Short communication

Participation in randomised clinical trials is linked to emotion regulation strategies

Tanguy Leroy a,*, Véronique Christophe a,b, Nicolas Penel c, Stéphanie Clisant c, Pascal Antoine a

a Université Lille Nord de France, Université Lille 3 URECA EA 1059, BP 60149, F-59653 Villeneuve d’Ascq Cedex, France
b Maison Européenne des Sciences de l’Homme et de la Société, USR CNRS 3185, 2, rue des Canonniers, 59000 Lille, France
c Centre Oscar Lambret, Unité Intégrée de Recherche Clinique, av 30, F-59002 Lille Cedex, France

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ABSTRACT

Objectives: Cancer patients’ anxiety may curb their enrolment in clinical trials (CTs). Thus, the strategies they employ to reduce their anxiety may also determine their enrolment in CTs. The purposes of this study are (1) to compare the anxiety and emotion regulation strategies between patients who are enrolled in CTs (cases) and patients receiving standard cancer treatments who have never taken part in any CT (controls), and (2) to assess the links between these strategies and anxiety.

Methods: In total, 76 cases and 108 controls completed two validated questionnaires assessing their emotion regulation style (ERQ) and anxiety (STAI-Y).

Results: Overall, anxiety scores in cases and controls do not differ. The two groups do not differ in regards to their cognitive reappraisal of situations. However, cases inhibit their emotional expressions less than controls. Both cognitive reappraisal and emotional expressions are linked to lower scores of anxiety.

Conclusions: Patients enrolled in CTs do not seem to be more anxious than those receiving a standard treatment. However, cancer patients’ anxiety depends on the emotion regulation strategies they use. Emotion regulation during physician–patient interactions should be investigated further as a possible factor for CT enrolment determination.

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1. Introduction

Clinical trials (CT) need to be conducted to assess treatment efficiency and safety in a rigorous way. As more patients are enrolled in CTs, the faster and the more efficiently new drugs and new therapeutic strategies are developed. However, enrolment of patients in cancer CTs is often considered insufficient [1–5]. To increase enrolment, barriers and facilitators to participation need to be identified. Studies conducted for that purpose underline factors related to patients, physicians, and study protocols. Barriers to enrolment mostly deal with concerns about the CT methods, the possible reduction of the patients’ quality of life, the potential impairment of the doctor–patient relationship, a negative overall attitude towards CTs, and difficulties regarding the selection of patients [2,4,6–8]. Moreover, some studies suggest that enrolment in CTs may induce anxiety because of the possible impairment of the quality of life, and the uncertainty about the actual benefits and side effects of treatments and, sometimes, about the nature of the treatment actually received [9–11]. Physicians may be reluctant to offer patients the opportunity to take part in CTs – especially in randomised CTs, which are the most uncertain and probably the most stressful situations – if they believe it may impair their emotional state. Therefore, the first aim of this study is...
to determine whether patients who are enrolled in randomised CTs are more anxious than other patients.

To avoid the harmful consequences of stress, people usually implement emotion regulation strategies. Emotion regulation refers to the strategies that people use to influence how they feel and the emotions they express [12]. There are inter-individual differences regarding the emotion regulation strategies that people use to cope with stress; because one's abilities to use efficient strategies - which fit the requirements of specific situations - are learned over a lifetime, as people have to cope with emotional events [13]. Some strategies - such as the positive reappraisal of one's difficulties (cognitive reappraisal) and the expression of emotions - are considered to be healthier and reduce anxiety, compared to others - such as the inhibition of one's emotional expressions (expressive suppression) [14]. During their consultations, even in an unconscious way, some physicians may notice whether patients tend to regulate their emotions in a healthy or an unhealthy way. Little is known, however, about the ways this may affect physicians' proneness to offer patients the opportunity to take part in CTs, which are potentially stressful. Therefore, the second aim of this study is to determine whether emotion regulation strategies differ depending on whether patients take part in a CT or not, and to assess how these strategies are linked to anxiety during treatments.

