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# Long-term effects of weight reduction on the severity of psoriasis in a cohort derived from a randomized trial: a prospective observational follow-up study<sup>1,2</sup>

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## ABSTRACT

**Background:** Weight reduction may reduce the severity of psoriasis, but little is known about the long-term effects.

**Objective:** We aimed to investigate long-term effects of weight reduction in psoriasis.

**Design:** We previously conducted a randomized trial ( $n = 60$ ) involving patients with psoriasis who were allocated to a control group or a low-energy diet (LED) group. Here we followed the participants for an additional 48-wk period. In total, 56 patients with psoriasis [mean  $\pm$  SD body mass index (in  $\text{kg}/\text{m}^2$ ):  $34.4 \pm 5.3$ ] underwent a 64-wk weight-loss program consisting of an initial 16-wk randomized phase with an LED for 8 wk and 8 wk of normal food intake combined with 2 LED products/d, followed by a 48-wk period of weight maintenance with the latter diet. After the randomization phase, the control group received the same 8 + 8-wk LED intervention, and all patients were then followed for 48 wk while on the weight-loss maintenance diet. The main outcome was the Psoriasis Area and Severity Index (PASI), and secondary outcome was the Dermatology Life Quality Index (DLQI).

**Results:** For the present study, 56 patients were eligible, 38 agreed to participate, and 32 completed. After the 16-wk LED-only period, the mean weight loss was  $-15.0$  kg (95% CI:  $-16.6$ ,  $-13.4$  kg), and PASI and DLQI were reduced by  $-2.3$  (95% CI:  $-3.1$ ,  $-1.5$ ) and  $-2.3$  (95% CI:  $-3.2$ ,  $-1.4$ ), respectively. At week 64, the mean weight loss compared with baseline was  $-10.1$  kg (95% CI:  $-12.0$ ,  $-8.1$  kg), and PASI and DLQI were maintained at  $-2.9$  (95% CI:  $-3.9$ ,  $-1.9$ ) and  $-1.9$  (95% CI:  $-3.0$ ,  $-0.9$ ), respectively.

**Conclusion:** Long-term weight loss in patients with psoriasis has long-lasting positive effects on the severity of psoriasis. This trial was registered at [clinicaltrials.gov](http://clinicaltrials.gov) as NCT01137188. *Am J Clin Nutr* 2016;104:259–65.

**Keywords:** psoriasis, weight reduction, obesity, long-term weight maintenance, inflammation

## INTRODUCTION

Psoriasis is a chronic inflammatory skin disease affecting  $\sim 2\%$  of the population in Northern Europe and the United States (1, 2). It is characterized by an immunological response mainly elicited by activated T helper 1 and 17 lymphocytes. Apart from infiltrating the affected skin areas, these cells also play a key role in eliciting a systemic low-grade inflammatory state by interacting with other cellular and humoral mediators such as IL-2, IL-12, IL-23, TNF- $\alpha$ , IFN- $\gamma$ , macrophages, dendritic cells, and mast cells (1, 3). Hyperproliferation and premature maturation of keratinocytes induce the typical erythroscaly psoriatic skin lesions, which are usually located on the scalp, elbows, knees, and lower back (1).

Epidemiologic studies have established that psoriasis is associated with obesity and that increased adiposity is a risk factor for incident psoriasis (4–7). Psoriasis and obesity are accompanied by low-grade systemic inflammation, and in theory, obesity-derived proinflammatory mechanisms may worsen the severity of psoriasis in overweight individuals with psoriasis (8). Given the close association between psoriasis and adiposity, we

<sup>1</sup>Supported in part by Cambridge Manufacturing Company Limited, the Michaelsen Foundation, the Aase and Ejnar Danielsen Foundation, the Research Foundation of the Danish Academy of Dermatology, the Danish Agriculture and Food Council, the Jacob Madsen and Olga Madsen Foundation, the Danish Psoriasis Research Foundation, and the Medical Research Foundation of the Capital Region of Denmark. The Parker Institute is supported by unrestricted grants from the Oak Foundation.

<sup>2</sup>Supplemental Table 1 is available from the “Online Supporting Material” link in the online posting of the article and from the same link in the online table of contents at <http://ajcn.nutrition.org>.

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Received October 31, 2015. Accepted for publication May 13, 2016.

