

A randomized controlled trial of laser treatment among hirsute women with polycystic ovary syndrome

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Summary

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W.J.C. and M.R. have a private hair removal practice.

Background Facial hirsutism is one of the characteristic features of polycystic ovary syndrome (PCOS), and this can lead to high levels of depression and anxiety.

Objectives To evaluate the impact of laser treatment on the severity of facial hirsutism and on psychological morbidity in women with PCOS.

Methods A randomized controlled trial of five high-fluence treatments (intervention) vs. five low-fluence treatments (control) was performed over 6 months in a National Health Service teaching hospital. Subjects were 88 women with facial hirsutism due to PCOS recruited from hospital outpatient clinics and a patient support group in 2001–2002. The main outcomes were self-reported severity of facial hair (measured on a scale of 1–10), depression, anxiety (measured on the Hospital Anxiety and Depression Scale) and quality of life (measured on the WHOQOL-BREF).

Results Self-reported severity of facial hair in the intervention group ($n = 51$) fell from 7.3 to 3.6 over the 6-month study period; for the control group ($n = 37$) the corresponding scores were 7.1 and 6.1. The change was significantly greater in the intervention group [$_{\text{ANCOVA}} F_{(1,83)} = 24.5, P < 0.05$]. Self-reported time spent on hair removal declined from 112 to 21 min per week in the intervention group and from 92 to 56 min in the control group [$F_{(1,80)} = 10.2, P \leq 0.05$]. Mean depression scores fell from 6.7 to 3.6 in the intervention group, compared with 6.1 to 5.4 in the control group [$F_{(1,83)} = 14.7, P < 0.05$]. A similar change was seen for mean anxiety scores: intervention 11.1 to 8.2, control 9.6 to 9.3 [$F_{(1,84)} = 17.8, P < 0.05$]. Psychological quality of life also improved more in the intervention group, from 49.6 to 61.2 vs. 50.1 to 51.5 in the control group [$F_{(1,84)} = 10.9, P < 0.05$].

Conclusions Laser treatment appeared to reduce the severity of facial hair and time spent on hair removal as well as alleviating depression and anxiety in women with PCOS. These findings suggest that ways of making this method of hair removal more widely available to women with facial hirsutism should be considered.

Facial hair in women causes distress.¹ As in other disfigurements, hirsute patients invest considerable time and emotional resources trying to keep the condition hidden.^{2–4} The usual identifiable medical cause is polycystic ovary syndrome (PCOS). This has a prevalence of approximately 10% in adult premenopausal women, and three-quarters of these will have hirsutism.^{5,6} The syndrome is also characterized by acne, obesity, insulin resistance and reduced fertility. High levels of depression and anxiety have been reported in patients with hirsutism.^{1,7} In addition, the time and effort needed to

remove the hair is a considerable burden. Qualitative research has found that hirsute women with PCOS feel freakish, dirty and unfeminine.^{8,9}

Laser hair removal, as first reported in 1996, gives hair-free intervals of several weeks soon after starting treatment; this lengthens with repeated treatment and the regrowth becomes sparser and finer.^{10,11} It works well only on dark hair. In the U.K. it is difficult to obtain laser hair removal on the National Health Service (NHS). In part this is because it has not been evaluated in the context of specific diseases that come under

the remit of the NHS. A further factor may be that the impact of facial hirsutism on psychological health has not been given sufficient consideration. While the efficacy of laser hair removal in the general population has been assessed positively in several studies, none has studied PCOS specifically.¹¹

This study was designed to test the hypothesis that laser treatment would reduce the impact of facial hair and its associated psychological morbidity in women with facial hirsutism.

Patients and methods

Subjects

The sample was recruited from women diagnosed with PCOS attending gynaecology, endocrinology and dermatology outpatient departments at a London teaching hospital, and from a PCOS patient support group called Verity. Posters and information packs were freely distributed in these settings during October and November 2001.

