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ARTICLE

Rien ne sert de courir, il faut partir à point ; Leçons apprises d'une intervention psychologique en oncologie : de l'importance de conduire des études pilotes et/ou de faisabilité dans les interventions complexes

Slow and Steady Wins the Race; Lessons Learned from a Psychological Intervention in Cancer Care: The Importance of Conducting a Pilot and/or Feasibility Study in Complex Interventions

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RÉSUMÉ

Cet article retrace l'histoire d'un projet de recherche qui a échoué. Nous avons conçu et implémenté une intervention psychologique visant à augmenter les compétences émotionnelles des patient·e·s atteint·e·s de cancer œsogastrique ou de cancer du poumon, après leurs traitements. L'étude était un essai contrôlé randomisé dans un hôpital public. Nous présentons le protocole final de l'étude, décrivons les difficultés rencontrées et nos réflexions à ce sujet, afin de transmettre notre expérience et les messages clefs qui vont avec aux chercheur·e·s et clinicien·ne·s pour la mise en œuvre de telles interventions. Tout d'abord, le rôle de la psychologie, des émotions et des compétences émotionnelles est encore largement sous-estimé en oncologie. Des efforts pédagogiques doivent être faits pour convaincre médecin·e·s et patient·e·s de l'importance de ces éléments. Deuxièmement, même les patient·e·s en détresse qui bénéficieraient d'une telle intervention ne la suivent pas, en particulier les hommes en raison de stéréotypes de genre. Il faut faire preuve de créativité pour présenter de telles interventions

de manière motivante pour les patient·e·s. Enfin, le message le plus important est que même si on a un très bon rationnel pour une intervention psychologique et que toutes les conditions favorables sont réunies, il est essentiel de mener une étude de faisabilité/pilote d'abord. En effet, même avec la préparation la plus minutieuse, on ne peut pas anticiper tous les obstacles car il existe un gap bien réel entre la théorie et la pratique.

MOTS CLÉS

Émotion ; compétences émotionnelles ; cancer ; interventions complexes psychologiques ; problèmes méthodologiques ; survivance

ABSTRACT

This article chronicles a failed research project. We designed and carried out a psychological intervention aimed at increasing esogastric and lung cancer patients' emotional competencies after treatments. We present the final protocol of the study, a randomized controlled trial in a public hospital, and describe the difficulties encountered and our subsequent reflections, to provide researchers and clinicians with advice for the implementation of such interventions. Firstly, the role of psychology, emotions, and emotional competencies, is still underacknowledged in cancer care. Pedagogical efforts must be made to convince both physicians and patients of the importance of those elements. Secondly and consequently, even distressed patients sure to benefit from such an intervention, do not take it up. In particular, male patients often declined the intervention due to gender stereotypes, and as such creativity is needed to present such interventions in a motivating way for patients. Finally, and most importantly, even if there is a good rationale for a psychological intervention and all favorable conditions are present, it is essential to first conduct a feasibility/pilot study. Indeed, even the most thorough preparation is no guarantee of anticipating all issues due to important gaps between theory and practice.

KEYWORDS

Emotion; emotional competencies; cancer care; psychological complex interventions; methodological issues; survivorship

Introduction and Rational

The Hauts-de-France region (HdF) is one of the most affected by cancer in France. Incidence and mortality of lung and esogastric cancers are particularly high. Indeed, the HdF presents an over-incidence of 21% for lung cancer in men and over 40% in both men and women for esogastric cancers [1]. Mortality is also higher in HdF with over mortality of more than 50% for esogastric cancers and 27% in men with lung cancer, compared to other regions in France [1]. Despite this particularly gloomy situation, compared to breast or prostate cancers, esogastric and lung cancers have received little attention in psychosocial research.

In addition to poor prognosis, these cancers seriously deteriorate patients' quality of life (QoL), especially in its emotional dimension [2,3]. Cancer patients are at risk of high psychological distress [4–6], which may impair prognosis and survival [4,5]. Maintaining a good QoL is therefore of utmost importance. However, the period between diagnosis and treatment [7] and the period of treatment are an ill-suited time to address patients' emotions. Indeed, treatments may be logistically and physically difficult, and exhausting for patients. Moreover, supportive care is mainly offered during hospitalization and treatments rather than in the surveillance phase after treatments. Thus, discharged patients often lack supportive care at this critical time [8,9]. This is all the more regrettable as psychosocial interventions are as helpful for patients during treatments as they are in survivorship [10]. And in this phase, patients still need psychological help. In fact, this period is characterized by trepidation and uncertainty, as patients still experience the lingering effects of treatment [11] and fear of recurrence [8].

To maintain good mental health despite the emotional challenges of the surveillance phase, patients need good emotional competencies (EC). EC are the ability to pay attention to one's and others' emotions to use them to inform one's thoughts and actions [12]. More precisely, EC refer to the ability to identify, understand, express in an appropriate manner (or make others express) and regulate one's emotions and those of others (e.g., to regain calm quickly after a difficult event or enhance mood when sad) [13]. Rather than being hindered by negative emotions, people with high EC use them as a source of information and motivation to change favorably difficult situations. While the term "emotional intelligence" may also be used, the term "emotional *competencies*" was coined later to convey the idea that it is more about *skills*, which can evolve, than about intelligence, which is thought to be stable over time. The positive impact of EC has been widely demonstrated in different contexts (e.g., better school performance and happier relationships). EC are also associated with better mental and physical health in the general population [14,15] and with better patients' QoL and psychological outcomes in cancer settings [e.g., 16], including less psychological distress in cancer survivors [17]. In summary, data suggest that good EC are associated with better health in general and clinical populations.

At the time of designing our research, in 2015, EC were little studied in the field of health; most of the cited articles above were conducted from 2015 to now. Interventions now exist for improving emotion regulation in early survivorship

[18], but EC, which include broader competencies than simply emotion regulation, have been the focus of fewer studies, especially at our project's inception in 2015. At that time, we assumed EC would improve QoL in patients under surveillance after treatments for esogastric or bronchopulmonary cancers. Since data had demonstrated that EC could be improved by intervention [19,20], we designed an intervention aimed at improving EC in esogastric or bronchopulmonary cancers.

Consequently, a randomized controlled trial (RCT) was designed in 2015. It aimed to assess the effect of an intervention aimed at increasing the EC of cancer patients who had completed their treatments (i.e., primary outcome) in an outpatient setting, in comparison with a control group practicing relaxation (see the method section for more details). Our hypothesis was that the EC intervention would increase patients' EC more than relaxation. The secondary outcome was patients' QoL. We postulated that the increase in patients' EC would lead to an improved QoL.

Such an intervention was a first for French hospitals. This novelty was a source of issues, many of which could have been avoided had a pilot and/or feasibility study been conducted, and a partnership established with patients. Specifically, checking the study's feasibility by looking at recruitment and retention rates, potential limitations to implementation and data collection, as well as integrating patient feedback and developing appealing ways to motivate patient participation. The conceptual model underlying RCTs is also questioned in psychological complex interventions. We hope that our experience will help researchers and clinicians understand the importance of these best practices for the success of future interventions in psycho-oncology.

History and Protocol of an RCT to Improve EC

EmoVie-K1

The intervention we conceived in 2015 was named "EmoVie-K1". It consisted in 3 group sessions led at the University hospital of Lille in northern France. Each session took place in the meeting room usually used for staff meeting and lasted 2 hours. A group format was favored over individual interventions to foster peer-support and ward off the feeling of isolation often reported after treatments. Furthermore, group-based formats have yielded better results with regards to decreasing fear of recurrence, a major issue in the surveillance phase [21]. It was decided to form a quorum of five patients to initiate a group of patients, as we deemed this number suitable to fuel exchanges within the group. The same psychologist carried out the intervention in both experimental and control groups.

The intervention was based on previous training that proved to be successful [22,23]. This training model includes six sessions: 1. Identification, 2. Understanding, 3. Expression, 4. Regulation of negative emotions, 5. Regulation of positive emotions (e.g., to maintain happiness after a positive event), and 6. Utilization of emotions. The model was shortened to three sessions while retaining the most important information, to avoid lengthy post-treatment interventions for fatigued patients and because the duration of an intervention does not seem to affect its efficacy [10]. The first session covered identification and understanding of emotions, the second their expression, and the third their regulation. Learning to utilize emotions was spread across the three sessions. In each session, participants were encouraged to reflect on the proposed themes themselves, give their opinions and share their experiences in relation to the topics discussed. Role playing was also used, and participants were encouraged to practice what they had learnt during the sessions in their lives. To do so, they received a two-page handout containing exercises to be done by the next session. The contents of the intervention were standardized to some extent, with a PowerPoint supporting important ideas and summarizing the key messages, but also personalized, with the psychologist using examples and issues raised by the participants. The CONSORT checklist, which lists the information to include when reporting nonpharmacologic RCTs, was used [24].

