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Original Article

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Impact of an Education Programme on IBD Patients' Skills: Results of a Randomised Controlled Multicentre Study [ECIPE]

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Abstract

Background: Better patient knowledge on inflammatory bowel disease [IBD] could improve outcome and quality of life. The aim of this study was to assess if an education programme improves IBD patients' skills as regards their disease.

Methods: The GETAID group conducted a prospective multicentre randomised controlled study. IBD patients were included at diagnosis, or after a significant event in the disease course. Patients were randomised between 'educated' or control groups for 6 months. Education was performed by trained health care professionals. A psycho-pedagogic score [ECIPE] was evaluated by a 'blinded' physician at baseline and after 6 and 12 months [M6 and M12]. The primary endpoint was the increase of ECIPE score at M6 of more than 20%.

Results: A total of 263 patients were included in 19 centres (male:40%; median age:30.8; Crohn's disease [CD]:73%). Of these, 133 patients were randomised into the educated group and 130 into the

control group. The median relative increase in ECIPE score at M6 was higher in the educated group as compared with the control group (16.7% [0–42.1%] vs 7% [0–18.8%], respectively, $p = 0.0008$). The primary endpoint was met in 46% vs 24% of the patients in the educated and control groups, respectively [$p = 0.0003$]. A total of 92 patients met the primary endpoint. In multivariate analysis, predictors of an increase of at least 20% of the ECIPE score were randomisation in the educated group (odds ratio [OR] = 2.59) and no previous surgery [OR = 1.92].

Conclusions: These findings support the set-up of education programmes in centres involved in the management of IBD patients.

Key Words: Xxx

1. Introduction

Over the past decade, inflammatory bowel diseases [IBD] have become worldwide diseases with an increasing incidence in newly industrialised countries. In Western countries, prevalence remains high, ranging from 0.25% to 0.44%.[1] In France, incidence rates are 8.2 for Crohn's disease [CD] and 7.8 for ulcerative colitis [UC] per 100 000 inhabitants.[2] IBD is most commonly diagnosed between the ages of 20 and 40,[3] but recent epidemiological data show that it affects an increasing number of young subjects, notably adolescents.[4]

To be diagnosed with IBD is a difficult experience for all patients, facing a reality that is not easy to understand. These chronic disorders will impair their quality of life and profoundly disrupt their lifestyle. During the disease course, patients will have to face different therapeutic strategies that need to be well understood in order to prevent some side effects and avoid non-observance, a source of therapeutic failure.[5,6] This is true during both active and quiescent phases of the disease.[7,8] Main concerns include the course, treatment, and complications of the disease, as well as different aspects of daily life including intimacy, sexuality, family, work, sport, and leisure.[9–14]

Better patient knowledge of the disease, its management and principles of treatment, could improve disease outcomes and decrease impact on daily life.[15–17] In a recent cohort study, more than half of the patients reported that they were not fully satisfied with the information received during the first 2 months after diagnosis.[18] Over the past decade, educational information on the internet, in particular on social media, have been exponentially increasing.[19,20] Although some contents are reliable and can potentially improve patients' knowledge, fake news and websites with no scientific background can also frequently be encountered.

According to the World Health Organization [WHO]: 'The therapeutic education has for objective to help the patients to acquire or to maintain the skills which they need to manage at best their life with a chronic disease'.[21] The first step is to evaluate patients' knowledge and the representations they have of their illness and its treatment. In the second step of therapeutic education, health care professionals teach, inform, explain, train, negotiate with, motivate, and accompany patients in the long-term follow-up of their disease. Therapeutic education aims to help them to understand their disease, to collaborate together, and to accept their responsibilities in their own care, allowing them to be active participants in their own treatment. The whole process might improve their quality of life.

The benefit of therapeutic education has been demonstrated in several chronic diseases such as diabetes.[22] In IBD, several studies on self-management interventions, peer-mentoring programmes, or psychological therapies reported interesting results.[23–27] However, if therapeutic education is known to be of importance during the child-adulthood transition,[28,29] its benefit in IBD global management has not been proved yet.

Several tertiary centres from the French 'Groupe d'Etude Thérapeutique des Affections Inflammatoires du Tube Digestif [GETAID]' have developed an educational programme specifically dedicated to IBD. The main aim of the present work was to demonstrate, in a randomised multicentre prospective study, that an educational programme could have a significant impact on IBD patients' skills with regards to their disease.

2. Methods

2.1. Patient inclusion

We conducted a multicentre, randomised, open-label study in 19 French tertiary centres from GETAID, participating in the therapeutic education programme [EDU-MICI]. Inclusion criteria were: [i] adults aged between 18 and 70 years; [ii] diagnosed with IBD [CD or UC]; [iii] with either a recent diagnosis [less than 6 months], or significant event in the disease course and/or change in treatment [recent hospitalisation, complication, surgery, or immunosuppressant or biologic considered]. Patients unable to communicate, understand, or participate in the educational programme, mainly for linguistic reasons were excluded.

All patients provided an informed written consent. The study was approved by the French Ethic Committee and declared to clinicaltrials.gov [NCT02550158].

2.2. Education programme [EDU-MICI]

A scientific committee, including professionals from tGETAID and a patients' association, 'Association François Aupetit [AFA]', designed the specific education programme EDU-MICI. Education was performed by a dedicated staff [mainly nurses] using an illustrated book, covering the different dimensions of life with IBD. At least two health professionals per centre were trained to become 'educators', following 50 h [8 days] of training. All the educators performed at least 10 education sessions. The format of the therapeutic education sessions was predefined, with an initial assessment of educational profile followed by at least two education sessions. The sessions were standardised in all the centres and were based on an illustrated book [portfolio] that reviews different aspects of the disease: aetiology, evolution, treatment, and social and personal problems. The five main topics raised during the sessions were 'To organise my daily life and improve my quality of life', 'To understand my disease', 'To talk about my disease and express my needs', 'To benefit from my care and treatments', and 'To consider preoccupations of a young IBD patient'.

