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Coping with checkpoint inhibitor adverse events: Assisting cancer patients in skills development - insights from the Immuno'Act© pre-experimental pilot study

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ABSTRACT

Objectives: Immune checkpoint inhibitors (ICIs) can lead to immune-related adverse events (irAEs), which can be severe if not promptly identified and managed. The therapeutic education tool Immuno'Act© has been created to teach cancer patients how to handle irAEs. This study aimed to assess: (1) the preliminary effects of the therapeutic patient education (TPE) session using Immuno'Act© on perceived self-efficacy (PSE), (2) the association between PSE and patients' decision-making to cope with health events, and (3) patients' acceptance of the tool.
Methods: This pre-experimental study included cancer patients treated with ICIs at the CHU of Liège, recruited by convenience. PSE was measured using an adapted self-administered questionnaire at least three weeks before the TPE session (T0), immediately afterwards (T1) and at least three weeks after T1 (T2). Decision-making was evaluated through patients' action choices in real-life scenarios presented in Immuno'Act©. Acceptance was assessed with brief scales covering perceived utility, ease of use, aesthetic aspects and overall judgment. Sociodemographic and clinical data were collected. Adjusted general linear mixed model evaluated PSE over time; adjusted linear and logistic regression models assessed associations with PSE changes and decision-making. Descriptive statistics summarised acceptance.
Results: Eighty patients participated. The PSE total score remained high throughout the study, with no effect from a single use of Immuno'Act© ($p = 0.91$). Up to 25 % of patients never chose the recommended action in coping with urgent and non-urgent irAEs. No association was observed between global PSE level and decision-making. Acceptance was rated positively by over 95 % of participants, with an overall judgment of $8.61 \pm 0.96/10$.
Conclusion: The positive acceptance of Immuno'Act©, combined with concerning findings, underscores the need to integrate such tools into clinical practice to support patients in managing irAEs.
Practice implications: Healthcare professionals should integrate tools like Immuno'Act© in routine care, with optimal implementation strategy to be determined.

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1. Introduction

Immunotherapy using Immune Checkpoint Inhibitors (ICIs) has revolutionised the prognosis of various cancers by improving overall survival in subsets of patients. The mechanism of action of ICIs is to reinforce antitumor immune responses by targeting the pathways cancer cells use to evade immune surveillance [1–3]. This innovative approach is associated with specific side effects called immune-related adverse events (irAEs), which manifest as autoimmune toxic effects [2,4]. All organ systems may be affected by irAEs including the dermatologic, gastrointestinal, hepatic, pulmonary, endocrine, and cardiovascular system [1,2]. While these effects are most common during the first 3 months of treatment, they can also occur several months after the end of the therapy. Although most irAEs are low-grade, they can also be life-threatening [1,5]. Their early detection and prompt treatment with immunosuppressors are crucial to prevent their progression to higher toxicity grades. In cases where irAEs occur during ICIs treatment, swift intervention can also limit the risk of permanent discontinuation [2,5,6].

Ideally, patients should promptly recognise the initial signs of irAEs and report them accurately. Therefore, patient education becomes paramount, as it enables patients to acquire the required knowledge and skills to respond adequately and timely to (potential) irAEs [6–8]. Self-efficacy is one of the possible mechanisms through which self-management induces behavioural changes [9]. Perceived self-efficacy (PSE) is defined as *people's belief in their capabilities to perform in ways that give them control over events that affect their lives* and is foundational to any decision to act [10,11].

Discrepancies can be observed between the level of PSE to manage symptoms and the effective ability to manage them [11]. Due to insufficient or faulty knowledge, the initial level of PSE can be either over- or underestimated [11]. Misinformation is prejudicial, particularly in conjunction with overconfidence as it could lead patients to make deleterious decisions for their health [12,13]. Because the benefits of patient empowerment through therapeutic education may be negated by the persistence of ill-informed confidence [13], it is important to study the association between PSE and its influence on decision-making to cope with irAEs.

In the oncology field, several coaching and educational interventions to manage symptoms have been shown to be feasible and effective in increasing PSE for symptom relief [8]. Building on these promising results, an educational tool named "Immuno'Act©" has been created to specifically assist cancer patients in managing irAEs and to serve as a supplementary resource to the information provided by the medical staff. Developed using the Barrows cards method, also known as "Portable Patient Problem Pack (P4)", it integrates problem-based learning theory, decision-making skills and critical thinking [14,15]. The Immuno'Act© can be considered a guided mastery experience, a major way of developing sense of efficacy [10], and verbal persuasion achieved through positive feedback provided by health professionals during a therapeutic patient education (TPE) session, providing another way to strengthen people's beliefs in their efficacy [10].

