Perceived personal controllability of IBD patients and the method of administering treatment

Ingrid Banovic\textsuperscript{a}, Daniel Gilibert\textsuperscript{b}, Jacques Cosnes\textsuperscript{c}. \\
a. Assistant Professor. Laboratoire IPSé (EA 4432)-Paris Ouest-Nanterre- La Défense, Pôle AAFE Esplanade Erasme, BP 26513, 21065 Dijon cedex. Ingrid.Banovic@u-bourgogne.fr \\
b. Professor, Laboratoire INTERPSY (EA 4180), Université de Lorraine. daniel.gilibert@univ-lorraine.fr \\
c. Hospital Practitioner-Professor, Service of Gastroenterology and Nutrition, CHU Saint-Antoine, Université Pierre et Marie Curie, Paris VI, France.

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Résumé

Introduction : Les rapports que le patient entretient avec son traitement ont été abordés via son efficacité perçue, ses effets secondaires, sa présentation galénique, son observance. Par ailleurs l’adaptation à la condition médicale serait meilleure lorsque le patient pense contrôler l’évolution de sa maladie. Toutefois le lien entre le contexte de prise et la contrôlabilité personnelle perçue des patients atteints de MICI est mal connu. L’objectif est de déterminer si le fait de recevoir son traitement à l’hôpital défavoriserait le sentiment de contrôle personnel et renforcerait le contrôle perçu des soignants. Méthode : Pour les 78 patients (36 ayant un traitement par injection [IV] et 42 ayant un traitement oral [PO]), les données médicales, la CGI, la MADRS, la TAS-20, une échelle dimensionnelle d’attributions causales, ont été recueillies. Résultats : La comparaison selon le type de traitement montre une plus forte contrôlabilité personnelle pour les patients IV et une absence de différence significative pour la contrôlabilité des soignants. La contrôlabilité personnelle est expliquée par le type de traitement et les conséquences perçues de la maladie sur leur vie. Conclusion : Le contrôle personnel perçu des patients IBD serait donc plus lié à l’amélioration des conséquences perçues de leur maladie sur la vie qu’aux contraintes liées au traitement médical.


Abstract

Introduction: The relations that the patient maintains with his treatment have been studied from the perspective of its perceived effectiveness, its secondary effects, its galenical presentation, and its observance. Moreover, adaptation to the medical condition would be better when the patient thinks he has control over the evolution of his disease. However, the relation between the context of the treatment and the perceived personal controllability of patients suffering from IBD is little known. The objective is to determine if the fact of receiving one’s treatment at the hospital would disfavor the personal feeling of control and would reinforce the perceived control of caregivers. Method: Medical data, the CGI, the MADRS, the TAS-20 and a dimensional scale of causal attributions were collected for 78 patients (36 with a treatment by injection [IV] and 42 with an oral treatment). Results: The comparison according to the type of treatment shows stronger personal controllability for the IV patients and no significant difference for controllability by caregivers. Personal controllability is explained by the type of treatment and the perceived consequences of the
Perceived personal controllability of IBD patients and the method of administering treatment disease on their life. **Conclusion:** Perceived personal control of IBD patients would then be linked more to the improvement of the perceived consequences of their disease on their life than to the constraints related to the medical treatment.

**Key-words:** IBD. Infusion. Treatment. Perceived personal control
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**Introduction**

Most studies about patients’ preference for their medical treatment have primarily focused on its perceived effectiveness (including its side effects), presentation of the dosage, cost and compliance (Chrystyn, 2005; Gold, 2011; Duarte et al., 2007). They showed that patients primarily prefer an effective drug with few side effects. Nevertheless, these general results are not constant for the effect of the constraint related to the frequency and the administration of the medical treatment (Gold et al., 2006; Fraenkel et al., 2006; Chancellor et al., 2008; Liu et al., 1997). They would depend on the medical context. For example, for IBD patients, their choice between two options of administration would depend more on their expected perceived effectiveness than its constraints (Allen et al., 2010). It has been observed that these patients did not perceive a treatment as more effective or having more negative consequences on their subjective quality of life than another one, even if one is more constraining and has more side effects (Banovic et al., 2009; Followfield et al., 2006; Cross et al., 2008). It seems that the representation of the disease could be more involved than its expected benefits and perceived constraints. Indeed, research with dialysis patients has shown how this treatment has an effect on the perception that these patients have concerning their disease (Quinan, 2007). Moreover their representation of their disease and their treatment explained a significant part of their autonomy and their self-esteem (Jansen, Rijken, Heijmans, Boeschoten, 2010). Thus, there is a link between the perception of the treatment and the representation of the disease. If the routine management of IBD is not as constraining as that of dialysis, some patients must go regularly to an outpatient center for less than half a day to receive their treatment by injection. This raises the question whether the way in which the treatment is administered (daily oral vs. injection at an outpatient center) has an influence on the perception of personal and medical caregivers’ control of IBD. This question is fundamental because during treatment at an outpatient center, the patient’s autonomy is hindered even if the objective of the medical staff is to manage the disease in order to allow patients to have a life that is as normal as possible.