First published online June 22, 2016; doi: 10.3945/ajcn.115.125849.

recently reported a randomized study on the effects of weight reduction with a low-energy diet (LED)<sup>10</sup> on the severity of psoriasis (9). In the study, obese patients with psoriasis were followed for 16 wk, and the weight reduction resulted in a trend in favor of a clinically important reduction in the severity of psoriasis and a significant improvement in self-reported quality of life. In addition, weight reduction significantly improved several risk factors for cardiovascular disease in these patients (10).

Concerns remain, however, regarding maintenance of weight reduction in the longer term, especially after rapid weight loss with an LED (11–13). We therefore determined the extent to which initial improvements in the severity of psoriasis [measured by the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI)] with weight reduction were maintained after 1 y in obese patients with psoriasis.

## METHODS

### Design

The current study was an extension of a previously published randomized trial in which patients with psoriasis were randomly assigned to either a 16-wk weight-loss intervention group or a control group (9). Here we report the subsequent 48-wk trajectories of both groups after entering the 16-wk dietary intervention and undergoing follow-up. The study was conducted at the Department of Dermato-Allergology of Gentofte Hospital at the University of Copenhagen between 1 June 2010 and 1 June 2012. The local ethical committee approved the present study, and the initial study was registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01137188). The procedures followed were in accordance with the ethical standards of the responsible committees on human experimentation (both institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

### Weight loss and maintenance phase

The full treatment program lasted for 64 wk and consisted of 2 periods: the LED-only period (lasting 16 wk) and the weight-loss maintenance period (lasting 48 wk). The dietary weight loss approach that applied during the first 8 wk consisted of a formula-based LED containing 800–1000 kcal/d (Cambridge Weight Plan). During the 8 wk that followed, the participants were re-introduced to regular foods, including 2 formula LED products given on a daily basis, and their daily caloric intake was increased to 1200 kcal/d. Those initially randomized to the control group received the same 8 + 8-wk initial LED intervention after completing the control period. The maintenance period started immediately after the 8 + 8-wk LED period and lasted for the remainder of the study (48 wk), during which all participants replaced 2 daily meals, 1 main meal and 1 snack meal, with formula LED products. All of the participants attended bi-monthly group sessions with the study dietitian, which involved anthropometric measurements, psychological encouragement, and support for adherence to the study diet and maintenance of weight loss. Anti-psoriatic treatment had to be stable and re-

mained unchanged during the study, and the participants were instructed not to change their anti-psoriatic treatment in any way. Medications for other medical conditions, e.g., arterial hypertension, could be changed if needed. To control for seasonal variations in ultraviolet-light exposure, the primary inclusion of patients was conducted throughout the year to limit this effect.

### Main outcome measure

The primary outcome measure was the severity of psoriasis, assessed by PASI and measured at baseline and at weeks 8, 16, 24, 32, 40, 48, 56, and 64 by the lead investigator (PJ), who was not blinded regarding the initial study randomization.

### Secondary outcome measures

Secondary outcomes included DLQI, which was used to assess the health-related quality of life (14). Additional outcome measures were body weight, height, BMI, fat mass, lean body mass, and waist and hip circumferences. We also drew blood for measurements of concentrations of high-sensitivity C-reactive protein, vitamin D (25-hydroxyvitamin D<sub>3</sub>), plasma glucose, glycated hemoglobin, triglycerides, and HDL, LDL, VLDL, and total cholesterol. All blood samples were analyzed at the Department of Clinical Biochemistry of Gentofte Hospital at the University of Copenhagen.

### Safety

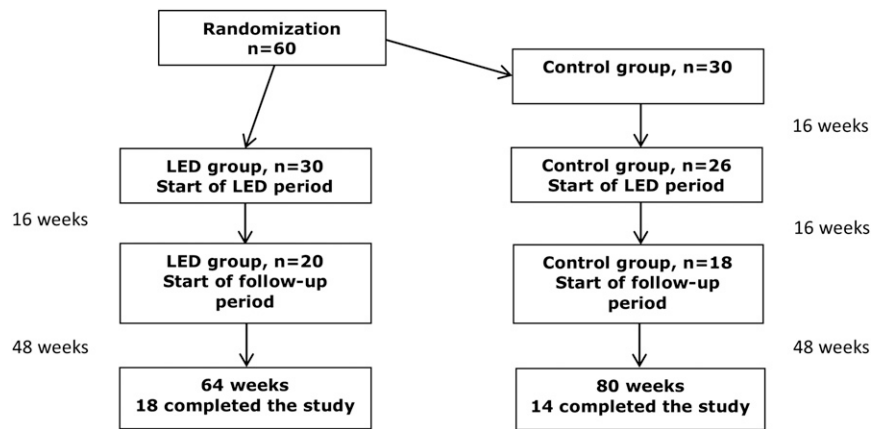
Consuming only low amounts of calories can cause certain transient side effects such as gout, gallstones, hair loss, dry skin, constipation, increased cold sensitivity, fatigue, hunger, and visual disturbances. The primary investigator (PJ) and study dietitian noted any adverse events at each visit.

