corrected for in regression analysis. Nevertheless, the baseline differences may have underestimated the effects of the MI intervention.

The findings in this study indicate that the different utility measures measure different aspects of HRQoL and that the choice of utility instrument can be expected to have a large impact on cost-utility studies (26). Also other studies have found such differences (27;28). This may indicate the need for using several utility measures in future research on patients with psoriasis in order to establish which instrument is most sensitive to change in this population. It is also interesting that even if the control group reported a better 15D score as well as better general health throughout the study, they concurrently used more health care and reported more productivity losses, and some needed biologic therapies.

In a recent review, Villacorta, Hay & Massali (29) underlined that using a general population's perspectives as preference may also create bias, as patients value healthy states more than those in the general population. Secondly, the preference-based measure (i.e. the 15D) and the non-preference based measure (i.e. the DLQI) may not cover the same aspects of health relevant to the patient, which may thereby unintentionally cause limited explanatory power for the non-preference-based measure (i.e. the DLQI). For instance, the resulting 15D measures may underestimate psoriasis disease burden due to its limited characterisation of psoriasis-specific HRQoL domains. Further research seems necessary in

order to characterise these associations, especially in regard to how accurate the 15D can assess the strain that psoriasis may inflict on HRQoL.

Exploring the cost-effectiveness of a behavioural health intervention is known to have different methodological implications compared to surgical, technical and pharmaceutical interventions (30). These kinds of interventions encourage participants to modify existing behaviours and adopt a healthier lifestyle. The conclusions of the CEA analysis of behavioural interventions often use a simple dichotomous outcome criterion (success or failure) (31), while behavioural change is a more multifaceted process with several (often small) steps towards positive change. In this study, the focus was not primarily on the health effects in the long term, but rather on reducing the risk factors that may exacerbate psoriasis and on supporting treatment adherence. Hence, any progress in behavioural change without accomplishing full behavioural change may be considered beneficial, assuming this change increases the probability, in due course, of achieving full behavioural change (31). Ignoring delayed effects may negatively bias CEA outcomes and, as a result, cost-effectiveness of behavioural interventions may be underestimated with the current methodology (30).

Some limitations should be considered when interpreting the results of this study. The perspectives cover health care utilisation, medication and participants' cost and productivity loss. However, the fact that all information is based on questionnaires may mean that some information was under- or over-rated because of the three-month intervals. Additionally, indirect costs do not include co-morbidity costs, caregiver burden, lost wages or lost leisure time. The fact that we calculated missing cost values as zero may also have influenced the analysis. Additionally, the limited follow-up of six months may have affected the results, as

behavioural and lifestyle changes may take an extended time to incorporate in everyday life, as advocated by the Transtheoretical Model of Behaviour Change (32).

This study shows that tailored follow-up with MI after CHT has the potential to be cost-effective, in addition to its positive effects on clinical outcomes (12). However, there are currently, as far as we know, no prospects for these patients to access individualised follow-up after returning to Norway. There is evidence suggesting that patients with psoriasis are less than satisfied with their current primary care (33). Patients feel that GPs lack the necessary knowledge and competence to manage all aspects of their complex skin disease (34), and qualitative research shows that GPs find the comprehensive management and follow-up needs of these patients difficult (35). Thus, further research into effective management options and self-management support options for patients with psoriasis seems needed. Future studies need to assess which QALY measure may be the most sensible method to detect short-term improvements regarding quality of life.

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Table I Unit costs of resources used