There is no definitive test for PCOS. It is a clinical diagnosis reached when any of a variety of features is present.¹² We accepted the diagnosis of our specialist colleagues. The research team took no part in establishing the diagnosis. Inclusion criteria were: facial hirsutism with dark hair and Fitzpatrick skin types I to pale V, suitable for the alexandrite laser. Suitability was initially assessed by asking potential participants about their skin and hair colour on the application form. This was later checked visually by the examining clinician before study entry. Severity of hirsutism was not an entry criterion. Exclusion criteria were: white, blonde or ginger facial hair, Fitzpatrick skin types medium V, dark V and VI, previous laser hair removal, insufficient English to complete questionnaires, age under 18 years. The Royal Free Hospital and Medical School ethics committee approved the study.

Study design

Potential participants were given written advice about the trial and the laser treatment and invited for a consultation to discuss this information. All the women received the same advice about avoiding a sun tan, and stopping plucking, waxing or threading. These behaviours either reduce the effectiveness or increase the risk of unwanted effects of laser treatment. Trimming and shaving were allowed. If they consented to this regimen they were randomized by the treating physician using a random numbers table. The treating physician was necessarily aware of the allocation to intervention or control groups but the subjects and the research psychologist administering the evaluation were not informed.

Both groups received laser treatment to their face only with an alexandrite laser, wavelength 755 nm, pulse width 20 ms, spot size 12.5 mm (Apogee 6200; Cynosure, Chelmsford, MA, U.S.A.), using an integrated chilled air delivery system for skin cooling (Cryo 5 Smartcool). Patients were not charged for treatment.

Intervention group

The intervention group received high-fluence treatment. Patch tests were performed under the chin 1 week before the first full treatment. The fluence was adjusted to the patient's skin tolerance to achieve erythema for 4–48 h without blistering or hyperpigmentation. Treatments were at 4–6-week intervals to coincide with regrowth of the hair. The mean fluence delivered to the intervention group was 23.6 J cm⁻² (range 14–30). They received a mean of 4.8 treatments during the 6-month study period. The 6-month study period was an arbitrary interval within which we hoped to demonstrate an effect. In a clinical setting we would expect patients to continue with treatment for longer.

Control group

The control group received sham patch testing and laser treatments at a low fluence of 4.8 J cm⁻², and a mean of 4.4 treatments over the study period ($t = -0.96$, $P > 0.05$). This low fluence was achieved by swapping laser handpiece elements, and this reduced the fluence below that normally available. This would be relatively ineffective but convincing. The experience for the control group was as full as possible, i.e. the same laser room, with its lingering smell of burnt hair, the same laser, the same doctor, the same amount of time and attention and the same advice as the intervention group. At the end of the study period the allocation was revealed and women in the control group were offered 6 months of high-fluence treatment free of charge.

Data collection

Separate records of the treatment and the evaluation were kept throughout the trial and allocation was not disclosed to the subjects, the research psychologist or the data entry clerk until data entry was complete. Data were collected systematically using three validated psychological instruments and a study-specific questionnaire, which included questions derived from patient interviews during a pilot phase of qualitative interviews. The questionnaire was self-completed by the participants, taking approximately 20 min to complete. This was performed at baseline and at 6 months. The data collected covered two broad areas.

Self-reported experience of hirsutism

Hair removal practices were initially explored during a pilot phase to assist the design of the questionnaire. The questionnaire sought information on self-reported hair severity on a scale of 1 (least severe) to 10 (most severe), time spent on hair removal, methods used (ever, current) and hair-free period achieved. Patients' views on the experience of laser treatment were elicited at the end of the trial during their last visit using five-point Likert scales.

Psychological morbidity

Anxiety and depression were measured with the Hospital Anxiety and Depression Scale (HADS), a 14-item scale which provides a state measure of anxiety and depression as well as assessing severity.¹³ Each item is scored from 0 to 3, generating total scores which range from 0 to 21 for the anxiety and depression subscales. Higher scores indicate greater severity. The scores are classified as normal (0–7), mild (8–10), moderate (11–14) and severe (15–21). Scores of 8 or above are seen as indicative of clinical need and referral for formal assessment. Participants' quality of life was assessed with the WHOQOL-BREF.¹⁴ This is an abbreviated version of the WHOQOL-100 quality of life assessment, with two items on overall quality of life and general health. The remaining 24 items are categorized into four domains: physical health, psychological health, social relationships and environment. Items are scored between 1 and 5, where high scores denote higher quality of life. Self-esteem was measured by the Rosenberg Self-Esteem Scale, a widely used measure of self-esteem in health psychology.¹⁵ Respondents rated the statements on a Likert scale from 1, strongly agree, to 4, strongly disagree. Scores ranged between 10 and 40. A low score indicates low self-esteem when positive items are reverse-scored.

