ORIGINAL ARTICLE

# Clinical Efficacy of Web-Based Versus Standard Asthma Self-management

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## Abstract

*Background*: Guided self-management is an important component of asthma care. Most trials have evaluated paper-based strategies. The effectiveness of new communication technologies remains uncertain.
*Objectives:* To compare the feasibility and clinical outcomes of a standard paper-based asthma self-management strategy with web-based strategies.
*Methods:* In a crossover trial, 21 patients using inhaled corticosteroids and long-acting ß$_2$-agonists (mean [SD] age 29 [10] years) were randomly assigned to use a sequence of web-based and paper-based diary and action plan. Quality of life, asthma control, lung function, and airway inflammation were assessed using the Asthma Life Quality Questionnaire (ALQ), Asthma Control Questionnaire (ACQ-5), Mini Asthma Quality of Life Questionnaire (Mini AQLQ), and office spirometry. The ratio of forced expiratory volume in the first second of expiration ($FEV_1$) to peak expiratory flow (PEF) rate (PiKo-1) and fraction of exhaled nitric oxide ($FE_{NO}$) were monitored. The main clinical outcomes were asthma control and $FE_{NO}$. Quality of data and adherence to monitoring tools were the main process outcomes.
*Results:* Significant improvements were observed in the AQL and ACQ scores, although lung function did not change. $FE_{NO}$ was significantly reduced only after a web-based strategy but a significant period effect occurred ($P$=.006). There were no differences in clinical outcomes between web-based and paper-based management. No intervention-related adverse effects were observed. Adherence seemed higher with the paper-based strategy ($P$<.001). However, paper data were unreliable when compared to automatic daily electronic $FEV_1$/PEF records. Twelve patients were very interested in continuing self-management with the web-based approach compared with 2 in using paper tools ($P$=.002).
*Conclusions:* Web-based management was feasible, safe, and preferred by patients. Short-term outcomes were at least as good, and data quality was improved.

**Key words:** Asthma. Crossover. Internet. Self-management.

## Resumen

*Antecedentes:* El autocontrol guiado es un componente importante en el cuidado del asma. En la mayoría de los ensayos se han evaluado estrategias basadas en papel. Todavía no está muy clara la eficacia de las nuevas tecnologías de la comunicación.
*Objetivos:* Evaluar la viabilidad y los resultados clínicos de una estrategia estándar de autocontrol del asma basada en papel en comparación con estrategias basadas en Internet.
*Métodos:* En un ensayo cruzado, 21 pacientes que utilizaban corticoesteroides y ß2-agonistas de acción prolongada inhalados (media [DE] de edad 29 [10] años) fueron distribuidos aleatoriamente para utilizar una secuencia de diario y plan de acción basados en la red y basados en papel. Se evaluaron la calidad de vida, el control del asma, la función pulmonar y la inflamación de las vías respiratorias utilizando el Cuestionario de Calidad de Vida en el Asma (ALQ), el Cuestionario del Control del Asma (ACQ-5), el Minicuestionario de Calidad de Vida en el Asma (Mini AQLQ) y una espirometría en el consultorio. Se controló a diario la relación entre la tasa de volumen espiratorio máximo en el primer segundo (VEMS) y el flujo espiratorio máximo (FEM) (PIKO-1) y la fracción de óxido nítrico exhalado (NOe). Los principales criterios de valoración clínicos fueron el control del asma y la fracción de NOe. Los principales criterios de valoración del proceso fueron la calidad de los datos y el cumplimiento en el uso de las herramientas de control.
*Resultados:* Se observaron mejoras significativas en las puntuaciones de los cuestionarios AQL y ACQ, si bien la función pulmonar no cambió.