Cost categories	Unit	Valuation	Costs (€)[1]	Source
Prepare MI calls & write summary	Per patient	(10 minutes /call x 6 calls : €31·9 x1·4)	44·62	Norwegian Nursing Association
Mapping talk (total 60 minutes)	Per patient	60 minutes	44·62	Norwegian Nursing Association
3 days course to master MI techniques	Per patient	((7·5h x €31·9 x 3days)x 1·4) / 86 patients	11·68	Norwegian Nursing Association
Cost/hour MI calls	Per patient	31·9 x 3·3(ML) x 1·4		Norwegian Nursing Association
Telephone cost /hour	Per patient		2·16	Telenor Group
Total cost of MI intervention[2]	Per patient		243	
Primary and secondary care (cost group 1)				
General practitioner	Per visits	Treatment time 20 minutes	84·6	The Norwegian Directorate of Health / The Norwegian Health Economics Administration (HELFO) & "Normal Tariff for private general practice in 2012"
Telephone consultations	Per talk		10	
Dermatologist	Visit	Reimbursement (DRG)	144	The Norwegian Directorate of Health /HELFO
UVB treatment / after 01.07.2012	Visit	Reimbursement (DRG)	37/72	
Specialists (internist & rheumatologist)	Visit	Reimbursement / charge	180 / 173	The Norwegian Directorate of Health /HELFO
Physiotherapy	Per treatment	Charge (1 hour)	114.5	Norwegian Physiotherapy Association (NFF)
Manual therapy	Per treatment	Charge (1 hour)	163	NFF
Chiropractor	Per treatment*	Charge	88/54	The Norwegian Directorate of Health /HELFO
Psychologist	Per treatment	Treatment time:1 hour	187	The Norwegian Directorate of Health /HELFO
Hospital stay caused by psoriasis	Days	Reimbursement (DRG)	3539	HELFO
Cost of alternative treatment[3]	Visits	Estimated	80 to 174	Checked 10 different tenderer and estimated a mean charge
Travel costs	Per visit	Estimated 2.5 visits/year	21	The Norwegian Directorate of Health (SAMDATA 2012)
Psoriasis medication, OTC and self-care products, (cost group 2)				
Cost of OTC medication	Various			Local pharmacy /The Norwegian Pharmaceutical Product Compendium
Patient administered biological medicines[4]	Various dependent on drug	DRG 1month / 3 months	16230·5/ 48692	The Norwegian Directorate of Health /HELFO
Methotrexate	Tablets per week		0·3 (1 tbl)	The Norwegian Pharmaceutical Product Compendium
Production loss (sick leave), (cost group 3)				
Median wage in Norway 2012	Hours	Wage rate per day	371·43	SSB: Statistics Norway

1: Euro =7·47 NOK, 2 The estimate is based on the minimum wages as of 06.06.2012, from the Norwegian Nurses' Association, for a registered nurse with 10 years' experience (1 hour work = € 31,87) * 1.4 (social expenditures). Cost of MI intervention:1·4= Gross wage *1·4 social expenditures, ML: Mean length of the MI interv: 3.3 hours. 3 Healer, podiatrist, acupuncturist, homeopath 4: Etanercept (Enbrel), Adalimumab (Humira) & Golimumab (Simponi); * Different costs 1.visit and visit 2 to 14.

Table II. Cost of the MI intervention, health care services and psoriasis treatment and productivity loss

Cost (€)	Study group Mean (SD)			Control group Mean (SD)			Between group difference after the intervention (T3 +T4 (Confidence Interval), p-value
	T1	T3	T4	T1	T3	T4	
Total cost MI intervention	0	**243 (65)**	0	0	**0**	**0**	**243 (227,254), p= <0.001**
General Practitioner (consult + telephone)	186 (158)	152 (167)	120 (115)	231 (465)	130 (137)	101 (131)	44 (-47, 136), p= 0·34
Dermatologist	113 (142)	47·5 (97)	33 (73)	248 (962)	100 (194)	73 (131)	-105 (-189,-20), p= **0·016**
UVB treatment	83 (216)	33 (144)	21 (164)	119 (382)	59 (241)	83.5 (201)	-104 (-216, 8), p= 0·068
Hospital admittance due to psoriasis	977 (8389)	0 (0)	55 (443)	830 (6881)	106 (851)	0.00 (0.0)	- 61 (-320,199), p= 0·65
Allied health care [1]	307(601)	158 (382)	215 (474)	276 (731)	130 (501)	232 (626)	- 4 (-338,330), p= 0·98
Other Medical specialists[2]	37 (95)	32 (80)	20(67)	69(357)	49 (205)	32(127)	-37 (-115, 41), p= 0·35
Alternative health products	14·5 (64)	0·7 (6·3)	0·06 (0·4)	47 (189)	6 (24)	6·8 (33)	-14 (-24, -3), p= **0·011**
Alternative treatment [3]	22 (71)	37 (189)	30(107)	57 (186)	90(260)	59 (157)	-118 (-220,-16), p= **0·002**
Total costs Cost group 1	**1746 (8473)**	**464 (634)**	**526 (766)**	**1876 (7904)**	**674 (1512)**	**579 (806)**	**-351 (-970, 268), p= 0·27**
Prescription anti PSO topical treatment (without Hydrocortisone (HK))	49 (84)	58 (94)	63 (86)	51 (66)	80 (92)	83 (144)	-37 (-98, 23), p= 0·22
Prescription topical medication with HK	13 (24)	41 (74)	32 (54)	8 (16)	31 (49)	33 (50)	9·8 (-22, 42), p= 0·54
Systemic psoriasis treatment	11 (38)	18 (56)	14 (55)	17 (66)	15 (69)	21 (71)	-6 (-55, 43), p= 0·81
Biological treatment (DRG based)	0(0)	0 (0)	0(0)	0(0)	316 (1170)	401 (1306)	- 799(-1499, -101), **p= 0·025**
OTC body lotion and emollients	90 (102)	114 (88)	119 (107)	87 (135)	113 (150)	102 (192)	8.9 (-92, 110), p= 0·86
Total costs Cost group 2	**185 (169)**	**228 (167)**	**232 (163)**	**239 (542)**	**547 (1183)**	**657 (1332)**	**-806 (-1518, -95), P= 0·027**
Total costs Cost group 3	1127 (3133)	1632 (4318)	1382 (3795)	1986 (4824)	2478 (5380)	1952 (4652)	-1048 (-3874, 1777), p= 0·46