IBD results from a sustainable and fluctuating malfunction of the intestinal immune system whose cause has not been identified and has no cure (Beaugerie, 2005; Cosnes et al., 2002). Steroids, immunosuppressants and surgery are the main therapeutic tools. Medical treatment is then fundamental to limit the effects of this debilitating disease and to improve the health condition of the patient. Medication with anti-tnfα (Infliximab) has markedly improved the management of the most severe or refractory forms of the disease (Felley et al., Revue Internationale sur le Médicament, vol. 4 (2), 2012)
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2008; Cohen, 2001; Gheorghe et al., 2003). Nevertheless, the major disadvantage of Infliximab given in infusion as a scheduled treatment is that it requires the patient to go to the hospital every 6 to 8 weeks. Nevertheless, despite the fear of side effects related to Infliximab, patients considered its efficacy more than its side effects which do not interfere with their usual functioning (Banovic et al., 2009).

Despite the improvement in IBD management, these patients must adapt to its fluctuating and unpredictable nature. It is now well-established that their subjective quality of life is impaired (Taft, Keefer, Artz, Bratten, Jones, 2011; Lesage, Hagège Tucat, Gendre, 2011) and that they have psychological distress (anxiety and depression), particularly when the disease is clinically active (Häuser, Janke, Klump, Hinz, 2011; Kiebles, Doerfler, Keefer, 2010). Furthermore, and in general, it has been shown that adaptation to the condition of health and psychological well-being (Pucheu et al., 2004; Volpe & Levin, 1998; Backenstrass et al., 2006) are better when the patient thinks he can control the evolution of his health (Roesch & Weiner, 2001; Shiloh et al., 2002; Chaney et al., 2004). Nevertheless, thinking that one is unable to control the perceived determining factor of the disease would have some advantages (Hobbis et al., 2003; Burish et al., 1984; De Smedt et al., 2011): reducing the suffering of the difficulty in exercising control and looking for help from the medical staff. It has been also suggested that under certain conditions, strong perceived personal control could be dysfunctional when the disease becomes objectively uncontrollable (Andrykowski, Brady, 1994; Tomich & Helgeson, 2006; Helgeson & Franzen, 1998; Tomich & Hegelson, 2006). However, what remains important in medical management is the trust that the patient has in the physician and his ability to control the disease medically (Schneider, Kaplan, Greenfield, Li, Wilson, 2004; Piette, Heisler, Krein, Kerr, 2005).

Knowing that compliance and adaptation to the medical condition are partly related to the perception of personal control on the disease, one may question the effect that the related constraints of outpatient treatment have on this perception (Williams et al., 2008). If the perception of the disease and its treatment are related to autonomy and self-esteem (Jansen, Rijken, Heijmans, Boeschoten, 2010; Murray, Brunier, Chung, Craig, Mills, Thomas, Stacey, 2009), a study has shown that oral medical treatment is perceived as having a positive influence on the efforts needed to cope with the disease (Catania, Didier, Leon, Sbanatto, Mariani et al., 2005). We may indeed wonder if the fact of having to go to the hospital
Perceived personal controllability of IBD patients and the method of administering treatment regularly for treatment disadvantages the sense of personal control of IBD patients and enhances the perceived control of medical caregivers.

Hypothesis

In keeping with the work of Banovic et al. (2009), the type of treatment should not have an effect on the evaluations related to the perceived effectiveness of the treatment.

