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Research Article

Quality of Life and Needs of Patients Undergoing CAR-T Cell Therapy: The Patients' Perspective

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Background: Despite the strong emphasis in recent scientific literature on the pharmacological features of CAR-T cells, patients' quality of life (QoL) and needs, by contrast, have received little attention.
Aim: This study aims to investigate patients' perspectives on their QoL and needs in a referral centre for CAR-T cell treatment in Italy.
Methods: This is a descriptive, qualitative and prospective study conducted at a single centre. Patients were recruited from a list of those who underwent the treatment or who were eligible to do so. Patients were asked to participate in a semistructured interview. The number of people to be interviewed was not predetermined but was established continuously until meaning saturation was achieved. The interviews were audio recorded, transcribed verbatim, and analysed through constructivist lenses using reflexive thematic analysis.
Results: Participants were 12 patients (age mean: 57.88; SD = 9.62; range = 39–70) enrolled in an Italian Comprehensive Cancer Center. From the analysis of the interviews, 7 themes were identified: (1) therapeutic journey to reach CAR-T cell therapy; (2) CAR-T cell images; (3) perception of the quality of care received; (4) three challenging moments; (5) emerging issues to address; (6) coping strategies and (7) needs. Some themes have been organised into subthemes that detail their specific aspects. Starting from the quotations, 41 needs have been identified and organised into 5 macro areas: (1) needs during hospitalisation; (2) existential needs; (3) needs for improving QoL; (4) need for quality and quantity of information and (5) needs for care. The list of needs has been transformed into a checklist, serving as a preliminary step for subsequent studies aimed at identifying and quantifying the needs of patients.
Conclusions: Results indicate that the QoL of patients undergoing CAR-T cell therapy is impaired during hospitalisation and in the subsequent months following infusion. Physical symptoms including fatigue, drowsiness, cognitive slowing or dysfunction emerged. Nonetheless, patients employ various coping strategies to cope with these challenging periods. A multitude of needs, often unaddressed, has emerged. For this matter, a first draft for a checklist of needs has been realised. Should future studies validate its structure, this tool may prove beneficial in both clinical and research settings to identify and monitor patients' needs throughout the continuum of their treatment pathway.

Keywords: cancer; CAR-T; coping; health related quality of life; needs; psycho-oncology; quality of life; thematic analysis

1. Introduction

Chimeric Antigen Receptor (CAR) T cells have revolutionised the treatment of patients with specific blood cancers (such as B cell non-Hodgkin's lymphoma, acute lymphoblastic leukaemia and multiple myeloma) who have relapsed after one or more conventional therapies [1–4].

Despite a 650% growth in CAR-T therapy within two years (2017–2019) [5], the care pathway remains long and filled with challenges, that may result in anxiety, depression and uncertainty among patients [6, 7]. Patients receive CAR-T cell therapy after having exhausted multiple lines of therapy, and experienced impairments in multiple dimensions of quality of life (QoL) due to the accumulation of toxicities from previous treatments [4, 8]. The treatment and immediate post-treatment periods are associated with the risk of side effects (such as cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome), which can range from mild to severe and require constant monitoring by the medical equipe, as well as the support of a caregiver [9]. Once treatment is completed, a period of isolation is expected, during which feelings of hope alternate with difficulties in coping with the uncertainty of the therapy outcome. In addition, the long-term effects of treatment, which are currently being studied, are not yet known. For these reasons, patients' QoL is severely compromised at every stage of the treatment [9].

Assessing patients' QoL and specific needs for each phase of CAR-T cell treatment is essential for creating personalised care pathways that take into account the actual physical and psychological conditions, resources and desires of patients themselves. However, to date, despite the significant emphasis on pharmacological aspects in recent literature [10–12], studies investigating these themes are lacking, and none has been conducted in Italy (for exceptions, see e.g., [9, 13–15]).

These studies unanimously emphasise the difficulty of addressing the uncertainty encountered by these patients daily, which results in a worse QOL, especially due to anxiety, depression, fatigue, pain, cognitive impairment, and reduced physical function. An interesting piece of qualitative research conducted in the UK [15] emphasised the challenges of the care pathway for patients receiving CAR-T cell therapy and underlined the importance of a dedicated nursing specialist to assist them throughout this difficult journey. Many patients, in addition to the fatigue associated with their care pathway, face the additional burden of receiving treatment at a specialised centre that is often distant from their place of residence, which negatively affects their QoL due to the cost of travel and accommodation near these centers. Furthermore, the above-mentioned study highlighted the highly favourable expectations of patients and caregivers for CAR-T cell therapy, emphasising its "revolutionary" and innovative elements.

1.1. Aims. This work is part of a larger project investigating the QoL and needs of both patients and caregivers at the Fondazione IRCCS Istituto Nazionale dei Tumori (INT; Milan, Italy). This study specifically focuses on patients and has two objectives:

1. To explore patients' perceptions in depth regarding their QoL at three key stages of their journey: before CAR-T cells treatment, during treatment, and at least three months after treatment completion.
2. To identify the needs of patients and to create a preliminary checklist to use in future studies.