La fracción de NOe se vio significativamente reducida solamente tras una estrategia basada en Internet, si bien se produjo un efecto período significativo ($p = 0,006$). No se observaron diferencias en los resultados clínicos entre el control basado en la red y el basado en papel. No se observaron efectos adversos relacionados con la intervención. El cumplimiento fue superior con la estrategia basada en papel ($p < 0,001$). No obstante, los datos en papel no fueron fiables en comparación con los datos generados con el enfoque basado en la red. Doce pacientes mostraron gran interés en continuar con el autocontrol con el enfoque basado en la red en comparación con 2 pacientes que utilizaron la herramienta en papel ($p = 0,002$).
*Conclusiones:* El control basado en la red fue viable, seguro y el preferido por los pacientes. Los resultados a corto plazo fueron al menos igual de buenos, y la calidad de los datos mejoró.

Palabras clave: Asma. Cruzamiento. Internet. Autocontrol.

## Introduction

Asthma is a global health problem. Many international surveys provide evidence for suboptimal asthma control despite the availability of effective therapies [1].

Most recent guidelines recognize the relevance of asthma self-management, defined as a partnership between the person with asthma (and parents/caregivers) and health care professionals that enables patients to gain the knowledge, confidence, and skills to assume a major role in the management of their disease [1]. The partnership is strengthened as patients and health care professionals discuss and agree on the goals of treatment, develop a personalized written self-management action plan (including self-monitoring), and periodically review asthma control and the treatment plan [1]. Although asthma self-management has the potential to provide patients with a range of process skills and deliver improvements in clinical and psychosocial indicators of asthma control, the process itself is subject to a series of limitations in a real-life setting. Unlike conventional asthma diary cards, which may contain a high number of false and retrospective entries [2,3], electronic recording may prevent false entries and identify mistimed entries. Furthermore, a higher proportion of measurements are completed, and measurements are timed more accurately [2-4].

We previously showed that adults with moderate to severe asthma are in favor of the use of web-based and mobile phone–based tools for different aspects of asthma monitoring and self-management [5]. However, few studies have assessed patients' preferences or the usability of web-based monitoring [6], and only 1 randomized clinical trial evaluated the long-term clinical efficacy of web-based asthma monitoring [7].

We aimed to compare a web-based asthma self-management strategy with a paper-based strategy in terms of feasibility, safety, and clinical efficacy.

## Methods

The study design and procedures complied with the recommendations of the Declaration of Helsinki (2000) and followed the Consolidated Standards of Reporting Trials statement [8] where applicable. The local research ethics committee approved the study and patients signed an informed consent document.

### *Participants and Study Design*

The study population comprised consecutive adults attending an outpatient allergy clinic with moderate to severe asthma (at least 6 months since diagnosis) treated with inhaled budesonide (320-1280 μg/day) and formoterol (9-36 μg/day) in a single inhaler during the previous month, and a prebronchodilator predicted forced expiratory volume in the first second of expiration ($FEV_1$) above 50%. As the drug treatment was freely distributed to patients during the study period (budesonide/formoterol 320/9 μg in a single turbohaler; Assieme, Labaratórios Vitória S.A., Amadora, Portugal) and in order to avoid variations in study results related to treatment differences, we chose to include only patients previously under treatment with the same medicines. The exclusion criteria included involvement in an asthma self-monitoring program during the previous year, being unable to use the Internet during the study period, and the presence of concomitant severe psychiatric, neurological, oncologic, or immunologic disease. A total of 21 patients aged between 18 and 62 years were included (Table 1).

The study had a crossover design, with patients randomly allocated using a computer-generated algorithm to a web-based or paper-based asthma diary and action plan, each for a period of 4 weeks (Figure 1). After randomization, there were no significant differences between the groups (Table 1).