T1: baseline, T3: 3 months after CHT (after the MI intervention), T4: 6 months after CHT. Cost gr 1: Use of primary and secondary health care, Cost gr.2: (Pso- therapy, syst + topical, OTC and self-care products), Cost gr.3: Productivity loss for employed patients. CI: Confidence interval, 1 Euro (2012) = 7·47 NOK, 1) as physiotherapist, manual therapist, chiropractor, psychologist 2) as rheumatologist, internist + assumed travel expenses, 3) as healer, homeopath, podiatrist.

Table III. QALY assessment

Treatment group	Utility measures	Baseline Mean (SD)	3 months Mean (SD)	6 months Mean (SD)	AUC (SD)*	Differential group difference QALYs (*)
MI intervention (MI)	15D	0·86 (0·095)	0·88 (0·097)	0·87 (0·084)	0·4365 (0·035)	- 0·0022 (-0·02,0·01), p= 0·77
Treatment as usual (TAU)	15D	0·90 (0·089)	0·90 (0·094)	0·90 (0·083)	0·4386 (0·039)	
MI intervention (MI)	DLQI	11·33 (5·71)	6·45 (5·54)	7·67 (5·79)	3·81 (2·26)	- 0·62 (-1·65, 0·41), p= 0·24
Treatment as usual (TAU)	DLQI	10·99 (6·10)	8·8 (7·18)	9·27 (7·14)	4·43 (2·94)	

15D: 0-1 (high = good health), DLQI: 0 – 28 **(low = good)**. Difference between groups: independent samples *t*-tests of means, (*): Multiple regression approach controlling for baseline scores of the Utility measure. Costs here are not included costs at baseline (3 months prior to the intervention). DLQI ICER has a negative sign because a positive outcome is measured by a reduction in DLQi , Δ= Incremental.

Figure 1. Incremental cost and QALYs (15D) for Motivational Interviewing when compared to treatment as usual.
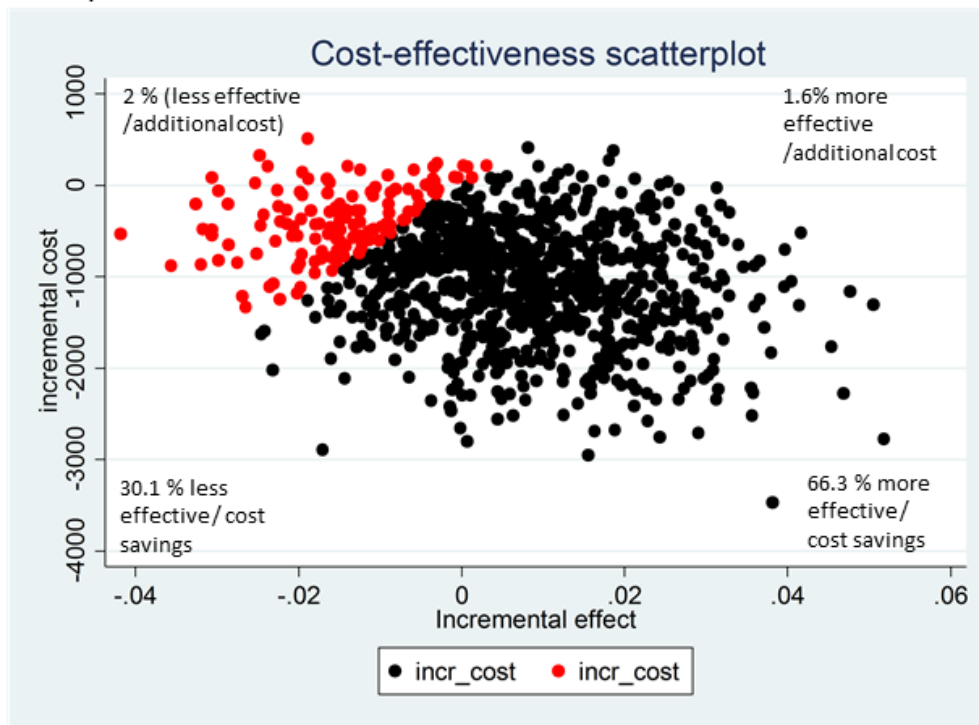
Bootstrapped costs and effects for 15D. Costs in euros within the 6 months after CHT.
Cost and effect pairs were estimated with 1000 bootstrap replications.