2.3. The psycho-pedagogic score [ECIPE]

To evaluate the impact of therapeutic education, we developed a specific psycho-pedagogic score called ECIPE [Controlled multicentre study of the Impact of a Programme of therapeutic Education in IBD]. The ECIPE score was composed of three sub-scores: A: Concepts and skills [five items]; B: Health behaviour [four items]; C:Daily organisation/communication [four items]. For each item, notation on a three-point scale was performed. Hence, the global ECIPE score was rated on a 39-point scale with the A sub-score on a 15-point and the B and C sub-scores on a 12-point scale, respectively [Supplementary Table 1, available as Supplementary data at *ECCO-JCC* online]. An independent evaluator not involved in the education sessions carried out the psycho-educational assessments.

2.4. Study design and randomisation

Patients were randomly assigned in a 1:1 ratio to undergo the education programme [the educated group] or not [the control group] for the first 6 months of the study [Figure 1]. The psycho-pedagogic score [ECIPE score] was calculated at inclusion, 6, and 12 months thereafter [M0, M6, and M12] by a physician independent of the education team and blinded to the allocation group of the patient. After 6 months, we followed a cross-over procedure and patients from the control group followed the same programme as the educated group.

2.5. Endpoints

The primary endpoint was the psycho-pedagogic impact of the education programme on IBD patients' skills with regard to their disease. It was measured by the change in composite ECIPE score from baseline to M6. An improvement in patients' skills was defined by an increase of the ECIPE score of more than 20%.

The secondary endpoints were:

[i] the changes of ECIPE scores between M6 and M12 in both groups;

[ii] the impact of the education programme on disease progression [rates of hospitalisation, complications, or surgery], adherence to treatment [assessed by the modified Morisky adherence scale], quality of life (assessed by the short quality of life score for IBD [SIBDQ]), work productivity (assessed by the work productivity and activity impairment questionnaire [WPAI]), and patients' concerns (assessed by the rating form of IBD patient concerns [RFIPC]);

[iii] the impact of the education programme on the health care professionals performing the sessions.

2.6. Statistical analysis

Randomisation was centralised and stratified by centre, type of IBD (Crohn's disease [CD] vs ulcerative colitis [UC]), and inclusion criterion (recent diagnosis [less than 6 months] vs significant event in the disease course and/or change in treatment). Balanced randomisation lists by permutation blocks were constituted. The size of the blocks was not communicated to the professionals involved in patient recruitment.

The sample size was estimated on the basis of the primary endpoint. We assumed that in the control group, an improvement in the patient's skills at M6 would be of 10%. With type I and II errors of 5% and 20%, respectively, we calculated that a sample size of 200 patients [100 in each group] would allow us to detect a difference of 15% or more in favour of the educated group.

Analysis was performed on an 'intent-to-educate' principle. For patients lost to follow-up, the ECIPE score was considered unchanged. Summary statistics, namely median [IQR] and percentages, are reported unless specified. Comparison of continuous outcomes used the non-parametric Wilcoxon rank sum test: comparison of binary outcome measures used the Fisher's exact test. The Wilcoxon sign test was used to assess intra-group variation of scores over time. Factors associated with ECIPE score at baseline were assessed using generalised linear models.

All statistical analyses were performed on R 3.6.2 software [https://www.R-project.org/]. Two-sided p-values of 0.05 or less denoted statistical significance.

3. Results

3.1. Patients' baseline characteristics

A total of 266 patients were screened, with 263 included in 19 centres [Figure 2]. Overall, median age at inclusion was 30.8 years, 106 [40.3%] were male, and 192 [73%] had CD. Median disease duration was 45.3 months (IQR [6.9–113]); 74 [28.5%] patients were active smokers, 200 [81.3%] had at least a bachelor's degree, and 143 [54.6%] were in couple; 44 patients [16.7%] were students at baseline. Among the 192 patients with CD, 155 patients [80.7%] had an ileal or ileocolonic location, 55 anoperineal lesions [28.7%], and 29 extra-intestinal manifestations [15.1%]. Among the 71 patients with UC, 36 had a pancolitis [50.7%] and seven had extra

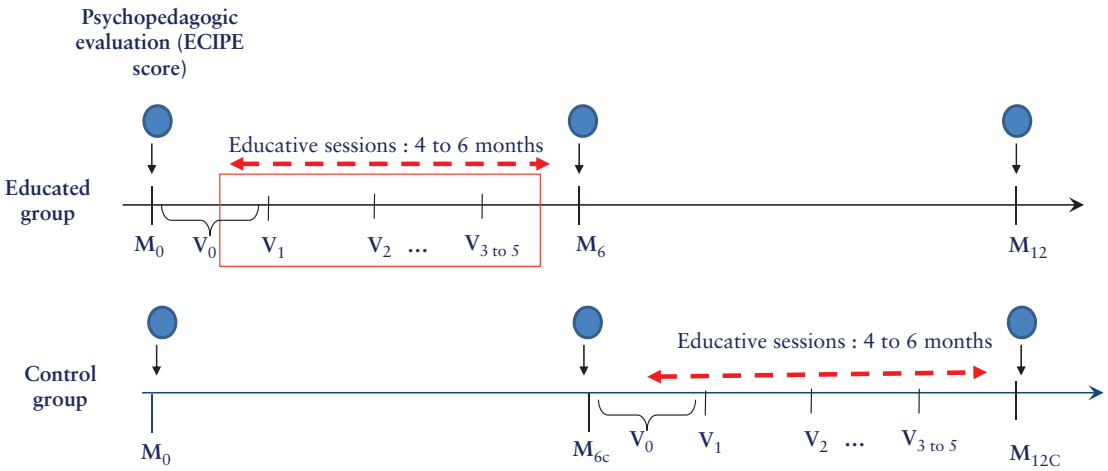

Figure 1. Study design.