In the control group, participants practiced relaxation in each session after a short free discussion about their experience of cancer. We found this to be a good activity for control groups as it allowed patients to receive an intervention not intended to increase EC.

Each arm of the study required thirty-eight patients to reach sufficient statistical power. The protocol was registered on ClinicalTrials.gov (NCT03306693, EmoVie-K), received the approval of the French National Ethics Committee (2017-02-05 RIPH 2°) and was funded by SIRIC OncoLille and Santélys. This was a single-center study. Esogastric or lung cancer patients being over 18 years of age, between six months and two years after the end of any antineoplastic treatment, were the main inclusion criteria.

Inclusions were carried out between 26/10/2017 and 14/01/2019. Of the 157 patients whose medical records were screened for possible inclusion, 134 could not be included. Among them, 35% (n = 47) were not included because physicians did not have enough time to present the study to them, 31% (n = 42) because they were not interested in the study and 15% (n = 20) because of the distance between their home and the hospital (Fig. 1). Only 23 agreed to participate and signed the consent form. Owing to the low recruitment rate and a subsequent end to the funding for the psychologist, the study had to be stopped on January 14th, 2019 (see Table 1 for the sample of participants).

To further understand why recruitment was so difficult, a meeting was organized in May 2019 with the two research assistants, the head of research assistants, the scientific leader of the study and the psychologist who led the sessions with patients. The difficulties encountered and suggestions for overcoming them are summarized below. The protocol of the EmoVie-K1 study was modified following these suggestions, moving to EmoVie-K2 (for more details, see Suppl. Table S1).

Difficulties related to EC. When presenting the study to the physicians, we did not perceive the confusion they might have towards the concept of EC and their potential lack of confidence in the study. While at the kick-off meeting, the physicians professed being comfortable offering participation in this study to patients, they later reported

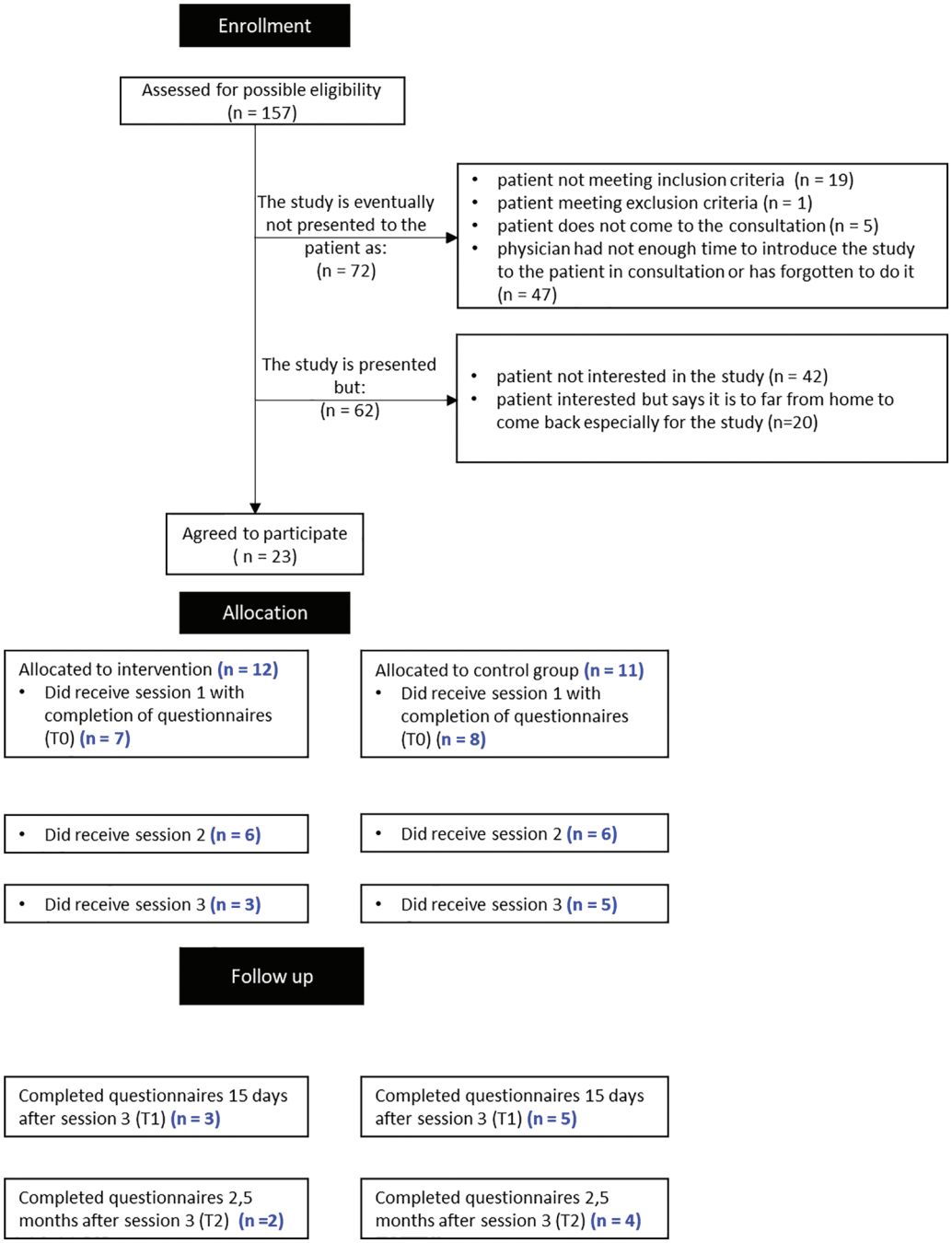

FIGURE 1. Flow chart of EmoVie-K1.

not feeling comfortable presenting a study on emotions and EC. Therefore, when starting EmoVie-K2 we invested more time providing physicians with evidence-based arguments on the importance of EC for both mental and physical health and simplifying the notion itself. We also systematically asked them how they would feel presenting the study to their patients, explaining the reason for this important question, and made suggestions for a more convincing presentation. Patients were mostly male and were not comfortable participating in a study related to emotions; we therefore introduced it differently. Another unexpected difficulty was that some patients attended the sessions out of curiosity rather than actual need. A new inclusion criterion was thus set to include only patients with significant clinical distress, i.e., a distress score ≥4 on the distress thermometer, which theoretically ranges from 0 (no distress at all) to 10 (maximal distress) [25–27].

Organizational issues. As five patients were needed to form a group, some participants had to wait up to six months before a group of 5 could be formed. Furthermore, once the groups were formed, there were difficulties finding a schedule that suited everybody. Therefore, the protocol was amended to set up individual sessions instead of the group sessions previously used. Another key issue was patients' travel-time from home to the hospital for sessions. We decided for EmoVie-K2 to adapt the intervention to a phone-call-based format, making an exception for the first session if patients preferred a face-to-face meeting or wanted to meet the psychologist. To facilitate the recruitment of patients, the study was also proposed to five

TABLE 1

EmoVie-K1-sample characteristics

	n (%)	Mean [range]
Age		63 [44–45]
Gender: Male	15 (65)	
Marital status		
Single	2 (9)	
In a relationship	10 (43)	
Divorced	2 (9)	
Widowed	1 (4)	
Missing data	8 (35)	
Education		
No diploma	3 (13)	
High school diploma	7 (30)	
Bachelor's degree	2 (9)	
More than bachelor	3 (13)	
Missing data	8 (35)	
Perceived financial situation		
Rather difficult	1 (4)	
Correct	5 (22)	
Comfortable	9 (39)	
Missing data	8 (35)	
Professional situation		
Employed	1 (4)	
Retired or does not work	14 (61)	
Missing data	8 (35)	
Pulmonary cancer	20 (87)	
Charlson comorbidity index[§]		
0	5 (22)	
1	7 (30)	
2	6 (26)	
3	2 (9)	
4	1 (4)	
5	2 (9)	
Time from diagnosis to inclusion (years)		1,59 [0,40–6,39]
Time from remission to inclusion (months)		3,79 [0–18, 50]
Time from inclusion to the 1st session (days)		90 [18–185]
Time from the 1st to the 2nd session (days)		10 [6–35]
Time from the 2nd to the 3rd session (days)		10 [8–14]

Note: [§]The Charlson comorbidity index is a weighted index that takes into account the number and the seriousness of comorbid diseases. The higher the score, the higher risk of mortality or other outcomes such a health consumption (e.g., hospital stay).

additional hospitals, who agreed to participate. Minor changes made to the study are described in Suppl. Table S1.