Appendix 1 Aims and Content of the Norwegian Climate/ helio therapy program at Gran Canaria

<u>Aims</u>
- Reduce disease severity
- Increase knowledge and insight about the disease, treatment and symptom management
- Increase awareness about how to reduce deteriorating risk factors such as smoking, stress and overweight
- Discuss recent knowledge about psoriasis comorbidity, how to reduce risk profiles and motivate positive lifestyle changes

<u>Content</u>
- Examination by the dermatologist and nurse at three occasions (at arrival, after 1 week and after 3 weeks) and personalized follow-ups when needed
- A combination of tailored sun treatment and salt-water bathing. Exposure according to skin type and current ultraviolet index
- Physical activities: morning 'workout' and voluntary participation in other physical activities such as water aerobics, walking/running, swimming, muscular training and relaxation techniques
- Interactive educational sessions conducted by a dermatologist, nurses and physiotherapist about psoriasis pathogenesis, manifestations, comorbidity, quality of life and treatment options and the importance of a healthy lifestyle focusing on physical activity, stress reduction and healthy eating.
- Educational sessions: creams and ointments (2 h), sun treatment (1 h), nutrition (2 h), physical activity (1 h), education about psoriasis (2 h), comorbidity related to the disease (1 h), medical treatment (2 h) and research (1 h)
- Group meetings (eight to 12 participants) focused on experiences of living with psoriasis, coping with stress, nutrition in daily life and self-management (1–3 h)
- Voluntary smoking cessation course (4–6 h)
- Interaction with others with similar health challenges in formal and informal settings

Appendix 2 Baseline characteristics

Variables	Study (N = 86) Mean (SD)	Control (N = 83) Mean (SD)	Between-group difference (95% confidence interval), P-value (a, b, c)
Male % (N) / Female (%)	59·3 (51)/ 40·7 (35)	53·0 (44) /47·0 (39)	$\chi^2 = 0·68$ (P = 0·41) (b)
Age (years)	46·16 (12·71)	46·46 (13·02)	0·30 (–4·2, 3·6), P = 0·88 (a)
PASI at arrival CHT	7·79 (4·78)	8·42 (4·04)	-0·63 (-1·98, 0·72), P= 0·36
PASI at departure CHT	1·93 (1·85)	2·3 (1·87)	-0·38 (-0·94, 0·19), P= 0·19
Duration of disease (years)	24·6 (14·29)	21·2 (13·42)	3·39 (–0·84, 7·63), P = 0·12 (a)
Self-assessed health status (1–5 = poor–excellent)	2·70 (0·90)	3·10 (0·89)	–0·40 (–0·67, –0·12), **P = 0·005** (a)
Level of education % (N)			
Prim/secondary school ≤ 10 years	16 (13)	11·3 (9)	
High school ≤ 13 years	45·7 (37)	46·3 (37)	$\chi^2 = 0·98$ (P = 0·41) (b)
College/university < 4 years	18·5 (15)	18·8 (15)	
College/university ≥ 4 years	19·8 (16	23·8 (19)	
Paid work (Yes/ No)	67/18	69 /12	$\chi^2 = 1·13$ (P = 0.29) (b)

PASI: Psoriasis Severity and Area Index, CHT: Climate Helio therapy . The values are means (± SD) unless otherwise indicated. SD: standard deviation. Difference between groups: (a) independent samples *t*-tests of means, (b) Pearson's Chi square (χ^2) tests of proportions and (c) Mann–Whitney U-tests of medians. N differs among individual analyses because of missing values.

