## **CLINICAL REPORT**

# Cost-utility Analysis of Supported Self-management with Motivational Interviewing for Patients with Psoriasis

Marie H. LARSEN<sup>1,2</sup>, Astrid K. WAHL<sup>1</sup>, Anne-Lene KROGSTAD<sup>2,3</sup> and ELINE AAS<sup>4</sup>

Departments of <sup>1</sup>Health Sciences and <sup>4</sup>Health Management and Health Economics, Institute of Health and Society, the Medical Faculty, University of Oslo, <sup>2</sup>Section for Climate Therapy, <sup>3</sup>Department of Dermatology, Oslo University Hospital, Oslo, Norway

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 was effective on several clinical parameters, but its cost-effectiveness is unknown. A cost-utility analysis was conducted alongside a randomized controlled trial (RCT) comparing MI with usual care. A total of 169 Norwegian patients were included. A within-trial analysis compared the costs and quality-adjusted life years (QALYs). Utilities were measured with the 15D instrument, supplemented with Dermatological Life Quality Index (DLQI). A timeintegrated summary score defined the clinical effects. QALYs were adjusted for baseline differences. MI provided equivalent quality of life and utility (15D: -0.0022 QALYs (95% C1 –0.02, 0.01), p = 0.77, and DLQI: –0.62 QALYs (95%CI -0.65, 0.41), p=0.24, at lower costs €-1103 (-2293, 87), p = 0.058, compared with treatmentas-usual. The MI intervention was thus cost-effective. This result was more evident when using the DLQI as outcome measure compared with 15D. Key words: psoriasis; motivational interviewing; cost-utility.

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Marie Hamilton Larsen, Department of Health Science, University of Oslo, Postboks 1130 Blindern, NO-0318 Oslo, Norway. E-mail: m.h.larsen@medisin.uio.no

Psoriasis is a complex, chronic inflammatory skin disease, which is associated with psychological distress (1) physical co-morbidities (2), disfigurement and social stigmatization (3). High body mass index and smoking may contribute to an increased risk of developing psoriasis (4), and such lifestyle factors may also exacerbate the disease (5).

Several measures in addition to traditional treatment have been taken to reduce the burden for these patients, such as stress management (6), cognitive therapy (7), diet (8) and self-management support (9). One important comprehensive treatment for Norwegian patients is 3 weeks of climate heliotherapy (CHT) in Gran Canaria. In order to optimize the benefits of CHT, a telephone-based motivational interviewing (MI) intervention focusing on

daily skin treatment and lifestyle changes following CHT was 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 (10). The efficacy of this MI intervention has been studied previously (11). Before a new method for self-management support can be implemented, a thorough analysis of 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 with that of TAU for patients with psoriasis following CHT.

## METHODS (for full details see Appendix S11)

Study design and participants

The cost-utility analysis was designed alongside a RCT of 169 Norwegian patients participating in 3 weeks of CHT, consisting of both sun treatment and patient education (Table SI¹). Full inclusion and exclusion criteria are presented in the original clinical paper (11). The study was approved by the research director and the Centre for Privacy and Information Security at Oslo University Hospital and by the Regional Committee for Medical Research Ethics for Southern Norway (ID: 2011/1019) and registered at http://www.clinicaltrials.gov (ID: NCT 01352780).

## Motivational interviewing and the intervention

MI is defined as "a collaborative, conversation style for strengthening a person's own motivation and commitment to change" (10, 12). Both groups participated in CHT prior to the MI intervention and were randomized to the control or the intervention group after discharge. A more detailed description of the intervention is published elsewhere (11). Patients in the study group received I face-to face mapping conversation of 45 min with the MI counsellor (main author), a work-book and 6 follow-up phone calls over the subsequent 12 weeks. The duration of the calls was between 15 and 60 min (mean (standard deviation; SD) time 32.5 (12.7) min). Participants received a mean of 3.3 (SD 1.3) h of phone counselling. All study participants underwent psoriasis TAU according to the usual clinical practice in Norway.

## Measures

Health outcomes and costs were collected from self-reported questionnaires, at baseline, 3 months, and 6 months post-randomization (after 3 weeks of CHT).

