

An educational programme for patients with psoriasis and atopic dermatitis: a prospective randomized controlled trial

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Summary

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Background Patient education in addition to standard treatment, with the aim of affecting care through courses, is a relatively new concept in dermatology. Here we introduce a randomized controlled trial (RCT) regarding a previously described 12-week educational programme for chronic skin diseases.

Objectives The primary objective of the RCT was to measure the effect of an educational programme on disease severity and quality of life in patients with psoriasis or atopic dermatitis.

Methods We recruited 50 patients from Ghent University Hospital. Patients with diagnosed psoriasis or atopic dermatitis were randomized (1 : 1) to the intervention or control group. The clinical outcome was measured by two blinded observers using the Psoriasis Area and Severity Index (PASI), Scoring Atopic Dermatitis or the Eczema Area and Severity Index. Quality of life was measured by dermatology-specific quality-of-life questionnaires. There was a follow-up period of 9 months.

Results We found that disease severity and quality of life improved significantly for patients with psoriasis ($n = 29$) but not for patients with atopic dermatitis ($n = 21$) at 3 months. Patients in the intervention group showed a significant reduction in mean PASI ($P = 0.036$), mean Dermatology Life Quality Index ($P = 0.019$) and mean Psoriasis Disability Index ($P = 0.015$), compared with the control group at 3 months. This improvement continued for at least 6 months, i.e. 3 months after the intervention, but was lost at follow-up after 9 months.

Conclusions Evaluating this form of educational programme, by means of a single-centre RCT, indicates its added value in the longer term management of psoriasis.

Chronic skin diseases, such as psoriasis and atopic dermatitis, have a profound negative impact on patients' quality of life.^{1,2} Because treatment is highly self-demanding, we see a low compliance to therapy, resulting in poor clinical outcomes.^{3,4} Therefore, patient education and motivation plays an increasingly important role in the long-term management of chronic skin diseases. Successful education increases patient satisfaction and improves health outcomes and adherence to treatment.^{5,6}

As more studies are needed within this context, we set up further research on our previously described group-based educational programme.⁷ We conducted a prospective, single-blinded, randomized controlled trial (RCT) in adult patients with psoriasis and atopic dermatitis, to investigate whether our educational programme is of added value to medical therapy. The effects on disease severity and quality of life were measured as primary end points at different time points. Furthermore, the level of depression, lifestyle changes and the effect on medical consumption were followed over 9 months.

Patients and methods

Patient population and study procedures

From February 2010 to 2011, 50 patients were recruited from three different sources: Ghent University Hospital ($n = 18$), patient advocacy groups ($n = 26$) and peripheral dermatologists ($n = 6$). Patients older than 18 years with psoriasis or atopic dermatitis were eligible to participate in the trial. At inclusion, patients were checked for diagnosis by a dermatologist. Exclusion criteria were other severe illnesses, psychiatric disorders and cognitive disorders. The patients were randomized (1 : 1) to the intervention or control group. This procedure involved computer-generated randomization of lists in which allocation was indicated, and stratified by diagnosis using a block size of two. Sequentially numbered envelopes were used by the investigator to assign patients to the intervention or control group. Patients assigned to the intervention group participated in the educational programme while still

receiving medical therapy, whereas patients assigned to the control group received only medical therapy. Three runs of the programme were included in the trial: 14 patients started in spring 2010, 23 in autumn 2010 and 13 in spring 2011. Patients were assessed at four study visits: before the start of the programme (baseline), after the programme (3 months) and at two follow-up visits at 6 and 9 months after the start. The study was approved by the local ethical committee (registration number B67020097924) and was registered on <http://www.clinicaltrials.gov> (NCT01077882).