2. Materials and methods

2.1. Participants

From May 2006 to June 2007, 221 patients receiving a cancer treatment in three medical hospitals located in Northern France were offered to participate in this study, regardless of gender, age, primary tumour location, and cancer stage. They were randomly selected among those whose physician had accepted that their patients meet with our psychologist. Finally, 184 patients (83.3%) agreed to participate in the present study without any compensation. They were 76 case patients (out of the 89 contacted — 85.4%) being treated for the first time in a randomised CT, and 108 controls (out of 132 — 81.8%) who were receiving standard treatments and who had never been offered to take part in any CT before. The only differences between the two groups were that lung cancer was more prevalent in cases, while leukaemia was more prevalent in controls (Table 1).

2.2. Ethics committee

This study has been authorised by the 4th Northern People Protection Committee, a French independent decision-making service that ensures studies are conducted in accordance with the Declaration of Helsinki.

2.3. Methods

All patients were met by a psychologist during one of their visits to the hospital to receive their treatment. After being explained the aims of the study, they signed an informed consent form. Then, cases and controls immediately filled out anonymously the same self-assessing questionnaires, that were (1) the French version of Spielberger’s State-Trait Anxiety Inventory (STAI-Y) [15,16], and (2) the French version of the Emotion Regulation Questionnaire (ERQ) [14,17]. The STAI-Y deals both with people's anxiety while they are filling out the questionnaire (state anxiety), and with their usual anxiety (trait anxiety). For each patient and for each type of anxiety, a score is thus calculated, ranging from 20 to 80: the higher the score, the more anxious the patient.

For the ERQ, it assesses patients' usual use of both cognitive reappraisal and expressive suppression. One score is thus calculated for each of these two strategies, ranging from 1 to 7: the higher this score, the more often the strategy is used by the patient.

2.4. Statistical analyses

The statistical comparisons were expressed in values according to the Student t test, the Fischer exact test, and the post-hoc LSD test. The statistical significance was set at 5%. For both questionnaires, scores to subscales were not calculated when responses were missing (0 to 9.2% drop-out depending on the considered group and subscale), leading to few differences in degrees of freedom in statistical analyses.

3. Results and discussion

Leukaemia is more prevalent in controls while lung cancer is more prevalent in cases. One may assume that such differences could affect the two groups' average scores of anxiety. Therefore, scores of state and trait anxiety have been compared in cases depending on tumour location (lung cancer vs. other cancers), as well as in controls (leukaemia vs. other cancers), showing no significant differences. As a precaution, the same analyses have been conducted about emotion regulation scores, leading to the same conclusions. In accordance with these findings, subsequent analyses deal with groups' average scores of anxiety and emotion regulation regardless of tumour location.
3.1. Anxiety

Overall, cases and controls do not differ according to their trait anxiety score (Mean \( M_{\text{cases}} = 38.9 \); Standard Deviation \( SD_{\text{cases}} = 9.5 \); \( M_{\text{controls}} = 41.4 \); \( SD_{\text{controls}} = 9.8 \); \( t(175) = -1.680 \); n.s.). All the same, they do not differ according to their state anxiety score (Mean \( M_{\text{cases}} = 75.5 \); \( SD_{\text{cases}} = 14.1 \); \( M_{\text{controls}} = 75.9 \); \( SD_{\text{controls}} = 12.5 \); \( t(178) = -0.234 \); n.s.). In other words, despite uncertainty, patients enrolled in randomised CTS did not report being more anxious than those receiving standard treatments. According to these findings, on average, participation to CTS does not seem to increase the patients’ level of anxiety. However, the actual impact of participation in CTS on anxiety probably depends on the patients’ emotion regulation abilities, and the differences between patients may occur according to the emotion regulation strategies they use.

