Supplementary material to article by M. H. Larsen et al. "Cost-utility Analysis of Supported Self-management with Motivational Interviewing for Patients with Psoriasis"

Appendix S1

MATERIAL AND METHODS

Study design and participants

This economic evaluation was designed alongside a randomized controlled trial of 169 Norwegian patients participating in CHT. Patients were 20–70 years old with moderate to severe psoriasis (PASI >7 at application), were capable of answering questionnaires and communicating by telephone. Full inclusion and exclusion criteria are presented in the original clinical paper (11).

Ethical approval

Throughout the study, the principles outlined in the Declaration of Helsinki were followed (12). 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 programme

CHT includes individualized sun exposure in increasing doses as the main treatment. Thus, the sun exposure is dependent on skin type and the current ultraviolet (UV) index. In addition, the programme emphasizes daily physical training, tailored education, group discussions and individual consultations and supervision by nurse and dermatologist. Hence, the 3 weeks of CHT programme consists of both sun treatment and patient education (Table SII¹).

Motivational interviewing

Motivational interviewing (MI) is defined as "a collaborative, conversation style for strengthening a person's own motivation and commitment to change" (10, 12). The MI counsellor focuses on assisting patients to identify their problems and also overcome ambivalence and resistance to behaviour change. Thus, MI is a method of engaging with patients to enable them to make their desired changes to personal health behaviours. 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 (10). For example, by estimating the importance of and their personal readiness for changing the desired behaviour, the patients may strengthen their determination to change and achieve increased self-efficacy.

Intervention

Both groups participated in CHT prior to the MI intervention and were randomized to the control or the intervention group after discharge, 1–2 days before returning to Norway. A more detailed description of the intervention is published elsewhere (11). Briefly, patients in the study group received 1 face-to-face mapping conversation (45–60 min) with the MI counsellor (main author) before returning home from Gran Canaria and 6 follow-up calls using the MI technique during the next 12 weeks. The follow-up calls discussed on 4 main self-management domains: diet, physical activity, stress management and psoriasis treatment, with psoriasis treatment as the only mandatory topic for each call. Patients could also choose other behaviour topics, perceived to be more important to them; such as smoking cessation, weight reduction or alcohol abuse, or domains of life that caused stress or concern, such as demanding work situations, personality traits or traumatic life events. A bubble sheet for agenda mapping was used to identify a first focusing domain to pursue change (11).

In addition, participants received a personal workbook with some open questions for reflection about change and some visual MI tools and exercises. The duration of the calls was between 15 and 60 min. The mean (SD) conversation time was 32.5 (SD 12.7) min and each participant received a mean of 3.3 (SD 1.3) h of phone counselling. Participants allocated to the control and study groups all obtained psoriasis TAU (from a dermatologist or a general practitioner (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 3 months, and at 6 months post-randomization (after 3 weeks of CHT). The baseline questionnaires covered resource use during the 3-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 (HROoL) generated by healthcare interventions (13). One year of perfect health equals 1 QALY. 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 5 levels ranging from "no problems" to "extreme problems" (14). Based on the Finnish valuations, the single index (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. The questionnaire is well validated and easy to use (14) (http://www.15d-instrument.net). The Cronbach's alpha was 0.81 for this study. A difference of 0.015 was recently stated 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). In this study, Cronbach's alpha was 0.90.

Cost

Information on healthcare utilization, medication, participants' costs and productivity loss was obtained through the 3-month and 6-month questionnaires. Information on cost per unit was collected from several sources (Table SII¹).

The different costs are analysed and presented in 3 different cost categories (Table SIII¹). Cost group 1 includes direct costs for primary and secondary healthcare services. Patients were asked to recall use of hospital services (i.e. outpatient and inpatient consultations, UV light treatment), medical specialists care (e.g. GP, dermatologist and rheumatologist), allied healthcare (e.g. physiotherapist and psychologist), as well as use of alternative medicine care (e.g. healer and acupuncture). Here we assessed the costs according to charge per treatment or Diagnosis-Related Group (DRG) codes for 2012. The DRG system classifies hospital services into groups that are medically related and homogeneous with regard to use of resources. DRG

Supplementary material to article by M. H. Larsen et al. "Cost-utility Analysis of Supported Self-management with Motivational Interviewing for Patients with Psoriasis"

is a way of describing the hospital's case-mix and depends on the patient's diagnosis, the procedures performed, complicating conditions, age, and discharge status. Each DRG is given a weight that reflects the treatment cost relative to an average patient. Thus, a more resource-intensive treatment will provide higher reimbursement than less resource-intensive treatment (17). In 2012, the cost for 1 DRG point was \notin 5,112 referring to an average patient. Travel cost was added to consultations with specialists, psychologists and hospital visits. UVB treatment was estimated together 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 OTC 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 (18). Changes in work status were recorded on the followup questionnaires. Patients who were students, unemployed, retired due to age, or on disability pension were excluded, as they were presumed to have no productivity losses. 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. This cost was estimated to be equal to average income and social costs. 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 were able to work part-time, this productivity cost was reduced in proportion to the time worked.

The cost of delivering the intervention is presented in Table SII¹.

Economic evaluation

We calculated QALYs by plotting HRQoL against time and applying the area under the curve approach using the trapezoidal method (20). This procedure generates a QALY gained for each patient over the 6-month period of the study. The 2 trial groups were then compared with generate the estimate of mean differential QALY. The incremental cost-effectiveness ratio (ICER) was calculated as the mean difference in costs between the 2 groups divided by their difference in QALYs gained, defined by:

1 C F D = -	Cost of intervention - Cost of TAU	_	ΔC
	Health effect of MI intervention – Health effect TAU		ΔE

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. To avoid ambiguous interpretations of the ICER, we also report the findings by Net Monetary Benefit (NMB), defined by NBM= $\lambda * \Delta E - \Delta C$. where lambda (λ) is the threshold value for a health gain and is suggested to be €62,500. All else equal, one should adopt programmes with net monetary benefit that are greater than 0 (19). 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 1.000 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 (21, 22).

Statistical 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, USA). 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. In addition, 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 (\in), using an exchange rate of ϵ 1=NOK7.47 (medium value in 2012). All costs and outcomes fell within a 6-month period, and therefore discounting was not appropriate.