2. Methods

2.1. Study Design. This study is both descriptive and prospective. Given the research objective, the limited literature on the subject, and the small number of patients eligible for this type of treatment, this study adopted a qualitative research methodology by a constructivist approach. This methodology is especially suitable when the goal is to gain an in-depth understanding of how individuals experience a particular phenomenon, as it allows to capture the complexity of personal perceptions and experiences [16, 17].

2.2. Participants. Patients who had already received CAR-T cell treatment were recruited from a list maintained by the Division of Haematology at INT. Patients scheduled to undergo treatment were recruited during their hospital stay at INT for infusion. In this case, recruitment was conducted by either their oncologist (A. Chiappella) or a researcher psychologist (S. Alfieri or E. Criscuolo).

The number of patients to be interviewed was not predetermined. Recruitment began by contacting all patients who had either undergone infusion or were about to receive it, and it continued until meaning saturation was reached [18]. By meaning saturation, we refer to the adequate verbalisation necessary to produce sufficient information that portrays a rich, complex, and multifaceted narrative of the phenomenon in question. [19]. Therefore, the analysis was conducted continuously throughout patient recruitment.

Inclusion criteria were: (1) patients considered for CAR-T cell therapy or who have already received this treatment; (2) adult patients ($\geq$ 18 years old) and (3) written informed consent provided.

Exclusion criteria were: (1) having any documented or psychiatric or neurological disorder which may interfere with interviews and (2) not being able to read and understand the Italian language.

2.3. Instruments. Each participant was involved in a semi-structured interview. A topic guide (Appendix 1: Semi-structured interview outline), developed by the research team (S. Alfieri, E. Criscuolo, C. Borreani, A. Chiappella) and aligned with the research aims, was used to structure the interviews and ensure all relevant topics were discussed. With participants' consent, the interviews were audio-recorded and transcribed verbatim. The topic guide included questions about the therapeutic journey, QoL, needs, and coping strategies to manage the challenges of treatment.

Table 1: Characteristics of participants in the interviews.

PPTs	Sex	Age	Marital status	Educational qualification	Region of residence	Profession	Year of the first diagnosis	Type of first diagnosis	Start date CAR-T cell therapy	Interview date	Time elapsed from the CAR-T infusion to the interview
1	M	64	Married/ cohabiting	Master's degree/four years degree or higher	Lombardy	Manager	2015	Multiple myeloma	December 2021	03/05/ 2023	2 years
2	M	70	Missing	Missing	Lombardy	Missing	Missing	Missing	May 2023	04/05/ 2023	During hospitalisation
3	F	67	Married/ cohabiting	Elementary/middle school degree	Lombardy	Worker	2011	Non-Hodgkin's lymphoma	May 2023	15/05/ 2023	During hospitalisation
4	M	57	Married/ cohabiting	High school degree	Lombardy	Entrepreneur	2015	Multiple myeloma	February 2023	15/06/ 2023	4 months
5	F	59	Married/ cohabiting	High school degree	Lombardy	Employee	2021	Non-Hodgkin's lymphoma	November 2022	16/06/ 2023	7 years
6	M	60	Married/ cohabiting	High school degree	Lombardy	Skilled worker	2022	Non-Hodgkin's lymphoma	June 2023	05/06/ 2023	During hospitalisation
7	F	53	Married/ cohabiting	Master's degree/four years degree or higher	Lombardy	Lawyer	2010	Multiple myeloma	March 2023	26/06/ 2023	3 months
8	F	39	Single	Bachelors	Veneto	Employee	2016	Non-Hodgkin's lymphoma	August 2019	07/07/ 2023	4 years
9	F	Missing	Married/ cohabiting	Bachelors	Emilia Romagna	Employee	2014	Non-Hodgkin's lymphoma	November 2023	11/12/ 2023	1 months
10	M	67	Missing	Missing	Missing	Missing	Missing	Multiple myeloma	May 2023	13/01/ 2024	7 months
11	F	50	Divorced or separated	Master's degree/four years degree or higher	Lombardy	Employee	2022	Follicular lymphoma	January 2024	26/03/ 2024	Before hospitalisation
12	M	46	Married/ cohabiting	High school degree	Lombardy	Trader	2018	Non-Hodgkin's lymphoma	September 2022	27/03/ 2024	During hospitalisation

Table 2: Themes, subthemes and definitions of themes.