The primary objective of our study was to assess the preliminary effects of a TPE session using Immuno'Act© on PSE. Secondary objectives were to explore the association between PSE and decision-making to cope with health events in the context of immuno-oncotherapy and to evaluate patients' acceptance of the Immuno'Act©.

2. Methods

2.1. Study design, population and sample size

This pre-experimental pilot study (one-group pretest-posttest design) included cancer patients starting a new cycle of ICIs at the University Hospital of Liège between October 2022 and August 2023. Participants were recruited using a convenience sampling method. Eligibility criteria comprised adults aged 18 or older, fluency in French, ability to answer questionnaires and participate in a TPE session and having signed an informed consent form. The exclusion criterion was previous use of Immuno'Act©.

This study was implemented within patients' care pathway and consisted of three measurements points. T0 (baseline) was conducted during the next programmed ICIs administration following the first administration and at least three weeks before the TPE session using Immuno'Act©. At this point, patients had already received information about irAEs from their oncologist, nurses, and hospital leaflet, and could also seek additional information from external sources such as the internet. T1 was conducted immediately after the TPE session, and T2 took place at least three weeks after T1, with exact timing depending on the treatment schedule (Supplementary Figure 1).

To assess the preliminary effects of a TPE session using Immuno'Act© on PSE level, a power calculation for analysis of variance (ANOVA) was executed with one group, three measurements, a power of 0.80, an α of 0.05, a small effect size of η^2partial = 0.025 [16] and a correlation between repeated measures of 0.60 (indicating the relationship between repeated measures in a within-subjects design). The sample size was estimated at 52 participants. Power analysis was performed with G*Power 3.1.9.7.

The study was approved by the Ethics Committee of the University Hospital of Liège, Belgium (2022/171).

2.2. Education intervention with Immuno'Act©

The Immuno'Act© educational tool has been created to teach cancer patients treated with ICIs how to manage irAEs. This tool addresses an educational need identified by patients, caregivers and healthcare providers [17]. Developed in collaboration with IPCEM (https://ipcem.org/), the content of the tool and its delivery modalities were defined by oncologists and TPE specialists to ensure clinical accuracy and relevance. The TPE session was delivered individually and could include a caregiver, with session length not predefined and depending on each patient's needs.

The Immuno'Act© comprises nine cards, each presenting a health event that the ICI-treated cancer patient might encounter. Three cards depict a high-grade irAE requiring urgent medical attention: pneumonitis, hepatitis, and myocarditis. Three other cards relate to a low-grade irAE requiring non-urgent medical attention: skin toxicity, colitis, and fatigue. Two cards present health events not related to irAEs: diarrhea due to food poisoning and muscular pain following physical exercise. In the last card, the patient meets a new healthcare provider for the first time and has to communicate about his treatment.

During the session, the patient was asked to choose one card in each category of health events, the last card being used with all patients. Then, the patient had to choose one or several actions presented on the card or suggest another action to cope with the adverse health event described. Subsequently, the patient and the healthcare provider trained to use the tool, engaged in discussion about the reasons for each chosen action and their consequences. This collaborative approach aims to make patients reflect on the outcomes of their actions rather than providing immediate judgments of right or wrong choices. Positive feedback and teach-back method were employed by the healthcare provider during TPE to enhance understanding and retention. At the end of the session, the patient received an irAEs management summary.

2.3. Study parameters

Sociodemographic (age, gender, professional status, educational and literacy levels) and clinical data (cancer type, prior use of ICIs and history of irAEs) were collected. Literacy was assessed using the Single Item Literacy Screener (SILS) [18], with participants reporting how often they need help reading health materials, classified as adequate (never), marginal (rarely), or inadequate (sometimes, often, or always).

The level of PSE was measured by the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer) [19]. Assessments of PSE were conducted at baseline (T0), directly after the TPE session using Immuno'Act© (T1) and at least 3 weeks later (T2), depending on the treatment schedule. This English validated tool, translated into French, comprises 12 items covering three domains: maintaining a positive attitude, understanding and participating in care and seeking and obtaining information. Items are rated on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). The theoretical score of the CASE-cancer ranges from 12 to 48, with higher scores indicating higher PSE. To assess PSE to cope with irAEs, six items were added and rated in the same way (coping self-efficacy in the context of irAEs (CSE-irAEs) Score range: 6–24). No psychometric validation has yet been conducted for this added subscale. Reported scores included overall (Total Score range: 18–72), CASE-cancer and CSE-irAEs.

Decision-making was assessed during the TPE session. For each Immuno'Act© card, the action(s) selected by the patient were recorded on a grid. Three categories of patients were defined based on their choice (s) of action: patients who directly chose or proposed the recommended action to cope with the health event, those who eventually opted for the recommended action or proposed an accepted action, and those who never managed to choose the recommended action.

After using Immuno'Act© (T1), patients were asked whether they had previously received or consulted information about irAEs, to document their prior exposure to information.