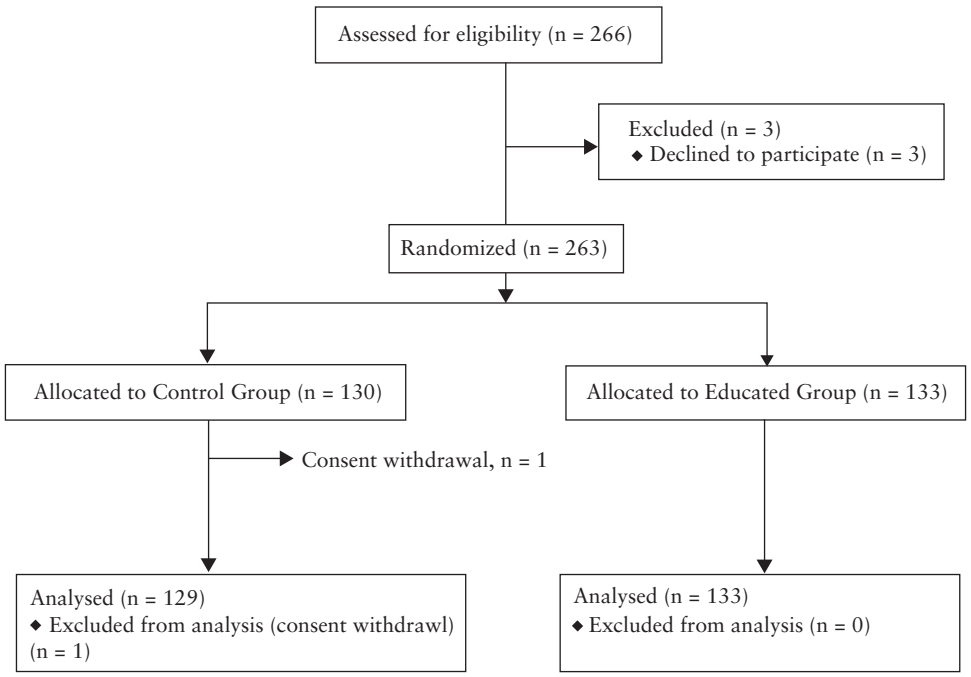

Figure 2. Consolidated Standards of Reporting Trials [CONSORT] 2010 flow diagram.

Table 1. Baseline characteristics in control and educated groups.

Baseline characteristic	Control group *n* = 129	Educated group *n* = 133
Age, median [IQR]	32.5 [24.9–42.2]	29.9 [25.2–42.0]
Disease duration, median [IQR]	40.6 [7.3–122.8]	49.5 [6.4–111.9]
Male	51 [39.5%]	54 [40.6%]
Active smoker	31 [24.2%]	40 [30.1%]
Couple	72 [56.3%]	71 [53.4%]
No child	67 [51.9%]	78 [58.7%]
Employed	80 [62.0 %]	72 [54.1 %]
Bachelor's degree of higher	104 [87.4 %]	95 [75.4 %]
CD	97 [75.2%]	95 [71.4%]
Previous surgery	41 [31.8%]	31 [23.3%]
Steroids	107 [83.0%]	39 [92.5%]
Thiopurines or methotrexate	83 [64.3%]	94 [70.7%]
Anti-TNF [IFX or ADA]	77 [59.7%]	80 [60.2%]

IQR, interquartile range; CD, Crohn's disease; TNF, tumour necrosis factor; IFX, infliximab; ADA, adalimumab.

intestinal manifestations [9.9%], 72 [27.4%] had a previous surgery, and 177 [67.3%] and 157 [59.7%] were treated by immunosuppressants or anti-tumour necrosis factors [TNFs] [infliximab or adalimumab], respectively. A total of 91 [34.6 %] patients had a recent diagnosis <1 year [including 62 [23.6 %] <6 months].

A total of 133 patients were randomised into the educated group and 130 into the non-educated group. One patient in the non-educated group withdrew his consent after randomisation [Figure 2]. Further results are based upon 262 patients. Baseline characteristics were well balanced across both groups [Table 1].

3.2. Scores at baseline

At baseline, 261 patients had an ECIPE score evaluation [129 and 132 in the control and educated groups, respectively]. The baseline median ECIPE scores were similar in both groups (19 [14–23] in the control group vs 19 [15–24] in the educated group). The three subscores, for concepts and skills; health behaviour; and daily organisation, were also balanced across randomised groups, with median [IQR] of 5 [4–7]; 6 [4–8]; 7 [5–9] in the control group vs 6 [4–8]; 6 [4–8]; 7 [6–9] in the educated group, respectively.

Data concerning the ECIPE score at baseline are listed in Table 2. Factors correlated with the ECIPE score at baseline were age (20 [15–24] if <30 years vs 19 [15–23] if >30), gender (20 [16–24] in women vs 17.5 [13–22] in men), and latest degree (from 17 [13–19] for bachelor's up to 20 [16–24] for higher degrees). At baseline, medians of SIBDQ, WPAI, RFIPC, and the observance score were also well balanced between control and educated groups (39 [29–50] vs 38 [27–50]; 10 [3–45] vs 10 [2–43]; 11 [7–14] vs 11 [7–15]; and 1 [0–3] vs 2 [1–4], respectively).

Results were heterogeneous among the items considered but comparable between both groups. The lowest results [at least 75% of patients with a 0–1 score] were obtained for the A1 [Knowledge of affected organs], A2 [Origin of the disease], and A3 [Understanding the outcome of the illness] items. Conversely, the highest results [at least 75% of patients with a 2–3 score] were obtained for the C3 [Integration of work and activities in personal and professional life] and C4 [Quality of communication] items.

3.3. Scores variation between M0 and M6

In all, 27 patients [20%] from the educated group did not attend at least two education sessions and 12 patients [9.3%] from the control group were lost to follow-up. In the intention-to-educate analysis, their ECIPE score was considered as unchanged between M0 and M6. Overall, among the 261 patients with an ECIPE score at baseline, 222 [84.7%] had a second evaluation 6 months later.

AT M6, 92 [35.1%] improved their skills related to the disease [increase of the ECIPE score of more than 20%]. Patients who met the primary endpoint had a significant increase of all ECIPE subscores, SIBDQ, WPAI, and RFIPC scores, but not of treatment observance as compared with patients who did not increase their skills regarding the disease [Table 3].