Themes	Theme definition	Subthemes
1. The Therapeutic Journey to Reach CAR-T Cell Therapy	An account of a patient's therapeutic journey to CAR-T infusion	- The physical and psychological burden of treatments prior to CAR-T cell therapy - The stress and disappointment of repeated failures
2. CAR-T cell images	Thoughts and/or imagery, conscious or unconscious cognitive patterns related to CAR-T cell therapy	- Hope - Fear - Experimental procedure - Long hospital stays - Side effects
3. Perception of Quality of Care Received	Evaluation of care before, during and after CAR-T cell infusion	Strengths: - HCP ability to communicate clearly - HCP ability to reassure - HCP availability and accessibility to direct contact Critical issues: - Difficulty or impossibility of finding available spots to undergo tests - Limited time available to read informed consent form carefully
4. Emerging Issues to Addess	Issues that patients face before, during, and after CAR-T cell therapy	- Physical and psychological adaptation to treatment - Emotions - (Not) informing loved ones about the ongoing treatment - Economic impact
5. Three challenging moments	How patients experience and have experienced key moments related to CAR-T cell treatment	- Hospitalisation period - 3–6 months after infusion - More than 6 months after infusion
6. Coping strategies	Patients' strategies to cope with the difficulties of CAR-T infusion	- Proactive coping strategies - Restructuring one's way of thinking and being - Seeking closeness
7. Needs	Condition of dissatisfaction or perceived lack that may create tension or discomfort in patients	- Needs during hospitalisation - Existential needs - Needs to improve QoL - Needs for quality and quantity of information about CAR-T cells - Needs fo care

The interviews were conducted by two principal researchers (S. Alfieri and E. Criscuolo) to mutually enhance different points of view and obtain more comprehensive and complex information. S. Alfieri is a researcher with approximately twenty years of expertise in qualitative research, whereas E. Criscuolo is a psychotherapist specialised in oncohaematological illnesses.

2.4. Analysis. Verbatim transcripts were analysed using reflexive thematic analysis, as described by Braun and Clarke [17, 20, 21]. Reflexive thematic analysis is the chosen method for identifying, analysing, organising and describing patients' worlds and experiences. Within this method, a theme emerges via "interpretative stories about data, stemming from the researcher's subjectivity, and crafted through their rigorous but positioned reading of the data" (p.9) [16].

Aiming to achieve richer interpretations of meaning [22], two researchers (S. Alfieri and E. Criscuolo) read the transcripts multiple times to gain an overview of the material and its meaning. Keeping the purpose of the study in mind, researchers highlighted text and took notes and headings in the margins to capture all aspects of the content. All thoughts and impressions of the material were recorded. No predefined structures were used; a deductive approach to coding offered an interpretative framework to analyse and comprehend the data. [16]. After the initial coding of the interviews, a more detailed analysis was conducted to identify subthemes and find links between themes. This iterative process involved going back and forth to check the codes against the material [21]. The transcriptions were analysed using the paper-pencil method.

2.4.1. Creating the Checklist. Starting from the quotations, a series of needs were identified (i.e. "*I would need to hear some positive news, to be told: 'You're cured', that's what I would need" pt. 9*). Each need was reformulated in a synthetic sentence, maintaining its meaning (i.e., *"Thinking that CAR-T cell therapy will be OK"*). Needs that were repeated several times, even if expressed into different words, were included in the checklist only once. Whereas verbalisation contained multiple needs, all of the latter have been taken in consideration. Once a first version of the checklist was prepared, researchers' team (S. Alfieri, E. Criscuolo, C. Borreani and B. Scacciati) discussed extensively: (1) comprehensibility, (2) relevance and (3) intrusiveness of each statement. Disagreements were resolved through new proposals and discussion.

2.5. Study Context. The "Fondazione IRCCS Istituto Nazionale dei Tumori" (National Cancer Institute; INT) of Milan, foundation and government-designated centre for treatment and research (IRCCS), is a leading cancer center in Italy pursuing mainly clinical and translational research, exploring and developing the fields of biomedicine and public health, in order to deliver high-quality healthcare services. Research at INT aims to improve prevention, early diagnosis and treatment of cancer diseases, and the QoL of cancer patients. In the field of cell therapy, it was the only Italian center to participate in 2016 in an experimental study with CAR-T cells in aggressive lymphomas. A CAR-T team has been created in the INT since 2018, coordinated by the Hematology Unit staff. These aspects make INT a particularly "fertile" context for carrying out research on CAR-T cell therapy. INT has been designated a Comprehensive Cancer Centre by the Organization of European Cancer Institute (OECI) in recognition of its excellence both in patient care and the development of new treatments.

2.6. Ethical Issues and Privacy. The study was conducted in accordance with the Helsinki guidelines for research involving human subjects and was approved by the INT Ethics Committee (INT 189-22). All participants signed written informed consent for study participation, privacy (GDPR), and audio recording. Privacy was ensured by changing patient's name into textual and numeric strings (pseudo-anonymisation).

3. Results

3.1. Study Participants. From May 1st, 2023, to March 31st, 2024, 12 patients out of 15 agreed to participate in the study; one declined due to very poor physical condition, and two could not be reached. 50% ($n = 6$) of the participants are female. In terms of educational background, 33.3% ($n = 4$) have a high school degree, 25% ($n = 3$) a master's degree, 16.7% ($n = 2$) a bachelor's degree, 8.3% ($n = 1$) a middle school degree, and two did not respond. The characteristics of the participants are shown in Table 1.