A self-administered questionnaire was designed to assess tool acceptance, defined *as a posteriori pragmatic evaluation, implying that a real activity was required from the user prior to acceptance* [20]. The questionnaire was completed after using Immuno'Act© (T1) and included five items on perceived utility, ease of use, ease-to-understand vocabulary and instructions, and illustrations adequacy (four response options, dichotomised for analysis), three items on aesthetics, robustness and overall judgment (10-point scale), and one item on session length (too short, appropriate, too long). At T2, patients completed one item evaluating the usefulness of the irAEs management summary (four response options, dichotomised for analysis).

2.4. Statistical analyses

Results were expressed as mean ± standard deviation (SD) for normally distributed quantitative variables and as median and interquartile range (IQR) (P25–P75) for skewed variables. Frequencies summarised qualitative variables.

The general linear mixed model (GLMM) examined the evolution of PSE scores over time and according to sociodemographic characteristics, clinical profiles and informed status. PSE scores were represented at each time point in boxplots (median and quartiles) with mean and standard error.

For decision-making in each health situation, logistic regression assessed the chance of directly choosing the recommended action to cope with the health event based on sociodemographic, clinical characteristics and informed status. All analyses were adjusted for the card selected by patient (except for the last card that was used in all patients). Logistic regressions were performed to study the association between decision-making and PSE scores at T0, with results reported as odds ratios (OR) and 95 % confidence intervals (95 % CI).

To examine the association between PSE scores at T1 and T2, as well as their differences from scores at T0, and decision-making for each health situation, linear regression was applied. All analyses were adjusted for the chosen card (except for the last card used in all patients). Results were reported with parameter estimates (β), standard errors (SE) and p-values.

Statistical calculations were conducted on the maximum number of available data. Missing values were neither replaced nor imputed. Results were considered significant at the 5 % critical level ($p < 0.05$). Statistical analyses were performed using SAS version 9.4 (SAS Institute, NC, USA) and the figures were created using R version 4.2.2.

3. Results

3.1. Recruitment and participation rates

One hundred and forty patients were identified to participate in the study (Fig. 1). Among them, 110 patients were eligible and 99 patients consented to participate (T0). The attrition rates at T1 and T2 were 13.1 % and 19.2 %, respectively, leaving 80 patients to reach the T2 evaluation. Only one patient stopped his participation in the study due to fatigue. The other reasons for loss of follow-up were interruption of the ICI because of a palliative care transition (n = 7), a severe irAE (n = 5), a surgery (n = 2) and death (n = 4).

The median time elapsed between the first ICI administration and the first measurement (T0) and respectively between T0 and T1, and T1 and T2 was 3 weeks (P25-P75: 3–4).

3.2. Study subjects

The sociodemographic and clinical data of the study population are described in Table 1. The mean age of the study population was 66.4 ± 11.3 years. Slightly more than half of the study sample were men (61.3 %). Twenty-four (30.0 %) patients had a high level of education including doctorate, master's and bachelor's degrees. Adequate literacy level was observed in one person out of two (51.9 %). The majority of patients (82.5 %) were not professionally active, being either retired or unemployed. Regarding clinical profile, lung cancer was the predominant type of cancer (53.8 %). Most patients had a metastatic cancer (65.0 %) and received another treatment with the ICI (61.3 %), mainly chemotherapy (69.4 %). A small number of patients had received an ICI in the past (6.30 %) and eight patients (10.3 %) had experienced irAE(s) before using Immuno'Act©.

Ten patients (13.5 %) declared that they had not received any information concerning irAEs prior to their participation in this study.

3.3. Evolution of perceived self-efficacy scores

As showed in Fig. 2, there was no significant change in PSE scores over time. PSE scores remained high throughout the study, with medians of PSE Total Scores of 62, 61 and 61 out of 72 at T0, T1 and T2, respectively. No association was detected between PSE scores over time and sociodemographic characteristics, clinical features and informed status (Supplementary Tables 1–3). Trends were observed for higher "CSE-irAEs" Score in women ($p = 0.060$), previous use of ICIs ($p = 0.098$) and history of irAE(s) before the use of Immuno'Act© ($p = 0.068$) (Supplementary Table 2). A trend was also noted for PSE Total Score and the history of irAE(s) before the use of Immuno'Act© ($p = 0.095$) (Supplementary Table 3).

3.4. Decision-making to cope with a health event

The results related to decision-making for coping with a health event are presented in Table 2. Five patients (6.20 %) selected the direct recommended action to cope with a high-grade irAE requiring urgent medical attention. One person in five (20.0 %) did not apply any recommended action, as shown in Table 2. In cases of myocarditis, the probability of choosing directly the recommended action was higher compared to the pneumonitis (OR=6.56, IC95 %: 1.07–40.2), while no significant difference was observed among the other cards requiring urgent medical attention for irAEs.