Table 2. Baseline ECIPE score in the control and educated groups.

	Value	Control group [*n* = 129]	Educated group [*n* = 132]
A1: Knowledge of affected organs	0	31 [23.9%]	27 [20.5%]
	1	75 [57.7%]	76 [57.6%]
	2	18 [13.9%]	19 [14.4%]
	3	6 [4.6%]	10 [7.6%]
A2: Origin of the disease	0	42 [32.3%]	41 [31.1%]
	1	71 [54.6%]	65 [49.2%]
	2	16 [12.3%]	24 [18.2%]
	3	1 [0.8%]	2 [1.5%]
A3: Understanding the outcome of the illness	0	31 [23.9%]	26 [19.7%]
	1	79 [60.8%]	75 [56.8%]
	2	14 [10.8%]	26 [19.7%]
	3	6 [4.6%]	5 [3.8%]
A4: Theoretical knowledge on treatments	0	3 [2.3%]	2 [1.5%]
	1	70 [53.9%]	70 [53.0%]
	2	51 [39.2%]	52 [39.4%]
	3	6 [4.6%]	8 [6.1%]
A5: Practical skills about the treatment	0	15 [11.5%]	12 [9.1%]
	1	67 [51.5%]	62 [47.0%]
	2	43 [33.1%]	47 [35.6%]
	3	5 [3.9%]	11 [8.3%]
A: Overall Concepts and skills sub-score		5 [4–7]	6 [4–8]
B1: Role of nutrients	0	25 [19.2%]	15 [11.4%]
	1	47 [36.2%]	41 [31.1%]
	2	35 [26.9%]	40 [30.3%]
	3	23 [17.7%]	36 [27.2%]
B2: Role of tobacco	0	27 [20.8%]	37 [28.0%]
	1	47 [36.2%]	37 [28.0%]
	2	40 [30.7%]	36 [27.2%]
	3	16 [12.3%]	22 [16.8%]
B3: Knowledge on usage and risks of corticosteroid therapy	0	37 [28.5%]	31 [23.5%]
	1	49 [37.7%]	59 [44.7%]
	2	30 [23.0%]	28 [21.2%]
	3	14 [10.8%]	14 [10.6%]
B4: Motivation to improve knowledge on disease	0	3 [2.3%]	4 [3.0%]
	1	41 [31.5%]	29 [22.0%]
	2	51 [39.2%]	53 [40.2%]
	3	35 [27.0%]	46 [34.8%]
B: Health behaviour sub-score		6 [4–8]	6 [4–8]
C1: Use of medical and paramedical resources	0	18 [13.9%]	29 [22.0%]
	1	45 [34.5%]	27 [20.5%]
	2	50 [38.5%]	65 [49.2%]
	3	17 [13.1%]	11 [8.3%]
C2: Ability to speak about the disease with others	0	7 [5.4%]	4 [3.0%]
	1	37 [28.5%]	38 [28.8%]
	2	35 [26.9%]	42 [31.8%]
	3	51 [39.2%]	48 [36.4%]
C3: Integration of work and activities in personal and professional life	0	14 [10.8%]	12 [9.2%]
	1	32 [24.6%]	29 [22.1%]
	2	62 [47.7%]	63 [48.1%]
	3	22 [16.9%]	28 [20.6%]
C4: Quality of communication during the evaluation	0	0 [0%]	1 [0.8%]
	1	36 [27.7%]	29 [22.0%]
	2	74 [56.9%]	70 [53.0%]
	3	20 [15.4%]	32 [24.2%]
C: Daily organisation of life sub-score		7 [5–9]	7 [6–9]
Overall ECIPE Score		**19 [14–23]**	**19 [15–24]**

In the intention-to-educate analysis, significantly more patients in the educated group met the primary endpoint as compared with the control group (61 patients [45.9%] vs 31 [24%], respectively, $p = 0.0003$). The median relative increase of the ECIPE score at M6 was higher in the educated group as compared with the control group 16.7% [0–42.1%] vs 7.4% [0–18.8%], respectively, $p = 0.0008$). Results were also significant in the per protocol analysis (27.8% [9–47.4%] vs 9.1% [0–20%], respectively, in the educated and the control group; $p < 0.0001$). These significant differences were also found in the Concepts and skills sub-score (relative median

increase: 20% [0–57%] vs 0% [0–28.6%] in the educated and control groups, respectively, $p = 0.001$) and in the Health behaviour sub-score (relative median increase: 20% [0–50%] vs 0% [0–25%] in the educated and control groups, respectively, $p < 0.0001$). Regarding Daily organisation of life, variation between M0 and M6 was not significantly different between the groups (relative median increase: 0% [0–28.6%] vs 0% [0–25%] in the educated and control groups, respectively, $p = 0.84$]. No significant difference was noted between the groups in SIBDQ, WPAI, RFIPC, and observance scores variation at M6 and in numbers of flares and hospitalisations.

3.4. Factors associated with patients' skills improvement

In univariate analysis, patients' skills improvement, defined by increase of the ECIPE score of more than 20% [met in 92 patients], was significantly associated with a high ECIPE score at baseline [$p < 0.0001$], the absence of previous surgery [$p = 0.022$], and the randomisation in the educated arm [$p = 0.0003$]. In multivariate analysis, the last two factors remained significant [Table 4]: odds ratio [OR] 0.52 [0.28–0.97], $p = 0.04$; and 2.59 [1.52–4.39], $p = 0.0005$, respectively, for previous surgery and randomisation in the educated arm. No obvious centre effect was noted [Figure 3].

3.5. Evaluation of the ECIPE score 12 months after inclusion

Between 6 and 12 months after inclusion, patients of the control group received the same education programme as patients from the educated group. Among the 117 patients, 93 [79%] attended at least two education sessions and had an ECIPE score evaluation at M12. Among the 105 patients who had an M6 ECIPE score in the educated group, eight [7.6%] were lost to follow-up and did not have an evaluation at M12. At M12, both groups reached the same median ECIPE score (median score: 26 [22–30] vs 27 [24–30] in, respectively, the control and the educated groups). An increase of the evaluation was noted in the control group (median increase: 5 [2–7]) whereas it remained stable over time in the educated group (median variation: 1 [-1; 3]) despite the cessation of the education programme [Table 5].