3.2. Emotion regulation strategies

Cases and controls do not differ according to their use of cognitive reappraisal (\( M_{\text{cases}} = 4.65 \); \( SD_{\text{cases}} = 1.30 \); \( M_{\text{controls}} = 4.90.9 \); \( SD_{\text{controls}} = 1.32 \); \( t(178) = -1.199 \); n.s.), but cases less likely to use expressive suppression (\( M = 3.78 \); \( SD = 1.47 \)) than controls (\( M = 4.44 \); \( SD = 1.58 \); \( t(174) = -2.79 \); \( p < .01 \)). There are several possible explanations for this last result, and a crucial challenge for future research will be to understand whether this difference between cases and controls existed previously or is due to the treatments. Patients are often required to fill out questionnaires regarding their quality of life and emotional state as part of a CT. Therefore, they are more likely to express their emotions and avoid expressive suppression, which would result in a lower score of expressive suppression in the present study. However, here, patients were asked about the ways in which they usually regulate their emotions, rather than the ways in which they have regulated them recently. This measurement of emotion regulation styles as a stable characteristic does not support the hypothesis that patients use less expressive suppression as a consequence of their enrolment in a CT. Another possibility is that cases were less likely to use expressive suppression than controls before their enrolment in a CT. From this point of view, future research would have to evaluate how much patients’ expressive suppression affects their relationship with their physician and, as a consequence, how much it may affect the likelihood to be offered to take part in a CT. Regardless, a patient’s emotion expressiveness either as a determinant or as a consequence, is positively linked to participation in randomised CTS. The links between expressive suppression and participation to CTS should thus further be investigated.

3.3. Links between emotion regulation strategies and anxiety

To assess the links between cognitive reappraisal and anxiety, the whole sample (cases and controls indistinctly) was split in three thirds according to the patients’ scores of cognitive reappraisal. Cut-offs were tallied from the scores of cognitive reappraisal for which the cumulative frequencies are closest to 33.3% and 66.7% of the sample. Then, analyses consider only the two extreme thirds: “low score” (\( M \leq 4.34 \); \( N = 66 \); 35.9%) and “high score” of cognitive reappraisal (\( M \geq 5.50 \); \( N = 62 \); 33.3%). Trait anxiety is higher in controls who use cognitive reappraisal the least, compared to all other groups (\( p < .05 \); Fig. 1). Similar analyses were conducted comparing patients with a “low score” (\( M \leq 3.50 \); \( N = 60 \); 32.6%) versus the ones with a “high score” of expressive suppression (\( M \geq 5.00 \); \( N = 63 \); 34.2%). Trait anxiety is lower in cases who use expressive suppression the least than in all other groups of patients (\( p < .05 \); Fig. 1). Unexpectedly, there is no significant link between expressive suppression or cognitive reappraisal, and state anxiety. Patients filled out the questionnaires while they were at the hospital, receiving an injection of their treatment, which is a stressful situation. During such events, cognitive reappraisal and expression of emotions may not help to prevent situational anxiety. However, in the long term, lower anxiety scores in cancer patients are linked to cognitive reappraisal as well as the expression of their emotions for those who are enrolled in a CT. These findings are in line with previous results dealing with the emotional consequences of these two strategies [14].

![Graph](image-url) **Fig. 1.** Mean score of trait anxiety depending on the use of cognitive reappraisal and expressive suppression in cases and controls (scores may range from 20 to 80, the higher the score, the higher the anxiety). Note: In each graph, when letters differ; means differ.
The assessment of emotion regulation strategies may thus be useful as a possible predictor of emotional adjustment in cancer patients who may be enrolled in CTs, and the use of healthy strategies should be promoted in psychological care. Finally, we have to emphasize that cases using expressive suppression the most are not more anxious than controls. Therefore, the lack of emotional expressions should not be considered as a particularly unhealthy emotion regulation style.

4. Conclusions

This study shows on the one hand, that anxiety does not seem to increase when patients participate in CTs, especially for patients who use healthy emotion regulation strategies. On the other hand, this study suggests that patients who are enrolled in CTs inhibit their emotional expressions less. Future research has to explore this link, especially to assess how the patients’ use of expressive suppression may affect their likeliness to be offered to take part in a CT. Besides, the present study only deals with cancer CTs, which are almost never placebo-controlled. Therefore, future research should assess anxiety and emotion regulation in patients suffering from other diseases, in order to verify to what extent the present conclusions can be generalised to other populations and other designs of CTs. Exploring what factors actually impact enrolment in CTs remains a determinant issue for improving patient care. Further investigations should thus be conducted to better understand the roles of emotion regulation in patients as well as in physicians during the informed consent process.

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