### Statistics

This 1-y extension study was not designed based on a priori assumption about power with a corresponding sample size. However, anticipating that at least half of the participants enrolled (60 in total) would accept the invitation to be part of and complete the subsequent follow-up study, it would be reasonable to detect a remaining weight loss of 10 kg. For a paired *t* test of a normal mean difference with a 2-sided significance level of 0.05, assuming a common SD of 15 kg and correlation 0.5, a sample size of 30 pairs has substantial power (94.2%) to detect a mean difference of 10 kg. Even if the remaining weight loss among the observed individuals was only 8 kg, our study would have been reasonably well powered (80.6%).

All data analyses were carried out according to a pre-established analysis plan with software by SAS Institute Inc. (version 9.3). We reported all descriptive statistics and tests in accordance with the recommendations of the network for “Enhancing the quality and transparency of health research” by use of a merged format between the Consolidated Standards of Reporting Trials statement and the Strengthening the Reporting of Observational Studies in Epidemiology statement (15–17). For descriptive statistics summarizing the data, mean values and SDs were used unless otherwise stated. Medians and IQRs (quartile 1 and quartile 3) were used for skewed variables.

<sup>10</sup> Abbreviations used: BOCF, baseline observation carried forward; DLQI, Dermatology Life Quality Index; LED, low-energy diet; PASI, Psoriasis Area and Severity Index.



**FIGURE 1** Trial profile ( $n = 56$ ) showing the entire 64-wk study period consisting of the 16-wk LED period and a 48-wk weight maintenance period. Note: The participants in the control group (16 wk) also underwent an additional 16-wk LED period before entering the remaining 48-wk follow-up period. LED, low-energy diet.

In the primary analyses for the longitudinal part of the study describing the trajectory over time, we used restricted maximum likelihood linear mixed-effects models for repeated-measures data, a method that assumes that the missing values for participants who were lost to follow-up can be predicted from those who remained in the study (18). Missing data that satisfy this condition are said to be “missing at random” (19). Thus, the reported (primary) analyses were based on the linear mixed-model estimates without data imputation. The linear approach for repeated measurements was based on the Diggle model, which was fitted in SAS software (version 9.4) by use of PROC MIXED based on restricted maximum likelihood estimates of the parameters. The factor [Subject] was considered as a random effects factor (Random int/Subject = PtID). The assessment of the group (LED compared with controls) and time effects (Repeated/Subject = PtID Type = SP(Gau)(Time) Local) was of interest in testing for a possible interaction, and both group and time were considered as systematic factors by using the baseline value as covariate to reduce the random variation and increase power.

For sensitivity analyses, alternative imputation techniques were also performed because the statistical modeling approaches for missing data based on the “missing at random” assumption might be controversial in a typical weight-loss trial, i.e., those who drop out are likely to differ from those who remain in the study (18, 20). We therefore used the “baseline observation carried forward” (BOCF) technique for replacement of missing data. Indeed, this assumption may be more appropriate, given the usual recidivism after weight loss, i.e., those who drop out have a tendency to return to their baseline weight (20).

## RESULTS

In the primary study, the patients were randomly assigned to either a 16-wk intensive dietary weight loss intervention with a formula LED only (800–1000 kcal/d) for 8 wk and 8 wk of gradual introduction of normal food intake aimed at weight maintenance (reaching 1200 kcal/d including 2 formula LED products/d) or a control group, as indicated in **Figure 1** (9). Of the 30 subjects randomly assigned to weight-loss intervention (LED), 27 completed the study (3 dropped out because of lack of motivation). Of the 30 subjects randomly assigned to the control

group, 4 dropped out because of lack of motivation, leaving 26 subjects who subsequently underwent the same 16-wk LED period as those who were primarily assigned to the LED group. Loss of motivation led to 2 more dropouts during that LED period. Thus, 51 patients (original intervention group,  $n = 27$ ; original control group,  $n = 24$ ) were available to enter into the follow-up program, and of these, 38 agreed to participate (20 from the LED group and 18 from the control group) in the 48-wk weight-maintenance program described here, which was completed by 32 subjects (**Figure 1**). Five dropped out because of loss of motivation, and one