Survivorship. Although the inclusion criterion of a 6-month period after the end of treatment was initially decided to avoid fatigue just after treatment, patients reported they would have benefited more from an earlier intervention. Therefore, the EmoVie-K2 study was proposed immediately after the end of treatment. Patients also reported that they did not enjoy returning to the ward where they were treated. Accordingly, when patients opted for the first face-to-face session (rather than by telephone), they were received in non-medical premises of the hospital and were grateful for this warm environment.

EmoVie-K2

To summarize, the major changes were to move towards *individual* sessions (instead of group ones), carried out over the phone (instead of at hospital), with recruitment occurring immediately after the end of treatments. The design was otherwise the same as EmoVie-K1 (Fig. 2). The final version of the full intervention is presented in Suppl. Table S2.

The intervention was based on the same training as EmoVie-K1. However, regulation of emotions was addressed in the second session, this time, before expression of emotions, to give participants more time to process the difficult EC of emotion regulation. Other than being done over the phone, the control intervention remained the same as in EmoVie-K1. Participants in both arms were invited to do exercises for the following session, as previously.

Eighty-six patients (43 patients by arm) were needed for sufficient statistical power. Randomization was performed in a 1:1 ratio, without stratification factor. Measures of EC (primary outcome) and QoL (secondary outcomes) were conducted just before the first session (T0), 15 days after the end of the sessions (T1) and 2 months after T1 (T2) (Fig. 2).

EmoVie-K2 obtained ethical approval in September 2018 ("EmoVie-K2", 2017-02-05 MS1 RIPH 2°) and inclusions began on 15/02/2021, during a national pandemic-related lockdown. This project was funded by the 'Direction de la recherche, de l'enseignement supérieur et des formations sanitaires et sociales, Région Hauts-de-France'. Despite all the modifications described above, the inclusion rate remained low.

A new meeting was therefore organized in June 2022, with the principal investigator, the two research assistants, the head of research assistants, the psychologist who led the sessions with patients and the two scientific leaders of the study. It appeared that the distress criteria created a new problem. While the literature reports distress in cancer survivors [28], almost no patients had a distress score ≥ 4. Nurses involved in the study reported that participants, whom they knew well, may have concealed their true distress to physicians out of fear of disappointing them. The term "distress" also seemed to have been problematic and confusing to patients. Furthermore, it may be difficult for

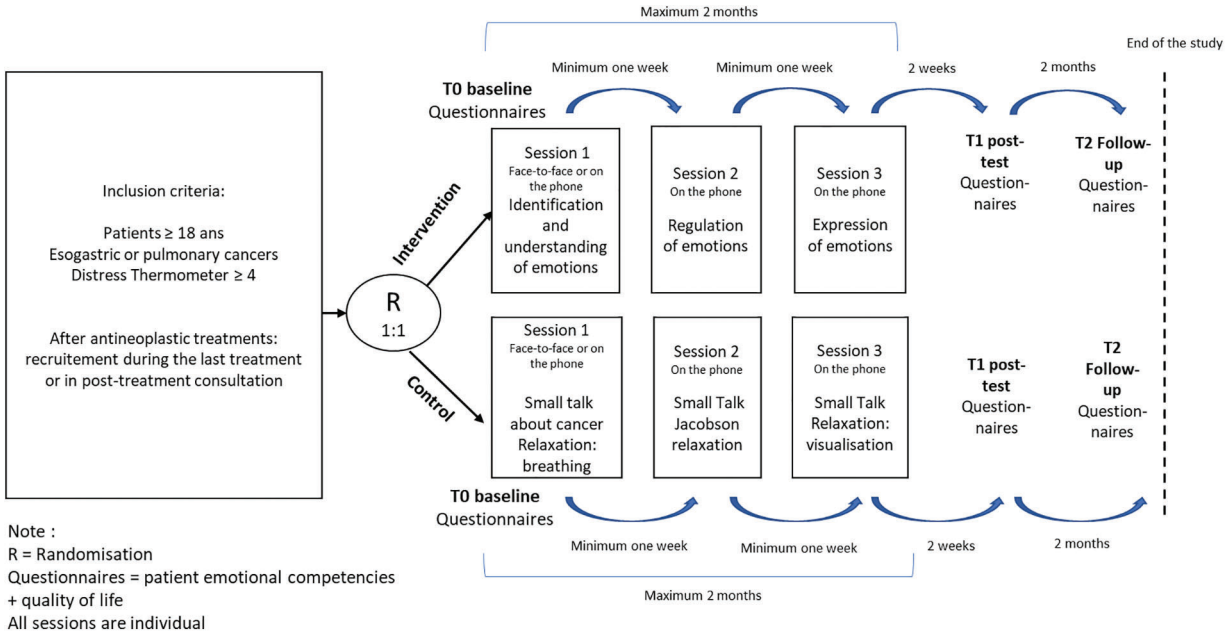

FIGURE 2. Design of EmoVie-K2.

patients with low EC, that is by definition patients with poor emotional insight, to accurately rate their distress. Like other authors who have addressed the same problem [29], we thought of using the revised Edmonton Symptom Assessment System to assess distress, and lower the criterion to a score above 2 for at least one of the following Edmonton Symptom Assessment items: Fatigue (meaning 'lack of energy'), Cancer-related ruminations ('to think about cancer often'), Fear of recurrence ('fear that cancer will come back'), how the patient is doing in general ('this time, the question is not just about cancer but about how you are generally feeling right now').

Unfortunately, due to the protocol changes taking too long to implement administratively, the solution was never implemented, and the study came to a close on 31/03/2023.

Key Elements to Keep in Mind for a Study about EC in Survivorship

The role of psychology, emotions, and EC in cancer care

In 2017, a group intervention aimed at improving EC in cancer care was unheard-of in French hospitals. Unlike diabetes or obesity, patient education, including patient education about emotions and EC, is not widespread in cancer care. To illustrate this point, only 3% of patient education programs concern cancer patients in HdF [30]. In a recent second order meta-analysis on the effectiveness of patient education, only 4 meta-analyses out of the 40 included in total concerned cancer patients [31]. Even though cancer treatment has demonstrated strong progress in recent years, the perception of cancer as a chronic disease can be questioned, as can the place of psychology. Even in 2023, psychological research is not widespread in French hospitals and concepts such as emotions and EC are difficult to grasp for patients but also for physicians. Some physicians still regard the role that psychology and emotions may play in patients' pathologies with some skepticism [32]. Presenting a psychological study to both physicians and patients must be planned carefully and delivered convincingly, using evidence-based data. The study's "pitch" (who, when, the words used, etc.) should be tested in a feasibility study along with other aspects.

Time and place

To better help cancer survivors, we can highlight two points from our experience. First, to not wait too long after treatments end to offer help, as it may come too late. The transition from treatment to surveillance should be prepared even before treatment ends. Ideally, interventions like ours could be presented toward the end of treatment. Second, the hospital may not be the best place for this as it is often a reminder of difficult memories that survivors need to move on from. Furthermore, hospitals are overloaded with biomedical RCTs and accordingly do not prioritize psychosocial interventions. Patient associations would probably be a better place to carry out the sessions.

