

## Original article

# Health-related quality of life assessment in young adults with seasonal allergic rhinitis

**Background:** In health-related quality of life (HRQL) studies on allergic rhinitis, both disease-specific and generic questionnaires have been extensively used. Seasonal allergic rhinitis (SAR) has been studied mainly by focusing on symptomatology. The present study aimed to evaluate the SAR-HRQL by means of two questionnaires, the Medical Outcome Study Short Form Health Survey (SF-36) and a new instrument examining satisfaction in 32 aspects of daily life: the Satisfaction Profile (SAT-P).

**Methods:** Thirty-three patients with SAR (aged  $33.5 \pm 8.5$  years; 12 men, 21 women) were evaluated during and 2 months after the pollen season. Data were compared with reference samples by *t*-test, and baseline and follow-up HRQL scores were compared by a matched-pair test.

**Results:** Patients' HRQL scores collected during the pollen season were significantly lower than reference sample data in many SF-36 scores and in one SAT-P item. No differences emerged between SF-36 and SAT-P scores collected outside the pollen season and reference sample scores. Compared to baseline, outside the pollen season, patients reported significantly higher scores in the following SF-36 scales: physical functioning ( $P=0.002$ ), physical role ( $P=0.00001$ ), bodily pain ( $P=0.01$ ), and vitality ( $P=0.008$ ); and significantly higher scores in only two SAT-P items (physical well-being [ $P=0.009$ ] and resistance to stress [ $P=0.01$ ]).

**Conclusions:** Our data confirm the utility of using symptomatologic and health-status questionnaires in evaluating the HRQL of SAR patients. More general quality of life questionnaires may prevent the symptomatologic and functional problems from being adequately recognized and managed. SAT-P can be a fruitful additional tool in HRQL evaluation.

**G. Majani<sup>1</sup>, I. Baiardini<sup>2</sup>,  
A. Giardini<sup>1</sup>, G. E. Senna<sup>3</sup>,  
P. Minale<sup>4</sup>, S. D'Ulisse<sup>2</sup>,  
G. Ciprandi<sup>2</sup>, G. W. Canonica<sup>2</sup>**

<sup>1</sup>Servizio di Psicologia, Fondazione S. Maugeri, Clinica del Lavoro e della Riabilitazione, IRCCS, Istituto Scientifico di Montescano; <sup>2</sup>Allergy and Respiratory Diseases, D.I.M.I., University of Genoa (GE), Genoa; <sup>3</sup>Allergy Unit, Borgo Roma Hospital, Verona (VR); <sup>4</sup>Allergy Unit, San Martino Hospital, Genoa (GE), Italy

Key words: generic questionnaire; quality of life; satisfaction profile; seasonal allergic rhinitis.

Dr Giuseppina Majani  
Servizio di Psicologia  
Fondazione S. Maugeri  
Clinica del Lavoro e della Riabilitazione  
IRCCS Istituto Scientifico di Montescano  
27040 Montescano (PV)  
Italy

Accepted for publication 14 November 2000

Allergic rhinitis is a disease affecting many aspects of patients' daily lives. Adults with rhinitis can suffer from many common symptoms such as stuffy nose, runny nose, sneezing, etc.

Recently, allergic rhinitis has been studied with two main aims: to identify and quantify its impact on the patient's life and to assess changes in clinical trials (1–5). In health-related quality of life (HRQL) studies on allergic rhinitis, both disease-specific and generic questionnaires have been extensively used. More precisely, the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) (6–9) is the most widely used specific instrument developed in order to assess symptoms and treatment impact as rated by patients. Among generic instruments, the Medical Outcome Study Short Form Health Survey (SF-36) has been often used to assess the impact of rhinitis on the patient's life with special attention to physical and emotional limitations (4, 10, 11).

Within the context of allergic rhinitis, seasonal allergic rhinitis (SAR) has been studied mainly by focusing on symptomatology (12–15).

A recent paper in the specialized literature (16) underlines the importance of distinguishing between health status and quality of life by demonstrating that, when rating quality of life, patients place greater emphasis on mental health than physical functioning. The reverse happens when rating health status: physical functioning is considered more important than mental health.