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*Health outcomes*. Health outcome was quality-adjusted life years (QALYs) (13) based on the 15D utility instrument (14). Based on the Finnish valuations, the 15D score was calculated on a scale from zero (equivalent to being dead) to 1 (equivalent to full health, i.e. no problems on any dimension). Cronbach's α was 0.81. A difference of 0.015 was stated recently as the minimum important change in 15D scores (15). 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 (16). Cronbach's  $\alpha$  was 0.90.

#### Cost

Cost group 1 includes direct costs for primary and secondary healthcare services (use of hospital services, medical specialists' care, and allied healthcare and alternative medicine care). Charge per treatment or Diagnosis-Related Group (DRG) codes for 2012 assessed the costs (17). In 2012, the cost for 1 DRG point was  $\mathfrak{C}5,112$ , referring to an average patient.

Cost group 2 contains pharmaceuticals and use of prescribed psoriasis medication and cost of "over-the-counter" (OTC) and skin-care-related self-care products.

Cost group 3 covered cost for production loss for employed patients, limited to work absenteeism (18). The human capital approach was used to estimate the costs of sick leave (19), estimated as the number of days each participant was absent from work due to psoriasis. We used the median gross income in 2012 in Norway (NOK446,200=€59,732 per year) (Statistics Norway 2012, http://www.ssb.no) adjusted by 1.4 to account for social costs. For patients who worked part-time, this productivity cost was reduced in proportion to the time worked. The cost of delivering the intervention is presented in Table SII¹ together with information on cost per unit.

## Economic evaluation

QALYs were calculated by plotting health-related quality of life (HRQoL) against time and applying the area under the curve approach using the trapezoidal method (20). The incremental cost-effectiveness ratio (ICER) was calculated as the mean difference in costs between the 2 trial groups divided by their difference in QALYs. Because a positive outcome is measured by a reduction in DLQI, we adjusted by including a negative sign in the definition of the ICER including DLQI. To avoid ambiguous interpretations of the ICER, we also report the findings by Net Monetary Benefit (NMB), defined as NBM= $\lambda$ \*  $\Delta E - \Delta C$ , where lambda ( $\lambda$ ) is the threshold value for a health gain and is suggested to be €62,500. All else being equal, one should adopt programmes with net monetary benefit greater than zero (19). Cost-effectiveness acceptability curves (CEACs) were estimated to consider the uncertainty surrounding the costeffectiveness (in €) of the MI programme (21, 22).

## Statistical analysis

Normally distributed continuous data are indicated as mean value with SD and non-normally distributed data as median value with minimum and maximum values. To analyse differences between groups, we used independent sample t-tests with corresponding 95% confidence intervals (95% CI) 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. All analyses were performed with the use of SPSS version 21, Excel or STATA software. We estimated uncertainty around the ICER using bootstrapping, generating 1,000 replications of each ratio (replicated ICERs). We controlled for imbalance in baseline HRQoL in the estimation of mean differential QALYs by regression analysis, as

recommended by Manca et al. (23). Missing values on cost items, healthcare utilization, 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 ( $\mathfrak{E}$ ), using an exchange rate of  $\mathfrak{E}1=$ NOK7.47 (medium value in 2012). All costs and outcomes fell within a 6-month period, and therefore discounting was not appropriate.

## **RESULTS**

Baseline characteristics for each group are described in Table I. For this economic evaluation, no significant differences were 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=0.005).

#### 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), indicating a between-group difference of -0.32 (95% CI -0.60, -0.003), p=0.029. After 3 months, the 15D score for the MI group increased to 0.88 and then decreased to 0.87 at 6 months. The controls remained at 0.90. After adjusting for baseline differences as recommended (23), the mean incremental effect for the 6-month-long study period showed no significant differences between the groups -0.0022 QALYs (95% CI -0.02, 0.01), p=0.77 (Table II).

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 3 months. Betweengroup differences were -2.81, (-4.76, -0.85), p = 0.005. These differences were not significant at 6 months. The incremental effect after adjusting for baseline showed no significant differences, -0.62 QALYs (95% CI, 0.41, -1.65), p = 0.24, (see Table II).