Gender issues

Aged male patients, who represent a majority of patients in lung and esogastric cancers, are known for declining psycho-oncological care more often than women [33]. Studies have highlighted the still-powerful gender norms that keep distressed men from seeking and accepting help as it would be a threat to and betrayal of their masculinity [34,35]. Even in recent psychosocial studies, female patients represented 89% [36] and 91% [29] of the participants. Ingenious communication is needed to broach the topic of distress and help, perhaps by adopting indirect language or using humor [34]. Interestingly, professionals may find it easier to offer assistance when a certain threshold of distress has been reached, as it legitimizes the suggestion that help is needed [34]. Unfortunately, even the rating of distress proved problematic and may not mirror the reality of our male patients. An adaptation of the cut-off values for male

patients, and for patients from both genders when their distress is assessed in front of their physicians, may help. Another solution, which is the best practice in Switzerland and Belgium, is that physicians only say to patients that a study is open, by describing very shortly the broad theme of the study, and then ask them if they would accept to be contacted by phone to receive further information. If yes, they are contacted by a research assistant they do not know, to which it is easier to tell their true distress or concerns, or to say "no" if they are not interested in participating in the study.

Low uptake of psychosocial interventions

Although counterintuitive, patients experiencing distress does not mean they will accept help. For example, 71% of distressed cancer outpatients declined help as they preferred managing by themselves [37], especially among rural cancer survivors [38]. Among cancer survivors with moderate depressive symptoms, 30% declined psychological intervention, reporting not to need help [39]. Among colorectal cancer patients experiencing high distress (distress thermometer ≥5), 39% declined help for the same reason [40]. Custers et al. [40] drew attention about the gap between literature and real-world uptake of interventions, especially psychological ones. Other authors consider low uptake to be a universal phenomenon of psychosocial care, evidencing the mismatch between patients' needs and received care [41]. This might be even truer in socioeconomically deprived regions such as northern France, where we tried to carry out our study, as people may not prioritize dealing with emotions or psychological issues. It is also possible for proposed help to not be relevant for patients.

Methodological issues: respecting the steps of an RCT

Even if some of the difficulties we have been confronted with appear the same as encountered (although not necessarily reported) by other researchers, one of the causes of our failure is that we did not fully adopt a framework such as the one proposed by Campbell [42] or by Skivington et al. [43] for complex interventions. For example, Campbell et al. proposed the design and development of RCTs in 5 steps:

1. Preclinical phase to gather theory for the choice of intervention format, hypotheses, and variables to control for,
2. Phase I: defining the components of the intervention such as the content of the sessions in our case,
3. Phase II: exploratory trial, i.e., feasibility and pilot studies,
4. Phase III: the RCT in itself,
5. Phase IV: long-term implementation of the intervention in real settings. Related to the last phase, one can differentiate efficacy, i.e., to what extend does the intervention produce the intended outcomes in experimental or ideal settings, from effectiveness, i.e., to what extent does the intervention produce the intended outcomes in a real-world setting [43].

Our unfortunate experience came, in part, from realizing phase I as a team constituted purely of research psychologists, and skipping phase II, two mistakes that we will now discuss.

The need to involve patients at the very beginning of research conception

Before designing an intervention, we must examine whether there is a need for and a demand from, the patients, and if they judge the proposed intervention to be relevant and respond to their needs. Co-construction of the interventions with patients as partners appears as a clear potential solution in this respect. Involving patients in research design is on the rise, but there is still some resistance from researchers [44]. However, more valuable interventions for maladaptive emotions could be designed with the help of patients (see for example [41] about the need to question maladaptive and adaptive emotions in cancer settings).

Take home message: the absolute necessity of a feasibility study

A feasibility study "asks whether something can be done, should we proceed with it, and if so, how. A pilot study asks the same questions but also has a specific design feature: in a pilot study a future study, or part of a future study, is conducted on a smaller scale." [45]. In their study investigating the reasons for non-participation and low uptake of a psychological intervention for colorectal cancer survivors, the authors concluded by recommending "to perform pilot and feasibility studies in advance of a large RCT to overcome barriers with recruitment and uptake and to select the most appropriate and optimal research design and sampling method" [40]. The advantage of a feasibility study in our case would have been to inform us of recruitment and retention rates, practical issues and barriers to intervention implementation, patients' feedback about the intervention, and the feasibility of collecting data for the study outcomes.

Conclusion

It is a recent trend for researchers in psycho-oncology to carry out and publish feasibility and pilot studies. They can be perceived as a priori unnecessary; however, our painful experience shows that they are essential. In fact, many issues that we encountered could have been dealt with in due time or prevented altogether had we performed a feasibility/pilot study.

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Marie-Mai N'Guyen, Laura Caton; data collection: Laura Caton, Marie-Mai Nguyen, Gildas D'Almeida, Alexis Cortot, Guillaume Piessen; analysis and interpretation of results: Sophie Lelorain, Christelle Duprez, Laura Caton; draft manuscript preparation: Sophie Lelorain, Christelle Duprez, Laura Caton. All authors reviewed the results and approved the final version of the manuscript.

Disponibilité des données et du matériel/Availability of Data and Materials: Difficulties encountered in EmoVie-K1 and EmoVie-K2 and actions taken or envisaged are summarized in Suppl. Table S1 and the protocol of the study is provided in Suppl. Table S2.

Avis éthqiues/Ethics Approval: The protocol was registered on ClinicalTrials.gov (NCT03306693, EmoVie-K), received the approval of the French National Ethics Committee (2017-02-05 RIPH 2°).

Conflits d'intérêt/Conflicts of Interest: All the authors have no conflict to disclose nor competing interests.

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Table S1 (Supplementary File 1). Difficulties encountered and actions taken or envisaged

Category of difficulties	Difficulties encountered and reasons for failure of EmoVie-K1	Who reported the difficulties? How were the difficulties identified?	Solutions found: EmoVie-K2	New problems	New envisaged solutions
1. EC-related	Physicians were not comfortable with presenting an emotion-related study to their patients, they were not comfortable with the concept of EC. They did not 'believe' in the study.	Physicians and research assistants	Physicians were provided with evidence-based studies and meta-analyses showing the impact of EC on numerous patient outcomes. The concept of EC was presented in a simple and accessible way to physicians (e.g. skills that help in making good decisions and taking action, feeling better and having a positive outlook on life).		
2. EC-related	Pulmonary and esogastric cancer patients are mostly men and they are not as comfortable with emotions as women. Many of them were reluctant to participate in an emotion-related study.	Physicians and research assistants noticed this when presenting the study to participants. For example, one participant said 'it's bad to think about emotions' and no convincing argument was given in return.	The way of introducing the study to participants, especially male participants, needed to be revised. Some words frightened patients and had to be avoided: psychology, emotions, therapy. Instead, the intervention is now presented as 'three individual sessions aimed at promoting physical and mental health and helping to feel stronger after treatments. These sessions are practical, they reinforce patients' strengths and deal with potential concerns in a practical way'.		

3. EC-related	Some patients already had rather good EC.	The psychologist found that some patients did not need the intervention. For example, a retired man came because he had time and was ‘always curious to discover new things’ but he had no real need for help in dealing with his emotions. This is problematic because the RCT may appear as non-effective, while in fact some patients simply did not need help [10, 46].	A new inclusion criterion was defined: distress score ≥ 4 at the distress thermometer, which theoretically ranges from 0 (no distress at all) to 10 (maximal distress). Patients ≥ 4 need help [25–27] and are thus relevant targets for the intervention.	Almost no patient had a score ≥ 4. Nurses noticed that patients who were distressed, however, reported a low score of distress (< 4). Patients were probably reluctant to disclose their true level of distress to their surgeon or oncologist out of fear of offending them. They may have found it difficult to express their distress to the person who ‘saved’ them from cancer. + The term ‘distress’ was considered problematic by staff, who reported that patients did not understand the term clearly and asked for clarification + It is difficult for some patients to assess their distress, which is an emotional state. Yet these patients are the ones who need the intervention the most.	A new inclusion criterion was defined: a score ≥ 2 for, at least, one of the following items: -Fatigue (explaining to patients that ‘fatigue means lack of energy’) -Cancer-related ruminations (explaining that ruminations mean ‘to often think about cancer’) -Fear of recurrence (‘fear that cancer will come back’) -How the patient is doing in general (‘this time, the question is not just about cancer but about how you feel right now in general’ from ‘I feel perfectly fine’ (0) to ‘I don't feel fine at all, worst possible state’ (10).