The aim of our study was to evaluate the HRQL in young adults suffering only from SAR, during and outside the pollen season, by means of the SF-36 and the Satisfaction Profile (SAT-P). The SF-36 was chosen as a measure of health status (17, 18). The SAT-P (19–22) is a new questionnaire which provides a satisfaction profile of daily life and can be considered an indicator of subjective HRQL, as previously assessed

in cardiopathic patients (21). The SAT-P has been used as a complementary tool, in order to explore the HRQL from a subjective perspective.

## Material and methods

### Subjects

We studied 33 consecutively selected outpatients with SAR characterized by a typical history of more than 2 years of disease and proven sensitization to one or more pollens as assessed by a skin prick test. The skin prick test was performed according to methodology and criteria proposed by the Italian Society of Allergy and Clinical Immunology (23). The allergen extracts used were all produced by the DHS-Bayer Group; the panel consisted of mites (*Dermatophagoides farinae* and *D. pteronyssinus*), cat, dog, grass mix, Compositae mix, *Parietaria judaica*, birch, hazelnut, olive tree, *Alternaria tenuis*, *Hormodendrum*, and *Aspergillus* mix. In order to be included in the study, patients had to be sensitive to grass and *Parietaria* only, and symptoms had to have been present for at least the preceding 4 weeks.

Patients were excluded if affected by sinusitis, nasal polypsis, septal deviation, or other anatomic abnormalities. They were also excluded if they had infectious rhinitis, perennial rhinitis, or bronchial asthma. Another exclusion criterion was ongoing treatment with antihistamines, nasal corticosteroids, or specific immunotherapy. Patients were also excluded if they had a chronic disease that could affect their HRQL, or if a major event had recently occurred in their lives.

Finally, patients unable to fill in the questionnaires because of sensory or cognitive deficits or language problems were excluded from the study.

### Rhinitis severity assessment

Physician-assessed symptom severity was based on a total symptom score. We considered five nasal symptoms (rhinorrhea, congestion, sneezing, itching, and hyposmia) and three ocular symptoms (itching, watering, and redness). For each of the eight items, severity was assessed on a 4-point scale, ranging from no symptoms (score 0) to severe (score 3). Therefore, the total score could range from 0 to 24.

### HRQL questionnaires

We used two generic questionnaires: the SF-36 and a new questionnaire aimed at assessing patients' subjective satisfaction with daily life: the SAT-P.

The SF-36 is a general health-status scale. It consists of 36 items which refer to nine health measures (physical and social functioning, role limitations due to physical and emotional problems, mental health, vitality, bodily pain, general perception of health, and change of health) (17, 18).

The SAT-P is a questionnaire providing a satisfaction profile. Satisfaction can be defined as the cognitive product of the comparison between ideal life and reality, and can therefore be quantitatively measured. The SAT-P consists of 32 items which refer to daily life. The patient is asked to rate his satisfaction with each of them, independently of his objective health status, on a 10-cm horizontal visual analog scale (score range: 0-100): the higher the score, the higher the satisfaction level. The SAT-P structure is shown in Table 1 with some items listed.

The questionnaire proved to be valid, reliable, and sensitive to change (21, 22). The factorial analysis extracted five factors: psychological functioning, physical functioning, work, sleep-eating-leisure, and social functioning.

Reference values distributed by age and sex both for the SF-36 (18,

Table 1. SAT-P factors and items

| Factors                              | Examples of items                                                            |
|--------------------------------------|------------------------------------------------------------------------------|
| Psychological functioning (10 items) | Mood<br>Self-confidence<br>Couple relationship                               |
| Physical functioning (nine items)    | Physical well-being<br>Quality of sexual intercourse<br>Resistance to stress |
| Work (five items)                    | Organization of work<br>Financial situation                                  |
| Sleep/eating/leisure (five items)    | Quality of sleep<br>Amount of spare time<br>Relationship with friends        |
| Social functioning (three items)     | Relationship with friends                                                    |

The SAT-P is copyrighted and is published in Italian, English, and French by Edizioni Erickson, C.so Buonarroti, 13, Trento, Italy; [www.erickson.it](http://www.erickson.it).

24) and for the SAT-P (22) were used. More specifically, the SF-36 reference values are representative of the general population; the SAT-P reference values were obtained from healthy subjects.

### Procedure

The patients were enrolled during the pollen season of spring 1998 (April–June). All of them compiled the HRQL questionnaires by themselves a few minutes before the first visit.