**TABLE 1**  
Baseline characteristics of all randomly assigned patients<sup>1</sup>

	LED group ( $n = 30$ )	Controls ( $n = 26$ )	<i>P</i> value
Women, <i>n</i> (%)	14 (47)	11 (42)	0.74
Age, y	50.7 ± 10.2	51.5 ± 9.8	0.58
PASI score	4.8 (3.8–8.2)	4.9 (2.5–6)	—
DLQI score	5.5 (2–10)	3 (2–5)	—
Systemic anti-inflammatory treatment, <i>n</i> (%)	7 (23)	5 (19)	0.71
Height, m	1.75 ± 0.1	1.74 ± 0.1	0.79
Weight, kg	106.7 ± 25.0	103.0 ± 19.4	0.81
BMI, kg/m <sup>2</sup>	34.7 ± 5.9	34.0 ± 4.5	0.92
Lean body mass, kg	59.4 ± 12.7	60.2 ± 13.0	0.81
Fat mass, kg	43.9 ± 10.9	44.4 ± 18.8	0.46
Waist circumference, cm	111.3 ± 17.4	107.6 ± 10.1	0.94
Hip circumference, cm	115.1 ± 11.0	114.3 ± 11.2	0.64
Vitamin D, nmol/L	65 (46–91)	49 (35–76)	—
Total cholesterol, mmol/L	5.6 ± 1.1	5.5 ± 0.8	0.75
HDL cholesterol, mmol/L	1.22 ± 0.36	1.30 ± 0.44	0.69
LDL cholesterol, mmol/L	3.43 ± 1.10	3.64 ± 0.63	0.9
VLDL cholesterol, mmol/L	0.65 ± 0.27	0.59 ± 0.21	0.4
Triglyceride, mmol/L	1.41 (1.10–1.96)	1.43 (0.89–1.68)	—
Plasma glucose, mmol/L	6.2 ± 1.8	5.9 ± 0.8	1.0
HbA1c, %	6.4 ± 0.8	5.8 ± 0.5	0.0003
hs-CRP, mg/L	3.1 (1.2–5.9)	3.0 (1.8–5.5)	—

<sup>1</sup>Values are means ± SDs or medians (25th–75th IQRs) unless noted otherwise. DLQI, Dermatology Life Quality Index; HbA1c, glycated hemoglobin; hs-CRP, high-sensitivity C-reactive protein; LED, low-energy diet; PASI, Psoriasis Area and Severity Index.

dropped out because of a job change and relocation to another part of the country.