4. EC-related	Patient-reported questionnaires, 50-item PEC (Profile of Emotional Competencies) and SF-36, too long and too complex (e.g. double negatives, unclear items)	During the completion of questionnaires at the beginning of the 1st session, patients asked many questions to the psychologist, as they had difficulties understanding the items.	Short-PEC with 13 items [47] to assess patients' emotional skills and FACT-G instead of SF-36 for quality of life.
5. EC-related	2-hour sessions: too long	The psychologist noticed that patients were distracted and tired towards the end of the sessions.	Shortened sessions: 1.5-hour sessions
6. EC-related	Session 3 'regulation of emotions' was difficult for patients.	The psychologist and the patients themselves	Session 3 'regulation of emotions' was inverted with session 2 'expression of emotions'. It gave more time to patients to process this session. It is also preferable to be able to regulate emotions before being able to express them appropriately. The contents were also slightly modified to keep the most essential information.
1. Organizational issues	Group sessions of five patients meant having to wait for the inclusion of 10 patients for randomization.	Data analysis showed that mean time from inclusion to session 1 was 90 days.	Individual sessions. A survey showed that cancer survivors prefer individual professional counselling over professionally-led cancer support groups [48]. Male patients are known to be reluctant to share their difficulties in group settings [see the discussion of 49]. Cancer

			survivors prefer individual counselling to support groups [48] and individual sessions are more effective than group interventions in reducing patients' anxiety [46].		
2. Organizational issues	Group sessions of five patients meant having to find a common date for these five participants and the psychologist and a date at which the meeting room was available.	The psychologist	Individual sessions		
3.Organizational issues	Time and distance to come to the hospital to attend sessions. As a result, only patients in the neighborhood attended the sessions, thus reinforcing social inequalities. Patients sometimes lived very far from the hospital.	Patients cited by the research assistants	Face-to-face sessions only for the first session when possible, otherwise over the phone, and 2nd and 3rd session over the phone in all cases. We tried to combine the first session with a medical appointment so that the patient does not have to come to the hospital especially for the study.		
4.Organizational issues	Patients' transport and parking fees were not reimbursed.	Patients cited by the research assistants	A budget was set aside to cover these costs.		
5.Organizational issues	Physicians did not have time to introduce the study in consultations.	Research assistants reported that many patients who met the inclusion criteria, to whom the study was supposed to be presented, were not informed about the	Nurses were more involved in the study to remind physicians to shortly mention the study during consultations. Thereafter, whenever it was possible, they themselves	The solution did not work. Nurses do not have time and are not always involved in the study.	The psychologist who led the sessions spent some time in the wards to meet the eligible patients in person.

		program. This was frustrating for the research assistants who had spent time screening for eligible patients.	presented the study to the patients in more detail. Nurses could also present the study to patients before the consultations, so that the physicians would just have to make the patients sign the consent form. Both ways, physicians could save time and the study could still be presented well to patients.
6.Organizational issues	Single-center research: too many clinical trials are underway in the University Hospital of Lille and EmoVie-K1 was not a priority.	Physicians and research assistants	Five additional hospitals in the region were invited to participate in the study and accepted. These hospitals are less involved in research and thus had more time to devote to EmoVie-K2.
7.Organizational issues	Physicians forgot to introduce the study to participants.	Physicians and research assistants	Regular reminders of the study via a one-page newsletter were sent to physicians. It contained the number of inclusions in each center to motivate all centers.
1. Survivorship	Patients were too far from the end of treatment and did not want to hear about the hospital again or wished the intervention had been offered to them earlier.	Patients cited by the psychologist and research assistants	Previous inclusion criterion from six months to two years after treatment changed in favor of 'just after the end of treatment'.

2.Survivorship	Patients did not like to come back to the ward where they had been treated.	Patients cited by the research assistants	The first session was organized in the Patient Education Department of the University Hospital of Lille. The department, although on the hospital site, is in a separate building which is not medicalized and decorated in a welcoming way.

Note: Although it is impossible to objectively rank the difficulties encountered from the most to the least problematic, we have tried to place first the difficulties reported as the most problematic for each category; EC = Emotional Competencies

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Table S2. Supplementary File 2: EmoVie-K2, intervention description using the template for intervention description and replication (TiDieR) checklist.

Note that full references are listed at the end of the manuscript.

Item 1. Brief name: Provide a name or phrase that describes the intervention

The name of the RCT is EMOVIE-K2. The intervention is a short educational intervention aimed at increasing the emotional competencies (EC) of cancer survivors compared to a short relaxation intervention. In both arms, the intervention is composed of three individual sessions of 90 minutes each.

Item 2. Why: Describe any rationale, theory or goal of the elements essential to the intervention (see the introduction of the article for further details and the references)

EC are associated with mental and physical health in the general population [14, 15] and with patients' QoL and psychological outcomes in cancer settings [16]. As there is evidence that EC can be trained in the general population [19], one can assume that those skills could also be trained in cancer survivors with subsequent positive outcomes.

The intervention is based on EC theories [12] that define five main intrapersonal and interpersonal EC as follows:

	Intrapersonal dimension The ability to:	Interpersonal dimension The ability to:
Identification of emotions	*precisely* identify ones' emotions such as anger, sadness, anxiety, joy, relief, satisfaction, etc	Same ability but for other people's emotions.
	People with good identification skills are also good at describing the *intensity* of their emotions.	Likewise

Understanding emotions	understand ones' emotions, that is to trace back the emotions to their causes (an unmet need for negative emotions or an important met need for positive emotions).	Likewise but the understanding of other people's emotions also implies adopting their perspective in order to understand their needs (even though they might be different from ours) and the importance of those needs for them
Expression of emotions	express ones' emotions in an appropriate way, clearly say to others how one feels but without attacking them or shouting at them. People with these skills have enough self-confidence to express themselves in an appropriate way.	make people express their emotions. People with these skills show empathy and compassion towards others so that the latter feel free to express their emotions to them. When others have difficulty expressing themselves, emotionally-skilled people ask them relevant questions to help them identify and express their emotions.
Regulation of emotions	regulate ones' own emotions, to cheer oneself up when sad, to calm oneself down after a difficult experience or when angry and to maintain one's positive emotions over time (joy, satisfaction, recognition) to benefit from their positive effects during a long time. People with these skills are also well aware of the situations that can trigger negative or positive emotions in them and are able to anticipate those situations to respectively avoid or provoke them when possible.	help other people regulate their emotions as described on the left. These people help others see the other side of the coin, lessen the impact of their negative emotions and strengthen the positive ones. They also help others become aware of the impact of certain situations on them in order to either avoid or induce these emotions.

Use of emotions	take into account one's emotions to guide one's choices and behaviors	take other people's emotions into account in order to better interact with them and help them adapt their choices and behaviors

Item 3. What (materials): Describe any physical or informational materials used in the intervention, including those provided to participants or used in the intervention delivery or in the training of intervention providers

For readability reasons, items 3 and 4 are presented together.

Item 4. What (procedures): Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities

Procedure for each session

For both arms and each session:

- The psychologist calls the participants (the date and time have been set in advance) and warmly welcomes them in order to facilitate the therapeutic alliance.

- Participants will be asked if they have read about the session of the day beforehand, using the hand-out.

- For the second and third sessions: the previous session and the days that have gone by between the previous session and the current one are reviewed. For the first session, the psychologist asks the participants how they are doing, the difficulties or positive things they have encountered regarding their disease, treatment, family, or whatever difficulties and resources they wish to talk about.

- Participants are then invited to discuss their difficulties or feelings about the exercises, to ask questions about the previous workshops if necessary or share moments of the week.

- The session unfolds, participants are invited to express themselves about the workshop all along. At the end, a summary is proposed, and the participants are asked what they have learnt or what has marked them.

- To conclude the session, participants are encouraged to do the exercises for the next session (or in the following days for the last session).

Activities, and/or processes used in the intervention, including any enabling or support activities.

During the session, participants are regularly invited to share personal examples of how they deal with stress and emotions. The psychologist is encouraged to set an example by sharing his/her own strategies, difficulties and successes in managing emotions.

The participants are also asked to reflect on what is proposed by the psychologist and give their opinion about it.

All the activities are described below.

Materiel given to the participants

A hand-out is given to the participants before each session to help them remember what was said and the exercises to be done. Hand-outs are available upon request (in French).

INTERVENTION GROUP - CONTENTS OF THE INTERVENTION

Overview

The first session deals with the identification and understanding of emotions, the second one with the expression of emotions, and the third one with the regulation of emotions. The use of emotion is disseminated across the three sessions so that there is no specific session dedicated to it.