Appendix 3 Total cost for the different cost groups

| Cost groups	Study group Mean (SD)	Control group Mean (SD)	Between group difference, (CI), p- value
*Total cost of Cost group 1 (T3&T4)	€ 940 (1177)	€ 1291 (2074)	€ -351 (-970, 268), p = 0·27
*Total cost of Cost group 2 (T3&T4)	€ 464.4 (276)	€ 1271 (2544)	€ -806 (-1518, -95), **p = 0·027**
*Total cost of Cost group 3 (T3&T4)	€ 3069 (6965)	€ 4118 (8656)	€ -1048 (-3874, 1777), p = 0·46
Total cost of MI (T3)	€ 241(65)	€ 0 (0)	€ 241 (227, 254), **p= <0·001**
*Summarized ALL cost groups +MI (T3&T4)	4212 (5931)	5992 (7948)	€-1780 (-4567, 1035), p= 0·21
*Summarized cost group 1&2 and MI	**1606 (1281)**	**2708 (3928)**	€-1103 (-2293, 87,11), p= **0·058**

*Costs here are not included cost at baseline = cost for the three months prior to the intervention, T3: 3 months after CHT (after the MI intervention), T4: 6 months after CHT, Cost gr 1: Use of primary and secondary health care, Cost gr.2: Hydrocortisone, systemic PSO therapy, topical therapy, OTC and self-care products, Cost gr.3: Productivity loss for employed patients.

Appendix 4 Consumption volume of topical and emollient therapy

Consumption volume	Baseline Mean grams (SD) Median (min- max)		After **three months** Mean grams (SD) Median (min- max)		After **six months** Mean (SD) Median (min- max)		Differential group difference after the intervention (T3 +T4) , p- value
	MI (N=86)	TAU (N=83)	MI (N= 72)	TAU (N=63)	MI (N=65)	TAU (N=60)	
Total **amount** of used HC and prescription anti pso medicine (all topical treatment)	78 (159) 167.50 (0-1660·00)	70 (105) 100.00 (0-1240·00)	67 (108) 120.00 (0-2120·00)	92 (107) 130.00 (0-1660·00)	92 (157) 120.00 (0-1200·00)	95 (164) 125.00 (0-1225·00)	Z= - 0·32, p= 0·75 [a]
Total **amount** of used OTC body lotion and emollients	836 (1028) 500.00 (0- 5350·00)	812 (1139) 500.0 (0- 7750·00)	1169 (977) 1000.00 (0-4960)	1032 (966) 925.00 (0-5500·00)	1235 (1207) 1000 (0- 6175·00)	971 (1522) 600.00 (0-10380·00)	Z= -1·44 , p= 0·15 [a]

T3: 3 months after CHT (after the MI intervention), T4: 6 months after CHT. Cost group 2: Use of self-care products, (HK, systemic psoriasis therapy, topical treatment, emollients and body lotion) at each follow up, by treatment group (mean, SD) or (mean, SD and median (min-max)). [a] Mann–Whitney U-test of medians.

Appendix 5. Cost acceptability for incremental costs per QALY for the MI intervention when compared to TAU. Cost acceptability curve 6 months after CTH