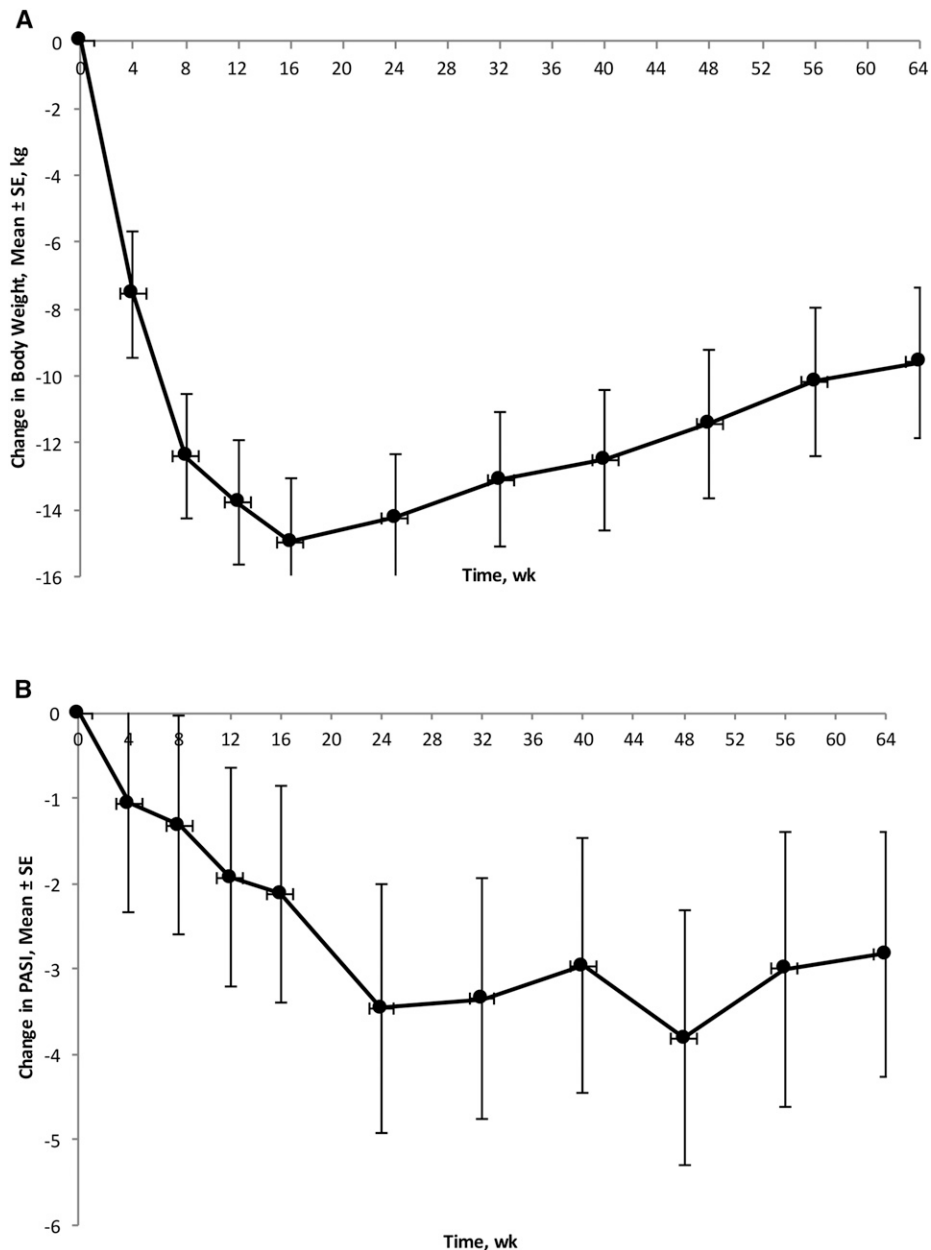
As shown in **Table 1**, the patients were obese with a mean BMI (in  $\text{kg}/\text{m}^2$ ) of  $\sim 34$ . They had mild-to-moderate psoriasis, as indicated by a median PASI score of  $\sim 5$ . The median baseline high-sensitivity C-reactive protein was  $\sim 3$   $\text{mg}/\text{L}$ , indicating a state of low-grade systemic inflammation.

### Weight change and maintenance

As presented in **Figure 2A** and **Table 2**, during the LED period of the study (weeks 0–16), weight, BMI, waist circumference, hip circumference, and fat mass all decreased statistically significantly. During the 48-wk weight-maintenance period (weeks 16–64), there was a gradual regain of weight of 4.9 kg, and

the mean weight loss at week 64 was  $-10.1$  kg (95% CI:  $-12.0, -8.1$  kg) compared with baseline (**Figure 2A**). The corresponding (conservative) sensitivity estimate from the BOCF-adjusted model indicated that the weight loss at week 64 was 5.8 kg.

The PASI score had decreased by a mean of 2.3 (95% CI:  $-3.1, -1.5$ ) by the end of the LED period (week 16) (**Figure 2B** and **Table 2**). As shown in **Figure 2B**, the PASI score continued to decrease during the weight-maintenance period from weeks 16 to 24, and from that point onward (weeks 24–64), the severity of psoriasis decreased further [ $-2.9$  (95% CI:  $-3.9, -1.9$ )], despite a simultaneous and substantial mean regain in weight of 4.9 kg; based on the BOCF estimates, the change in PASI after 64 wk corresponded to 1.7 PASI units.



**FIGURE 2** Long-term effects of weight reduction on the severity of psoriasis in 56 patients. Mean  $\pm$  SE changes over time from baseline are shown. (A) Body weight. (B) PASI. PASI, Psoriasis Area and Severity Index.