The patients were sensitive only to grasses and *Parietaria*. They were administered the symptomatologic scale during the clinical examination. After the consultation and treatment prescription, the patients were asked to come back for a second visit and assessment of the HRQL at least 2 months after the end of the pollen season. Overall, 33 patients met the inclusion and exclusion criteria and were enrolled in the study; all of them were reassessed at the follow-up. Written informed consent was given by all the patients.

### Statistical analyses

The descriptive analysis included the following variables:

- 1) *demographic characteristics*: sex, age, educational level, marital status, and employment status
- 2) *clinical data*: nasal obstruction, rhinorrhea, nasal itching, sneezing, hyposmia, ocular itching, watery eyes, and ocular redness.

SF-36 scores collected both during and outside the pollen season were compared to reference values by means of the *t*-test. SF-36 scores were also compared with data from a perennial rhinitic sample (4) by means of the *t*-test for independent samples.

SAT-P scores collected both during and outside the pollen season were compared to reference values by means of ANOVA adjusted for age, due to the different age distribution of the two samples.

Due to the small sample size, baseline and follow-up SF-36 and SAT-P scores were compared by the Wilcoxon matched pairs signed-ranks test.

For all the analyses, the *P* value was set at 0.01.

The statistical analyses were performed by the SPSS/PC program; SF-36 data were previously processed by means of a SAS program provided by the Italian Mario Negri Foundation.

## Results

The patients' demographic characteristics are shown in Table 2.

Table 2. Sample characteristics

|                    | n=33         | (%)  |
|--------------------|--------------|------|
| Sex                | M            | 36.4 |
|                    | F            | 63.6 |
| Age (years)        | 33.5 ± 8.5   |      |
| Marital status     | Single       | 54.5 |
|                    | Married      | 45.5 |
| Years of education | 0–5          | 6.1  |
|                    | 6–8          | 24.2 |
|                    | 9–13         | 48.5 |
|                    | More than 14 | 21.2 |
| Employment status  | Employed     | 66.7 |
|                    | Housewife    | 18.2 |
|                    | Student      | 15.2 |

#### Clinical data

The symptoms frequently reported by the patients during the pollen season were nasal congestion (100%), itchy nose (100%), sneezing (100%), rhinorrhea (97%), and itchy eyes (90.9%). The mean value of the total symptom score during the pollen season was 14.1 (SD 3.6).

#### HRQL

*SAR patients' SF-36 and SAT-P scores compared to reference sample scores.* SAR patients' SF-36 scores collected during the pollen season proved to be significantly lower than reference sample score in the following variables: physical functioning (87.6 vs 93.2;  $P=0.0094$ ), physical role (53.8 vs 85.1;  $P=0.00001$ ), vitality (54.7 vs 64.1;  $P=0.0027$ ), social functioning (64.4 vs 79.3;  $P=0.0001$ ), and emotional role (56.1 vs 79.11;  $P=0.0003$ ).

No differences emerged between SAR patients' SF-36 scores collected outside the pollen season and reference sample scores.

No differences emerged between SAR patients' SF-36 scores collected during the pollen season and perennial allergic rhinitis' SF-36 scores collected by Bousquet et al. (4). Table 3 shows the SF-36 scores obtained by

the reference sample, the SAR patients during and outside the pollen season, and the perennial allergic patients.

Only one SAT-P item (physical well-being) of SAR patients when evaluated during the pollen season proved to be significantly different from the reference sample (49.5 vs 61.2;  $P=0.009$ ).

No differences emerged between SAR patients' SAT-P scores collected outside the pollen season and reference sample scores.

*SF-36 and SAT-P scores of patients with SAR during and outside the pollen season.* Fig. 1 shows the comparison between SF-36 scores during and outside the pollen season. The Wilcoxon test demonstrated that outside the pollen season patients reported statistically significantly higher scores in the following scales: physical functioning ( $P=0.002$ ), physical role ( $P=0.00001$ ), bodily pain ( $P=0.01$ ), and vitality ( $P=0.008$ ).

Fig. 2 shows the comparison between SAT-P scores during and outside the pollen season. The Wilcoxon test showed that outside the pollen season patients reported statistically significantly higher scores in the following items: physical well-being (49.5 vs 61.5;  $P=0.009$ ) and resistance to stress (60.7 vs 70.8;  $P=0.01$ ). Outside the pollen season, patients reported statistically significantly higher scores in the following SAT-P factors: psychological functioning (67.1 vs 71.9;  $P=0.009$ ) and physical functioning (57.5 vs 66.6;  $P=0.003$ ).