3.2. Theme Generation. From the analysis of the interviews, seven themes have been created, some of which were further split into subthemes. Table 2 summarises the themes, along with definitions of the latter and the consequent subthemes. Meaning saturation was reached at the ninth interview. Three additional interviews were conducted to explore new facets, but new themes did not emerge.

3.2.1. The Therapeutic Journey to Reach CAR-T Cell Therapy. Patients were meticulous in describing their therapeutic journeys, which were generally very long and arduous. Although the pathways of the interviewed patients were diverse, they were united by two common elements: (1) the physical and psychological burden of treatments prior to CAR-T cell therapy, including side effects and prolonged hospital stays; and (2) the stress and disappointment of repeated failures, coupled with the need to believe that CAR-T cell therapy will be effective.

CAR-T cell therapy was not typically described as the most physically and emotionally demanding treatment; for example, autologous transplantation was often considered more demanding. The main difficulty regarding CAR-T is that it is an experimental therapy, and there are no guarantees regarding the outcome.

> *'In fact, it's only the psychological aspect [that's the most difficult], because I was able to endure the therapy very well, even better than the institutional protocol that's done*

with autologous transplantation [. . .]'. More than anything else, given that it was an experiment, it was the fear of the unknown (pt. 1).

This is related to the need to believe that CAR-T will work (see the section on existential needs):

'I see the future here [with CAR-T] [. . .], I see my life continuing because [. . .] I still have many projects to pursue [. . .]'. 'I know there are two doors, but I [. . .] can only see one at the moment.' (pt. 2).

3.2.2. CAR-T Cell Images. CAR-T cell images' refers to thoughts and/or imagery, conscious or unconscious cognitive patterns through which the interviewees have built and made sense of CAR-T cell treatment. For the respondents, CAR-T cells embodied an innovative therapy that brought hope, but also evoked fear. Hope lied in the possibility of a complete cure or, at the very least, an improved QoL for some time. Conversely, fear stemmed from the understanding that it is an experimental procedure, which participants believed was still in its embryonic stage, with much left to be discovered.

'In the word infusion, I put so many things. . . that the infusion of these CAR-T cells will lead me to cure the disease, or at least give me a respite for a few years.' 'And so it is happening.' (pt. 4).

'On the one hand, I still have some fear, in the sense that what I seem to understand from the literature is that the treatment doesn't have solid data yet, so I'm just watching from the sidelines. . .' (pt. 7).

A patient expressed her fears about not feeling well, the loss of her hair and the potential neurological effects due to the therapy:

'[It scares me] in general, the idea of not being well [. . .]'. Losing my hair at this point would really upset me! Maybe even more than the first time! Because now I have recovered, with my physical appearance! [. . .] It's unclear if people can visit me, but I don't think they can! [. . .] In addition, among the various side effects, there is delirium. . . well, delirium gives me a bit of a chill [the patient laughs] as a side effect! [. . .] Another reported side effect is the possibility that I may be unable to express myself. I'm already having such problems, so I'm starting from a place of lack. [. . .]But I had also read that there can be difficulties in expressing oneself, difficulty in understanding written information! [. . .]. That worries me! I mean, the idea of no longer being present with myself! 'And then there is delirium, what does that mean?' (pt. 11).

Alongside the widespread polarity of fear versus hope, some people associated the term 'CAR-T' with long hospital stays (see the section "Three challenging moments"), while others viewed it as a challenging treatment to endure due to its significant side effects.

'When you say CAR-T to me. . . I think. . . almost a month in hospital! [. . .] It's not like taking an aspirin; there are still some critical issues.' (pt. 12).

3.2.3. Perception of Quality of Care Received. Patients reported being satisfied with the care they received at the INT, but they expressed less satisfaction with other private centres or those without an oncology specialisation. It results being very important for patients to feel that they are not just numbers, but individuals.

In particular, patients expressed satisfaction with the quality of care they received from healthcare professionals (HCPs) when:

1. HCPs communicated clearly.

'They have always been very clear about my journey, nothing has ever been hidden from me; I have always known that it is a serious illness, but one that can be cured thanks to the research that has been done.' (pt. 5).

This includes being available to answer questions that patients may have for their HCPs:

'The CAR-Ts were explained to me very thoroughly and often. At the time there was a junior doctor in the department [. . .] who was very precise. I am a person who asks a lot of questions; [. . .] so I asked a lot of questions and found in him a person who really enjoyed explaining things to me. (pt. 8).