Regarding low-grade irAES, fewer than half of the patients chose the recommended action directly and one in four patients did not apply any recommended action. The probability of choosing directly the recommended action was lower for colitis (OR=0.22; 95 % CI: 0.05–0.88) and for fatigue (OR=0.13; 95 % CI: 0.04–0.47) compared to skin toxicity.

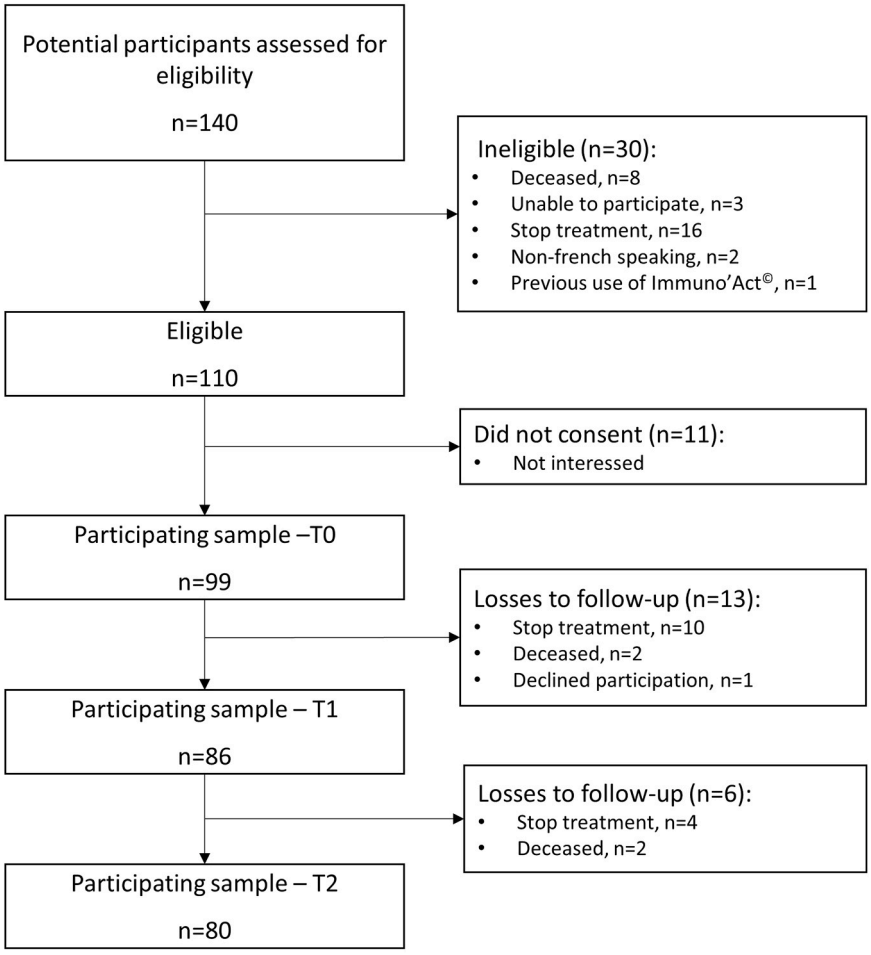

Fig. 1. Flowchart of the study recruitment and loss of follow-up.

However, there was no significant difference between colitis and fatigue.

For other health situations, more than half of the patients (65.0 %) directly chose the recommended action to cope with the health event and this was similar between the two cards (OR=1.82; 95 % CI: 0.72–4.60).

Previous history of irAEs before using the Immuno'Act© was strongly associated with the direct choice of the recommended action in irAEs requiring urgent medical management (OR[a] =15.4, 95 % CI: 1.96–121) (Supplementary Table 4). In other health situations, access to information before using the Immuno'Act© increased the probability of directly choosing the recommended action, although not significantly ($p = 0.094$). More women than men communicated about their ICI treatment, although without statistical difference ($p = 0.099$) (Supplementary Table 4).

3.5. Association between decision-making to cope with health events and PSE scores at T0

No association was observed between decision-making in any health situation and the various PSE scores. Directly choosing the recommended action tended to be more frequent with higher CSE-irAEs Scores ($p = 0.056$) (Supplementary Table 5).

3.6. Influence of decision-making to cope with a health event on PSE scores at T1 and T2

The various PSE scores at T1 and T2, as well as their differences from T0, showed no significant association with decision-making except for two observations. Firstly, when patients needed to cope with a low-grade irAE, the CSE-irAEs Score decreased between T0 and T2 for those who directly chose the recommended action ($p = 0.0078$). Secondly, the difference between T2 and T0 for the Total Score was greater for patients who directly opted for the recommended action in other health situations ($p = 0.040$). A trend at T1 for the CSE-irAEs Score also indicated a potential association, with scores tending to be higher when patients directly chose the recommended action in low-grade irAEs compared to those who did not ($p = 0.087$) (Table 3).