#### Discussion

The SF-36 questionnaire proved to distinguish the SAR sample from the reference sample better than the SAT-P during the pollen season. Furthermore, the SF-36 profiles obtained by SAR and perennial allergic rhinitic patients seemed to overlap. When evaluated outside the pollen season, SAR patients did not differ from the reference sample in their HRQL.

These results suggest that in terms of general HRQL,

Table 3. Comparison between SAR patients' and reference sample SF-36 scores, and between SAR patients' and perennial allergic rhinitic patients' SF-36 scores

| SF-36 variables           | Reference sample<br>(n=373)<br>Mean ± SD | SAR patients (n=33)<br>During the pollen season<br>Mean ± SD | P*      | SAR patients (n=33)<br>After the pollen season<br>Mean ± SD | P° | Perennial allergic rhinitic<br>patients (n=111)<br>Mean ± SD | P# |
|---------------------------|------------------------------------------|--------------------------------------------------------------|---------|-------------------------------------------------------------|----|--------------------------------------------------------------|----|
| Physical functioning      | 93.2 ± 11.4                              | 87.6 ± 15.9                                                  | 0.00940 | 94.5 ± 11.2                                                 | NS | 88.6 ± 13.6                                                  | NS |
| Physical role limitation  | 85.1 ± 28.9                              | 53.8 ± 36.8                                                  | 0.00001 | 87.5 ± 29.3                                                 | NS | 60.6 ± 37.8                                                  | NS |
| Bodily pain               | 77.4 ± 23.2                              | 70.9 ± 27.6                                                  | NS      | 85.1 ± 23.3                                                 | NS | 76.9 ± 26.0                                                  | NS |
| General health            | 70.1 ± 17.7                              | 67.0 ± 16.6                                                  | NS      | 73.7 ± 14.7                                                 | NS | 62.4 ± 20.6                                                  | NS |
| Vitality                  | 64.1 ± 17.4                              | 54.7 ± 14.5                                                  | 0.00270 | 63.0 ± 13.4                                                 | NS | 54.6 ± 24.4                                                  | NS |
| Social functioning        | 79.3 ± 20.5                              | 64.4 ± 19.8                                                  | 0.00010 | 75.0 ± 22.5                                                 | NS | 73.1 ± 23.6                                                  | NS |
| Emotional role limitation | 79.1 ± 34.7                              | 56.1 ± 37.7                                                  | 0.00030 | 69.8 ± 40.9                                                 | NS | 64.2 ± 38.8                                                  | NS |
| Mental health             | 68.1 ± 19.7                              | 66.0 ± 15.9                                                  | NS      | 70.5 ± 18.3                                                 | NS | 64.8 ± 20.4                                                  | NS |

\* SAR patients (n=33) assessed during pollen season compared with reference sample (18, 24).

° SAR patients (n=33) assessed after pollen season compared with reference sample (18, 24).

# SAR patients (n=33) assessed during pollen season compared with perennial allergic rhinitic patients (4).

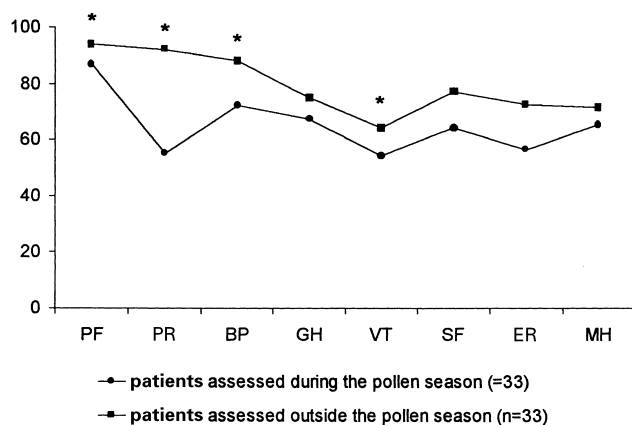


Figure 1. Comparison between SF-36 scores of SAR patients assessed during and outside pollen season. The higher the score, the higher the functional status (\* $P < 0.01$ ). PF: physical functioning; PR: physical role limitation; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; ER: emotional role limitation; MH: mental health.

SAR affects patients' health status more than their subjective satisfaction: only the SAT-P item physical well-being was able to distinguish patients from reference subjects.