Intervention: group-based educational programme

The 12-week educational programme consisted of 2-h sessions twice a week, including several components: (i) education on the patient's skin disease, (ii) education on a healthy lifestyle, (iii) application of stress-reducing techniques and (iv) feedback. The first part included an information session on the patient's skin disease given by a dermatologist, and three skin care sessions given by a dermatological nurse and pharmacist. The second part contained education on diet, responsible physical training, sleep hygiene, smoking, substance abuse, psychodermatology and practical philosophy, given by a team of trainers: a dietician, training expert, psychiatrist, psychologist and philosopher. The third part consisted of weekly physical training, yoga and mindfulness meditation taught by a sports, yoga and mindfulness teacher. The fourth and final part contained two feedback sessions with a dermatologist. Detailed content of the programme is described in Lambert *et al.*⁷

Primary outcomes

Disease severity

Two clinicians performed the assessments of disease severity at the four study visits and were blinded for randomization. The clinical severity of psoriasis was assessed by the Psoriasis Area and Severity Index (PASI),⁸ and the severity of atopic dermatitis by Scoring Atopic Dermatitis (SCORAD) and the Eczema Area and Severity Index (EASI).⁹ Clinicians were trained to define the PASI, SCORAD and EASI before start of the trial. The level of agreement between both clinicians' assessments on PASI, SCORAD and EASI was very good. The intraclass correlation coefficient was 0.86 [95% confidence interval (CI) 0.72–0.94] for PASI, 0.89 (CI 0.74–0.96) for SCORAD and 0.92 (CI 0.82–0.97) for EASI.

Quality of life

Patients completed the following validated, self-administered quality-of-life questionnaires at the four study visits: Dermatology Life Quality Index (DLQI),¹⁰ Skindex-29,¹¹ Psoriasis Disability Index (PDI)¹² and Quality of Life Index for Atopic Dermatitis (QoLIAD).¹³ DLQI and Skindex-29 are dermatology-specific quality of life instruments. DLQI is a historical

comparator and focuses on disability, thereby not fully capturing the emotional aspects of patients' lives. Skindex-29 is a more sensitive instrument for different dimensions of quality of life, including emotions. PDI and QoLIAD are disease-specific quality-of-life questionnaires. More information about the questionnaires is given in Lambert *et al.*⁷

Secondary outcomes

Depression severity

The Beck Depression Inventory (BDI) is a self-completed questionnaire with 21 questions. It is one of the most widely used instruments for measuring depression severity.¹⁴ Patients were categorized as having minimal (0–9), mild (10–18), moderate (19–29) or severe (30–63) depression. BDI scores were collected during four study visits.

Lifestyle

Patients were queried monthly for changes in smoking behaviour and physical activity. Physical activity was categorized as: sedentary activity (1), light physical activity (walking, biking) < 4 h weekly (2), or at least 4 h weekly (3), and moderate physical activity (sports) < 4 h weekly (4), or at least 4 h weekly (5).¹⁵ Stress was examined by the Everyday Problem Checklist during four study visits.¹⁶ Patients were categorized as having a low (men ≤ 6, women ≤ 4), normal (men 7–36, women 5–33) or high (men ≥ 37, women ≥ 34) stress level.

Medical consumption and cost-effectiveness evaluation

The medical therapy of the patients was divided into topical therapy, systemic therapy, combination of topical and systemic therapy or no therapy. Topical therapy included corticosteroids with or without calcipotriol, calcineurin inhibitors, tar ointment and hydration. Systemic therapy included methotrexate, ciclosporin, acitretin, oral corticosteroids and ultraviolet (UV) B. Patients were asked about changes in medical therapy monthly. Also, medical consumption was followed, i.e. costs for medication and doctor visits related to the management of the skin disease. EuroQol-5D (EQ-5D) questionnaires were used as a standardized instrument to measure health outcomes. For cost–utility analysis, the gain in quality-adjusted life years utility was plotted against time, using the area under the curve approach (cost in euro/EQ-5D gain).