Each session is individual and the psychologist adapts examples to the participants' concerns or topics of interest. Moreover, the hand-outs are designed to enable participants to share the contents with their family and friends. Most of the contents described below is available in the hand-outs given to participants.

After each session, participants are encouraged to do the exercises for the next session, either alone or with family and friends. For the third and final session, exercises have to be done before the first follow-up (i.e. within two weeks).

First session: identification and understanding of emotions

General introduction

- An introduction to the whole intervention is given, explaining that there are 5 EC, which will be addressed successively over the three sessions with gradual difficulty. All the known benefits of EC (on health, relationships, work efficiency, stress management, etc...) are explained to create high expectations and motivate the participants.

- The objectives of the session are stated:
    - To understand the role of emotions
    - To be able to identify emotions
- A reflection on the definition and usefulness of emotions is then proposed.

Identification of emotions

- There are two prerequisites to identifying emotions: to know and to understand what an emotion is. A definition is given and the lifespan of an emotion is explained using a visual support: an emotion appears after it has been triggered; its intensity increases then decreases, and it finally disappears. The importance of emotions is explained: emotions give us information on what is going on to help us to adapt and react to a particular event. Then, an explanation is given about why it is important to identify emotions: this skill has beneficial effects in itself (e.g. improving health, improving well-being) and is the basis for the other ones. Once the participants have understood the usefulness of identifying emotions, we move forward. This part is important to motivate participants to engage in the intervention.
- Four keys for the identification of emotions are discussed and developed:
    - Body/face: what changes can you feel, observe in your body? Does your heart beat faster? Are you agitated?
    - Thoughts: what are you thinking? What are your thoughts right now?
    - Behaviors: are you smiling? Crying? Hiding?
    - Situation: what is the situation about? Good news, bad news?
- The five main emotions (joy, sadness, fear, disgust, anger) are presented using a visual support. For example, the behavior associated to joy may be smiling, the associated thought may be "*This is amazing!*", one of the body/face modifications may be an increased heart rate, and the associated situation may be good news. The participants are asked to choose a situation and to develop the associated keys and emotion(s). Being able to recognize and describe emotions is a skill that can be improved throughout life with a little practice.

Understanding of emotions

- Participants are asked the following question: in your opinion, what information is given by emotions? After discussion, we come to the conclusion that emotions inform us about our needs, whether met (i.e. pleasant emotions) or unmet (i.e unpleasant emotions), and therefore about the action(s) to take accordingly. The intensity of these emotions is directly related to the importance of the need.
- Basic human needs are explained: autonomy, competence, relatedness, security, stimulation, recognition, coherence (feeling that life is meaningful and purposeful). Participants are asked to choose the two or three most important needs for them and explain why they are so important. We then explain that needs are different for each participant, and the way to fulfill them may also change from one person to another.
- Triggers of emotions are then discussed. What triggers the emotion (for example, the inability to attend a long-planned gig because of cancer) is often the only thing we focus on, rather than identifying and addressing the unmet need, which is much more helpful to soothe the emotion.

Participants are asked to guess what unmet need underlies the emotion in the previous example and what could be done to fulfil this unmet need, instead of attending the gig.

- Finally, we talk about the fulfillment of human needs. There are several ways to fulfill a need, although some are more relevant than others. The means used to meet needs must follow six criteria: they have to be realistic, rewarding, controlled, mood-improving, and not be harmful to another need or someone else's need. We end this session by evoking the difficulty to meet every single need: all our needs may not be fulfilled because we may have conflicting needs or because our needs may be contrary to those of others, thus necessitating compromises. This part introduces the need to regulate our emotions when we have to delay the fulfillment of a need.
- A summary of the session is proposed and participants are invited to share what they think will be the most useful thing to remember for them, among what has been learnt in the session.

Hand-out for the 1st session: exercises to practice before the next session

Two exercises are proposed using 2 tables:

1. In Table 1, note the three most important needs for you among six basic needs and identify the means you use to meet these needs. Rate the level of satisfaction you experience from 0 to 10 (1 = not satisfied at all, totally unmet need, 10 = completely satisfied, fully met need). Consider other ways that could improve this satisfaction. Table 1 allows the participants to write their three needs, means, satisfaction and alternative means to meet each one of them.
2. Using Table 2, describe and analyze a situation in which you felt a strong emotion (positive or negative) by identifying the situation, the trigger, your thought(s), your body's reactions, behaviors and emotions. Still using this table, try to apply this exercise to a situation in which one of your loved ones felt a strong emotion (positive or negative). Here is an example: the situation is 'speaking in front of a group'. The trigger is this unwanted situation, the thought is '*They'll think I'm not as good as them'*, the body reactions are an increased heart rate, shaky hands and voice. Behaviors are nail-biting and hiding behind the laptop, and the emotion is fear.

Participants have to do these exercises (they can do them as many times as they want) and are encouraged to share the difficulties and positive experiences they encountered during the following session.

Second session: regulation of emotions

- The objective of the session is given: to learn how to regulate our emotions.
- We start this session by asking the participants if they have encountered any difficulties or positive experiences with the exercises from the previous session and if they wish to discuss it.

- To introduce the regulation of emotions, the participants have to tell the psychologist what emotion regulation means to them. The psychologist reminds the group that emotions are necessary, so regulation is not about making them disappear but rather about modulating the intensity, duration and expression of emotions. Two examples are given on the logbook.
    - Negative emotion: you have heard very sad news and you are crying. Somebody knocks on your door: you stop crying just for a couple of minutes. You open the door. You are still sad but you just modify the expression of it for a few minutes.
    - Positive emotion: you got a pay increase, you are happy and smiling. Your friend tells you he has been fired, you stop smiling. You are still happy about your raise but you don't express it in front of your friend.
- Participants are then asked to think about how they generally regulate their emotions: what do they usually do? Does it work well? In which conditions does it work? We then explain that there are many different regulation strategies, depending on emotion, situation and personal preferences. Several strategies are presented in three categories: capitalization, anticipation and reaction.
    1. *Capitalization* is about being aware of positive things that we tend to forget and to which we do not pay attention anymore: I'm able to have dinner with my husband every night and it makes me happy. The capitalization allows us to develop and maintain positive emotions, and thus be in a good mood.
    2. *Anticipation* is about how to avoid, in a healthy way, negative emotions or to create positive emotions: I know traffic will drive me crazy, so I anticipate and leave 20 minutes earlier to avoid traffic. I know that going for a walk in the forest will make me happy, so I decide to go more often.
    3. *Reaction* is about doing something when you already feel an emotion. The reaction can either be to change the situation when possible or to modulate the emotion:
        - Changing the situation: there is a flashing light in my office. It makes me angry, I change the light, I am not angry anymore.
        - Redirecting attention: there is some noise is my office. It makes me angry, so I listen to music in order not to pay attention to this noise, therefore I am not angry anymore. Redirecting attention can also be achieved by putting things into perspective and taking a step back: maybe we give too much importance to the problem, so it's time to focus on something else and move on.
        - Reappraisal: I broke my leg; I am stuck at home and frustrated because I can't do everything I used to. However, if I change my point of view, I realize that it gives me time to do things for which I don't usually have time, like reading or calling my friends.
        - Relaxing: I am stressed because I have to present my work to my boss, I do some breathing exercises to calm down and be able to present my work confidently.
- Some strategies are more appropriate than others. We summarize appropriate and non-appropriate strategies on a table, using the same categories as above. For example, appropriate anticipation is to avoid a specific situation, when and if it is possible. Non-appropriate anticipation is to avoid every single situation which could lead to a negative emotion.
- We conclude with motivational words to highlight that emotion regulation can take time, requires motivation and patience but has numerous benefits: better mental and physical health including less perceived stress and anxiety, better work performance, facilitated relationships (e.g. family, friends and colleagues), etc…

Hand-out for the 2nd session: exercises to practice before the next session

Three exercises are proposed:

1. Identify the strategies you use on a daily basis and assess their effectiveness on a scale of 1 to 10 (1 = not effective, 10 = very effective). From the overview strategies and available examples, identify a new strategy that you could use. A table and an example are available to help participants: the situation is 'I'm stuck in traffic', the associated emotion is anger, the strategy is listening to my favorite music. The efficiency of this strategy is 5. An alternative strategy I could use is to leave earlier to avoid traffic.
2. Identify a situation or an emotion that you have trouble managing on a daily basis. Choose a regulation strategy that could allow you to manage your emotion and put it into practice. How did it work?
3. Positive emotions are absolutely necessary to help the regulation of negative ones. Physical activity, doing things that you really like to do, expressing gratitude and achieving one's goals generate positive emotions. Choose one of these strategies according to your possibilities, write it down and do it in the coming week. Your choice must be realistic in order for you to actually do it and reap the benefits.