2. They were able to reassure patients, i.e., to keep them in a safe place, emotionally speaking:

'I like going to the doctor because I feel comfortable in an environment that cares about me.' (pt.1);

3. They were available and accessible when needed, allowing patients for direct contact:

'I called the department and the doctor [. . .] told me: "It's nothing, don't worry!" Even though it was Sunday morning, the doctor answered me! [. . .] The patient needs to have direct contact [. . .] 'It's not like you have to spend 6 hours on the phone with the secretary.' (pt.10)

Some patients used the term 'being pampered' to summarise these aspects; this perception proved to be important, especially during the delicate moment of hospitalisation.

Among the critical issues, patients expressed concerns about:

1. The difficulty or impossibility of finding available slots in a short time to undergo the tests they needed. Patients would like to be given priority to more urgent cases.

'It's just a question of organisation. . .' Because an echocardiogram ends up taking [. . .] 20 minutes. [. . .]. I don't think it would take much, it's just the fault of our bureaucracy.' (pt. 2).

2. The limited time available to be able to read the informed consent form carefully:

'Even the package that was quickly delivered to me with 80 sheets. . . [The doctor said to me:] "This is the one. . . Then you have to sign here. . ." [. . .] But I had to take 24 hours before signing. . .' (pt. 10).

3.2.4. Emerging Issues to Address

3.2.4.1. Physical and Psychological Adaptation to Treatment. CAR-T cell treatment presents emerging issues for patients. Certain challenges have been experienced with prior treatments (e.g., managing specific side effects and psychological distress), while others were novel (e.g., for some patients, CAR-T therapy represents the final treatment option) and necessitated both physical and psychological adaptation to the situation.

Some patients experienced fatigue, difficulty sleeping at night and cognitive slowing after infusion. These symptoms required a readjustment of one's lifestyle, both at work and at home.

'Even if I work part-time, I still have this great fatigue. . . I feel a bit stuck.' (pt. 5).

In particular, one patient emphasised the importance of learning to "take your own time", trying to accommodate the new needs of one's own "body and mind".

'I have noticed that one has to take their time, that they want to stay in bed a little longer, approach things more slowly, with more serenity'. [. . .] Of course, there are things that you can't do anymore because of the lack of strength. [. . .] For example, walking just 2 km can be quite an achievement. I'll give you another example: pushing the shopping trolley, going shopping, getting to the car, going out, feeling tired [. . .]. Many say: "I can't, I can't be without a job!" But it is a very delicate phase, and the body and the mind must be calm.' (p. 2).

3.2.4.2. Emotions. During the CAR-T cell infusion, patients experienced a wide range of emotions, which could sometimes be contradictory.

The prevailing emotion throughout most of the interviews was hope, which concerned the potential effectiveness of CAR-T cell therapy (see also the theme 'CAR-T cell images).

'I hope the last attempt goes well.' (pt. 9).

On one hand, patients hoped that CAR-T cell therapy would have had a positive outcome. As noted in the section on images of CAR-T cells, some individuals hesitated to acknowledge that treatment itself might not work. On the other hand, there was a cautious concern regarding the signs of improvement observed in those who have undergone the therapy:

'To be honest, I'm afraid to say: "It seems to work, this CAR-T!". . . the PET scan showed a remission, but. . .' (pt. 9).

Another dominant emotion was fear, although many patients did not allow themselves to discuss it. If left unmanaged, fear could be disabling:

'I was scared, my antibodies were very low, [the doctors] said: "You are at risk, be careful of infections". They kept nagging me! I didn't leave the house, my mother is in a care facility and I didn't go to see her because I was afraid, [the treatment] affected my life a lot.' (pt. 9).

Patients highlighted moments when the predominant emotion was despondency, often as a result of feeling responsible for their illness:

'I see the future, I see my life going on because I have so many projects to do, and I believe in it all. This time it will be long, but in the end, I say to myself: "I have to get out of this, I have to heal. I want to heal!" [. . .]. There have also been some moments of discouragement because one may think: "What have I done wrong in my life?" [. . .] but I have always lived them with the thought that there is a cure anyway. . .' (pt. 1).

It was very reassuring for patients to know that CAR-T was not the final option available for them to be cured:

'Even the last time, when I had the CAR-T, [the doctors] told me: "You know that even if it happens that your tumour comes back, this is not the last way, we still have other ways, there are several", and that's important because [. . .] if I got the MRI report today telling me that the disease has come back, I wouldn't jump out of the window thinking that this is the last thing. [. . .] I have fought so far, there will be other things I can do.' (pt.5).

Irritability was another emotion that was not always verbalised by patients, but it was evident through their stories, especially when they felt unaccepted and misunderstood by those around them:

'My husband has a bad habit of belittling this [my state of mind] a lot. Intending to help me, when I say, "Yes, I have these worries. . ." he replies: "Come on, it will be OK." That irritates me, and I think: "You don't know what you're talking about; you don't know what I've been through, what I've suffered!"'(pt. 9).