Statistics

Power calculation showed that 34 patients were needed for this RCT. There is an 80% probability that the study would detect a treatment difference at a two-sided 0.05 significance level if the mean difference between treatments is 2 and the standard deviation is 2. Data were analysed using SPSS software (SPSS Inc., Chicago, IL, U.S.A.). Mixed modelling analysis was performed to identify differences in time between the

intervention and control groups for each outcome variable. These data were presented as mean and 95% CI. The intraclass correlation coefficient was the measured level of agreement between both clinicians. The Spearman correlation coefficient measured the correlation between quality of life and disease severity.

Results

Patient population

Fifty patients participated in our trial, 29 with psoriasis and 21 with atopic dermatitis. There were 24 men and 26 women. The mean age was 39.6 ± 12.2 years, with a range of 21–63 years. The mean duration of disease was 19.5 ± 11.1 years. At baseline, the average disease severity was mild for psoriasis; mean PASI was 7.7 ± 3.9 . For atopic dermatitis, the average disease severity was moderate; mean SCORAD was 38.9 ± 16.3 and mean EASI was 11.1 ± 9.3 . The average quality of life for the total group was moderately to severely affected at baseline; mean DLQI was 8.5 ± 5.5 and mean Skindex-29 was 44.4 ± 16.8 . BDI showed a mean value of 9.8 ± 7.4 , which represents a minimally depressive state. The highest educational attainment of the total group was low in 4%, medium in 38% and high in 58%; 57% were professionally active and 43% were professionally inactive (including students and pensioners); 71% had a multiperson household and 29% were living alone. Regarding treatment modalities, 76% of the patients were on topical therapy, 2% on systemic therapy, 14% on topical and systemic therapy and 8% received no therapy at baseline. Table 1 shows the base-

line characteristics of the patients in the intervention and control groups.

Up to 3 months, there were nine dropouts, and a further three patients dropped out during the following 6 months. Reasons for dropout in the intervention group included lack of time, the programme being too intensive and moving house. In the control group, worsening of skin disease and loss of motivation were reasons given for dropout. Figure 1 shows a flow diagram of progress through the phases of the trial.

Primary outcomes

Disease severity and quality of life improved significantly after participation in the programme in the psoriasis group, but not in the atopic dermatitis group. These effects were maintained for at least 6 months but were lost at 9 months follow-up. Moreover, we saw a moderate correlation between quality of life and disease severity in the patients with psoriasis and atopic dermatitis. At baseline, the Spearman correlation coefficient between PASI and DLQI was 0.6, and between SCORAD and DLQI it was 0.5.

Disease severity and quality of life in patients with psoriasis

We analysed data from 29 patients with psoriasis at 3 months. At 6 and 9 months, data from 28 patients with psoriasis were analysed. One patient was excluded from analysis because here condition deteriorated severely due to stress caused by workplace bullying.

Table 1 Baseline characteristics of patients in the intervention and control groups

Variables	Intervention	Control
Sex: M/F (%)	48/52	48/52
Diagnosis: psoriasis/atopic dermatitis (%)	60/40	56/44
Age (years)	38.5 (± 12.3)	40.6 (± 12.2)
Duration of disease (years)	18.9 (± 11.0)	20.1 (± 11.4)
Age at onset of disease (years)	19.6 (± 17.3)	20.5 (± 17.4)
Education: low/medium/high (%)	4/22/74	4/52/44
BMI	24.4 (± 4.2)	25.3 (± 4.9)
PASI	8.9 (± 4.3)	7.1 (± 3.8)
SCORAD	38.9 (± 18.0)	38.8 (± 15.5)
EASI	11.9 (± 10.9)	10.4 (± 8.1)
DLQI	9.7 (± 6.0)	7.5 (± 5.0)
Skindex-29 total	45.5 (± 16.1)	43.3 (± 17.7)
Skindex-29 symptoms	58.1 (± 15.4)	55.8 (± 18.4)
Skindex-29 emotions	48.9 (± 19.6)	49.0 (± 22.7)
Skindex-29 functioning	35.2 (± 20.4)	30.8 (± 21.4)
QoLIAD	9.1 (± 5.6)	9.6 (± 6.1)
PDI	9.0 (± 6.8)	7.6 (± 7.8)
BDI	11.3 (± 8.2)	8.4 (± 6.5)