3.7. Acceptance of the Immuno'Act© tool

The majority of participants (>95 %) perceived the utility, ease of use, ease-to-understand vocabulary and instructions of the Immuno'Act©. Ninety-five percent found the length of use appropriate and 98.8 % considered the illustrations well suited. Participants rated the aesthetics of the tool at 8.43 ± 1.00 out of 10 and its robustness at 8.50 ± 0.97 out of 10. The overall judgment of Immuno'Act© was 8.61 ± 0.96 out of 10. Additionally, 85.0 % of the study sample perceived the utility of the summary sheet. Detailed results are presented in Table 4. The median duration of Immuno'Act© usage observed during a TPE session was 20 min (IQR: 16.0–25.0).

Table 1
Sociodemographic, clinical characteristics and informed status of the sample (n = 80).

Age (years), mean± SD	66.4 ± 11.3
Gender, n (%)	
Male	49 (61.3)
Female	31 (38.8)
Educational level, n (%)	
Less than upper high school diploma	35 (43.8)
Upper high school diploma	21 (26.3)
Higher education	24 (30.0)
Professional status, n (%)	
Still working	14 (17.5)
Unemployed/Retired	66 (82.5)
Literacy level, n (%)	
Adequate	41 (51.9)
Marginal	21 (26.6)
Inadequate	17 (21.5)
Cancer classification, n (%)	
Gynaecologic	2 (2.50)
Digestive	9 (11.3)
Skin	4 (5.00)
Lung	43 (53.8)
Urological	15 (18.8)
Breast	3 (3.80)
Head and neck	3 (3.80)
Unknown primary	1 (1.30)
Metastatic cancer, n (%)	52 (65.0)
Treatment(s) associated with immunotherapy, n (%)	
Chemotherapy	34 (69.4)
Targeted therapy	5 (10.2)
Radiotherapy	2 (4.10)
Surgery	2 (4.10)
Chemotherapy + Hormonotherapy	1 (2.00)
Chemotherapy + Targeted therapy	2 (4.10)
Chemotherapy + Surgery	1 (2.00)
Chemotherapy + Study protocol	1 (2.00)
Radiotherapy + Surgery	1 (2.00)
Prior immunotherapy, n (%)	5 (6.30)
History of irAE(s) before used of Immuno'Act©, n (%)	8 (10.3)
Information received and/or consulted about irAEs before assessment of decision-making, n (%)	70 (87.5)

4. Discussion and conclusion

4.1. Discussion

Considering our results, patients showed high PSE throughout the follow-up, although up to 25 % never chose the recommended action in coping with urgent and non-urgent irAEs. Immuno'Act© appeared to be positively accepted by patients.

The use of Immuno'Act© did not seem to influence PSE levels, which remained stable over time. This observation could be attributed to the single use of Immuno'Act© [21]. Previous intervention studies reporting increases in PSE generally relied on repeated and more intensive nursing interventions designed to support symptom self-management [22–26]. Other intervention studies have shown either trends toward improvement of PSE [27] or no effect on PSE levels [28]. This variability illustrates the difficulty of comparing interventions that differ widely in format, frequency, intensity and clinical context (such as chemotherapy or post-surgery care), as well as the multitude of scales used to assess PSE.

Surprisingly, despite high PSE scores, most patients did not directly choose the recommended actions to cope with an irAE, particularly in situations requiring urgent medical attention. The only factor associated with the probability of choosing the recommended action was previous experience of irAEs. This result suggests that experience sharing could enhance the awareness of the importance for some irAEs and raises questions about the use of Immuno'Act© in a group session. Vicarious experience, another way to strengthen people's beliefs in their self-efficacy by observing similar individuals successfully completing a task [10], adds further consideration to its usage in a group setting. In non-urgent situations, less than half of patients directly chose the recommended action. These observations are alarming because, in urgent situations, patients' lives are at risk, and in non-urgent situations, symptoms could worsen, potentially leading to higher levels of toxicity or death. The danger could be aggravated by the fact that patients tend to overestimate their ability to cope with an irAE. As specified by Dunning et al. [29], self-assessment is an inherently difficult task. There is typically a modest association between self-perception and actual behaviour, with individuals often overestimating their abilities, expertise and prospects, leading to excessive optimism and overconfidence [29]. According to Kruger and Dunning [12], the tendency of unskilled individuals to overestimate themselves not only leads them to draw incorrect conclusions and make unfortunate choices but also impedes their metacognitive ability to recognise their own shortcomings. In that sense, they observed that improving the skills of individuals helped them to recognise the limitations of their abilities to self-assess [12].