## Costs

Our estimated mean cost per participant for the delivery of the MI intervention was €243 (Table SII¹). No significant differences were found in either of the cost groups at baseline. Table SIII¹ summarizes 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 healthcare 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 healthcare services for both groups at 3 months and 6 months after CHT treatment, compared with the 3 months before. The study group consulted the dermatologist significantly less often than the control group subjects during the

Table I. Baseline characteristics

Variables	Study (n=86)	Control (n=83)	Between-group difference (95% CI), <i>p</i> -value <sup>a-c</sup>
Male/Female, (%) n	59.3 (51)/40.7 (35)	53.0 (44)/47.0 (39)	$\chi^2 = 0.68 \ (p = 0.41)^b$
Age, years, mean (SD)	46.2 (12.7)	46.5 (13.0)	$0.30 (-4.2, 3.6), p=0.88^{a}$
PASI at arrival climate heliotherapy, mean (SD)	7.79 (4.78)	8.42 (4.04)	-0.63(-1.98, 0.72), p=0.36
PASI at departure climate heliotherapy, mean (SD)	1.93 (1.85)	2.3 (1.87)	-0.38 (-0.94, 0.19), p=0.19
Duration of disease, years, mean (SD)	24.6 (14.3)	21.2 (13.4)	$3.39 (-0.84, 7.63), p=0.12^a$
Self-assessed health status (1–5=poor–excellent), mean (SD)	2.70 (0.90)	3.10 (0.89)	$-0.40 (-0.67, -0.12), p = 0.005^a$
15D instrument (14), mean (SD)	0.86 (0.095)	0.90 (0.089)	-0.32, $(-0.60, -0.003)$ , $p = 0.029$
Level of education, $\%$ (n)			· · · · · · · · · · · · · · · · · · ·
Primary/secondary school ≤10 years	16 (13)	11.3 (9)	$\chi^2 = 0.98 \ (p = 0.41)^b$
High school < 13 years	45.7 (37)	46.3 (37)	, ,
College/university < 4 years	18.5 (15)	18.8 (15)	
College/university ≥4 years	19.8 (16	23.8 (19)	
Paid work (Yes/No), n	67/18	69 /12	$\chi^2=1.13 \ (p=0.29)^b$

Difference between groups: and end individual analyses because of missing values. n differs among individual analyses because of missing values.

PASI: Psoriasis Severity and Area Index; CI: confidence interval; SD: standard deviation.

6 months following CHT, indicating less cost €–105 (–189, –20), p=0.016. The same tendency was seen in ultraviolet B (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 6-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  $\in$ -799 (-1,499, -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  $\in$ 1,048 less in production losses in the 6 months following CHT, but this difference was not significant (p=0.46).

When computing all 3 cost groups in the 6 months post-CHT, the study group had a lower cost than the TAU group, with a mean difference of  $\in$ 1,780. When excluding productivity loss from the calculation, the mean incremental cost was  $\in$ -1,103 (-2,293, 87), p=0.058 (Tables SIV¹ and SV¹).

Incremental cost-effectiveness ratio (ICER)

When using 15D QALYs, the ICER ( $\Delta$ costs (C)/  $\Delta$ effectiveness (E)) and the NMB ( $\lambda$ \*  $\Delta$ E- $\Delta$ C) was, respectively, €500,909 and €965.5 (small negative incremental effect and negative incremental costs). The ICER when using DLQI was €-1779, indicating a positive incremental effect and cost savings (Table II). For both ICERs MI is a dominant strategy. Fig. 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.

No statistically significant differences were found in costs and effects between MI and TAU, and the 15D cost-effectiveness plane for this comparison confirmed this. The

Table II. Health outcomes (15D and DLQI) according to treatment group and time period

Treatment group	Utility measures	Baseline Mean (SD)	3 months Mean (SD)	6 months Mean (SD)	AUC (SD)*	Differential group difference QALYs*
Motivational interviewing intervention	15D	0.86 (0.095)	0.88 (0.097)	0.87 (0.084)	0.4365 (0.035)	
Treatment-as-usual	15D	0.90 (0.089)	0.90 (0.094)	0.90 (0.083)	0.4386 (0.039)	-0.0022 ( $-0.02$ , 0.01), $p=0.77$
Motivational interviewing intervention	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	DLQI	10.99 (6.10)	8.8 (7.18)	9.27 (7.14)	4.43 (2.94)	

DLQI: Dermatological Life Quality Index; SD: standard deviation; QALYs: quality-adjusted life years.