Analysis

Sample size was calculated by taking a single item from one of the validated psychological instruments. We estimated that to detect a 50% reduction in the percentage of women reporting one of the psychological outcomes following the intervention would require a total sample size of 80 women (α 0.05, β 0.8). Data were analysed using SPSS 10.0 software (SPSS, Chicago, IL, U.S.A.). For categorical data χ^2 tests were used. For continuous variables, such as age and the main outcome measures, t-tests were performed. Change scores were analysed using ANCOVA on the post-test scores, with the pretest scores as a covariate control. Analyses were performed on an intention-to-treat basis; for those subjects who were lost to follow-up, missing variables were carried forward from baseline data.

The evaluation of the patients' experience of laser treatment was conducted at the end of the trial on the 75 participants who completed the study. Mean and SD were calculated for data describing the evaluation of the laser treatment and the impact of facial hair. To test for the differences between the groups both independent group t-tests and the Mann–Whitney U-test were used. As there were no differences between these analyses only the t-test is reported.

Results

Participant flow and characteristics

Three hundred and twenty-five information packs were distributed. One hundred and forty-nine potential subjects returned

an application form, of whom 51 were excluded as they did not fulfil the selection criteria. Of the 98 women eligible for randomization, 10 refused randomization, 51 entered the intervention group and 37 entered the control group. By the end of the trial at 6 months seven subjects (14%) were lost from the intervention group and six (16%) lost from the control group (Fig. 1).

There were no significant differences between the two groups across a wide variety of social and demographic variables. The sample was characterized as white, well-educated, of high social class and employed, which reflects the local catchment area. At baseline there were no significant differences in the main outcome measures (Table 1).

The experience of hirsutism

The sample reported having facial hair for a mean \pm SD of 13.6 ± 7.7 years (range 1–35). Two-thirds of the women had been plucking their hair before entering the study, and 58% of the women reported having tried at least four hair removal methods previously. Two-thirds had taken medication for their facial hair in the past. The sample spent a mean \pm SD 104 ± 117 min each week on facial hair removal (median 60, range 0–600). Half the sample felt often or almost always overwhelmed by their facial hair, and half reported almost always putting a lot of effort into facial hair removal.

Self-reported severity in the intervention group fell from 7.3 to 3.6 on a scale of 1–10. For the control group the figures were 7.1 to 6.1 [ANCOVA $F_{(1,83)} = 24.5$, $P < 0.05$]. This shows that the intervention group reported a significantly greater benefit than the control group after allowing for baseline scores. Self-reported time spent on hair removal decreased

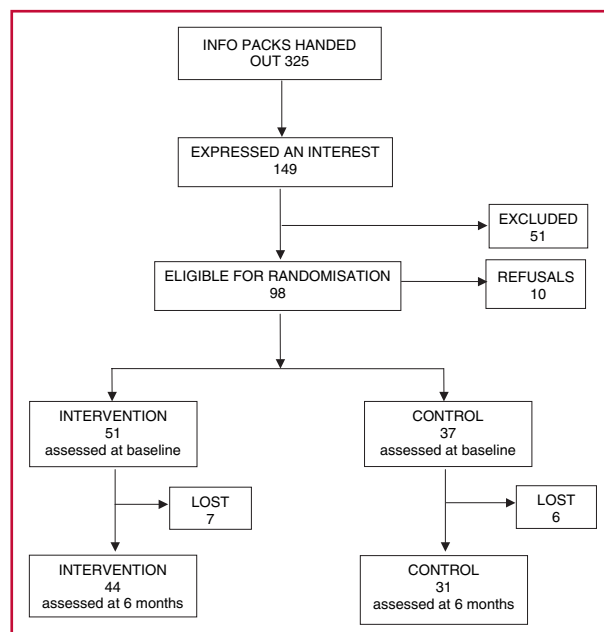


Fig 1. Participant flow and follow-up.