### *Procedures*

The Asthma Life Quality Questionnaire (ALQ) [9], Asthma Control Questionnaire (ACQ-5) [10], and Mini Asthma Quality of Life (Mini AQLQ) [11] were evaluated before and after both strategies. After a clinical interview and physical examination, spirometry was performed (Vitalograph 2120, Vitalograph, UK) and exhaled nitric oxide evaluated (NIOX, Aerocrine AB, Sweden) using standard techniques [12]. During the interventions, patients received instructions on how to use the monitoring instruments (including PiKo-1, n-Spiro, Longmont, Colorado, USA) [13], the web-based application, and the paper-based diary and action plan). Patients were asked to use the monitoring instruments once daily just before taking their inhaled medication. At the end of the study, a self-administered questionnaire, written open-ended questions, and short interviews were used to assess patients' preferences and opinions regarding the monitoring tools. The patients' physicians scheduled regular appointments along with study visits and were responsible for the pharmacological treatment

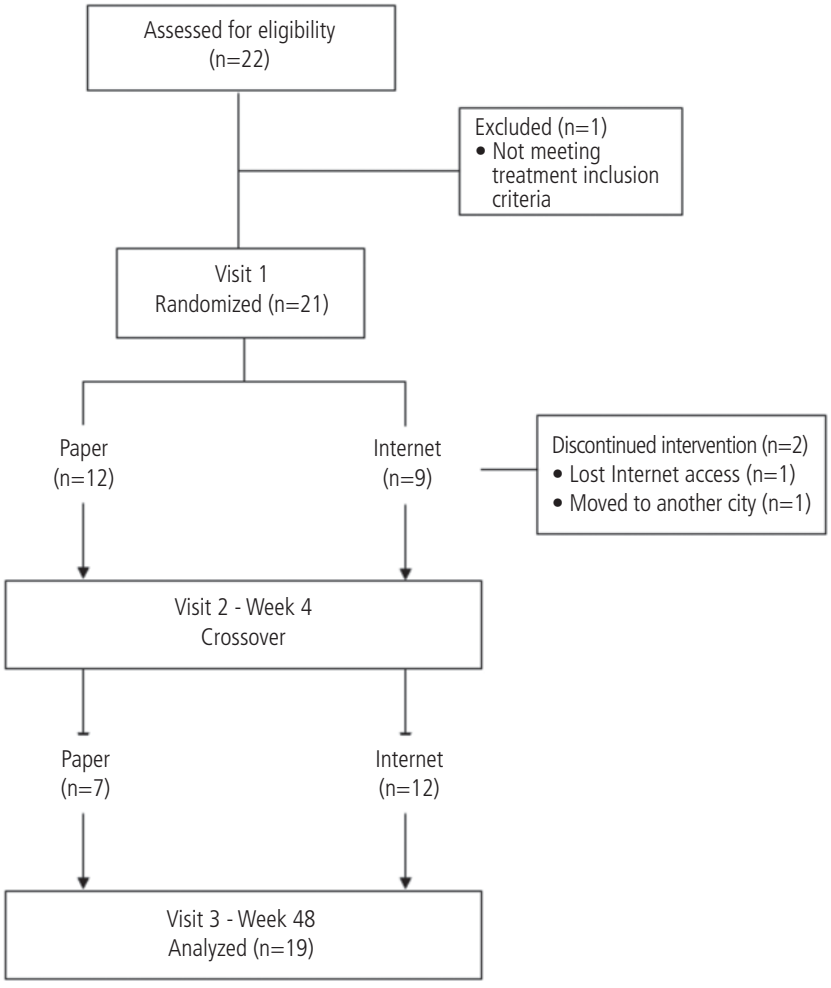


Figure 1. Study flow-chart.

Table 1. Baseline Characteristics of Patients[a]

| | Total (N=21) | Paper and Internet (n=12) | Internet and Paper (n=9) |
|---|---|---|---|
| Female, n (%) | 15 (71) | 8 (67) | 7 (78) |
| Age, y | 29 (10) | 26 (6.2) | 32 (12.2) |
| Asthma duration, y | 19 (12) | 16 (8.2) | 24 (14.9) |
| ALQ score | 10 (3.6) | 9 (3.7) | 11 (3.5) |
| ACQ score | 1.4 (1.07) | 1.2 (1.07) | 1.9 (0.97) |
| AQLQ score | 5.3 (1.15) | 5.5 (1.15) | 4.8 (1.09) |
| $FEV_1$, % predicted | 90 (21) | 97 (16) | 81 (23) |
| PEF, L/min | 92 (22) | 97 (18) | 86 (27) |
| $FE_{NO}$, ppb[b] | 48.6 (30.0-81.5) | 40 (22.2-73.7) | 65 (22.2-181.3) |