Due to constraints generated by infusions given at the hospital and a higher effective presence of the medical staff, significant differences are expected to be observed in favor of less personal controllability and stronger medical caregivers’ controllability for patients with IV treatment (compared to patients taking oral treatment).

Material and Methods

Seventy-eight patients (forty-seven women, thirty-one men) were recruited at a Parisian hospital when they had a consultation with their physician or when they had an infusion at the outpatient treatment center. These patients were enrolled after an explanation of the study and they signed an informed consent form. Sixty-six patients had been previously diagnosed with Crohn’s disease (CD) and twelve with ulcerative colitis (UC). Thirty-six patients had a treatment by infusion (IV) and forty-two took oral medication (PO). Forty-five patients had an inactive disease and thirty-three had an active disease at the moment of the assessment\(^1\). All these patients were observant: the patients taking oral medication were described as adherent by their physician, and the patients taking their treatment by infusion are in fact compliant.

\(^1\) The activity of the disease is not specific to a method of treatment. Among the patients in the PO group, 17 had a clinically active disease and 25 an inactive disease, against 16 and 20 respectively for the IV treatment (chi-square test non significant). The variable Clinical activity of the disease was conserved for the multiple regressions as a potentially explicative variable.
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Sample

<table>
<thead>
<tr>
<th></th>
<th>Global Sample (n=78)</th>
<th>IV (n=36)</th>
<th>PO (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of women</td>
<td>47 (60.25%)</td>
<td>22 (61.11%)</td>
<td>25 (59.52%)</td>
</tr>
<tr>
<td>Number of patients with an active disease</td>
<td>33</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Age</td>
<td>42.58 (±13.88)</td>
<td>35.89 (±10.63)</td>
<td>48.32 (±13.87)</td>
</tr>
<tr>
<td>Age of diagnostic</td>
<td>29 (±12.27)</td>
<td>25.28 (±9.22)</td>
<td>31.50 (±14.57)</td>
</tr>
<tr>
<td>Disease Duration</td>
<td>13.70 (±9.05)</td>
<td>12.75 (±8.45)</td>
<td>14.52 (±9.57)</td>
</tr>
<tr>
<td>Number of hospitalizations</td>
<td>0.48 (±0.766)</td>
<td>0.77 (±0.89)</td>
<td>0.22 (±0.52)</td>
</tr>
<tr>
<td>number of severe flare-ups</td>
<td>1.31 (±1.42)</td>
<td>1.75 (±1.20)</td>
<td>0.93 (±1.50)</td>
</tr>
<tr>
<td>number of light flare-ups</td>
<td>0.29 (±0.58)</td>
<td>0.30 (±0.57)</td>
<td>0.29 (±0.59)</td>
</tr>
<tr>
<td>PSHI</td>
<td>12.63 (±15.98)</td>
<td>10.72 (±15.76)</td>
<td>14.27 (±16.17)</td>
</tr>
</tbody>
</table>

Table 1. Means scores for the global sample and the two groups (IV vs. PO) for the medical variables.

Clinical and sociodemographic factors

Clinical and sociodemographic data included disease activity, age, gender, C-reactive protein (CRP), ferritin, current medical treatment, duration of the disease, number of prior hospitalizations, number of relapses, cumulative severity of intestinal resection assessed with the Post-surgical Handicap Index (PSHI; Cosnes et al., 1994). Disease history information was obtained from the MICISTA Registry (Sokol et al., 2008). The information on the status of the clinical activity of the disease was provided by the patient’s physician.
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Perceived effectiveness of medical treatment

The Clinical Global Impression (CGI) (Guy, 1976) is a scale consisting of 3 independent items, which are used in almost all studies in which medical care or the effectiveness of a drug is evaluated. The first item (CGI1) measures the severity of the patient's current disorder and the second (CGI2) measures global improvement on a scale consisting of seven response levels. The third item (CGI3) is a combined measure of the clinical effect and the side effects. It measures the combination of the therapeutic benefit (on four levels: large, moderate, minimum, zero effect) and the level of inconvenience caused by the negative side effects resulting from the treatment (on four levels: no side effect, side effects which do not interfere with usual functioning, side effects which significantly interfere with usual functioning, side effects which exceed the therapeutic effect). Initially, this tool was intended for caregivers. However, it can also be completed by patients in order to obtain their evaluations of their state of health, its improvement and their treatment.