Third session: expression of emotions

- The objectives of the session are given: to learn how to express emotions in an appropriate way so that it is beneficial for both the person expressing and the person receiving and listening to the emotion expressed.

- We start this session by asking the participants if they have encountered any difficulties or positive experiences with the exercises from the previous session and if they need to discuss it.
- First, we explain that emotions are expressed through behaviors such as crying or laughing, but they can also be spoken and written. We state the benefits of expressing emotions instead of suppressing them: better mental and physical health, and better relationships with others. Suppression of emotions is associated with harmful body consequences. This is true for both pleasant and unpleasant emotions. When positive emotions are not expressed, their beneficial effect is almost lost. An example is given: people who cannot laugh or smile when watching a funny movie do not find it very funny compared to those who can smile or laugh.
- To whom can we express our emotions?
  - To ourselves: writing about a situation and its associated emotions is a good way to take a step back and regulate emotions. Moreover, it can be the first step to facilitate the expression of our emotions to someone else.
  - To somebody who is not involved in the situation: to feel valued, listened to, to receive advice, social support, concrete help, etc…
  - To the person who is responsible for the situation, in order to find a solution together.
- Telling about our emotions fosters communication; to optimize communication, we give four keys:
  - Describe what triggers the emotions, without any judgment. Use facts and precise events instead of generalizations and overstatements.
  - Express your emotion, sticking to the emotions you know rather than giving an interpretation. A table of adjectives, which describe interpretations rather than emotions, is given to participants (e.g. I feel betrayed, attacked, ignored, manipulated, etc…).
  - Express the unmet need that underlies your emotion.

- Propose solutions that meet both your needs and those of the other person. This means that you have to take time to understand and consider the needs of the other person too. Compromises may be helpful if they satisfy both parties. Say what positive emotions you would experience if the proposed solution was retained.

- This might seem easy in theory but it is difficult to apply correctly in practice. This is why four conditions are also required to succeed communicating this way: both parties have to be available and have time to talk; they have to be calm, sober and not too tired. If the discussion becomes tense (loud voices, aggressiveness), stop it and wait until you have calmed down.

Hand-out for the 3rd session: exercises to practice during the following days

1. In this list, find the sentences that seem to be a suitable expression of your emotions:

- It's your fault if I'm angry! [blame of others, inappropriate]
- I blame myself for not being able to come to sport with you because of my stomach ache [self-blame, inappropriate]
- You are selfish! [blame]
- I have a feeling that you are mad at me right now because you've contradicted me twice in a row, it makes me sad, please tell me what's going on? [ok, it might help to start a constructive talk]
- You don't understand what I'm going through [it's not an emotion, it's an interpretation]
- You never stop making noise, it tires me out [never = blame and exaggeration, inappropriate]
- I feel misunderstood [interpretation]

2. Identify situations that generate negative emotions and develop these situations in a suitable communication format. Talk to the person related to your emotions. Tables are proposed to help (situation, fact, emotion, need, solution).

3. Wait for a situation in which you will be annoyed by the behavior of someone close to you or not (e.g. a clerk). Try to understand the situation from the point of view of the other person, then to express your emotions calmly and tell how better you would feel if the person could help you in the desired way. See how the situation evolves after that.

CONTROL GROUP - CONTENTS OF INTERVENTION

In the control group, the three sessions are quite similar: first, participants are invited to share their current or past experience of cancer during a short free talk, then a brief introduction is given regarding the kind of relaxation the session is about. Finally, relaxation is practiced. The exercises practiced are the same as the ones participants will have to practice on their own in between sessions.

Material given to participants

A logbook is given to participants before the first session to help them remember each session and the exercises to do. Each session is individual. The logbook is also designed to enable participants to share the contents with their family and friends. Most of the contents described below is available in the hand-out given to participants.

At the end of each session, participants have to do exercises for the following session. For the third and final session, exercises have to be done before the follow-up session (i.e. within two weeks).

The psychologist informs the participants that some exercises may be more or less comfortable to perform. They are encouraged to practice only the exercises they feel comfortable with. Participants have to evaluate their relaxation state before and after each exercise on a scale of 1 to 10 (1= completely relaxed, 10= very tense / not relaxed at all).

First session: relaxation and breathing

General introduction

- An introduction to the whole intervention is given, starting with the definition of relaxation: relaxation is a state of decreased alertness, decreased heart rate, respiratory rate, and blood pressure associated with a feeling of well-being. People are relaxed when they present the following characteristics:
    - Regular breathing
    - A normal pulse
    - Relaxed members
    - Sagging eyelids
    - A deep sense of well-being
- This state is supposed to counteract stress and anxiety.
- The psychologist explains that relaxation achieves a state of rest and well-being and that there are many relaxation techniques: yoga, mindfulness, meditation, breathing exercises (session 1), muscle relaxation (session 2), relaxation by visualization (session 3), etc…
- To create high expectations and motivate participants, we list the short-term and long-term benefits of relaxation (feeling better and relaxed during exercise, understanding events more calmly, reducing pain, improving the quality of life, improving the quality of sleep, reducing anxiety, etc...)
- To encourage participants, we propose exercises which are easy to perform, even for those who have never practiced relaxation.

Relaxation and breathing

- The first session is about breathing exercises because they have a major advantage: they are easy to do wherever and whenever the participants wish:
    - In their bed, as they wake up to start the day serenely
    - In their shower or bath, to fully enjoy the moment
    - In transport, to manage the stress of delays for example
    - In waiting rooms, to anticipate a stressful meeting
    - At the office, to refocus
    - Before sleeping, to fall asleep easily and improve sleep quality
- We insist that performing these exercises a few minutes a day is an easy habit to take and can improve your quality of life in several ways.

Breathing exercises

Three exercises are practiced:

1- Lie on your back (you can fold your legs up if it's more comfortable). Put one hand on your chest, the other one on your stomach, and breathe naturally, without exercising any control. Just feel the air coming in and out. Observe what's going on in your chest and belly. Is your chest moving under your hand, is it your belly, or both?

2- Two positions are possible:
    - In a standing position: back straight, feet shoulder-width apart, knees slightly bent. Distribute the weight of the body evenly on your two legs.
    - Lying down: feet shoulder-width apart, arms alongside the body.
      Your whole body should be completely relaxed.
    - Inhale calmly through your nose. Observe the passage of this warm breath over the nose to the rib cage and the abdomen.
    - Exhale slowly and consciously through your mouth. Repeat several times.
    - Gradually lengthen both inhalation and exhalation.

3- Sitting on a chair, back straight, put your feet flat on the ground. Your legs should not be crossed, your hands on your thighs. Close your eyes, take a deep breath, and block the air in your lungs. Put your hands on your chest and imagine your lungs like a big, bright balloon. Exhale slowly, visualizing the balloon deflating. Then imagine the balloon expanding again as you inhale. Inflate and deflate this balloon several times, focusing on your sensations, until you feel relaxed.

Exercise to practice before the next session

- Participants have to reproduce the same breathing exercises.

Second session: Jacobson relaxation

- The principle of Jacobson relaxation is explained to participants: Jacobson hypothesizes that muscle tension, our thoughts and emotions are linked: when you are stressed, your body tends to tense up. It also works the other way round; by reducing muscle tension, one can induce muscle relaxation and therefore mental relaxation, in other words, reduce stress. This technique is based on muscle contraction and relaxation.

Jacobson relaxation

- Find a comfortable position:
    - Sitting down, put your hands flat on your thighs.
    - Lying down, put your arms alongside your body.
- Close your hands tightly for 10 seconds, then relax gradually, focusing on relaxing your muscles.
- Lift your shoulders as high as possible, reaching for your ears. Hold for 5 seconds and then gradually release. Repeat 5 times.
- Hold your chin at the level of your torso for a few seconds before relaxing.
- Open your mouth and stick your tongue out as far as possible for 10 seconds, then release. Then, press your tongue against your palate for a few seconds, before relaxing again.
- Press your shoulders against the backrest or the ground and tilt your body slightly forward, so that your back is slightly arched. Hold for 10 seconds, then release.
- Stretch your toes to the maximum, as if you wanted to put yourself on tiptoe. Hold for 10 seconds, then relax and focus on your relaxed state.

