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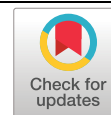
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ARTICLE

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 clés 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](https://www.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 Santély. 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

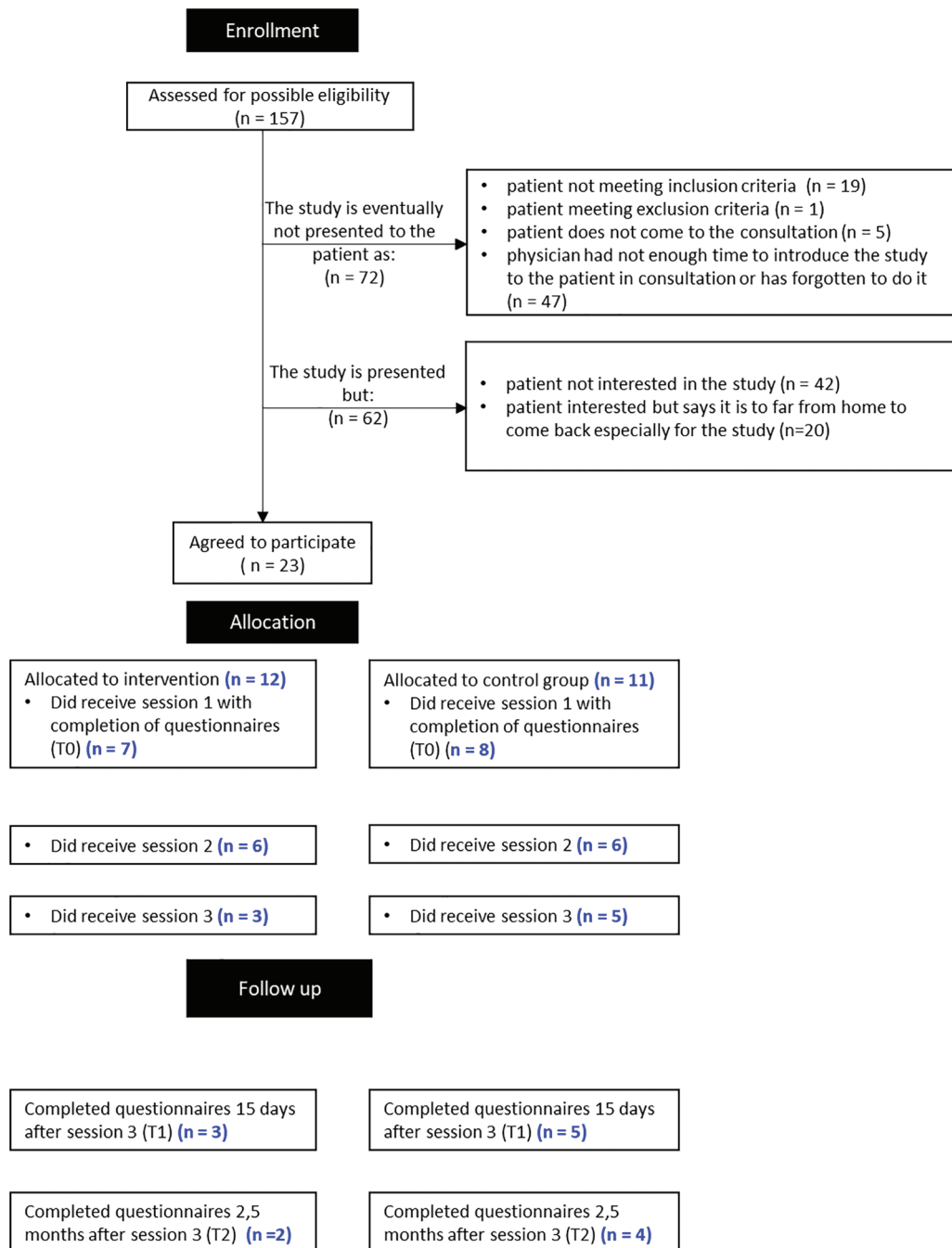


FIGURE 1. Flow chart of EmoVie-K1.

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 1 st session (days)		90 [18–185]
Time from the 1 st to the 2 nd session (days)		10 [6–35]
Time from the 2 nd to the 3 rd 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

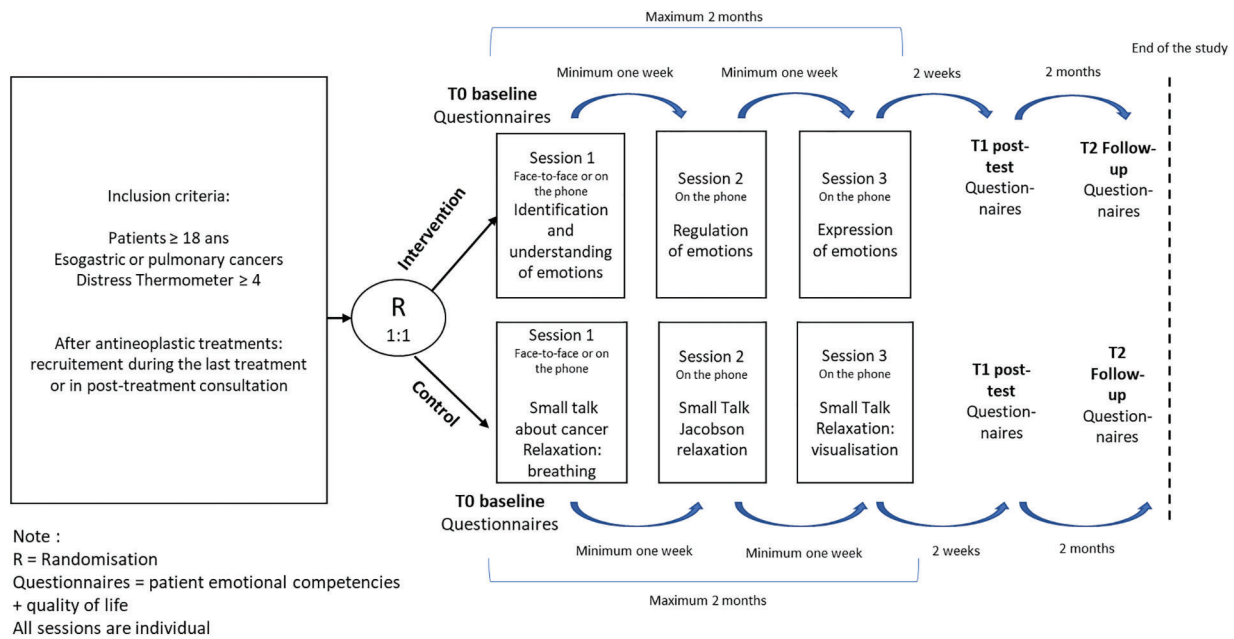


FIGURE 2. Design of EmoVie-K2.

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 extent 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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Contributions des auteurs/Author Contributions: The authors confirm contribution to the paper as follows: study conception and design: Sophie Lelorain, Christelle Duprez,

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 éthiques/Ethics Approval: The protocol was registered on [ClinicalTrials.gov](https://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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