**TABLE 2**

Changes in the severity of psoriasis and adiposity variables after a low-energy diet and weight-maintenance program in 56 obese patients with mild-to-moderate psoriasis<sup>1</sup>

	After a low-energy diet (change 0–16 wk)	After the full study period (change 0–64 wk)
PASI	–2.3 (–3.1, –1.5)	–2.9 (–3.9, –1.9)
DLQI	–2.3 (–3.2, –1.4)	–1.9 (–3.0, –0.9)
Weight, kg	–15.0 (–16.6, –13.4)	–10.1 (–12.0, –8.1)
BMI, kg/m <sup>2</sup>	–4.9 (–5.4, –4.4)	–3.1 (–3.7, –2.5)
Lean body mass, kg	–2.4 (–3.1, –1.7)	–4.8 (–5.6, –3.9)
Fat mass, kg	–11.0 (–13.5, –8.6)	–10.8 (–14.8, –6.8)
Waist circumference, cm	–12.7 (–14.2, –11.2)	–8.9 (–10.5, –7.2)
Hip circumference, cm	–9.1 (–10.2, –8.0)	–6.3 (–7.5, –5.1)
Vitamin D, nmol/L	6 (–1, 13)	–7 (–15, 2)
Total cholesterol, mmol/L	–0.6 (–0.8, –0.4)	0.04 (–0.2, 0.3)
HDL cholesterol, mmol/L	1.95 (–0.49, 4.39)	0.12 (–3.10, 3.35)
LDL cholesterol, mmol/L	–0.2 (–0.4, –0.06)	0.1 (–0.2, 0.3)
VLDL cholesterol, mmol/L	–0.1 (–0.2, –0.1)	0.0 (–0.1, 0.1)
Triglycerides, mmol/L	–0.6 (–0.7, –0.5)	–0.3 (–0.5, –0.1)
Plasma glucose, mmol/L	–0.7 (–0.9, –0.5)	–0.4 (–0.6, –0.1)
HbA1c, %	–0.6 (–0.7, –0.5)	–0.7 (–0.8, –0.6)
hs-CRP, mg/L	–1.1 (–1.9, –0.3)	–1.4 (–2.5, –0.3)

<sup>1</sup>Values are means (95% CIs) and were estimated from the longitudinal mixed linear model handling missing data as missing at random. DLQI, Dermatology Life Quality Index; HbA1c, glycated hemoglobin; hs-CRP, high-sensitivity C-reactive protein; PASI, Psoriasis Area and Severity Index.

The DLQI remained largely unchanged relative to baseline [–1.9 (95% CI: –3.0, –0.9)] (Table 2). Changes in the metabolic variables are presented in Table 2, illustrating a return to baseline values for the cholesterol concentrations, whereas the initial favorable effect of weight reduction on glycated hemoglobin concentrations was maintained. The quantitative association of effect size between weight loss and the psoriasis outcomes (PASI and DLQI) is shown in **Supplemental Table 1**. Weight reduction peaked approximately at week 16, which coincided with the greatest improvement in both PASI and DLQI.

To answer the question concerning whether the changes in PASI and DLQI were associated with the observed weight loss on the individual patient level rather than the group level, Spearman's correlation analyses were calculated (**Figure 3**). As depicted in Figure 3, there was no statistically significant association for any of these.

### Safety

We recorded only mild side effects, all of which occurred during the LED period. One patient had sensations of hunger throughout the study, 5 had mild headache during the first 2 wk, 20 were more tired than usual at some point during the study, 3 were constipated, 14 felt lightheaded or dizzy from weeks 4–8, and 14 experienced increased cold sensitivity. No serious adverse events were recorded during the 48-wk weight-maintenance period.