Consistently, outside the pollen season, the SF-36 proved to detect better an improvement in some measures of patients' health status, whereas only two SAT-P items out of 32 were significantly higher.

Although the results of the two questionnaires could seem contradictory, they are essentially consistent, and seem to adhere to what is observed in clinical practice: SAR patients do complain about their symptoms during the pollen season, but they do not report substantial changes in their satisfaction profile.

Cognitively, patients are aware of the transient nature of their symptoms: they must wait and cope with symptoms only for a relatively brief period. Their discomfort becomes evident through the symptoms and the health-status measures, and not through their subjective satisfaction with life.

When a chronic disease exists, life is seen and judged through it. We suggest that this does not happen in seasonal rhinitis, which is seen rather as an unpleasant cluster of transient symptoms and functional impairment, and this is an area in which relief can be clearly perceptible.

## References

1. JUNIPER EF, GUYATT GH, ANDERSSON B, FERRIE PJ. Comparison of powder and aerosolized budesonide in perennial rhinitis: validation of rhinitis quality of life questionnaire. *Ann Allergy* 1993;70:225-230.
2. JUNIPER EF, GUYATT GH, DOLOVICH J. Clinical aspects of allergic disease. Assessment of quality of life in adolescents with allergic rhinoconjunctivitis: development and testing of a questionnaire for clinical trials. *J Allergy Clin Immunol* 1994;93:413-423.
3. DE GRAAF-IN 'T VELD T, KOENDERS S, GARRELDIS IM, VAN WIJK RG. The relationships between nasal hyperreactivity, quality of life, and nasal symptoms in patients with perennial allergic rhinitis. *J Allergy Clin Immunol* 1996;98:508-513.

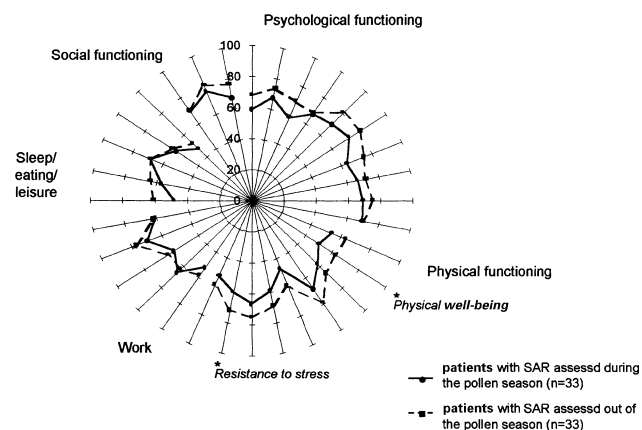


Figure 2. Comparison between SAT-P item scores of patients with SAR assessed during and outside pollen season. The higher the score, the higher the satisfaction level (\* $P < 0.01$ ).

Research on the implicit cognitive models of diseases confirms the intrinsically different nature of health status and general quality of life and the different cognitive processes implied in the construction of the mental representation of diseases according to chronicity, severity, unchangeability, etc. (25-28).

The preliminary data of our research confirm the utility of using both symptomatologic and health-status questionnaires in evaluating the HRQL of patients suffering from SAR.

More general questionnaires on quality of life may provide data not directly connected with the treatment of the disease, and by providing a positive picture of the patient's life, they may prevent the symptomatologic and functional problems from being adequately recognized and managed. Furthermore, this study demonstrates that SAT-P may be fruitful as a complementary tool in HRQL evaluation in allergic rhinitis too.

## Acknowledgments

This study has been partially supported by ARMIA (Associazione Ricerca Malattie Immunologiche e Allergiche), and a MURST (Ministry of University and Scientific and Technologic Research) grant to G.W.C.; I.B. is the recipient of a Hoechst Marrión Foundation Fellowship on quality of life in allergy.