Abbreviations: ACQ, Asthma Control Questionnaire; ALQ, Asthma Life Quality Questionnaire; AQLQ, Asthma Quality of Life Questionnaire; $FE_{NO}$, fraction of exhaled nitric oxide; $FEV_1$, forced expiratory volume in 1 second; PEF, peak expiratory flow.
[a]Data are presented as mean (SD) unless otherwise stated.
[b]Geometric mean (95% confidence interval). Baseline groups were not significantly different.

prescribed. Relief therapy could be used throughout the study period according to the referring physician's indications and consisted mainly of short-acting inhaled $ß_2$-agonists.

### *Interventions and Outcomes*

*Web-based self-management:* A web-based application named *Portal for Assessment and Self-management of Asthma* (P'ASMA) was developed. P'ASMA is accessible online (www.pasma.med.up.pt) and can be used both at medical facilities and during patients' daily life. P'ASMA makes it possible to collect and centrally store an electronic patient record that can provide patients and physicians with immediate feedback about a patient's condition and thus facilitate decisions on therapy. The Internet application includes restricted areas for patients and physicians. Relevant technical details have been reported elsewhere [14]. The patient registers monitoring data (peak expiratory flow rate [PEF], $FEV_1$, symptoms, and exacerbations) and receives immediate graphic and written feedback based on the action plan designed by his/her physician. Automatic messages and alerts to the patient, physician, or both are triggered when predefined conditions are met (eg, a red mark in the action plan or a scheduled consultation). Physicians have complete access to their patients' medical records, including monitoring and questionnaire data. Based on data recorded by the doctor during consultation, classifications of asthma control, severity, and risk of near fatal asthma are shown. Summaries of monitoring data and questionnaire scores are also provided.

*Paper-based self-management:* Paper-based tools included an asthma symptoms diary adapted from Juniper et al [15] and validated in Portuguese [9], with the same questions as those on the web application symptoms monitoring form. Patients were given a handwritten asthma action plan similar to the one inserted by their physician in the web application.

The main clinical outcomes were asthma control and fraction of exhaled nitric oxide ($FE_{NO}$). Adherence to monitoring tools was the main outcome. Secondary outcomes included quality of life, spirometry parameters, and patient opinion.

 

### *Statistical Analysis*

The sample size was calculated based on ACQ-5, the main clinical outcome of the study, which, in a previous work, had the largest within-patient standard deviation [16]. The present study was designed with 90% power to detect a 0.3 unit difference between the interventions in the ACQ score with a 2-tailed significance level set at 5%. A 17-patient sample was established for this 2-treatment crossover study. Considering a 20% dropout rate, 21 patients were included.

$FE_{NO}$ distribution was markedly asymmetrical and was logarithmically transformed. $FE_{NO}$ data are shown as the geometric mean and the antilog of the 95% confidence interval calculated on the log scale. Other clinical outcome variables are presented as mean (SD) or median (IQR). The Fisher exact test was used to compare independent proportions; the *t* test and Mann-Whitney test were used to compare continuous variables between sequence groups; and the Wilcoxon, Friedman, and paired *t* tests were used to compare related samples. The statistical tests used are identified in the tables of results. To estimate the period effect, distributions of the differences in outcomes after interventions in the 2 sequences were compared using the *t* test. This analysis [17] evaluates possible period effects owing to external factors, such as change of season, and is generally considered to influence both treatments in a similar way. Possible interactions between the interventions and the time period (sequence of interventions) were also assessed using the *t* test. Statistical analysis was carried out using SPSS 12 (SPSS Inc, Chicago, Illinois, USA). Statistical significance was set at $P<.05$.