One of the reasons for this incorrect judgement is the emotional load of situations, that is frequently underestimated by individuals, leading to mispredictions of their preferences when faced to a medical decision [29]. This is particularly true for patients [30]. Furthermore, individuals may exhibit confidence in self-diagnosis when facing symptoms, relying on common-sense health theories that they endorse with unwarranted assurance. While these theories may appear compelling to them, they are often wrong and potentially harmful if misplaced confidence guides their actions [29].

Several psychological mechanisms contribute to flawed self-assessments, falling into two general classes. Firstly, inaccurate self-assessments occur because individuals frequently lack the necessary information for accurate evaluations and may not consider the gaps in their knowledge. Secondly, these assessments may be flawed because individuals neglect relevant and useful information that is within their grasp [29].

The misconception that information from expert sources alone can drive behaviour change is prevalent. Based on traditional medical models of the doctor-patient relationship, many healthcare providers assume that conveying expertise means transmitting information. This model suggests that informing individuals about the negative consequences of their behaviour will prompt them to change. However, the foundational belief that information and knowledge alone determine behaviour is incorrect, as various life factors often hinder compliance with recommended practices [31]. The transition from processing information to implementing health behaviour poses a significant challenge, especially for those with limited resources, such as people with low literacy levels [32].

Therefore, a thoughtful approach is needed, incorporating an understanding of patients' motivations and the external pressures influencing them [31], with education emerging as a pivotal component [32]. Patient education is an interactive learning process proposed to patients and their caregivers that meets the need to acquire knowledge and skills related to medical and disease self-management. Some educational programs have shown their effectiveness, e.g. in terms of cutting costs [33].

In relation to the association between decision-making and PSE levels at T1 and T2, our findings revealed that patients maintained high and stable PSE levels independently of the decision they took. These observations deviate from Bandura's theory, which suggests an immediate decrease in PSE levels for individuals with high initial PSE levels attempting symptom management if they ultimately fail. The observed persistent overconfidence can be attributed to the cognitive bias known as the Dunning-Kruger effect. This effect suggests that individuals have inaccurate perceptions of their performance in cognitive tasks. Specifically, those who perform poorly assume that their performance is typical and consequently overrate it [12,13].