Cost effectiveness acceptability curve - CEAC
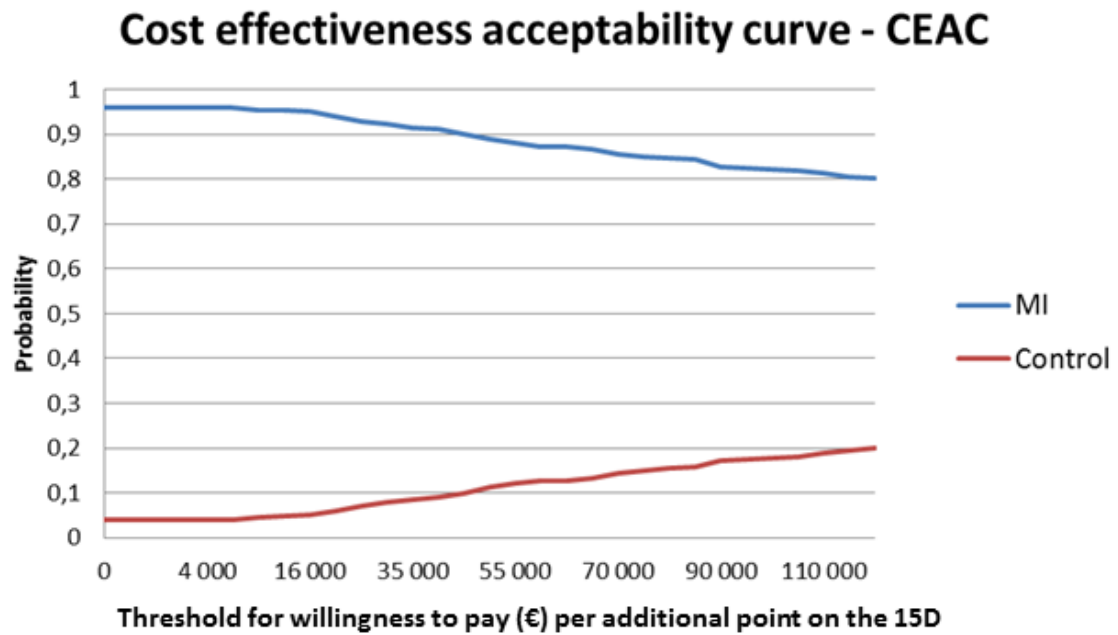
Acceptability curve regarding the probability of superior cost-effectiveness of MI in comparison to TAU. Curve estimated with 1000 bootstrap replications. The x-axis (values of ceiling ratio) represents a range of maximum monetary values in Euros that a decision maker might be willing to pay for an additional unit of effect.

Appendix

Appendix 1: RCT studies that has evaluated MI in chronic care settings.

Author /year/ country of origin	N	Design	Diagnosis/Targeted outcome	Intervention (SG)/comparison (CG)	Fidelity to MI	Main results
Smith (408) (1997) USA	22 women	Pilot-RCT	**Noninsulin-dependent Diabetes /** self-care and weight GHb	CG: A standard 16-week group behavioural weight-control programme SG: Same + three MI sessions	Not reported	Participants in the MI group had significantly better glucose control post-treatment. Both groups had significant weight losses, but there were no differences between the groups.
Brug et al. (2007) (346) The Netherlands	37 dieticians 209 patients	RCT	**Diabetes**/counselling style, self-reported saturated fat, vegetable intake, BMI and waist circumference, and HbA1c	SG: Dieticians who received basic MI training CG: Dieticians without MI training	Not reported	Patients of MI dieticians had significantly lower saturated fat intake levels at post-test compared with the patients of control dieticians. No effects on HbA1c, BMI and waist circumference.
West (2007)(224) USA	217 patients	RCT	**Diabete**s / self-care, weight and HbA1C assessed at 0, 6, 12 and 18 months.	Group-based behavioural obesity treatment, with 42 sessions + individual sessions of MI or attention control (five sessions)	Not reported	MI improves weight loss outcomes. Significantly greater HbA1c reductions at 6 months but not at 18 months. Benefits were not sustained among African-American women.
Brodie et al. (2008) (349) UK	60 patients	RCT	**Chronic heart failure**/quality of life (Short Form-36), Living with Heart Failure questionnaire and Readiness for Physical Activity scale	Three groups: 'standard care', 'motivational interviewing' or 'both' treatment groups for five months to increase physical activity	No reported experienced interventionist	MI increases QoL and is more effective than TAU in several QoL outcomes. QoL is associated with the level of physical activity.
Ogedegbe et al. (2008) USA (409)	190 African American women	RCT	**Hypertension** / adherence (electronic pill monitors), within patient change in BP in 12 months	SG: TAU + behavioural MI counselling at 3,6,9 and 12 months (30-40 min) by CG: TAU	Calls taped and rated by experienced MI rater, results not presented	MI counselling led to steady maintenance of medication adherence over 12 months, compared to a significant decline noted in the TAU group. A non-significant trend toward a net reduction in systolic BP in favour of the MI group
DiLorio et al. (354)(2009) USA	22 patients	RCT	**Epilepsy/** self-management, self-efficacy, adherence + % of prescribed doses taken and % of doses taken on time	SG: Discussed medication management in five sessions with MI (four by telephone) CG: TAU + four courtesy phone calls	Feedback on MI skills but no competency level reports.	Higher levels of self-efficacy, outcome expectancies for medications and seizure management, and social aspects of epilepsy knowledge in the MI group but no significant differences.