## Results

No significant differences were observed in clinical outcomes between the web-based and paper-based sequences. A significant improvement was observed in the ACQ and AQL scores, although lung function did not change (Table 2). $FE_{NO}$ was significantly reduced only after web-based monitoring. However, a significant period effect was observed for ACQ ($P=.010$) and $FE_{NO}$ ($P=.006$), and a significant intervention–period interaction was observed for $FE_{NO}$ ($P<.001$). Furthermore, the 95% CI of the differences in the effects attained with the interventions were inferior to the minimal clinically important change in ACQ and AQLQ scores and below the limits of reproducibility of the instruments used to determine $FE_{NO}$ and pulmonary function parameters.

No differences in changes in the daily patient-reported outcomes were observed between groups (Table 3). Although the difference between the effects of the interventions for $FEV_1$ was 1.1 L ($P=.032$), a significant period effect was observed ($P=.035$).

Adherence to the paper-based strategy was significantly greater than to the web-based strategy ($P<.001$); however, the results for monitoring with the PiKo-1 device were similar between groups, namely, 526/1044 (50%) for the paper-based strategy and 518/1044 (50%) for the web-based strategy (Figure 2).

No differences existed in the time needed to use either strategy ($P=.675$). Patients' opinions were reported in 16 (76%) cases. Two patients gave a negative rating for the web-based approach and 11 for the paper-based approach. Twelve patients (57%) were very interested in continuing to monitor their asthma using the web-based approach and 2 using the paper-based approach ($P=.002$). One patient chose the paper diary only, and 12 patients did not want to use the paper diary. Furthermore, one-third of patients were happy to monitor their symptoms daily, whereas 20% preferred to do it less than once a week. Further details on patient opinion and adherence to monitoring tools have been previously reported [14]. No intervention-related adverse effects were observed.

**Table 2.** Clinical Outcomes After Each Intervention and the Differences in the Effects Between the 2 Interventions[a]

| | Post-Internet | *P*[b] | Postpaper | *P*[b] | Internet-Paper | *P*[b] |
|---|---|---|---|---|---|---|
| $FE_{NO}$ | 33 (20.1-40.4) | .032 | 35 (20.1-44.7) | .107 | –1.0 (–1.5 to 1.3) | .760 |
| ACQ | 0.76 (0.75) | .013 | 0.76 (0.52) | .019 | -0.2 (–0.63 to 0.27) | .417 |
| AQLQ | 5.78 (1.02) | .029 | 5.68 (0.93) | .011 | 0.1 (–0.33 to 0.49) | .683 |
| PEF | 97 (23) | .371 | 97 (22) | .578 | 0.2 (–5.5 to 5.9) | .931 |
| $FEV_1$ | 92 (21) | .914 | 93 (23) | .510 | 2.1 (–2.43 to 6.7) | .339 |

Abbreviations: ACQ, Asthma Control Questionnaire; AQLQ, Asthma Quality of Life Questionnaire; $FE_{NO}$, fraction of exhaled nitric oxide; $FEV_1$, forced expiratory volume in 1 second; PEF, peak expiratory flow.
[a]Data presented as mean (SD), except for $FE_{NO}$ (geometric mean [95% confidence interval]) and for the difference between Internet and paper (mean [95% confidence interval]).
[b]$P<.05$ (paired *t* test).

**Table 3.** Changes in the Daily Patient-Reported Outcomes Between the Study Visits[a]

| Daily | Change During Paper-Based Strategy | *P*[b] | Change During Internet-Based Strategy | *P*[b] | Internet-Paper | *P*[b] |
|---|---|---|---|---|---|---|
| PEF (L/min) | –19.9 (–46.0 to 6.2) | .120 | 36.8 (–16.7 to 90.4) | .160 | 76.5 (–2.1 to 155.0) | .055 |
| $FEV_1$ (l) | –0.17 (–0.60 to 0.25) | .379 | 0.60 (–0.05 to 1.24) | .068 | 1.11 (0.12 to 2.10) | .032 |
| Symptoms | 0.05 (–0.22 to 0.32) | .709 | 0.08 (–0.38 to 0.53) | .708 | 0.09 (–0.55 to 0.73) | .752 |

Abbreviations: $FEV_1$, forced expiratory volume in 1 second; PEF, peak expiratory flow.
[a]Changes were calculated as the difference between patient mean value in the fourth and the first week of using the monitoring tool. Data are presented as mean (95% confidence interval).
[b]$P<.05$ (paired *t* test).