Values are mean ($\pm$ SD) unless otherwise indicated. BMI, Body mass index; PASI, Psoriasis Area and Severity Index; SCORAD, Scoring Atopic Dermatitis; EASI, Eczema Area and Severity Index; DLQI, Dermatology Life Quality Index; QoLIAD, Quality of Life Index for Atopic Dermatitis; PDI, Psoriasis Disability Index; BDI, Beck Depression Inventory.

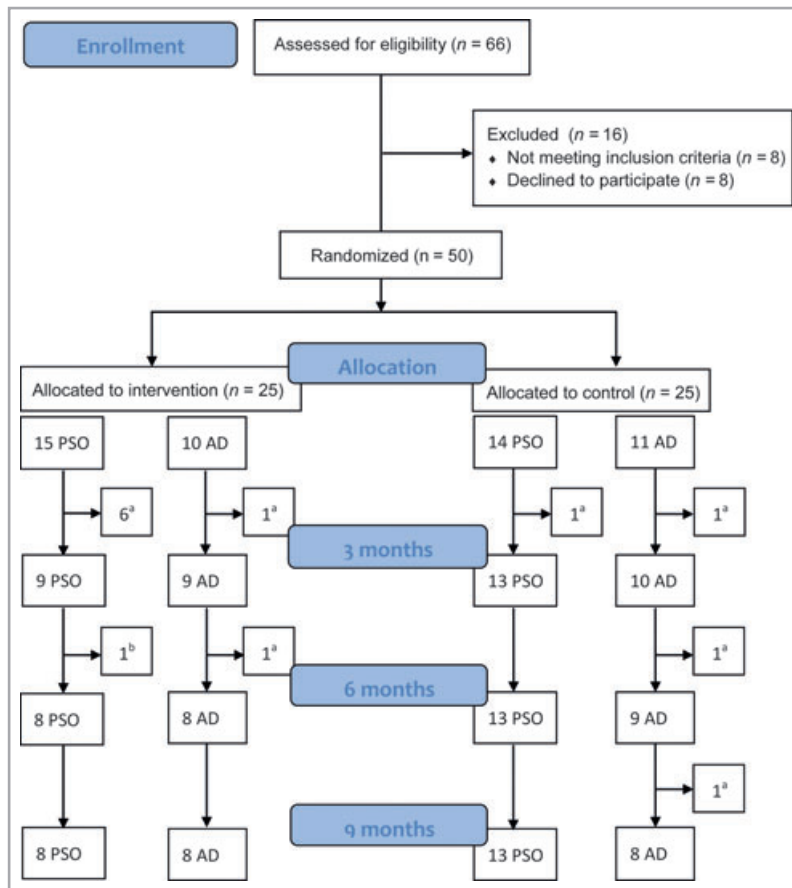


Fig 1. Flow diagram of the progress through the phases of the trial. ^aDropouts, ^bexcluded from analysis. PSO, patients with psoriasis; AD, patients with atopic dermatitis.

Psoriasis area and Severity Index

At 3 months, intervention patients showed significant reduction ($P = 0.036$) in mean PASI going from 8.4 (CI 6.0–10.8) at baseline to 6.8 (CI 4.3–9.3) at 3 months, compared with the control group, which had mean PASI going from 7.1 (CI 4.8–9.4) at baseline to 8.1 (CI 5.8–10.4) at 3 months.