Table 3. ECIPE sub-scores and other scores evolution in patients with an increased ECIPE score of more than 20% at M6 compared with those without such improvement.

Evaluated score	Evaluated skills	Odds ratios [95% CI]	*p*
ECIPE sub-scores	Competence	1.11 [1.01–1.21]	0.023
	Behaviour	1.16 [1.05–1.28]	0.004
	Organisation	1.16 [1.02–1.31]	0.023
SIBDQ	Quality of life	1.02 [1.01–1.03]	0.0008
RFIPC	Patient's concerns	1.07 [1.03–1.11]	0.001
WPAI	Work productivity	1.01 [1.00–1.02]	0.041
Adherence	Treatment observance	1.05 [0.91–1.21]	0.5

CI, confidence interval; SIBDQ, short quality of life score for inflammatory bowel disease; RFIPC, rating form of inflammatory bowel disease patient concern; WPAI, work productivity and activity impairment.

4. Discussion

In this large, prospective, multicentre, randomised study, we show that a standardised educational programme improves patients' skills, as demonstrated by a significant increase of a psycho-pedagogic score in the educated group as compared with the control group.

The psycho-pedagogic ECIPE evaluation was set up and designed after multiple meetings of the GETAID scientific committee, with the support of Prof. Golay's team in Switzerland [specialised in therapeutic education for obesity, diabetes, and metabolic disorders] and adapted to the main concerns of IBD patients [in collaboration with the French patients' association].[30,31] Composed of three sub-scores [Concepts and skills, Health behaviour, and daily organisation in life], this tool combines in a single evaluation the preoccupations and worries frequently reported in IBD. We arbitrarily considered an increase of more than 20% of the score as an improvement of patients' skills. Significantly more patients in the educated group met this primary endpoint as compared with the control group. Moreover, we found an overall, significant increase of patients' knowledge, thanks to the educational sessions. Importantly, the increase of the ECIPE score was associated with an improvement of quality of life [assessed by the SIBDQ], work productivity [assessed by the WPAI], and patient's concerns about the disease [assessed by the RFIPC].

A positive impact of the therapeutic education programme has been demonstrated in several chronic diseases such as diabetes, vascular diseases, rheumatological diseases, and depression.[32–34] The final aim of such a programme is to make the patient the actor in her or his disease. Although the latest ECCO recommendations on Crohn's disease management underline the need to increase educational activities for patients, the experience in IBD remains limited.[35] IBD might appear an ideal candidate for this therapeutic approach. However, the intrinsic heterogeneity of these complex diseases, with different patterns of location, symptoms, and behaviour, is an important challenge to standardise therapeutic education programmes.

Table 4. Predictive factors at baseline associated with patients' skills improvement [increase of the ECIPE score of more than 20% at Month 6].

Baseline characteristic	Odds ratio [95% CI] Univariate analysis	*p*	Odds ratio [95% CI] Multivariate analysis	*p*
Age	0.99 [0.97–1.01]	0.31		
Gender	0.99 [0.59–1.66]	0.97		
Active smoker	1.02 [0.58–1.81]	0.94		
Couple	0.88 [0.53–1.47]	0.63		
Bachelor's degree or higher	1.23 [0.72–2.10]	0.44		
Employed	0.93 [0.55–1.58]	0.84		
Student	1.78 [0.92–3.44]	0.09		
CD	1.19 [0.68–2.09]	0.55		
Previous surgery	0.49 [0.26–0.90]	0.022	0.52 [0.28–0.97]	0.04
Arm of randomisation	2.68 [1.58–4.54]	0.0003	2.59 [1.52–4.39]	0.0005

CI, confidence interval; CD, Crohn's disease.

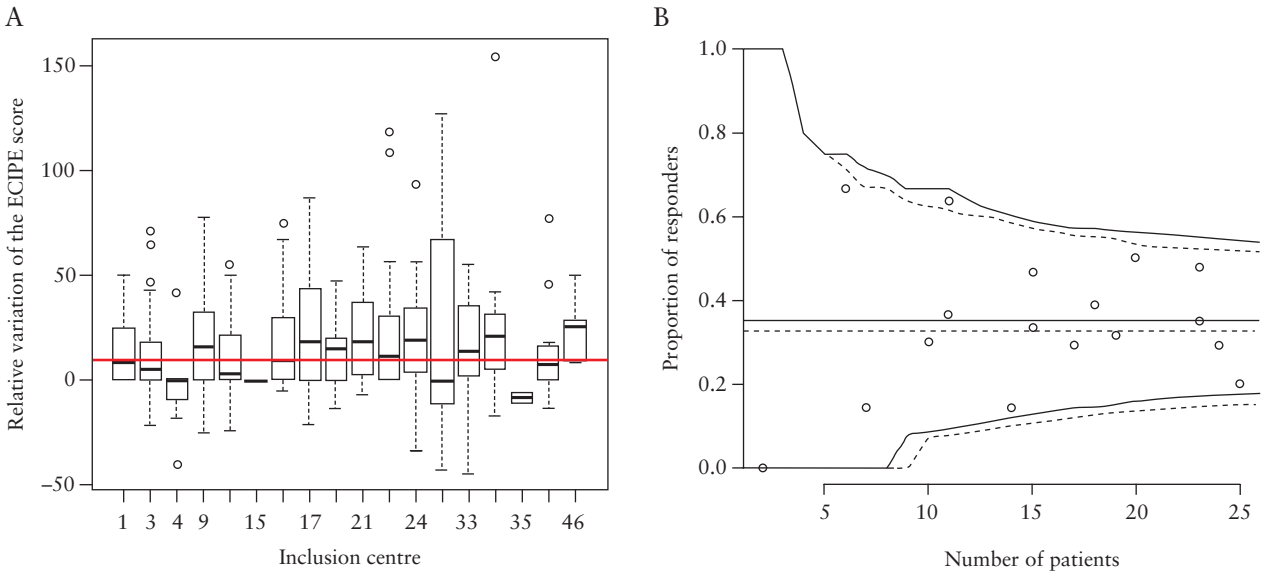

Figure 3. A: Relative variation of the ECIPE score depending on the inclusion centre. The overall median ECIPE score variation is represented by the red line. B: Proportion of responders [relative variation of at least 20% of their ECIPE score], according to the centre, based on their included patient volume. Such a plot assumes that the results in centres with the largest number of patients will be plotted near the average, and results in centres with the smaller number of patients will be spread evenly on both sides of the average. Deviation from this shape can indicate centre effect.