Table 1 Participant characteristics at study entry

Variable	Intervention (n = 51)	Control (n = 37)	Significance
Mean \pm SD age (years)	33.5 \pm 8.0	32.5 \pm 6.5	t = 0.568, P = 0.6
Marital status			
Single/divorced/separated	32 (63%)	21 (57%)	$\chi^2 = 0.321$, P = 0.6
Married/cohabiting	19 (37%)	16 (43%)	
Ethnic origin			
White	41 (80%)	28 (76%)	$\chi^2 = 0.282$, P = 0.6
Nonwhite	10 (20%)	9 (24%)	
Work status			
Employed	41 (80%)	27 (73%)	$\chi^2 = 0.672$, P = 0.4
Unemployed/other	10 (20%)	10 (27%)	
Highest educational attainment			
Up to GCSE	13 (25%)	9 (24%)	$\chi^2 = 0.665$, P = 1.0
A-level	10 (20%)	8 (22%)	
Degree	17 (33%)	10 (27%)	
Postgraduate	6 (12%)	6 (16%)	
Other	5 (10%)	4 (11%)	
Home ownership			
Owner-occupier	29 (57%)	18 (49%)	$\chi^2 = 1.60$, P = 0.4
Renting	16 (31%)	11 (30%)	
Other	6 (12%)	8 (22%)	
Car ownership			
Yes	31 (61%)	24 (65%)	$\chi^2 = 0.152$, P = 0.7
No	20 (39%)	13 (35%)	
Main outcome measures at study entry (mean \pm SD)			
HADS Depression	6.7 \pm 4.5	6.1 \pm 3.7	t = 1.114, P = 0.3
HADS Anxiety	11.1 \pm 3.5	9.6 \pm 4.5	t = 1.708, P = 0.1
Rosenberg Self-Esteem	27.7 \pm 5.4	26.3 \pm 5.7	t = 0.632, P = 0.5
WHOQOL-BREF Environmental	62.4 \pm 13.8	59.1 \pm 16.8	t = -1.032, P = 0.3
WHOQOL-BREF Social	49.5 \pm 22.6	49.3 \pm 31.6	t = -0.283, P = 0.8
WHOQOL-BREF Physical	64.3 \pm 19.9	68.7 \pm 19.3	t = 0.029, P = 1.0
WHOQOL-BREF Psychological	49.6 \pm 18.8	50.8 \pm 20.6	t = 1.006, P = 0.3

HADS, Hospital Anxiety and Depression Scale.

from 112 to 21 min weekly in the intervention group and from 92 to 56 min weekly in the control group after 6 months [$F_{(1,80)} = 10.2$, $P \leq 0.05$; Table 2].

At baseline the intervention group reported that their maximum mean \pm SD hair-free period using any method was

12.4 \pm 13.4 days. The corresponding figure for the controls was 11.2 \pm 9.5 days ($t = 0.45$, $P > 0.05$). After 6 months the intervention group reported a mean \pm SD hair-free period of 24.4 \pm 18.5 days and the controls 5.9 \pm 9.1 days. The decrease in mean hair-free days in the control group may have

Table 2 Main outcome measures (mean scores \pm SD)

	Intervention		Control		P-value ^a
	Baseline	6 months	Baseline	6 months	
Self-reported severity	7.3 \pm 1.8	3.6 \pm 2.8	7.1 \pm 1.9	6.1 \pm 2.6	< 0.05
Minutes per week removing hair	112 \pm 135	21 \pm 19	92 \pm 88	56 \pm 73	≤ 0.05
HADS Depression	6.7 \pm 4.5	3.6 \pm 3.5	6.1 \pm 3.7	5.4 \pm 3.8	< 0.05
HADS Anxiety	11.1 \pm 3.5	8.2 \pm 3.8	9.6 \pm 4.5	9.3 \pm 4.9	< 0.05
WHOQOL-BREF Psychological	49.6 \pm 18.8	61.2 \pm 16.7	50.1 \pm 20.6	51.5 \pm 21.5	< 0.05
WHOQOL-BREF Social	49.5 \pm 22.6	57.8 \pm 24.0	49.3 \pm 31.6	53.6 \pm 27.2	> 0.05
WHOQOL-BREF Physical	64.3 \pm 19.9	70.6 \pm 18.9	68.7 \pm 19.3	67.9 \pm 20.5	> 0.05
WHOQOL-BREF Environmental	62.4 \pm 13.7	65.6 \pm 15.9	59.1 \pm 16.8	60.6 \pm 18.8	> 0.05
Rosenberg Self-Esteem	27.7 \pm 5.4	30.9 \pm 5.3	26.3 \pm 5.7	28.7 \pm 6.0	> 0.05