At 6 months, intervention patients showed significant reduction ($P = 0.017$) in mean PASI going from 8.6 (CI 5.8–11.4) at baseline to 6.5 (CI 3.6–9.4) at 3 months, and 5.9 (CI 3.0–8.9) at 6 months compared with the control group, which showed mean PASI going from 7.1 (CI 4.6–9.7) at baseline to 8.1 (CI 5.6–10.7) at 3 months and 7.8 (CI 5.2–10.3) at 6 months.

At 9 months, intervention patients showed reduction in mean PASI going from 8.6 (CI 5.6–11.6) at baseline to 6.5 (CI 3.3–9.8) at 3 months, 6.0 (CI 2.7–9.2) at 6 months and 7.0 (CI 3.8–10.3) at 9 months, compared with the control group, which showed mean PASI going from 7.1 (CI 4.3–9.9) at baseline to 8.1 (CI 5.3–10.9) at 3 months, 7.8 (CI 5.0–10.6) at 6 months and 7.0 (CI 3.8–10.3) at 9 months, but this did not reach significance ($P = 0.116$, Fig. 2a).

Dermatology Life Quality Index

At 3 months, patients in the intervention group showed significant reduction ($P = 0.019$) in mean DLQI going from 8.4

(CI 5.6–11.2) at baseline to 4.4 (CI 1.3–7.4) at 3 months, compared with the control group, which showed mean DLQI going from 6.6 (CI 3.9–9.3) at baseline to 6.4 (CI 3.6–9.2) at 3 months.

At 6 months, patients in the intervention group showed reduction in mean DLQI going from 8.0 (CI 5.0–11.0) at baseline to 4.8 (CI 1.4–8.2) at 3 months and 4.7 (CI 1.3–8.0) at 6 months, compared with the control group, which showed mean DLQI going from 6.6 (CI 3.8–9.4) at baseline to 6.4 (CI 3.5–9.3) at 3 months and 6.9 (CI 4.1–9.8) at 6 months, but this did not reach significance ($P = 0.089$).

At 9 months, intervention patients showed reduction in mean DLQI going from 8.0 (CI 4.9–11.1) at baseline to 4.8 (CI 1.4–8.2) at 3 months, 4.7 (CI 1.3–8.0) at 6 months and 4.0 (CI 0.6–7.4) at 9 months, compared with the control group, which showed mean PASI going from 6.6 (CI 3.7–9.5) at baseline to 6.4 (CI 3.5–9.3) at 3 months, 6.9 (CI 4.0–9.8) at 6 months and 5.8 (CI 2.9–8.8) at 9 months, but this did not reach significance ($P = 0.100$, Fig. 2b).

Psoriasis Disability Index

At 3 months, intervention patients showed significant reduction ($P = 0.015$) in mean PDI going from 9.0 (CI 5.0–13.0) at baseline to 4.3 (CI 0.1–8.4) at 3 months compared with the control group, which had mean PDI going from 7.6 (CI 3.8–11.5) at baseline to 6.7 (CI 2.9–10.6) at 3 months.