Table 5. Variation of the ECIPE score in the per protocol cohort between Month 6 and Month 12.

	Baseline		Month 6		Month 12	
	n	ECIPE score	*n*	ECIPE score	*n*	ECIPE score
Control group [education M6-12]	129	19 [14-23]	117	20 [16-25]	93	26 [22–30]
Educated group [education M0-M6]	132	19 [15-24]	105	26 [22-30]	97	27 [24–30]

M, month.

We show here that applying a systematic programme with a personalised and specific baseline evaluation of each patient, identifying their specific needs, followed by a standardised educational programme provided by trained professionals, and a final evaluation at the end of the programme, has a significant positive impact on patients' knowledge and skills in a broad field of concerns [disease knowledge, treatment, complications, daily life, social activities…]. The direct interactions with health care educators probably provided more reliable information as compared with the non-filtered data on the internet or social networks.[36]

As a kind of validation of the educational programme, patients from the control group received the same educational training sessions 6 months after the inclusion in the study. They had a comparable increase of the psycho-pedagogic ECIPE score at M12. Interestingly, the score remained stable over time in the educated group, showing the durable effect of the programme. Taken together, these data confirm the positive impact of the programme and its prolonged effect over months. Importantly, an increase of more than 20% of the ECIPE score was associated with an increase of all ECIPE sub-scores, quality of life, work productivity, and answers to patients concerns assessed by, respectively, the SIBDQ, WPAI, and RFIPC scores. In contrast, no effect was found on treatment observance. It is known that adherence to treatment is associated with many factors including disease duration and activity, patient's doubts about personal need for treatment, and concerns about potential adverse effects.[37,38] The 6-month duration of our study might have been too short to show a difference in this particular outcome.

Previous surgery and the absence of an education programme were associated with an absence of improvement of patients' skills. The first factor is counter-intuitive, because we might think that an important event like surgery could act as a trigger to acquiring better knowledge. However, the somewhat higher ECIPE score found at baseline in patients with previous surgery (with median score at 20 [15–25.5] vs 19 [15–23] otherwise) could partially explain the lower rate of score improvement.

We decided to include patients at two key moments of their disease history: at diagnosis and at a significant event affecting the IBD course. These situations are important steps in the disease course and are privileged moments for explaining important notions such as chronic disease, long-term treatment, and their interactions with daily life. Sufficient knowledge must be acquired by the patient to better understand the origin of the disease, its risk factors, locations, possible evolution toward complicated forms, and potential impact on many fields of the daily life, and to set up a thorough treatment which will not have to be unexpectedly interrupted. However, the explanation of these complex notions requires time and availability to answer further questions. In daily, busy practice, it is complicated to find the necessary amount of time. The organisation of an educational programme, as evaluated in this trial, could improve disease treatment and quality of life and reduce patients' anxiety.

Although not specifically evaluated and measured by predefined outcomes, the educational programme led to other benefits reported by the participants. It helped patients to break isolation by leading them to talk more easily about their disease. Moreover,

a true collaboration between health care professionals and patients led to a bidirectional positive impact. Recent literature underlines the dissociation between patients' and professionals' points of view concerning IBD.[39] Many educators reported an improvement of their understanding of patients' needs and expectations. They also acquired knowledge and methods to better address concerns of IBD patients.

Our score used to evaluate the efficiency of the programme was an original one, which had never been used in previous studies. We wanted to have a combined tool scoring all the distinct aspects of the psycho-pedagogic approach. It was defined a priori, with the help of an expert team in therapeutic education, and after multidisciplinary meetings involving patients. We believe that this score allowed us to assess as precisely as possible the impact of the educational sessions.

The implementation of such an educational programme is demanding for centres specialised in the management of IBD, and requires strong motivation of the team. Indeed, this activity is time consuming and is based on a specific training of several health professionals, frequently nurses and/or dieticians. Importantly, the benefit of the programme was demonstrated in all centres, independently of their size.

In conclusion, in this prospective, multicentre, randomised, controlled study designed as a clinical trial, we demonstrate that a standardised therapeutic educational programme can improve patients' skills with regard to their disease in critical aspects of IBD management. This positive effect is reproducible and long-lasting over time. The increase of patient's skills was also associated with an improvement of quality of life, work productivity, and patients' concerns. Taken together, these findings support the set-up of education programmes in centres involved in the management of IBD patients. Data are available on request.