Author /year/ country of origin	N	Design	Diagnosis/Targeted outcome	Intervention (SG)/comparison (CG)	Fidelity to MI	Main results
Rubak et al. (2009) (340) Denmark	628 patients 40 GPs	RCT	**Diabetes/** engagement in self-care	SG: Target-driven intensive treatment with MI CG: Target-driven intensive treatment	Not reported	Significantly improved metabolic status after one year, regardless of whether MI received.
Heinrich et al. (2010) (360) The Netherlands	33 nurses 584 patients	Cluster RCT	**Diabetes/**self-management behaviours and process outcomes, the use of www.diep.info and background variables	SG: New counselling style in standard quarterly consultations with patients by nurses CG: TAU counselling style	Feedback on two audiotaped consultations	Disadvantageous effects on fat intake and HDL cholesterol, advantageous effects on control and knowledge. No effects were found on vegetable or fruit intake, physical activity, HbA1c, weight, BP, total cholesterol, LDL, QoL or self-efficacy.
Ismail et al. (2010) (359) UK	344 patients	RCT	**Diabetes/** self-management and blood glucose (HbA1c)	MET + cognitive behavioural therapy (CBT) compared with TAU, (ii) MET compared with TAU, (iii) or MET + CBT compared with MET	Reported by MITI	A combination of MET and CBT may be useful. MET alone was less effective than TAU. Economic evaluation was inconclusive. No effect on secondary outcomes such as depression and QoL.
Zwikker (2012) (410) The Netherlands	123 patients	RCT	**RA**/Beliefs about medication (BMQ) and medication non-adherence	SG: Two MI-guided group sessions led by a pharmacist CG: Brochures about their DMARDs	Reported by BECCI instrument	No difference between groups in terms of changes in beliefs about medication or in improved medication adherence over time.
Williams et al. (2012) (411) Australia	75 patients	Pilot RCT	**Diabetes/ chronic kidney disease and hypertension** / blood pressure, medication adherence, biochemical markers of disease control	SG: self-monitoring of blood pressure, a medication review, a 20-minute DVD, and fortnightly MI follow-up telephones for 12 weeks by nurse. CG: TAU	Not reported, use of fidelity checklist	No statistically significant differences between groups, A non-significant trend towards lower BP in the MI group

Author /year/ country of origin	N	Design	Diagnosis/Targeted outcome	Intervention (SG)/comparison (CG)	Fidelity to MI	Main results
Smith et al. (2012) (348) USA	13 patients	RCT	**MS/** Feeling Scale, The Enjoyment Scale, Fatigue Scale	SG: 8-week exercise programme +three brief MI sessions. CG: 8-week exercise programme + three health coaching sessions	Reported by MITI	Large effects favouring the MI condition were found for physical exertion, affect (Feeling scale) during exercise and fatigue, but no effects were found for adherence. Note: small sample size.
Gabbay (2013) (339) USA	545 patients	RCT	**Type 2 diabetes/** HbA1c, BP, LDL, depression, QoL and cost-effectiveness	SG: Nurse Case Management, 6 x 1 hour individual MI + every 6 months in 2 years + mail and telephones CG: TAU	Reported by BECCI instrument	MI improved BP, HbA1c, lipoprotein and depression.
Ang et al (2013) (347)	216 patiets	RCT	**Fibromyalgia (FM)/** increase in 30 min exercise and Fibromyalgia Impact questionnare **(**FIQ) + 6 minutes walking test	SG: 6 MI sessions CG: 6 FM self-management lessons	Reported by MITI	No significant trea<tment group difference, but MI patients improved in FIQ scores at 6 months + larger increment in 6 min walking test.
Lavoie et al. 2014) (355) Canada	54 patients	Pilot-RCT	**Asthma/** adherence to inhaled corticosteroids, asthma control tests and self-efficacy	SG: 3 × 30 min of MI within 6 weeks CG: TAU by psychologist	Reported by MI skills code	Clinically significant improvements in adherence behaviour, asthma control levels and self-efficacy at 6 months, and maintained for 1 year. Well accepted by patients.