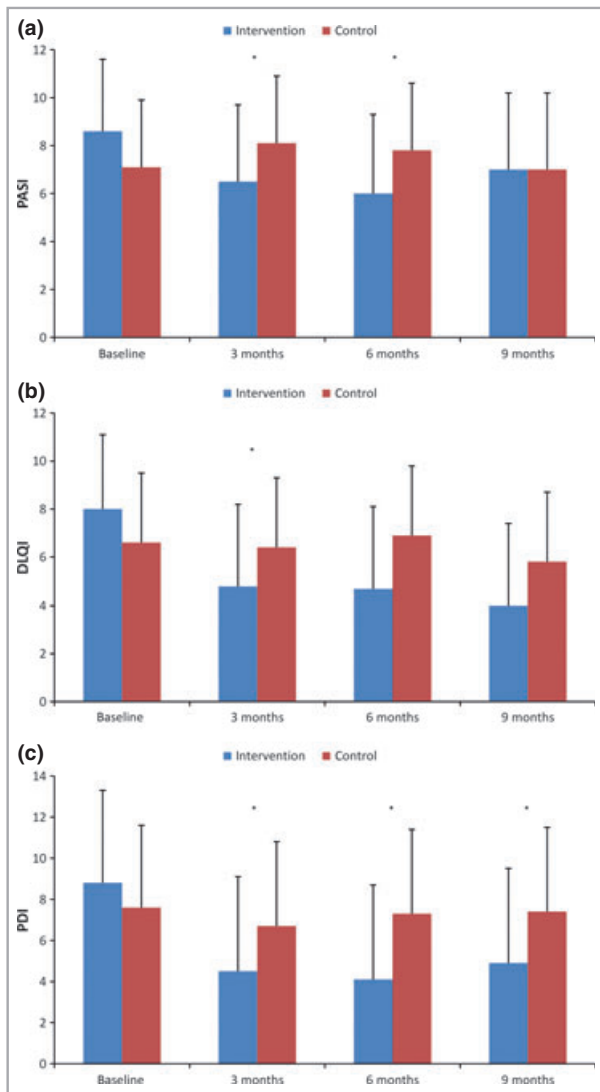


Fig 2. (a) Disease severity of psoriasis, as assessed by the Psoriasis Area and Severity Index (PASI), for intervention patients (blue columns) and control patients (red columns) at baseline, 3, 6 and 9 months follow-up. All values are mean and 95% confidence interval. * $P < 0.05$. (b) Quality of life of patients with psoriasis, as assessed by the Dermatology Life Quality Index (DLQI), for intervention patients (blue columns) and control patients (red columns) at baseline, 3, 6 and 9 months follow-up. All values are mean and 95% confidence interval. * $P < 0.05$. (c) Quality of life of patients with psoriasis, as assessed by Psoriasis Disability Index (PDI), for intervention patients (blue columns) and control patients (red columns) at baseline, 3, 6 and 9 months follow-up. All values are mean and 95% confidence interval. * $P < 0.05$.

At 6 months, intervention patients showed significant reduction ($P = 0.020$) in mean PDI going from 8.8 (CI 4.5–13.0) at baseline to 4.5 (CI 0.1–9.0) at 3 months and 4.2 (CI –0.3–8.6) at 6 months, compared with the control group, which showed mean PDI going from 7.6 (CI 3.7–11.6) at baseline to 6.7 (CI 2.7–10.7) at 3 months and 7.3 (CI 3.3–11.3) at 6 months.

At 9 months, intervention patients showed significant reduction ($P = 0.021$) in mean PDI going from 8.8 (CI 4.3–13.2) at baseline to 4.5 (CI –0.1–9.1) at 3 months, 4.1 (CI –0.5–8.7) at 6 months and 4.9 (CI 0.3–9.5) at 9 months, compared with the control group, which showed mean PDI going from 7.6 (CI 3.6–11.7) at baseline to 6.7 (CI 2.6–10.8) at 3 months, 7.3 (CI 3.2–11.4) at 6 months and 7.4 (CI 3.3–11.6) at 9 months (Fig. 2c).

Skindex-29

No significant differences in Skindex-29 were seen between the intervention and control groups of patients with psoriasis.

Disease severity and quality of life of atopic dermatitis

We analysed data from 21 patients with atopic dermatitis. No significant differences were seen between the intervention and control groups of patients with atopic dermatitis for SCORAD, EASI, DLQI, Skindex-29 or QoLIAD.

Secondary outcomes

Depression severity

At 9 months, we analysed depression data from 29 patients with psoriasis. Patients in the intervention group showed a significant reduction ($P = 0.029$) in mean BDI going from 12.3 (CI 8.3–16.4) at baseline to 10.5 (CI 6.1–14.9) at 3 months, 9.1 (CI 4.7–13.5) at 6 months and 6.1 (CI 1.7–10.5) at 9 months, compared with the control group, which had mean BDI going from 7.4 (CI 3.5–11.3) at baseline to 6.3 (CI 2.3–10.3) at 3 months, 8.1 (CI 4.1–12.0) at 6 months and 7.3 (CI 3.2–11.3) at 9 months (Fig. 3). No significant differences for BDI were seen between the intervention and control groups for atopic dermatitis.