3.2.4.3. (Not) Informing Loved Ones About the Ongoing Treatment. CAR-T-cell therapy had a significant impact on patients in terms of social issues and need for support. Foremost, among these issues, was the decision of whether to inform their loved ones about the diagnosis and treatment. In general, children or elderly parents were the ones most commonly unaware of the situation:

'The children didn't know until last year [. . .] my wife was forced to tell them when I had meningitis and [the doctors]

had practically pronounced me dead [. . .] Even my parents, they still don't know anything about the disease.[. . .] Apart from a few friends who knew, but then they didn't. . . I didn't spread the news that I'm ill' (pt. 4).

Patients who chose to share their illness and treatment reported varied experiences: some have noticed that certain friends and family members distanced themselves, while others showed greater closeness. Patients described these experiences as 'revelations' as the illness helped them understand whom they could and could not rely on.

3.2.4.4. Economic Impact. Protective and detrimental factors have been identified regarding the economic impact that the disease and its treatment inevitably had on patients, both directly (e.g., treatment costs) and indirectly (e.g., inability to work).

Protective factors included the National Health Service (NHS), which covers most services, tests and therapies. In addition, the NHS provides exemptions for cancer patients so that they do not have to pay co-payments. However, the limited availability of free slots for many laboratory tests or diagnostic imaging often forced patients to rely, at least partially, on private healthcare, which can be very expensive and misaligned with their financial situation.

The economic impact varies by contract type: employees are the most protected, with 180 days of paid sick leave per year. Conversely, freelancers are the most vulnerable to illnesses, as they not only struggle to work, but also typically lack access to sickness benefits. For those without savings to rely on, the financial impact of the disease can be severe. For small business owners, an illness requires a reorganisation or redistribution of activities and workloads. However, this study's interviewees did not experience a severe economic impact, as they could continue to work according to their energy levels or by delegating tasks to others. Finally, retired patients, especially the elderly, often relied on assistance from voluntary organisations, if they were unable to draw on their savings.

'We live in a village. To come here six times, my husband and I asked a voluntary organisation for help; they gave us 80 euros. We are two pensioners, we have a house, we have worked all our lives, and we have also saved some money for illness. Of course, the cost [of treatment] is there! Back and forth. . . it means we won't go on holiday this year' (pt. 3).

Another protective factor was represented by financial support from family members (such as parents or a partner), which became crucial if the patient was unable to work and did not receive sickness benefits.

'As mine was a very long journey, I had already used up my sick days, so I took several months off. [. . .] Luckily I lived with my parents all those years. I wasn't homeless, but if I had my own house and a mortgage to pay, I'm sure those months off would have been hard. But I think it's quite a common thing, I was quite lucky to keep a job, a lot of people can't even keep a job' (pt.8).

Finally, the role of organisations was crucial, as they provided financial assistance for patients' transportation during treatment and offered accommodation in cases of health migration.

One obstacle lied in exceeding the days permitted by the sickness allowance (available only to employees), which is 180 days under the Italian national contract. The patients interviewed in this study reported recovery periods that often surpassed this allowance, forcing workers to take unpaid leave if they were unable to return to work once their benefits were exhausted.

Another obstacle cited by respondents with contracts was the inability to work overtime to 'make ends meet' due to a lack of energy:

'I know it's all covered by the National Health Service anyway. . . I've seen that [CAR-T cell therapy] is crazy expensive! If we were in America, I don't know if I could afford it! For the rest, I'm lucky enough to have a 'steady' job anyway, so I don't risk losing it! The illness did have some impact, economically speaking! [. . .] because I was used to going to work, often working overtime. . . and then when we work we get a meal card! [. . .] but it's obvious that [. . .] between therapies, hospitalisation, convalescence. . . there were days when I worked, but I did the bare minimum. . . I didn't do any more overtime! So that small increase I had is no longer there!' (pt. 11).

Finally, in Italy, 'healthcare migration' is a significant phenomenon: patients residing in regions without specialised centres are compelled to 'migrate', sometimes for extended periods, to cities where such centres are available. These are often large cities, such as Milan in this case, where the cost of living is quite high. Healthcare migration impacted not only the financial situation among patients, but also their social dynamics, as already discussed (Figure 1).

3.2.5. Three Challenging Moments

3.2.5.1. Hospitalisation Period. The interviewees perceived the hospital stay as particularly exhausting due to its length and the lack of engaging activities, aside from reading, using electronic devices, or undergoing medical examinations and tests. The requirement to stay in isolation further exacerbated the feeling of loneliness and made the passage of time seem even slower:

'In wards like the one where these treatments take place, there is a great lack of physical contact with the family, because you talk through a glass. This detachment is there but for obvious reasons' (pt. 12).