GHb: Glycosylated haemoglobin, SG: Study group, TAU: Treatment as usual, MI: Motivational interviewing, BMI: Body mass index, CBT: cognitive behavioural therapy, MET: motivational enhancement therapy, GPs: general practitioners, BMQ: Beliefs about Medicines Questionnaire, RA: rheumatoid arthritis, BECCI: Behaviour Change Counselling Index, MITI: MI Training Integrity Index, NCM: nurse case management, BP: Blood Pressure, T2DM= type 2 diabetes mellitus, CVD= cardiovascular disease, MS: Multiple sclerosis

Appendix 2
PSORIASISBEHANDLING SISTE 3 MÅNEDER

I denne delen av spørreskjema ønsker vi å få vite hvilke helsetjenester du har benyttet deg av de siste 3 måneder og kostnaden det har medført for deg. Vi ønsker også å registrere annen type psoriasisbehandling.

Bruk av helsetjenester :	*Antall konsultasjoner*	Bruk av helsetjenester:	*Antall konsultasjoner*
Allmenpraktiserende lege Hvor mange konsultasjoner har du hatt hos allmenpraktiserende lege? - Besøk på legekontor - Telefonkonsultasjon(er) Var årsaken til konsultasjonen relatert til psoriasis?	 ………………………… ………………………… Nei☐0 Ja☐1	**Andre terapeuter og behandlere:** Fysioterapi Kiropraktor Manuell terapi Psykolog Annet:	 . . . .
Legespesialist (Både poliklinikk og privatpraktiserende) Hudlege Lysbehandling Reumatolog Indremedisiner Annet:		**Alternativ behandling** (f.eks. akupunktør, homeopat) Fotterapi Homeopat Akupunktør Healer Hvor mye var kostnaden per konsultasjon? Hvor mye har du brukt på helsekostprodukter Annet :	 . . . . Kroner : . . . .
Sykehusinnleggelse? Har du vært innlagt på sykehus? Var årsaken relatert til psoriasis? Hvor mange dager: Psoriasis: Annet: **Grunn til innleggelse:**	 Nei☐0 Ja☐1 Nei☐0 Ja☐1	**Hvor mye reisekostnader hadde du en vei til :** Lysbehandling / hudlege /spesialist: Fastlege Annet (fysioterapeut, homeopat etc) spesifiser:	 Kroner: . . . . Kroner: . . . . Kroner: . . . . Kroner: . . . .

Har du brukt <u>Kortisonpreparater</u> siste 3 måneder? Hvis JA- skriv opp navnet på alle kortisonpreparater du har brukt, størrelse på tubene og antall.

Type / Navn	Navn på preparat/ preparater:	Str (ml / mg på tuben/ flasken)	Antall tuber/ flasker du har brukt siste 3 mnd
<u>Hydrokortison krem:</u> **Foreksempel:** Hydrokortison, Mildison, Daktacort, Terra-Cortril, Apolar, Apolar med dekvalin, Locoid, Pevisone, Betnovat Bettamousse, Elocon, Flutivate, Ibaril, Synalar, Diprosalic, Dermovat			
<u>Hydrokortison salve:</u> **Foreksempel:**Hydrokortison, Apolar, Apolar med dekvalin , Locoid, Pevisone, Betnovat , Elocon, Flutivate, Ibaril, Synalar, Dermovat			
<u>Hydrokortison liniment:</u> **Foreksempel:** Locoid, Betnovat , Elocon, Diprosalic,			
<u>Hydrokortison oppløsning:</u> **Foreksempel:** Betnovat, Dermovat			
<u>Hydrokortison shampo:</u> **Foreksempel:** Clobex			

3. Har du benyttet andre <u>reseptpliktige</u> salver / kremer etc for å behandle psoriasisutslettet de siste 3 måneder? Skriv navn, tubestørrelse og antall på det du har brukt.

Type / Navn	Navn på preparat/ preparater:	Str (ml / mg på tuben/ flasken)	Antall tuber/ flasker du har brukt siste 3 mnd
<u>Krem:</u> **Foreksempel:** Daivonex, Daivobet			
<u>Salver:</u> **Foreksempel:** Daivonex, Silkis, Daivobet, Protopic			
<u>Gel :</u> **Foreksempel:** Xamiol			
<u>Liniment :</u> **Foreksempel:** Daivonex			
<u>Annet?:</u>			