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Conflict of Interest

JM received honoraria from MSD, Janssen, Abbvie, Pfizer, Ferring, Takeda, and Vifor; NH received honoraria from Janssen, Tillots Pharma, and MSD; LM received honoraria from Bayer, Merck, Novartis, Takeda; CTP received lecture fees from Abbvie, Takeda, Maat Pharma, Janssen, and advisory board fees from MSD and Tillots; MN received honoraria from Abbvie, Adacyte, Amgen, Biogen, Ferring, Janssen, Mayoli-Spindler, MSD, Pfizer, and Takeda; RA received advisory board fees from Takeda, Abbvie, Norgine, Tillots, MSD, Biogen, and Janssen; JCG received honoraria from Abbvie, Pfizer, Janssen, Takeda, and MSD; SO received honoraria from MSD, Abbvie, Janssen,Otsuka, Takeda, Gilead, and GSK; XH received honoraria from Abbvie, Amgen, Biogen, Celltrion, Ferring, HAC Pharma, Hospira, Janssen, MSD, Pfizer, and Takeda; AA received honoraria from Abbvie, Janssen, Takeda, Ferring, and MSD; PS received honoraria from Takeda, MSD, Biocodex, Ferring, Pfizer, and AbbVie, and grant support from Biocodex; XR received honoraria from MSD, Abbvie, Biogen, Pfizer, Janssen, Takeda, and Theradiag; SN received lecturer or advisory board fees from AbbVie, MSD, Vifor Pharma, Pfizer, Janssen, and Ferring; GS received lecture fees and travel grants from MSD, Ferring, Takeda, Pfizer, Janssen, Vifor, HAC Pharma, Abbvie, Tillots, and Norgine; BM has no conflict of interest to declare; CS received honoraria from Takeda, lecture fees from Abbvie, Fresenius Kabi, Pfizer, and Janssen and travel accommodation from MSD, Takeda, Abbvie, Pfizer, and Janssen; MS received honoraria from Abbvie, Takeda, and Mylan: BC received honoraria from Abbvie, Mayoly Spindler, Sanofi, and Kyowa Kyrin; MF received honoraria from Abbvie, Ferring, MSD, Janssen, Takeda, Tillots, Gilead, Celgene, Boehringer, Biogen, Pfizer; FC received honoraria from Amgen, BMS, Celltrion, Enterome, Ferring, Janssen, Medtronic, Pfizer, Pharmacosmos, and Roche, as well as lecture fees from Abbvie, Astra, BMS, Ferring, Janssen, MSD, Pfizer, Pileje, Takeda, and Tillotts; LPB redeived honoraria from AbbVie, Janssen, Genentech, Ferring, Tillots, Pharmacosmos, Celltrion, Takeda, Boerhinger Ingelheim, Pfizer, Index Pharmaceuticals, Sandoz, Celgene, Biogen, Samsung Bioepis, Alma, Sterna, Nestle, Enterome, Allergan, MSD, Roche, Arena, Gilead, Hikma, Amgen, BMS, Vifor, Norgine, Mylan, Lilly, Fresenius, Oppilan Pharma, Sublimity Therapeutics, Applied Molecular Transport, OSE Immunotherapeutics, Enthera, grants from Abbvie, MSD, Takeda, and has stock options in CTMA; SC has no conflict of interest to declare; MA received honoraria from Abbvie, MSD, Janssen, Takeda, Pfizer, Novartis, Ferring, Tillots, Celgene, and Genentech/Roche.

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JM and MA: concept, design, and supervision of the study, patient inclusion, drafting of the manuscript. NH: drafting of the manuscript. LM, CT-P, MN, RA, SO, JCG, XH, AA, CB, PS, XR, SN, GS, BM, CS, MS, BC, MF, FC, LP-B: patient inclusion, data collection, and critical review of the manuscript. KD: interpretation of data and statistical analysis.

Supplementary Data

Supplementary data are available at *ECCO-JCC* online.

References

1. Alatab S, Sepanlou SG, Ikuta K, *et al*. The global, regional, and national burden of inflammatory bowel disease in 195 countries and territories,