Overall, the Immuno'Act© tool was positively evaluated by the

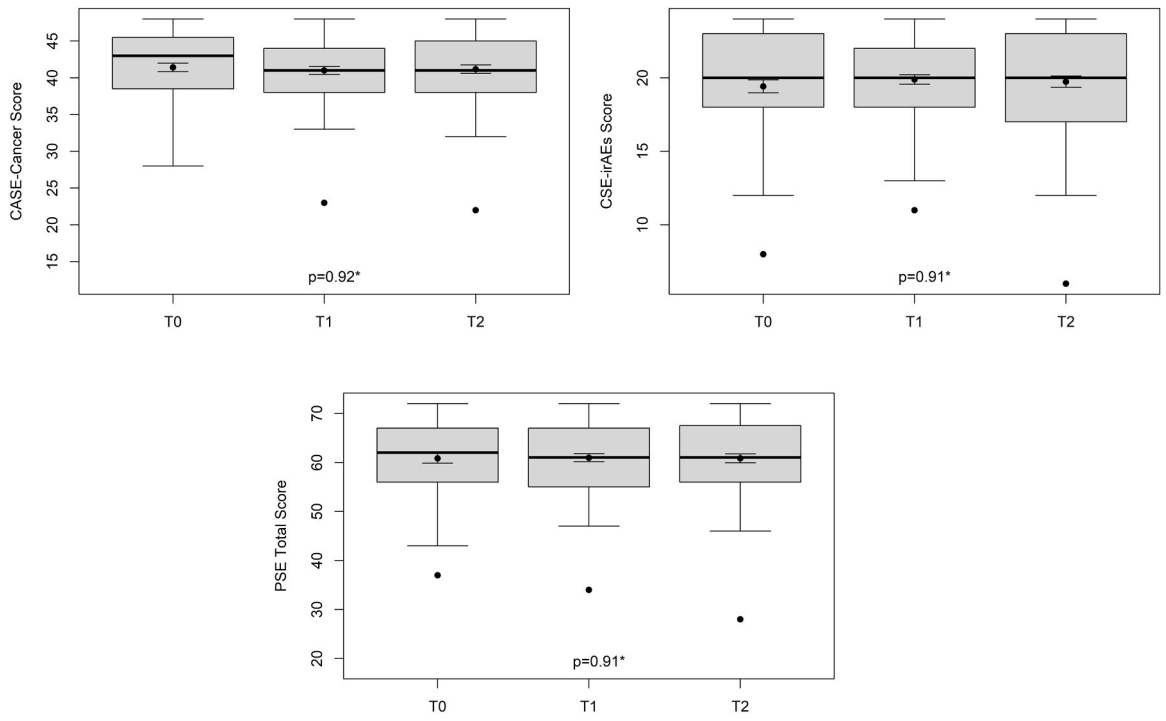

Fig. 2. PSE scores at each measurement time and its evolution by GLMM: A. CASE-Cancer Score, B. CSE-irAEs Score, C. PSE Total score. The horizontal bold line within the box represents the median value of the Score. The lower and upper boundaries of the box indicate the 25th and 75th percentiles, respectively. Additionally, the box plot displays the mean ± SE, denoted by a dot surrounded by two small lines. Outliers are indicated by individual dots. Lines extend from the ends of the box to the largest and smallest observed values that are not outliers. * Adjusted for time elapsed since the first treatment.

Table 2
Decision-making in various health situations based on real-life scenarios (n = 80).

	Card choice n (%)	**Decision-making**			**FC vs. LC/NC** Crude OR (95 % CI)
		Recommended action as 1st choice (FC), n (%)	Recommended action as last choice (LC), n (%)	Recommended action never chosen (NC), n (%)	
High-grade irAEs	**80 (100 %)**	**5 (6.20)**	**59 (73.8)**	**16 (20.0)**	
Pneumonitis	46 (57.5)	2 (4.30)	33 (71.7)	11 (23.9)	1.00
Hepatitis	22 (27.5)	0 (0.00)	17 (77.3)	5 (22.7)	0.40 (0.02–9.15)
Myocarditis	12 (15.0)	3 (25.0)	9 (75.0)	0 (0.00)	**6.56 (1.07–40.2)**
Low-grade irAEs	**80 (100 %)**	**36 (45.0)**	**24 (30.0)**	**20 (25.0)**	
Skin toxicity	19 (23.8)	15 (78.9)	3 (15.8)	1 (5.30)	1.00
Colitis	19 (23.8)	8 (42.1)	6 (31.6)	5 (26.3)	**0.22 (0.05–0.88)**
Fatigue	42 (52.5)	13 (31.0)	15 (35.7)	14 (33.3)	**0.13 (0.04–0.47)**
Other health situations	**80 (100 %)**	**52 (65.0)**	**25 (31.3)**	**3 (3.80)**	
Diarrhea due to food poisoning	35 (43.8)	20 (57.1)	13 (37.1)	2 (5.70)	1.00
Muscular pain following physical exercise	45 (56.3)	32 (71.1)	12 (26.7)	1 (2.20)	1.82 (0.72–4.60)
Treatment communication with a new healthcare provider	**79 (100 %)**	**34 (43.0)**	**43 (54.4)**	**2 (2.50)**	

majority of participants and can be considered well-accepted in the context of immune-based oncotherapy. Taken together with the other results, this positive acceptance supports the need to integrate such tools into clinical practice to help patients effectively manage irAEs.

The study showed strengths, particularly in its execution of the sample size calculation, ensuring the inclusion of an optimal number of patients to meet the primary objective (52 patients planned, 80 completed the whole study), which further bolstered the study's robustness. Although attrition occurred for various reasons (e.g. deaths, treatment discontinuation), no patient indicated that they left the study because of the use of Immuno'Act©. Nevertheless, attrition may limit the generalisability of findings on PSE, decision-making and patient acceptance, as participants who withdrew could differ systematically from completers. Some study limitations also need to be considered. Firstly, the adoption of a one-group pretest-posttest design represents a limitation. The absence of a control group impairs our ability to control for confounding factors, making a cautious interpretation of our findings necessary. Secondly, the scales used to measure PSE have limitations.

Table 3
PSE scores at T1, T2, and differences (T1-T0, T2-T0) regarding decision-making in health scenarios (n = 80).