4. BOUSQUET J, DUCHATEAU J, PIGNAT JC, et al. Improvement of quality of life by treatment with cetirizine in patients with perennial allergic rhinitis as determined by a French version of the SF-36 questionnaire. *J Allergy Clin Immunol* 1996;**98**:309–316.
5. BAGENSTOSE SE, BERNSTEIN JA. Treatment of chronic rhinitis by an allergy specialist improves quality of life outcomes. *Ann Allergy Asthma Immunol* 1999;**83**:524–528.
6. JUNIPER EF, GUYATT GH. Development and testing of a new measure of health status for clinical trials in rhinoconjunctivitis. *Clin Exp Allergy* 1991;**21**:77–83.
7. JUNIPER EF. Rhinitis management: the patient's perspective. *Clin Exp Allergy* 1998;**28**:34–38.
8. JUNIPER EF. Impact of upper respiratory allergic diseases on quality of life. *J Allergy Clin Immunol* 1998;**101**:s386–s391.
9. JUNIPER EF, THOMPSON AK, FERRIE PJ, ROBERTS JN. Development and validation of the Mini Rhinoconjunctivitis Quality of Life Questionnaire 1999;**30**:132–140.
10. BOUSQUET J, BULLINGER M, FAYOL C, MARQUIS P, VALENTIN B, BURTIN B. Assessment of quality of life in patients with perennial allergic rhinitis with the French version of the SF-36 Health Status Questionnaire 1994;**94**:182–188.
11. LEYNAERT B, BOUSQUET J, PERILLAT A, LIARD R, BRUN C, NEUKRICH F. Quality of life of young adults with allergic rhinitis: a population-based study. 1999 Meeting of the American Thoracic Society, D41, Poster: B117.
12. JUNIPER EF, GUYATT GH, ARCHER B, FERRIE PJ. Aqueous beclomethasone dipropionate in the treatment of ragweed pollen-induced rhinitis: further exploration of "as needed" use. *J Allergy Clin Immunol* 1993;**92**:66–72.
13. HARVEY RP, COMER C, SANDERS B, et al. Model for outcomes assessments of antihistamine use for seasonal allergic rhinitis. *J Allergy Clin Immunol* 1996;**97**:1233–1241.
14. JUNIPER EF, GUYATT GH, FERRIE PJ, GRIFFITH LE. First-line treatment of seasonal (ragweed) rhinoconjunctivitis. A randomized management trial comparing a nasal steroid spray and a non-sedating antihistamine. *Can Med Assoc J* 1997;**156**:1123–1131.
15. BERKOWITZ RB, BERNSTEIN DI, LaFORCE C, et al. Onset of action of mometasone furoate nasal spray (NASONEX) in seasonal allergic rhinitis. *Allergy* 1999;**55**:64–69.
16. SMITH KW, AVIS NE, ASSMANN SF. Distinguishing between quality of life and health status in quality of life research: a meta-analysis. *Qual Life Res* 1999;**8**:447–459.
17. WARE JE, SNOW KK, KOSINSKI M, GANDEK B. SF-36 Health Survey. Manual and interpretation guide. Boston: Health Institute, New England Medical Center, 1993.
18. APOLONE G, MOSCONI P, WARE JE. Questionario sullo stato di salute SF-36. Manuale d'uso e guida all'interpretazione dei risultati. Milan: Guerini e Associati, 1997.
19. MAJANI G, CALLEGARI S, PIEROBON A, et al. A new instrument in quality of life assessment. The Satisfaction Profile (SAT-P). *Int J Ment Health* 1999;**28**:77–82.
20. MAJANI G, CALLEGARI S. SAT-P Satisfaction Profile. Soddisfazione soggettiva e qualità della vita. Trento: Erickson, 1998.
21. MAJANI G, PIEROBON A, GIARDINI A, et al. Relationship between psychological profile and cardiological variables in chronic heart failure. The role of patient subjectivity. *Eur Heart J* 1999;**20**:1579–1586.
22. MAJANI G, PIEROBON A, GIARDINI A, CALLEGARI S. Satisfaction Profile (SAT-P) in 732 patients: focus on subjectivity in HRQL assessment. *Psychol Health* 2000;**15**:409–422.
23. Società Italiana di Allergologia e Immunologia Clinica: "Memorandum della Diagnostica delle Allergopatie". *Fed Med* 1987;**40**:861–874.
24. APOLONE G, MOSCONI P. The Italian SF-36 health survey: translation, validation and norming. *J Clin Epidemiol* 1998;**51**:1025–1036.
25. PETRIE KJ, WEINMAN JA. Perceptions of health and illness. Amsterdam: Harwood, 1997.
26. BENNET P, MURPHY S. Psychology and health promotion. Philadelphia: Open University Press, 1997.
27. HYLAND ME. The influence of beliefs on the quality of life of patients with allergic diseases [Editorial]. *Clin Exp Allergy* 1999;**29**:1591–1592.
28. MAJANI G. Introduzione alla psicologia della salute. Trento: Erickson, 1999.