1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet Gastroenterol Hepatol.* 2020;**5**:17–30.
2. Nerich V, Monnet E, Etienne A, *et al.* Geographical variations of inflammatory bowel disease in France: a study based on national health insurance data. *Inflamm Bowel Dis* 2006;**12**:218–26.
3. Keyashian K, Dehghan M, Sceats L, Kin C, Limketkai BN, Park KT. Comparative incidence of inflammatory bowel disease in different age groups in the United States. *Inflamm Bowel Dis* 2019;**25**:1983–9.
4. Ghione S, Sarter H, Fumery M, *et al.*; Epimad Group. Dramatic increase in incidence of ulcerative colitis and Crohn's disease [1988-2011]: a population-based study of French adolescents. *Am J Gastroenterol* 2018;**113**:265–72.
5. Horne R, Parham R, Driscoll R, Robinson A. Patients' attitudes to medicines and adherence to maintenance treatment in inflammatory bowel disease. *Inflamm Bowel Dis* 2009;**15**:837–44.
6. Baars JE, Siegel CA, van't Spijker A, Markus T, Kuipers EJ, van der Woude CJ. Inflammatory bowel disease-patients are insufficiently educated about the basic characteristics of their disease and the associated risk of colorectal cancer. *Dig Liver Dis* 2010;**42**:777–84.
7. Lix LM, Graff LA, Walker JR, *et al.* Longitudinal study of quality of life and psychological functioning for active, fluctuating, and inactive disease patterns in inflammatory bowel disease. *Inflamm Bowel Dis* 2008;**14**:1575–84.
8. Knowles SR, Wilson JL, Connell WR, Kamm MA. Preliminary examination of the relations between disease activity, illness perceptions, coping strategies, and psychological morbidity in Crohn's disease guided by the common sense model of illness. *Inflamm Bowel Dis* 2011;**17**:2551–7.
9. Ghosh S, Mitchell R. Impact of inflammatory bowel disease on quality of life: results of the European Federation of Crohn's and Ulcerative Colitis Associations [EFCCA] patient survey. *J Crohns Colitis* 2007;**1**:10–20.
10. Gatt K, Schembri J, Katsanos KH, *et al.* Inflammatory bowel disease [IBD] and physical activity: a study on the impact of diagnosis on the level of exercise amongst patients with IBD. *J Crohns Colitis* 2019;**13**:686–92.
11. Plevinsky JM, Wojtowicz AA, Poulopoulos N, Schneider KL, Greenley RN. Perceived impairment in sports participation in adolescents with inflammatory bowel diseases: a preliminary examination. *J Pediatr Gastroenterol Nutr* 2018;**66**:79–83.
12. Rivière P, Zallot C, Desobry P, *et al.* Frequency of and factors associated with sexual dysfunction in patients with inflammatory bowel disease. *J Crohns Colitis* 2017;**11**:1347–52.
13. Shmidt E, Suárez-Fariñas M, Mallette M, *et al.* A longitudinal study of sexual function in women with newly diagnosed inflammatory bowel disease. *Inflamm Bowel Dis* 2019;**25**:1262–70.
14. Parra RS, Chebli JMF, Amarante HMBS, *et al.* Quality of life, work productivity impairment and healthcare resources in inflammatory bowel diseases in Brazil. *World J Gastroenterol* 2019;**25**:5862–82.
15. Robinson A, Thompson DG, Wilkin D, Roberts C; Northwest Gastrointestinal Research Group. Guided self-management and patient-directed follow-up of ulcerative colitis: a randomised trial. *Lancet* 2001;**358**:976–81.
16. Waters BM, Jensen L, Fedorak RN. Effects of formal education for patients with inflammatory bowel disease: a randomised controlled trial. *Can J Gastroenterol* 2005;**19**:235–44.
17. Tran L, Mulligan K. A systematic review of self-management interventions for children and adolescents with inflammatory bowel disease. *Inflamm Bowel Dis* 2019;**25**:685–98.
18. Bernstein KI, Promislow S, Carr R, Rawsthorne P, Walker JR, Bernstein CN. Information needs and preferences of recently diagnosed patients with inflammatory bowel disease. *Inflamm Bowel Dis* 2011;**17**:590–8.
19. Guo L, Reich J, Groshek J, Farraye FA. Social media use in patients with inflammatory bowel disease. *Inflamm Bowel Dis* 2016;**22**:1231–8.
20. Yin AL, Hachuel D, Pollak JP, Scherl EJ, Estrin D. Digital health apps in the clinical care of inflammatory bowel disease: scoping review. *J Med Internet Res* 2019;**21**:e14630.
21. Guilbert JJ. Therapeutic patient education. *Educ Health* 2000;**13**:419.
22. Chatterjee S, Davies MJ, Heller S, Speight J, Snoek FJ, Khunti K. Diabetes structured self-management education programmemes: a narrative review and current innovations. *Lancet Diabetes Endocrinol* 2018;**6**:130–42.
23. Timmer A, Jantschek G, Moser G, *et al.* Psychological interventions for treatment of inflammatory bowel disease. *Cochrane Database Syst Rev* 2011. PMID: 21328288 Review.
24. Mackner LM, Ruff JM, Vannatta K. Focus groups for developing a peer mentoring programme to improve self-management in pediatric inflammatory bowel disease. *J Pediatr Gastroenterol Nutr* 2014;**59**:487–92.
25. Hashash JG, Sigal R, Wein-Levy P, Szigethy EM, Merusi JJ, Regueiro MD. Inflammatory bowel disease [IBD] connect: a novel volunteer programme for hospitalised patients with IBD and their families. *Inflamm Bowel Dis* 2016;**22**:2748–53.
26. Greenley RN, Gumidyala AP, Nguyen E, *et al.* Can you teach a teen new tricks? Problem solving skills training improves oral medication adherence in pediatric patients with inflammatory bowel disease participating in a randomised trial. *Inflamm Bowel Dis* 2015;**21**:2649–57.
27. Gracie DJ, Irvine AJ, Sood R, Mikocka-Walus A, Hamlin PJ, Ford AC. Effect of psychological therapy on disease activity, psychological comorbidity, and quality of life in inflammatory bowel disease: a systematic review and meta-analysis. *Lancet Gastroenterol Hepatol* 2017;**2**:189–99.
28. Brooks AJ, Smith PJ, Cohen R, *et al.* UK guideline on transition of adolescent and young persons with chronic digestive diseases from paediatric to adult care. *Gut* 2017;**66**:988–1000.
29. Shapiro JM, El-Serag HB, Gandle C, *et al.* Recommendations for successful transition of adolescents with inflammatory bowel diseases to adult care. *Clin Gastroenterol Hepatol* 2020;**18**:276–89.e2.
30. Pataky Z, Golay A, Rieker A, Grandjean R, Schiesari L, Vuagnat H. A first evaluation of an educational programme for health care providers in a long-term care facility to prevent foot complications. *Int J Low Extrem Wounds* 2007;**6**:69–75.
31. Lagger G, Pataky Z, Golay A. Efficacy of therapeutic patient education in chronic diseases and obesity. *Patient Educ Couns* 2010;**79**:283–6.
32. Davies MJ, D'Alessio DA, Fradkin J, *et al.* Management of hyperglycemia in type 2 diabetes, 2018. a consensus report by the American Diabetes Association [ADA] and the European Association for the Study of Diabetes [EASD]. *Diabetes Care* 2018;**41**:2669–701.
33. Foster NE, Anema JR, Cherkin D, *et al.*; Lancet Low Back Pain Series Working Group. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018;**391**:2368–83.
34. Solomon CG, Park LT, Zarate CA. Depression in the primary care setting. *N Engl J Med* 2019;**380**:559–68.
35. Torres J, Bonovas S, Doherty G, *et al.* ECCO Guidelines on therapeutics in Crohn's disease: medical treatment. *J Crohns Colitis* 2020;**14**:4–22.
36. Linn AJ, van Weert JCM, Gebeyehu BG, *et al.* Patients' online information-seeking behavior throughout treatment: the impact on medication beliefs and medication adherence. *Health Commun* 2019;**34**:1461–8.
37. Sewitch MJ, Abrahamowicz M, Barkun A, *et al.* Patient nonadherence to medication in inflammatory bowel disease. *Am J Gastroenterol* 2003;**98**:1535–44.
38. Horne R, Parham R, Driscoll R, Robinson A. Patients' attitudes to medicines and adherence to maintenance treatment in inflammatory bowel disease. *Inflamm Bowel Dis* 2009;**15**:837–44.
39. Vaucher C, Maillard MH, Froehlich F, Burnand B, Michetti P, Pittet V. Patients' and gastroenterologists' perceptions of treatments for inflammatory bowel diseases: do their perspectives match? *Scand J Gastroenterol* 2016;**51**:1056–61.