	High-grade irAEs		Low-grade irAEs		Other health situations		Treatment communication with a new healthcare provider	
	β[a] (SE)	p-value	β[a] (SE)	p-value	β[a] (SE)	p-value	β[a] (SE)	p-value
CASE-Cancer Score T1	1.89 (2.32)	0.42	0.67 (1.14)	0.56	-0.54 (1.13)	0.63	1.52 (1.06)	0.16
CSE-irAEs Score T1	1.11 (1.14)	0.43	1.21 (0.70)	0.087	0.05 (0.70)	0.95	0.74 (0.66)	0.26
Total Score T1	2.97 (3.53)	0.40	2.17 (1.77)	0.23	-0.82 (1.77)	0.65	2.36 (1.65)	0.16
CASE-Cancer Score T1-T0	0.77 (1.86)	0.68	0.28 (0.95)	0.77	-0.94 (0.92)	0.31	-0.10 (0.90)	0.91
CSE-irAEs Score T1-T0	0.33 (2.19)	0.88	-0.86 (0.84)	0.31	0.73 (0.81)	0.38	0.38 (0.78)	0.63
Total Score T1-T0	2.97 (3.53)	0.40	2.17 (1.77)	0.23	-0.82 (1.77)	0.65	2.36 (1.65)	0.16
CASE-Cancer Score T2	0.44 (4.18)	0.92	-0.34 (1.65)	0.84	-0.70 (1.58)	0.66	0.20 (1.54)	0.90
CSE-irAEs Score T2	0.84 (1.64)	0.61	-0.42 (0.83)	0.62	0.28 (0.83)	0.73	-0.09 (0.76)	0.90
Total Score T2	0.74 (3.85)	0.85	-0.004 (1.95)	0.99	1.63 (1.94)	0.40	0.53 (1.81)	0.77
CASE-Cancer Score T2-T0	-1.50 (2.13)	0.49	0.25 (1.10)	0.82	1.44 (1.07)	0.18	-0.58 (1.04)	0.58
CSE-irAEs Score T2-T0	-0.44 (2.01)	0.83	-2.07 (0.76)	**0.0078**	0.97 (0.75)	0.20	-0.69 (0.72)	0.34
Total Score T2-T0	-1.22 (4.09)	0.77	-1.70 (1.63)	0.30	3.24 (1.55)	**0.040**	-2.30 (1.54)	0.14

[a] Adjusted for the card chosen

Table 4
Evaluation of acceptance tool (n = 80).

Perceived utility, n (%)	77 (96.3)
Perceived ease of use, n (%)	78 (97.5)
Perceived ease-to-understand vocabulary, n (%)	78 (97.5)
Perceived ease-to-understand instructions, n (%)	78 (97.5)
Adequacy of illustrations, n (%)	79 (98.8)
Length of use judgment, n (%)	
Too short	1 (1.30)
Appropriate	76 (95.0)
Too long	3 (3.80)
Aesthetics judgment (/10), mean± SD	8.43 ± 1.00
Solid, robust materials judgment (/10), mean± SD	8.50 ± 0.97
Overall judgment (/10), mean± SD	8.61 ± 0.96
Perceived utility of the summary about irAEs management, n (%)	68 (85.0)

Notably, the CASE-Cancer tool lacked validation in its French version, and the CSE-irAEs Score was developed for this study, lacking validation. Thirdly, the educational tool's singular usage may contribute to the absence of observed modifications in PSE scores. Further work is needed to determine the optimal number of sessions, assess the added value of group sessions, and explore patients' perspectives on the TPE session using Immuno'Act© through a qualitative approach. Lastly, the results pertaining to decision-making should be interpreted with caution. The evaluation of decision-making was based on real-life scenarios, introducing a potential disparity from decision-making in the context of actual situations [29].

4.2. Conclusion

In real-life scenarios, up to 25 % of the patients failed to take recommended actions to cope with irAEs, which could potentially worsen their health in actual situations. Furthermore, the results suggest that patients may overestimate their PSE, indicating a gap in their awareness of how to cope with irAEs. Finally, this pilot study indicates that Immuno'Act© is well-accepted by patients.

4.3. Practice implications

The low rate of patients directly selecting recommended actions to manage an irAE, associated with misplaced overconfidence in their abilities, underlines the need for patient education beyond mere information provision. Future research should assess the effectiveness of Immuno'Act© and explore the underlying mechanisms influencing behavioural change. Additionally, studying the impact of inaccurate self-assessments is important to determine when such misjudgements may be beneficial or harmful. Investigating these aspects will provide valuable insights into using Immuno'Act©, contributing to the development of more effective patient education strategies in the context of immuno-oncotherapy.

CRediT authorship contribution statement

Laurence SEIDEL: Writing – review & editing, Visualization, Formal analysis. **Irène CAMPOS CORRAL:** Writing – review & editing, Resources. **Véronica GRECO:** Writing – review & editing, Resources. **Vanina EVRARD:** Writing – review & editing, Investigation. **Guy JERUSALEM:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Benoit PETRE:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Astrid PAULUS:** Writing – review & editing, Resources. **Anne SIBILLE:** Writing – review & editing, Resources. **Rémi GAGNAYRE:** Writing – review & editing, Methodology, Conceptualization. **Delphine KIRKOVE:** Writing – review & editing, Methodology, Conceptualization. **Streel Sylvie:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Sabrina UCCELLO:** Writing – review & editing, Investigation. **Christine GENNIGENS:** Writing – review & editing, Resources. **Pierre FRERES:** Writing – review & editing, Resources, Methodology. **Andrée RORIVE:** Writing – review & editing, Resources, Methodology.

Ethics approval statement

The study was conducted according to the declaration of Helsinki, with informed consent of the patient and as approved by the Ethics Committee of the University Hospital of Liège, in Belgium (2022–171).

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2026.109537.

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