Lifestyle

Patients were queried on a monthly basis for changes in smoking behaviour and physical activity. At baseline, 13 patients were smokers (26%), of whom seven were randomized to the intervention group. In the intervention group, one patient stopped smoking after 3 months and one patient reduced to half the amount of cigarettes after 6 months. There were no changes in smoking behaviour in the control group ($n = 6$). Figure 4 shows the physical activity of the patients. The intervention group had a significantly higher physical activity level ($P = 0.035$) than the control group during the entire study. At baseline, 64% of participants agreed on the negative influence of stress on their skin disease. The Everyday Problem Checklist ($n = 27$) revealed low stress levels in 7.4%, normal stress levels in 44.4% and high stress levels in 48.1% of patients at baseline. However, we could not show significant differences in stress levels between the control and intervention groups during the study.

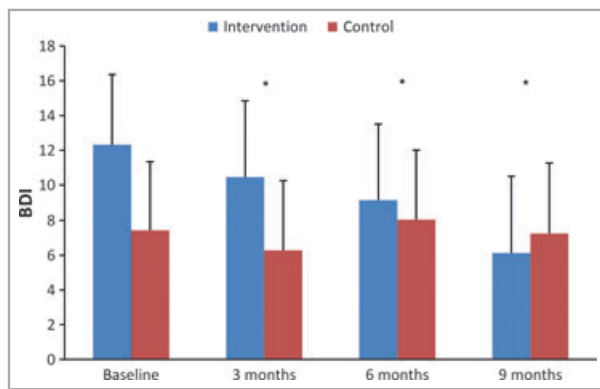


Fig 3. Mean depression scores for psoriasis, as assessed by the Beck Depression Inventory (BDI), for intervention patients (blue columns) and control patients (red columns) at baseline, 3, 6 and 9 months follow-up. All values are mean and 95% confidence interval.

* $P < 0.05$.

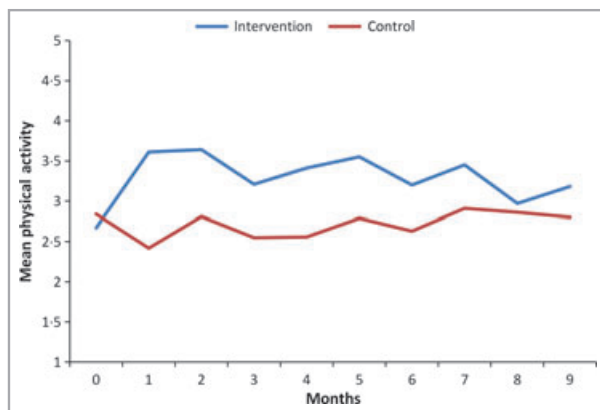


Fig 4. The intervention group has significantly more physical activity ($P = 0.035$) than the control group during the 9 months of the study. Physical activity: 1, sedentary; 2, light < 4 h per week; 3, light > 4 h per week; 4, moderate < 4 h per week; 5, moderate > 4 h per week.

Medical consumption and cost-effectiveness evaluation

Treatment interventions were allowed in both the intervention and control groups. We monitored treatments by questionnaire and found no major differences between the study arms over the period of the study (Table 2). We could not show significant differences in medical consumption between the control and intervention groups over the period of study. EQ-5D values in the intervention group were not significantly better than in the control group at 6 months. Cost-utility analysis taking into account programme cost per patient and medical resource use per individual patient did not show cost-effectiveness at 6 months.