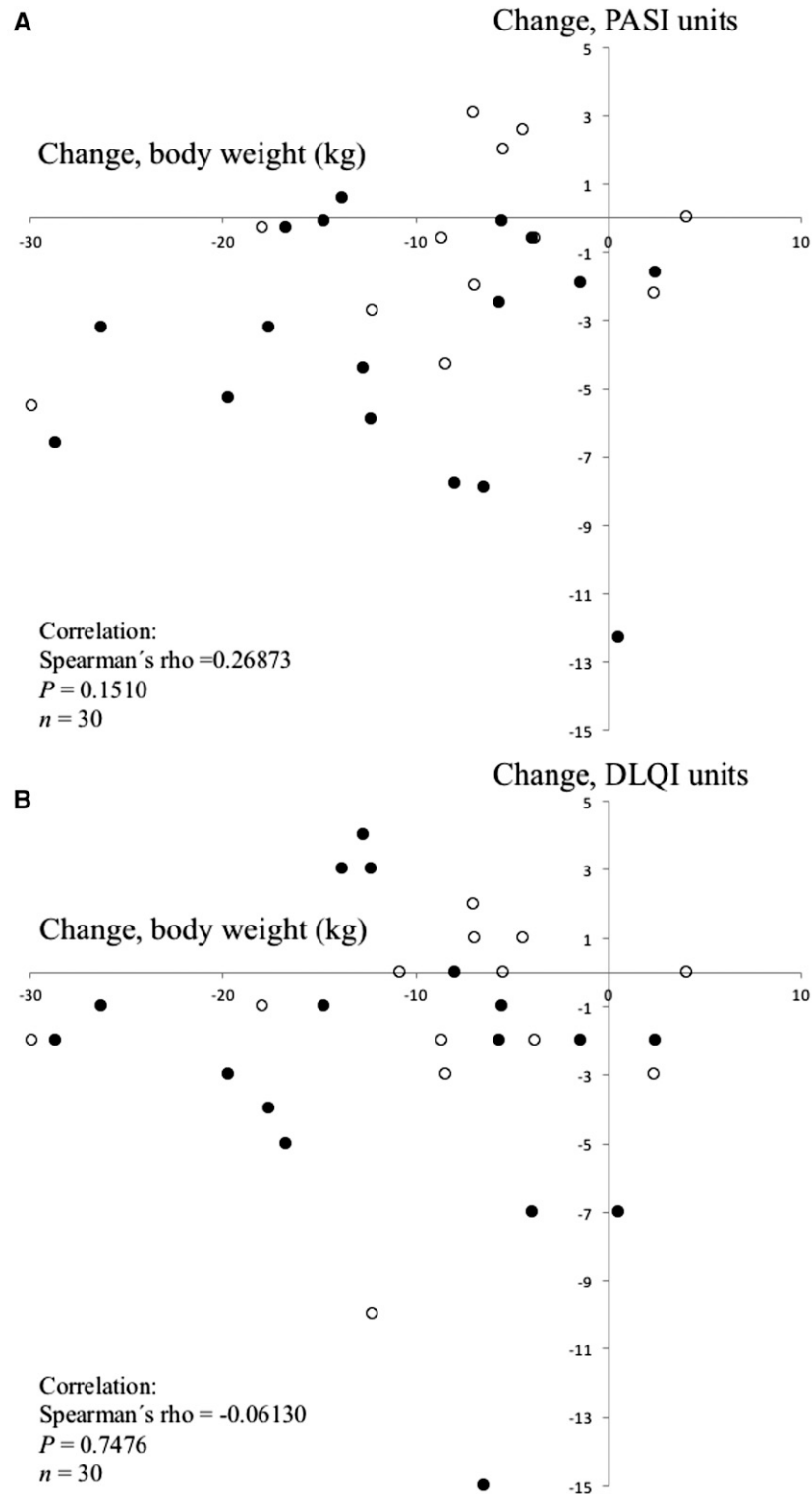
### DISCUSSION

In this 48-wk extension study of obese patients with psoriasis who underwent successful weight loss with a 16-wk LED, changes in the severity of psoriasis (PASI and DLQI) were

maintained after 64 wk (9). In addition, marked improvements in plasma glucose and glycated hemoglobin amounts remained unchanged after the weight maintenance period, whereas cholesterol concentrations had returned to baseline values. The participants maintained a significant mean weight loss from baseline to week 64 of –10.1 kg (95% CI: –12.0, –8.1 kg), corresponding to an average regain in weight of 4.9 kg from week 16 to week 64. From ancillary analyses, according to the Spearman's correlation, we were able to answer the clinically relevant question of whether the observed improvement in disease activity (i.e., PASI and DLQI) was associated with the observed weight change on the individual patient rather than the group level. The analysis showed that the beneficial effect mediated by weight reduction could not be explained by any obvious dose-response phenomena.