Psychological variables

Depression: the Montgomery and Asberg Depression Rating Scale (MADRS) is a simple, short, easy-to-use self-evaluation scale (Zigmond & Snaith, 1983). It is sensitive to change, differentiates well between the different degrees of severity of depression, and therefore represents a good overall index. The predominance of mental items over somatic items favors its use with patients exhibiting a somatic disorder in order to eliminate interference. The threshold depression score of the MADRS is 15 (Hermann, 1997).

Alexithymia was assessed with the TAS-20 which was translated, adapted and validated in French by Loas, Fremaux, Marchand (1995). Its components are: difficulty to identify feelings and to distinguish them from bodily sensations, difficulty describing feelings to others, thoughts turned outwards rather than towards inner sensations (thoughts with a pragmatic content). The TAS-20 has frequently been used in patients with IBD, including by Porcelli et al. (1999, 2003, 2004).

Causal attributions: patients were asked if they thought that their illness was a) not likely to change over time, b) may change over time, c) controllable by them, d) uncontrollable by them, e) rather related to the situation, f) rather linked to themselves, g)

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2 1= normal, not all ill; 2= borderline ill; 3=mildly ill; 4=moderately ill; 5= markedly ill; 6= severely ill; 7= extremely ill.
3 1= very much improved; 2= much improved; 3=minimally improved; 4= no change; 5= minimally worse; 6= much worse; 7= very much worse.
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had specific consequences, h) had an impact on their life in general, i) controllable by medical caregivers, j) uncontrollable by medical caregivers, k) controllable by their natural caregivers (family, close friends), l) uncontrollable by their natural caregivers. For each proposal, the participants were asked to indicate their level of agreement on a 7-point Likert scale (from "not at all" to "completely"). This method of investigation is similar to the revised causal attribution scale (CDSII, adapted and validated in French by Fontayne, Martin-Krumm, Buton, Heuzé, 2003), and includes the dimensions of locus of causality (internal / external), stability (stable / unstable), generality (general or specific impact), locus of personal control (controllable or uncontrollable by the patient himself) and external control (by others, this dimension was split here: for medical caregivers and for natural caregivers).

**Statistical procedure**

Descriptive analysis was carried out in order to verify if there were differences on the mean scores of the variables when patients were compared in function of their type of medical treatment (IV vs. PO) using an independent 2-sample \( t \)-test.

A Pearson’s correlation was conducted with all the variables to test the intensity of the relation between the medical variables (number of relapses in function of their severity, number of hospitalizations, clinical activity/inactivity of the disease, the type of treatment (IV vs. PO), PSHI) and the psychological variables (MADRS, TAS-20, CGI and causal attributions). Then, multiple regressions were done with only the variables that had a significant correlation (\( p=.01 \)) in order to determine which variables were: 1/ related to the evaluations of the CGI; 2/ linked to personal controllability and controllability by caregivers.

**Results**

<table>
<thead>
<tr>
<th></th>
<th>Global Sample (n=78)</th>
<th>IV (n=36)</th>
<th>PO (n=42)</th>
<th>Student test at 76ddl</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADRS</td>
<td>9.60 (±8.16)</td>
<td>10 (±8.48)</td>
<td>9.26 (±7.97)</td>
<td>( t=0.40, p&gt;.05 )</td>
</tr>
<tr>
<td>TAS-20</td>
<td>46.76 (±11.37)</td>
<td>46.63 (±11.93)</td>
<td>46.88 (±11.02)</td>
<td>( t=-0.10, p&gt;.05 )</td>
</tr>
</tbody>
</table>

Table 2. Means scores and comparison in function of the method of administering treatment (IV vs. PO) for depression (MADRS) and alexithymia (TAS-20).
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<table>
<thead>
<tr>
<th></th>
<th>Global Sample (n=78)</th>
<th>IV (n=36)</th>
<th>PO (n=42)</th>
<th>Student test at 76ddl</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGI1</td>
<td>3.37 (±1.60)</td>
<td>3.33 (±1.66)</td>
<td>3.40 (±1.56)</td>
<td>t=-0.20, p&gt;.05</td>
</tr>
<tr>
<td>CGI2</td>
<td>2.43 (±1.41)</td>
<td>2.19 (±1.24)</td>
<td>2.64 (±1.53)</td>
<td>t=-1.41, p&gt;.05</td>
</tr>
<tr>
<td>CGI3</td>
<td>2.84 (±2.51)</td>
<td>2.78 (±2.22)</td>
<td>2.90 (±2.76)</td>
<td>t=-0.22, p&gt;.05</td>
</tr>
</tbody>
</table>

Table 3. Means scores and comparison in function of the method of administering treatment (IV vs. PO) for the CGI.