HADS, Hospital Anxiety and Depression Scale. ^aP-value from ANCOVA comparing differences between the intervention and control groups at 6 months while allowing for any differences in baseline scores.

been due to their compliance with advice to stop plucking. Assuming no change in the control group, the differential between the two groups over time was still significant [$F_{(1,79)} = 28.6, P < 0.01$].

Psychological morbidity

The mean HADS depression score fell from 6.7 at baseline to 3.6 at 6 months in the intervention group and from 6.1 to 5.4 over the same period in the control group. This change was significantly greater in the intervention than in the control group on ANCOVA testing [$F_{(1,83)} = 14.7, P < 0.05$; Table 2]. Similarly, the mean HADS anxiety score fell from 11.1 to 8.2 in the intervention group, compared with 9.6 to 9.3 in the control group [$F_{(1,84)} = 17.8, P < 0.05$]. The percentage displaying clinical levels of anxiety (scores ≥ 8) fell from 84% to 61% in the intervention group and from 61% to 57% in the control group over the 6-month treatment period. The percentage displaying clinical levels of depression (scores ≥ 8) fell from 28% to 8% in the intervention group and from 33% to 30% in the control group.

The WHO quality of life mean scores, psychological domain, increased from 49.6 at baseline to 61.2 at 6 months for the intervention group compared with 50.1 to 51.5 for the controls. This difference was significant on ANCOVA testing [$F_{(1,84)} = 10.9, P < 0.05$].

There was no significant difference between the intervention and control groups in the change in self-esteem scores, nor in the quality of life scores for the environmental, social and physical domains. Self-esteem improved in both groups: intervention 27.7 to 30.9 ($t = -4.4, P < 0.01$), control 26.3

to 28.7 ($t = -3.8, P < 0.01$). However, the scores at 6 months did not differ significantly ($P > 0.05$).

Self-reported views at the end of the trial demonstrated a more positive experience in the intervention group compared with the control group. For example, in response to the question 'to what extent do you think the laser treatment has been more effective than your previous method?' the intervention group's total mean score was 4.8 compared with the control group's total mean score of 2.4 ($t = 10.2, P < 0.05$). While women in the intervention group were more likely to say that laser treatment was uncomfortable or painful, the mean scores on this item were low for both groups. Views about visiting the hospital and the benefit of talking to a doctor who understood their problem were similar for both groups, indicating that generally the control group had a similar experience to the intervention group (Table 3). However, although both groups generally said they felt better knowing that someone was able to help them, this was more pronounced for the intervention group ($t = 3.5, P < 0.05$).

In the intervention group 41 (80%) stated they would choose to continue with laser treatment, three (6%) preferred other methods and seven (14%) were lost to follow-up. The corresponding figures for the control group were 25 (68%), six (16%) and six (16%), respectively.

Discussion

This is the first randomized controlled trial of laser hair removal to examine both self-reported severity of facial hirsutism and psychological morbidity in women with PCOS. At study entry we found that women with facial hair suffered