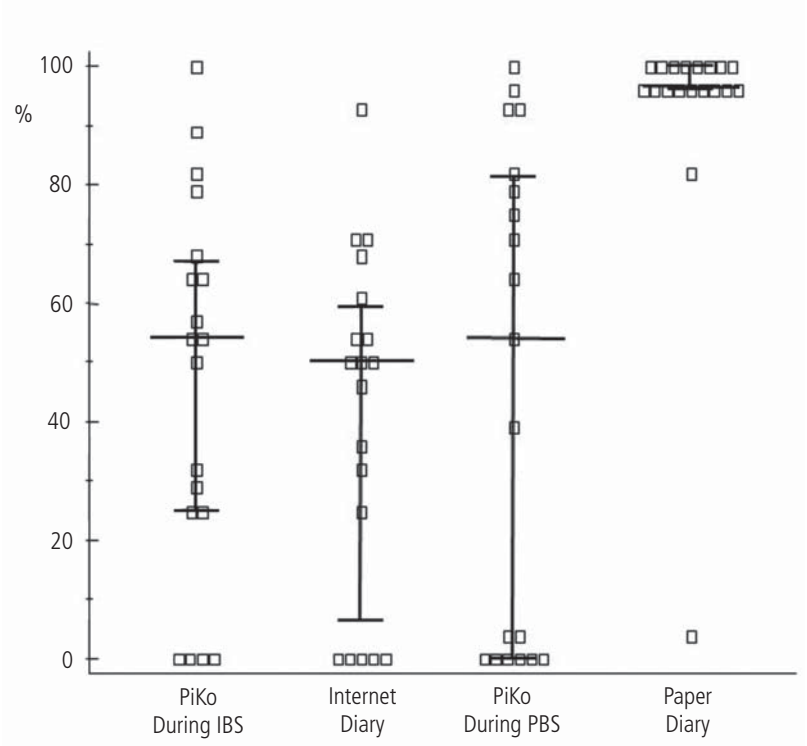


Figure 2. Adherence to monitoring with different instruments. Each square represents the percentage of recorded data for each patient: long horizontal lines represent the median and short horizontal lines the interquartile range. Adherence to the paper diary seems to be higher. However, data from PiKo-1 suggest that paper diaries overestimate monitoring, ie, patients invented values or recorded several values at once. IBS indicates Internet-based strategy; PBS, paper-based strategy.

## Discussion

To our knowledge, this is the first randomized crossover study to compare the feasibility and clinical outcomes of asthma self-management using a web-based or paper-based tool. We have shown that home monitoring of asthma supported by a web application was feasible and well accepted by patients. Although there were no differences in changes between groups, patients preferred the web format over the paper format for ongoing self-monitoring of asthma.

Our study is subject to a series of limitations. First, we did not assess the patient education tools of the web application or the features designed for the clinician. This was mainly because patient education, a major component of chronic care, should not be evaluated in crossover studies, because considerable carry-over effects are expected. As a central component of asthma self-management, patient education is indispensable for the implementation of the proposed tools. Second, the small number of patients included could have limited the ability to detect differences between groups. However, sample size was calculated with a 90% power to detect differences in the primary clinical outcomes. The duration of each intervention was 4 weeks. The primary clinical outcomes $FE_{NO}$ and ACQ changed in response to interventions after a few weeks [18]. In fact, we observed significant improvements from the first to the second visit and also from the second to the third visit. However, a longer observation period would be needed to assess other outcomes, such as exacerbations.