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 incremental cost-effectiveness ratio (ICER) has a negative sign because a positive outcome is measured by a reduction in DLQI.

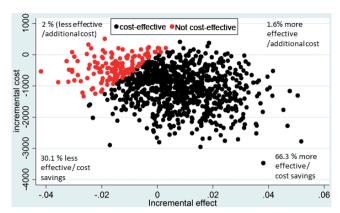


Fig. 1. Incremental cost and quality-adjusted life years (QALYs) (15D) for motivational interviewing compared with treatment-as-usual (TAU). Bootstrap costs and effects for 15D. Costs in euros within the 6 months after climate heliotherapy (CHT). Cost and effect pairs were estimated with 1,000 bootstrap replications.

CEAC (Fig. S1¹) showed that at a threshold value of zero, there was a 95% probability that MI was cost-effective. The acceptability curve indicates that, for higher thresholds for improvements in 15D (or cost of health lost), the intervention is less likely to be cost-effective and converge towards 67.9% probability of being cost-effective.

#### DISCUSSION

This study found that MI, as a follow-up after CHT, was less costly than TAU. MI was at least as effective as TAU and is the preferred alternative from a societal perspective. By adding a societal perspective we acknowledge that sectors other than the health service may incur costs or benefits as a result of a healthcare intervention such as MI. There is clearly a cost associated with psoriasis for the individual patient and the family (e.g. work loss, stress-related illnesses, and increased expenses) that fall under the general rubric of quality of life (24). However, there are limited data available that quantify and enable monetization of these issues. An accurate understanding of the societal costs of chronic conditions such as psoriasis is important for policy-makers. Information about costs of illness is often a necessary criterion for justifying and planning prevention and intervention.

It is most usual for a new health intervention to be associated with increased costs compared with the treatment-as-usual alternative (19). Thus, the reduced costs after implementing MI is a positive finding, as we had anticipated that the study group participants would rather utilize more healthcare costs, due to the focus on comprehensive psoriasis care in the motivational talks.

In this study, 2 different, but relevant, instruments were applied to illuminate the health effects. The results indicate that MI provides improvements in subjects' HRQoL when the disease-specific DLQI is used; however, there were no significant differences in QALYs gained. The MI group also achieved a 0.02 increase in

the 15D score just after the intervention, indicating a significant clinical difference (15); 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. Therefore, we chose to correct these differences using regression analyses, as patient's baseline utility is likely to be highly correlated with their QALYs over the follow-up period. Such imbalance when calculating differential QALYs may result in a misleading incremental cost-effectiveness ratio, regardless of whether these differences are formally statistically significant (23).

The findings of 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 (25). Also, other studies have found such differences (26, 27). 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. 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 healthcare and reported more productivity losses, and some needed biologic therapies.

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, For instance, the resulting 15D measures may underestimate psoriasis disease burden due to its limited characterization of psoriasis-specific HRQoL domains.

Exploring the cost-effectiveness of a behavioural health intervention is known to have different methodological implications compared with surgical and pharmaceutical interventions (28). 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) (29), 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 discussing current treatment choices, supporting the patients' self-management regarding symptom management. facilitating development of problem-solving skills and providing emotional support (11). Ignoring delayed effects may negatively bias CEA outcomes and, as a result, cost-effectiveness of behavioural interventions may be underestimated with the current methodology (28).

Some limitations should be considered when interpreting the results of this study. The fact that all information is based on questionnaires may mean that some information was under-or over-rated because of the 3-month intervals.

Some services as social care costs were not explicitly included, but are unlikely to influence the conclusions. In addition, 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. The limited follow-up of 6 months is a limitation to external validity and may have affected the conclusion of the study. We have no knowledge of whether the OoL differences between the groups will further decrease or remain stable within a longer time-frame. On the other hand, behavioural and lifestyle changes may take a long time to incorporate into everyday life, as described by the transtheoretical model of behaviour change (30). This may also positively influence the HROoL of the study group, because they have developed problem-solving skills and better self-efficacy towards behaviour change as the clinical paper advocates (11). 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.

This study found no significant impact of MI regarding QALY and no persistent impact on general QOL. However, considering that tailored follow-up with MI after CHT showed significant cost saving, the MI approach is cost-effective in addition to its positive effects on clinical outcomes (11).

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