Table 3 Self-reported views after 6 months of laser treatment

	Intervention: high fluence (n = 51)		Control: low fluence (n = 37)		P-value
	Mean	SD	Mean	SD	
To what extent do you think the laser treatment...					
has been effective	4.7	0.10	2.4	0.17	< 0.05
has been more effective than previous method	4.8	0.07	2.4	0.22	< 0.05
allows you more freedom in carrying out everyday tasks	4.5	0.12	2.4	0.23	< 0.05
has increased your confidence	4.6	0.09	2.6	0.22	< 0.05
is uncomfortable or painful	2.6	0.16	1.2	0.08	< 0.05
takes away the bother of having to remove facial hair yourself	4.5	0.10	2.5	0.27	< 0.05
Coming to the hospital for laser treatment...					
has overall reduced the amount of time spent on facial hair removal	4.5	0.14	2.6	0.23	< 0.05
has been very time-consuming	1.8	0.13	2.3	0.18	< 0.05
makes me feel better as I know that someone is able to help me	4.5	0.10	3.7	0.20	< 0.05
has been an inconvenience that I could have done without	1.1	0.09	1.3	0.10	> 0.05
has been useful as I have been able to talk to a doctor who understands my problem	4.1	0.15	4.0	0.18	> 0.05
While having laser treatment...					
I have found it hard to stop plucking or waxing my hair	1.8	0.15	2.3	0.24	= 0.05

Five-point scales: 1, not at all; 5, very much.

higher levels of psychological morbidity than the general population (Lipton *et al.* in press). After 6 months of laser treatment there was a significant improvement in the psychological state of the intervention group when compared with the controls. There was also a large and significant difference in the reported hair-free period between the groups. We cannot say if this psychological benefit would be sustained, although it is likely to regress to the mean as other life events become more significant. A small study found, not surprisingly, that quality of life deteriorated again if treatment was stopped and hair regrew.¹⁶

The levels of anxiety and depression at study entry were higher than those of women attending outpatient departments with newly diagnosed gynaecological cancer or breast cancer, and comparable with those of patients with psoriasis.^{17–19} High morbidity at outset corroborates findings from other studies.^{7,9} These women carry a burden of emotional distress and expend considerable physical effort trying to control their facial hair. Both the emotional and behavioural aspects of their lives responded well to laser treatment. This occurred despite the fact that laser treatment has no effect on any of the other symptoms associated with PCOS which might be expected to contribute to the distress.

There were several limitations to this study. The sample's sociodemographic characteristics reflected the local catchment area and patients were predominantly white and middle class. While the effectiveness of laser hair removal is unlikely to be related to social class, the effects reported here need to be explored with other groups of women. The low-dose treatment was the most convincing control we could devise with our equipment. The advice given to both groups before randomization was to stop plucking and waxing. This could have adversely affected the control group, depending on their compliance with the advice. The shortening of the hair-free period observed in the control group suggests that they were compliant with the request to stop plucking and waxing. An alternative explanation is that the low-fluence sham treatment had some stimulatory effect on the follicles. Effective blinding when patients are self-assessing outcomes is usually difficult and because of the nature of this intervention some patients could have guessed their allocation because of erythema and swelling. However, clinical observations suggested that there was confusion and uncertainty about allocation, even in the intervention group. The fact that self-esteem improved significantly and to a similar degree in both groups supports this observation.

The diagnosis of PCOS in this study was based on the clinical opinion of others. No confirmatory tests were sought by the researchers, and a negative ultrasound does not exclude PCOS. This is consistent with the consensus statement produced by 58 specialists convened to define PCOS in 1992 and a commentary by Balen in 1999.^{12,20} Most cases of idiopathic hirsutism would fall within this definition of PCOS. We acknowledge that there is lack of agreement among specialists on the definition of PCOS, and conclude that the majority of clinicians would have diagnosed the majority of our sample as having PCOS.

A strength of the study is that the analyses were conducted according to the intention-to-treat principle and that a high percentage of patients completed the trial in both the intervention and the control groups.

Laser hair removal seems to be an effective and beneficial treatment for a common condition that adversely affects most women with PCOS throughout their adult lives. The psychological and emotional burden of such hirsutism is high, and may be compounded by other symptoms associated with PCOS, such as obesity, acne and infertility. Treatment of the hirsutism alone produces measurable benefits to psychological morbidity as well as perceived severity of facial hair and hair removal behaviours. These benefits were evident after five treatments; it is our experience that hair-free periods continue to improve for several more treatments and then tend to stabilize. It would seem reasonable to assume that the behavioural and psychological benefits persist longer than for the 6 months studied here. This group of patients tends to need occasional top-up treatments to maintain their hair-free periods, so a cost-benefit analysis would seem to be an appropriate next step before public money is committed to long-term maintenance treatment. However, an induction course, limited perhaps to six treatments, should be considered while awaiting further research.

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