Our study also has important strengths. The evaluation of health information systems should include clinical outcomes and their impact should be compared against other tools [19]. This exploratory study aimed to compare the new instrument with the usual tools for guided self-management in order to establish whether the new technology was at least as good as the paper-based tools. We did not include a placebo group, since the efficacy of asthma self-management has already been demonstrated [20]. We aimed to evaluate a new asthma self-management tool compared with standard self-management. Hence our choice of a crossover design. Crossover trials are used for the study of new interventions [21], particularly when the new intervention involves a slight modification to the standard one. In this case, where comparisons of equivalent interventions are made (as might be expected in our study), a strong positive within-subject correlation is anticipated between intervention responses. Crossover designs provide additional sensitivity and power when compared with parallel-groups [22], thus making them a less costly and statistically more powerful solution. Moreover, interventions are evaluated in the same patients, allowing comparison at an individual rather than group level. In addition, as patients receive multiple interventions they can express preferences for or against them [23]. Crossover trials usually require about half the number of patients to produce the same accuracy as a parallel group trial. Furthermore, the variation in repeated responses within a patient is usually less pronounced than between different patients.

This is one of the few randomized studies evaluating web-based interventions for patients with asthma. Other studies reported good results for adherence and acceptance by patients [24]. In a 6-month, prospective, randomized comparative design involving 3 parallel groups with 100 asthmatic patients each, Rasmussen et al [7] compared 3 asthma management strategies: an Internet-based strategy, using a web tool with an electronic diary, an action plan for patients, and a decision support system for the physician; a specialist-based strategy, in which patients were followed by an asthma specialist and were given a peak flow meter and a written action plan; and a GP-based strategy, in which patients were followed by GPs according to the GINA guidelines [1]. At the end of the follow-up period, the Internet group had a significantly greater improvement in symptoms, asthma-related quality of life, and lung function. The number needed to treat (using the AQLQ improvement) for the Internet group was 5.46 compared with the specialist group and 5.69 compared with the GP group.

 

Recently, van der Meer et al [25] conducted a 1-year randomized controlled trial with 200 adults with asthma. Patients followed an Internet-based self-management program (weekly asthma control monitoring and treatment advice, online and group education, and remote web communications) or usual care. The authors found modest improvements in asthma control and lung function with the Internet-based intervention, but no reduction in exacerbations. Changes in asthma-related quality of life were not clinically significant. Our data are consistent with those of published studies and examine the short-term effects of self-monitoring tools on clinical control and biomarkers of inflammation.

Adherence to home monitoring was variable: around half of the scheduled measurements were recorded. This finding is similar to those of Turner et al [26], who reported only 65% adherence to the self-management plans in the peak flow meter group and 52% in the symptoms group. The completeness of home monitoring records was significantly different between the interventions, with an apparently higher adherence to paper tools. However, data from PiKo-1 and patients' questionnaires suggest that paper diaries overestimate monitoring: patients invented values or recorded several values at once. A more careful observation of the data suggests that the frequencies of home monitoring using the paper diary and the Internet application were similar. In a chronic pain study, Stone et al [27] used a paper diary equipped with a photo sensor that recorded when the diary was used: while the completeness of a paper diary was over 90%, the binder was opened on 32% of the study days. In fact, electronic time-coded diaries have been shown to be more reliable [3]. Nevertheless, the clinical relevance of the low reliability of paper diaries is not known. Furthermore, patients' answers indicate a need to customize monitoring schedules, based on agreement between the patient and the physician and taking asthma severity and control into consideration.

Parallel studies including a group without home monitoring are necessary in order to further assess the efficacy of the interventions. In addition, self-management supported by web-based applications in populations with low literacy and economic difficulties should be the subject of new studies [28].

In conclusion, the web-based asthma self-management approach was feasible and safe. Short-term outcomes were at least as good those of paper-based tools: data quality is improved as the integrity features increase the reliability of the data. Furthermore, patients preferred the web-based application for ongoing monitoring of their asthma.

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