Discussion

In this RCT, at 3 months we found that our educational programme contributed to an improved disease severity and quality of life in patients with psoriasis. This improvement

Table 2 The numbers (n) of patients undergoing particular types of medical therapy (topical, systemic, combination of topical and systemic therapy, no therapy) over the time of the study in the intervention and control groups, and by diagnosis

Time point	Type of therapy	Intervention, n		Control, n	
		Psoriasis	Atopic dermatitis	Psoriasis	Atopic dermatitis
Baseline	Topical	9	8	12	9
	Systemic	—	—	1	—
	Combination	2	2	1	2
	None	4	—	—	—
	Total	15	10	14	11
3 months	Topical	5	7	12	8
	Systemic	—	—	—	—
	Combination	2	1	—	2
	None	2	1	1	—
	Total	9	9	13	10
6 months	Topical	4	6	12	7
	Systemic	—	—	—	—
	Combination	2	1	—	2
	None	2	1	1	—
	Total	8	8	13	9
9 months	Topical	3	7	10	7
	Systemic	—	—	1	—
	Combination	2	1	1	1
	None	3	—	1	—
	Total	8	8	13	8

continued for at least 6 months, i.e. 3 months after the intervention, and was not related to major changes in medical therapy or influence of seasonal variation. Furthermore, an improvement in physical activity was seen in the intervention group but not in the control group. Lastly, there was a longer positive effect on the depression status of patients with psoriasis.

These findings support previous studies showing that patient education contributes to improved quality of life and clinical outcomes. In a multicentre RCT, Staab *et al.*¹⁷ showed that education for children with atopic dermatitis resulted in an improved quality of life and disease severity ($n = 992$). Also, Fortune *et al.*¹⁸ found that a cognitive behavioural symptom management programme for adult patients with psoriasis is beneficial in the management of psoriasis ($n = 93$). De Bes *et al.*⁵ critically evaluated studies regarding educational programmes in patients with chronic skin diseases conducted between 2000 and 2008. Interventions that were more intensive and were delivered over a longer time scale (3 months or more) were more successful than briefer interventions.¹⁹

Important limitations of our study are the influence of confounding factors such as changes in therapy. Treatment interventions were not restricted in either the intervention or control group. Most patients were receiving topical therapy, as they had mild disease. We monitored treatments by questionnaire and found no major imbalances between study arms

(Table 2), but we cannot exclude an influence of minor changes in therapy. Furthermore, the use of self-administered quality-of-life questionnaires could lead to bias because patients are not blinded for the treatment allocation. Nevertheless, bias by seasonal variation was reduced by staggering recruitment across seasons. There were 27 patients participating in spring and 23 participating in autumn.

No attempt was made with regard to our educational programme on eliciting the effects of individual components of the intervention. It would be interesting to study this in the future, especially with regard to psoriasis.

Evaluating this form of educational programme, through the means of a single-centre RCT, indicates its added value in the longer term management of psoriasis. We cannot provide a satisfactory explanation for the absence of effect in patients with atopic dermatitis. Certain disease-specific factors in psoriasis, such as metabolic comorbidities and susceptibility to addiction, might make diet and substance abuse of greater importance for patients with psoriasis than for patients with atopic dermatitis. However, we believe that these skin diseases have enough common ground with regards to their need for education.

Further research is needed on how education is best offered, especially as regards the frequency of contacts and the intervals between them. As the beneficial effects seem to wane after 6 months after the end of the programme, and as the programme is perceived to be very intensive, it might be an option to offer components on a more continuous basis. We do believe that the group (vs. individual) format offers an advantage, and can in practice be better reconciled with the time-consuming aspects of organizing patient education.

In conclusion, our data indicate that this format of patient education deserves more investigation in order to obtain more robust data, especially in psoriasis.

What's already known about this topic?

- Patient education plays an increasingly important role in the long-term management of chronic skin diseases, such as psoriasis and atopic dermatitis.

What does this study add?

- Evaluating this form of educational programme, by means of a prospective randomized controlled trial, indicates its added value in the long-term management of psoriasis.

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