<table>
<thead>
<tr>
<th></th>
<th>Global Sample (n=78)</th>
<th>IV (n=36)</th>
<th>PO (n=42)</th>
<th>Student test at 76ddl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>-2.56 (±2.52)</td>
<td>-2.69 (±2.33)</td>
<td>-2.45 (±2.69)</td>
<td>t=-0.42, p&gt;.05</td>
</tr>
<tr>
<td>Controllability Patient</td>
<td>-0.74 (±3.08)</td>
<td>0.08 (±2.72)</td>
<td>-1.45 (±3.22)</td>
<td>t=2.26, p=.02</td>
</tr>
<tr>
<td>Externality</td>
<td>-0.23 (±2.14)</td>
<td>-0.28 (±1.80)</td>
<td>-0.19 (±2.41)</td>
<td>t=-0.18, p&gt;.05</td>
</tr>
<tr>
<td>Specificity of consequences</td>
<td>-2.37 (±2.78)</td>
<td>-2.36 (±2.73)</td>
<td>-2.38 (±2.86)</td>
<td>t=0.03, p&gt;.05</td>
</tr>
<tr>
<td>Controllability Health team</td>
<td>2.42 (±2.26)</td>
<td>2.22 (±2.31)</td>
<td>2.60 (±2.24)</td>
<td>t=-0.72, p&gt;.05</td>
</tr>
<tr>
<td>Controllability Natural caregivers</td>
<td>-1.98 (±3.16)</td>
<td>-2.39 (±3.15)</td>
<td>-1.64 (±3.18)</td>
<td>t=-1.04, p&gt;.05</td>
</tr>
</tbody>
</table>

Table 4. Means scores and comparison in function of the method of administering treatment (IV vs. PO) for the causal attributions.

**The global sample**

The patients in the global sample did not suffer from a depressive mood and they did not present an alexithymic state (cf. Table 2).
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Patients perceived themselves as mildly ill (CGI1). They believed that their health state was much improved due to medical therapeutic care (CGI2). They also described their medical treatment as having a very good therapeutic effect with few side effects that did not significantly interfere with their functioning (cf. Table 3).

The patients described the causal determinants (cf. Table 4) of their disease as unstable over time. They also perceived them as neither internal nor external to themselves. The consequences of the disease were perceived as general on their life. The causal dimensions of the controllability of the determinants of the disease were described as: neither controllable nor uncontrollable by patients themselves, uncontrollable by their natural caregivers and controllable by the medical caregivers.

*Treatment mode, CGI and controllability*

The comparison in function of the type of medical treatment showed no significant difference for the CGI assessments (cf. Table 3).

There was no significant difference for causal attributions with the exception of personal controllability (cf. Table 4). Indeed, PO patients perceived their disease as uncontrollable by themselves while this dimension is neutral for IV patients. Moreover, treatment by IV did not increase a stronger perception of disease controllability by medical caregivers.

Oral treatment did not result in a perception of stronger personal controllability and treatment by IV did not lead to stronger medical caregivers’ controllability.

*Prognostic variables of CGI, personal and medical caregivers’ perceived controllability*

Based on the significant correlations observed between all of the medical, psychological and socio-demographic variables, a regression analysis was conducted in order to determine which ones were diagnostic of the intensity of the three evaluations of the CGI, of personal controllability and of controllability by caregivers.
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The intensity of the perceived severity of the disease (CGI1⁴) was related to (25% of the variance) the intensity of the severity of intestinal resection (β = .28, p = .006) and the state of activity of the disease at the time of evaluation (β = .37, p = .0003).