Exercises to practice before the next session

1- Jacobson relaxation practiced during the session.
2- On a daily basis, take some time to identify the muscle tensions that you feel. This is an exercise that you can do any time of the day, very quickly and in many situations: in public transport, when you line up at the supermarket, during your shower, etc...

Start from your feet and gradually go back up:

- Your feet touch the ground, are they really relaxed?
- Are your legs relaxed?
- What about your arms?
- Is your back resting on the back of your chair? Is it relaxed?
- Is your neck relaxed?

Then, try to release muscle tensions.

Third session: visualization and relaxation

Relaxation by the seaside

1. Lie down in a place where you won't be disturbed for the next few minutes. Extend your arms along your body and, adopting the position of the starfish, take all the room you need to feel comfortable.

2. Become aware of the areas where your body is pressing on the floor: your head, shoulders and upper back, arms, pelvis and buttocks, the back of your legs and finally your heels. Feel how your body is being subjected to gravity, attracted to the floor.

3. Then focus your attention on your breathing, without forcing it, just observing. Note that your abdomen rises slowly on inhalation and falls down gently on exhalation. Note the pauses between each breath, like silences of the body. Then let yourself go a few moments to this calm, slow movement.

4. Imagine that you are lying on a beach, right on the edge of the water. Above you, the sky is vast and blue and the sun warms you up nicely. The temperature is mild and a warm wind is blowing softly. You can feel the cool, wet sand beneath you, digging itself out to welcome your body. Enjoy this moment of relaxation.

5. As you listen to the waves, you realize that they come and go in rhythm with your peaceful breathing.

6. You can feel yourself floating on the surface of the water. The sun shines on you as the serene and cool sea rocks you gently. You can stay there for as long as you like, you'll never be far from the shore.

7. Whenever you feel ready, one last wave brings you back to the shore and gently drops you on the sand at your starting position. Taking a deep breath, you can anchor in yourself all the pleasant sensations you have just lived, to take them with you.

8. Finally, focus your attention on your fingertips and the tips of your feet: move them very slowly, then let the movement gently spread to your limbs, then to your whole body. Run your hands over your face, your ears and your neck. Whenever you're ready, open your eyes and put a smile on yourself and on the world.

Exercises to practice in the following days

1- Relaxation by the seaside practiced during the session
2- Identify a place where you feel relaxed, safe and where you enjoy spending time. It can be your vacation spot, your childhood garden, a park you visited abroad, a museum, etc... When you feel stressed or overwhelmed, close your eyes for 2 minutes and imagine yourself in this place. Look around, focus on your body and your breathing. When you are in this place, you are relaxed, your breathing is calm and regular. Your worries disappear, you find peace of mind.

Item 5. Who: for each category of intervention provider (for example, psychologist or nursing assistant), describe their expertise, background or any specific training.

The psychologist holds a master's degree in health psychology and has clinical and research experience in oncology. For this intervention, she was trained by a senior lecturer in health psychology with a solid clinical and research experience in oncology.

Item 6. How: describe the delivery mode (such as face-to-face or any other mode, such as internet or the telephone) of the intervention, and whether it was provided individually or in a group.

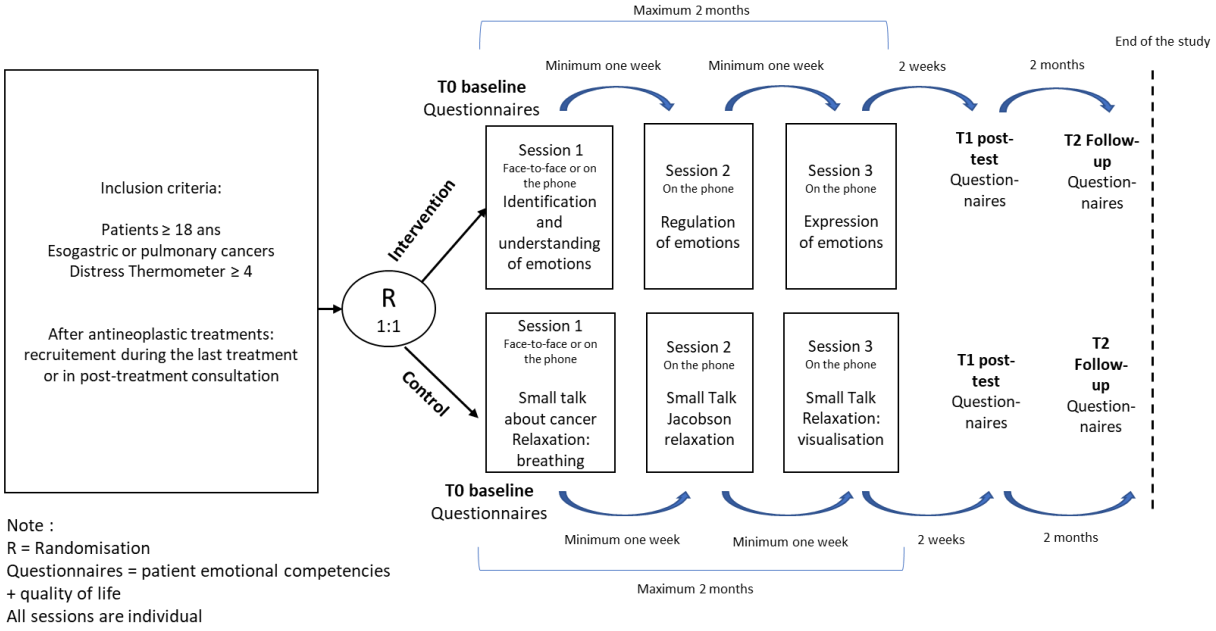
All sessions are individual sessions. The first individual session preferably takes place face-to-face in the participating center where the patient has been included. However, if the patient is unable to come to his or her referral center for this first session, it may be held over the telephone. The 2nd and 3rd sessions take place over the telephone.

Item 7. Where: describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.

When the first session takes place face-to-face, it is held in the hospital where the patient is being treated for cancer, i.e. one of the four hospitals of Northern France involved in the RCT: the teaching hospital of Lille, the hospital of Boulogne-sur-Mer, the hospital of Calais or the Andrée Dutreix Cancer Center. At the teaching hospital of Lille, the first session is organized in the Patient Education Department of the Hospital. The department, although on the hospital site, is in a separate building which is not medicalized and decorated in a welcoming way.

Item 8. When and how much: describe the number of times the intervention was delivered and over what period of time, including the number of sessions, their schedule, their duration and intensity.

Each arm (intervention and control) is composed of three sessions (see Figure below). Each session is supposed to last around 90 minutes, depending on the participant. Sessions are to be held 15 days apart on average (minimum 7 days, maximum 21 days). The three sessions need to be held within a maximum of 2 months.



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Item 9. Tailoring: if the intervention is planned to be personalized, titrated or adapted, then describe why, when, and how.

Each session is individual and the psychologist will adapt examples to the participant's difficulties if needed. Moreover, the hand-out is also written to enable participants to share the contents with their family and friends. The psychologist will also adapt her vocabulary. Moreover, each session starts with a free-speaking time for the participant to express his/her difficulties regarding the previous session, the exercises or other difficulties in life.

Item 10. Modifications: if the intervention is modified during the course of the study, describe the changes (what, why, when, and how)

See Supplementary File 1 (Table S1)

Item 11. How well (planned): if intervention adherence or fidelity is assessed, describe how and by whom. If any strategies are used to maintain or improve fidelity, describe them.

To improve patient adherence, the intervention is delivered by phone; the psychologist makes an appointment with the participant at the end of each session for the following one. All the known benefits of EC or relaxation are explained several times to create high expectations and motivate the participants. Participants' adherence will be assessed according to two criteria:

1- They have to follow the three sessions and complete the follow-up.
2- They have to practice the exercises in between sessions.

Regarding fidelity, only one psychologist is in charge of all three sessions and she uses a detailed guideline to check that fidelity is respected, or to note what was is not delivered as intended and why. The guideline is available upon request (in French).

Item 12: How well (actual): if intervention adherence or fidelity is assessed, describe the extent to which the intervention was delivered as planned.Not applicable: the intervention is still in progress