Patients also reported complications that have prolonged their stay in this regimen:

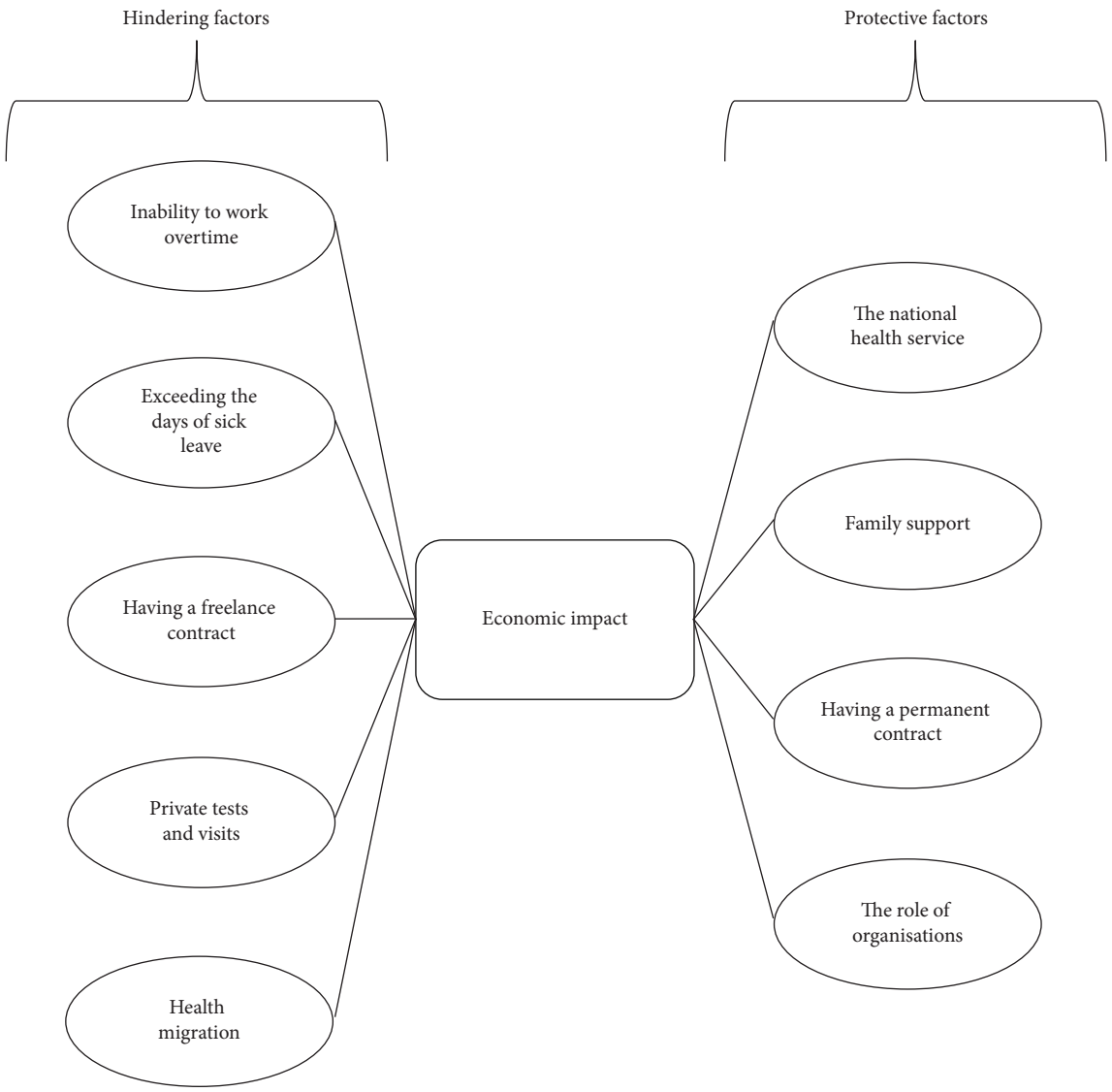

Figure 1: Summary of factors hindering and protecting economic situation.

'The hospitalisation was a disaster, after the second day I had a very high fever, which didn't go down with paracetamol [. . .], there is this antidote. After that, the fever went down; then, while I was in the hospital, I also got an intestinal bacterium, and I had problems for fifteen days. [. . .] I couldn't eat, nothing went down, those fifteen days were not good' (pt. 9).

All these elements led patients to seek psychological support during their hospital stay (see the subtheme "needs for care"). However, as patients themselves acknowledged, this challenging period was only temporary and, despite being very stressful, impacted their QoL for a limited time.

3.2.5.2. 3 to 6 Months After Infusion. QoL in the post-infusion period (approximately 3–6 months after the infusion) was characterised by three aspects. First, patients reported fatigue, drowsiness, and cognitive slowing or dysfunctions, which some attributed to medications, while others associated these symptoms with the CAR-T cell therapy itself. This issue was so debilitating that some patients felt they no longer recognised themselves:

'One thing that makes it a little difficult is the fact that you have to take these [. . .] antiepileptic drugs, which decompensate you a little bit anyway, because they retard you, you're always a little bit slowed down [. . .], so much so that the neurologist also saw me during the last visit, because when I write, I cross the letters and reverse the numbers . . . and I do bookkeeping!' (pt.5)

'The CAR-Ts really knocked me down, that is, I had trouble walking, and to this day I still have problems. . .. I'll give you a silly example: if I bend down to pick something up or open a cabinet when I get up, I don't have the strength to pull myself up. Now, after this month, I have a little more energy in the morning -- in the morning, I try to do something at home, I try to distract

myself. [. . .]I no longer recognise myself in my life, I used to be very dynamic, I used to run every day, I used to ride my bike' (pt.9).