The intensity of the improvement of clinical status (CGI2⁵) was linked to (27% of the variance) the clinical activity of the disease (β = -.41, p = .0004) and the intensity of depressive mood (β = .22, p = .04). The fact that patients believed that their clinical status was better, was related to an inactive disease and no depressive suffering.

There was no prognostic variable related to the intensity of the relationship between the therapeutic benefit and the consequences of side effects (CGI3⁶).

The intensity of personal controllability was linked⁷ (21% of the variance) to the type of medical treatment (β = .25, p = .01) and to the intensity of the specific consequences of the disease on the patient's life (β = .39, p = .0002). Personal controllability belief was explained by treatment by IV and a stronger perception of the limited consequences of the disease on their life.

The intensity of medical caregivers’ controllability was linked to⁸ (14% of the variance) the intensity of the specific impact on the patient's life (β = .30, p = .006). As was observed for personal controllability, the perception of medical caregivers’ controllability was explained by a stronger perception of the specific consequences of the disease on the patient’s life.

Discussion

The objective of this paper was to determine the link between the hospital constraints of treatment by IV with the perception of personal control of patients and with the perceived control of medical caregivers. Due to constraints generated by infusions given at the hospital and a higher effective presence of the medical staff, significant differences were expected to

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⁴ CGI1 correlated with PSHI (r = .34, p = .002), clinical activity of the disease (r = -.42, p < .0001).
⁵ CGI2 correlated with clinical activity of the disease (r = -.47, p < .001), the number of light flare-ups (r = .31, p = .005), depression intensity (r = .33, p = .003).
⁶ CGI3 correlated with clinical activity of the disease (r = -.36, p = .001), the number of severe flare-ups (r = .33, p = .003), the number of paucisymptomatic flare-ups (r = -.33, p = .003), depression mood intensity (r = .31, p = .005).
⁷ Patient controllability perception correlated with the specificity of consequences (r = .39, p < .0001).
⁸ Medical caregivers’ controllability perception correlated with the specificity of consequences (r = .32, p = .005).
Perceived personal controllability of IBD patients and the method of administering treatment be observed in favor of less personal controllability and stronger medical caregivers’ controllability for patients with IV treatment (compared to patients taking oral treatment).

The results showed that the type of treatment administration did not affect the ratings of the CGI. This confirms previous results which showed that the evaluation of perceived effectiveness was not related to the type of treatment, its limitations and real side effects (Banovic et al., 2009).

Moreover, contrary to what was expected, personal controllability was significantly lower for patients taking treatment orally than for those taking it by infusion. Therefore, there would be no link between the fact of self-managing one’s treatment on a daily basis and the fact of thinking that one can control the evolution of the disease through one’s actions. On the contrary, perceived personal control is stronger for the patients who do not have a direct action on their treatment. The fact that the perceived personal control of the patients with intravenous treatment was significantly stronger could be explained by the indication of IV treatments. Since IV treatments are primarily prescribed for resistant diseases, it is possible that patients have greater hope that their disease will be controlled, which would be reinforced by or related to a perception that the disease would have more limited consequences on their lives (Higgins, 2010; Goff, Mazor, Meterko, Dodd, Sabin, 2008).

Furthermore, the results also showed that treatment by infusion did not result in a stronger perception of disease controllability by medical caregivers. It appears that, here too, there is no direct relation between the medical caregivers’ real and concrete action and the patient’s perception of their controllability of the disease. If the caregivers’ controllability of the disease is not reinforced by the type of treatment, it was observed that this was systematically stronger than personal controllability in all the conditions studied. These results underline the importance of the confidence that the patients have in the caregivers’ action for the medical treatment of their disease (and this independently of the constraints that it can have; Schneider, Kaplan, Greenfield, Li, Wilson, 2004; Piette, Heisler, Krein, Kerr, 2005; Cooper, Collier, James, Hawkey, 2010).

In future work with a larger sample of patients taking an oral treatment or treatment by injection, it would be important to determine which are the other variables that could explain a good adaptation to the medical condition, and which of the two treatments (once the disease...
Perceived personal controllability of IBD patients and the method of administering treatment is stabilized or responding to conventional treatment) would be the most adequate (Goldring, Taylor, Kemeny, Anton, 2002; Sewitch, Lefondré, Dobkin, 2004; Jackson, Clatworthy, Robinson, Horne, 2010).
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References


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