The association between psoriasis and adiposity has been firmly established in epidemiologic studies (4–7). In theory, obesity-derived proinflammatory mechanisms may worsen psoriasis in overweight patients (8, 21, 22). One might therefore assume that weight reduction would improve skin condition in obese individuals with psoriasis. Indeed, numerous case reports of patients undergoing bariatric surgery have described a beneficial effect of weight loss on psoriasis in overweight patients (23–28). Also, Gisondi et al. (29) showed an increased response to cyclosporine after weight loss in obese patients with psoriasis, and in 2013 we published the results of a randomized LED weight-loss trial with PASI as the primary endpoint (9); this provided the patients for the current extension study, which was designed to follow maintenance of weight loss. Our randomized study showed a trend in favor of a clinically important reduction in the severity of psoriasis measured by PASI and DLQI and also that certain components of the cardiovascular disease risk profile of obese patients with psoriasis could be significantly improved after weight loss (9, 10). To our knowledge, there have been no studies on weight reduction in overweight patients with psoriasis with the severity of psoriasis as primary endpoint—and no such studies with extended follow-up periods.

Although weight loss can usually be achieved through dietary restriction, it appears to be common knowledge that people who manage to lose weight will regain the weight they have lost in the long term (11–13). In 2001, Anderson et al. (30) conducted a meta-analysis including 29 studies to explore the efficacy of long-term weight-loss maintenance. The authors found that individuals who had completed very-low-energy diet programs or had lost  $\geq 20$  kg in weight maintained a significantly greater weight loss at 5 y (mean weight-loss maintenance 30%) than after a slightly hypo-energetic balanced diet or weight loss of  $< 10$  kg (mean weight-loss maintenance 18%). Furthermore, a recent review pointed out that there is no significant difference between very-low-energy diets and low-energy diets in terms of weight loss after long-term follow-up (31). However, one may speculate that long-term maintenance of weight loss may be more difficult for obese patients with psoriasis than for healthy individuals. Patients with psoriasis may be more likely to fail at weight-loss maintenance because not only are they burdened by excess body weight, they are also under stress from the dermatologic treatment, the skin disease itself, and possibly concomitant comorbidity. Frequent dietary support meetings and encouragement may therefore be even more important to these patients to sustain the lifestyle changes in physical activity and food intake needed for successful weight maintenance.



**FIGURE 3** Scatter plots showing correlations between change in body weight and PASI (A) and change in body weight and DLQI (B). Solid circles indicate the low-energy diet group, and open circles indicate the control group. DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index.

Interestingly, recent research has shown that clinicians recognize that lifestyle intervention is beneficial in psoriasis, but they lack the skills to implement them (32, 33).

The present study has some limitations that should be considered when interpreting the results. First, this was not a prospective

observational follow-up study in its strictest sense, because we first subjected the original control group to the 8 + 8-wk LED period before these subjects entered the weight-maintenance program, whereas the original intervention group entered the latter program directly. However, there was no interaction between weight-loss

maintenance and original study group, indicating that weight-loss maintenance was unaffected by study group allocation. Second, the main investigator was not blinded regarding treatment allocation, thus introducing the risk of observer bias. Third, 18 patients (32.1%) declined to participate, thus introducing selection bias with the risk of overestimating weight-loss maintenance. Last, the patients had only mild-to-moderate psoriasis or were in stable anti-psoriatic treatment during the whole treatment period. It is possible that weight maintenance may be more challenging to individuals with more severe psoriasis.

In conclusion, obese patients with psoriasis can achieve a significant short-term weight loss with an LED program, which can be largely maintained by most of the patients at 1 y. The initial beneficial effects of weight reduction on the severity of psoriasis and on amounts of plasma glucose and glycated hemoglobin were maintained at 1 y, despite some regain of weight. Interestingly, our findings are in accord with the results of a randomized study by Li et al. (34) in which the effect of a 6-y lifestyle intervention on diabetes incidence persisted for 2 decades. Our results suggest that weight-reduction therapy should be part of a multimodal management approach in obese patients with psoriasis.

We thank Beatrice Dyring Andersen, Mette Gyldenløve, Marianne Løvendorf, Helle Rasmussen, Lena Larsson, and the staff of the Departments of Dermatology, Clinical Physiology, Nuclear Medicine, and Clinical Biochemistry of Gentofte Hospital, University of Copenhagen, for their assistance.

The authors' responsibilities were as follows—PJ, NRWG, AA, and LS: designed the study; PJ, CZ, NRWG, BKS, SS, and LS: performed the study; PJ, RC, CZ, SS, PRH, and LS: analyzed the data; PJ, RC, CZ, PRH, and LS: wrote the manuscript; PJ, RC, CZ, and LS: had primary responsibility for the final content; and all authors: read and approved the final manuscript. None of the authors had a conflict of interest.

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