The second aspect was the frequency of post-infusion check-ups, which required patients, who did not live in Milan, to relocate with a carer closer to the hospital, hence disrupting their daily routine with constant visits:

'My husband has already booked a place near here with the nuns, so I'm staying with him for 15 days. . . they told me to stay near the hospital because [from where I live] it's more than two hours by car and that's not good' (pt. 3).

Constant monitoring represented also a source of anxiety and fatigue as patients had to cope with the uncertainty of treatment outcomes:

'Yes, the daily routine was turned upside down, especially in the last period! If I could have gone on maintenance, I would have had a shot every 2 months and then I was quiet! There were no side effects; there was nothing! This therapy is a bit destabilising [. . .] I need a minimum of certainty in my life. . . and I don't have any! Because every two days [the doctors say] "let's see how you are, let's see if they call you, let's see if there's room. . .". I can't organise myself well! Neither with the work nor with the children!' (pt.11).

Another factor contributing to anxiety and fatigue was the nonlinear process of physical and psychological energy recovery. Patients reported, in fact, periods where they experienced good psycho-physical health, alternating with periods of great physical and mental fatigue. This alternation adds to the uncertainty patients experienced.*'I definitely noticed a decrease in muscle tone. The recovery after the infusion was not linear but up and down for five or six months. [With the autologous transplant, I was discharged, in my opinion, in a worse 'physical' condition. It took a long time, but it was a linear recovery. When I was discharged with the CAR-Ts, I felt better physically than with the autologous transplant, but the recovery was more wave-like, so there were days/weeks as if nothing had happened, and days/weeks when I felt more tired. So, the recovery was not linear [. . .] that affects the head more than anything else.' (pt. 8).*

Finally, the last aspect involved complications and fear of infection that arose during hospitalisation, which contributed to the fatigue of being away from home.

After the CAR-T I had another autoimmune reaction in my intestine, it was quite long. Theoretically, I should have stayed in Milan [. . .] more or less until the end of September, but then I stayed another two months because of the autoimmune complications. So it definitely [weighed] on me to be away from home!' (pt. 8).

Taken together, these aspects significantly impacted work activities, with many patients reporting long absences from work and facing difficulties in managing children and household responsibilities, consequently necessitating a reorganisation of their daily lives.

'Of course [my children] saw me as different, even just in appearance. . . Then when I was sick. . . they were with Daddy! I was sick there anyway, so I said, "Please keep them!" So they were tossed around, here and there, even though their dad and I are neighbours! But I had to tell them: "Today you are with me, tomorrow you are with your dad!" And that weighed on me, too! (pt. 11).

3.2.5.3. More Than 6 Months After Infusion. More than six months after the infusion, two interesting aspects have been identified. The first is that some patients reported returning to full 'normality' as in their preinfusion lives, or experienced only minor limitations (e.g., when travelling) indicating that the therapy no longer affected their daily lives.

'I feel good. . . I had some experiences in the past to recover from, like a blocked arm after a meningitis I had a year ago. . . I had some problems walking, and now I'm slowly recovering, but at the illness level, I feel well. That is to say, on a physical level, I feel well' (pt. 4).

'Apart from the terrible pain of going to the ER, I have suffered absolutely nothing since. I'm fine, [. . .] I don't work, but at home, I had to do some drywalling, I did it! [. . .] I have a vegetable garden!' (pt.6)

A second aspect, however, related to a new perspective on life centered on the concept of 'value', understood as an ongoing process of discovery of one's subjective "meaning of life":

'Now with the CAR-T [. . .] I think more about being well, about health afterwards. [. . .] I also think less about money [. . .] Then this thing here brings everything into play, even the way you look at life. In certain aspects you see it in a different way [. . .] the simplest things that maybe didn't matter before are now more important [. . .] For example, it could be an extra caress [. . .] something simpler. Being a little closer to everyone. . . [. . .] You notice a lot of things that you might not have noticed before. . . so I get excited.' [the patient cries] (pt. 2).

Figure 2 summarises the conceptual relationships between the themes and subthemes associated with the three critical phases of CAR-T cell therapy.

3.2.6. Coping Strategies. Coping strategies refers to the cognitive-behavioural way in which patients deal with stressful events and the emotional consequences. Coping strategies used by the interviewed patients can be grouped into three subcategories: proactive coping strategies, those aimed at restructuring one's way of thinking and being and,

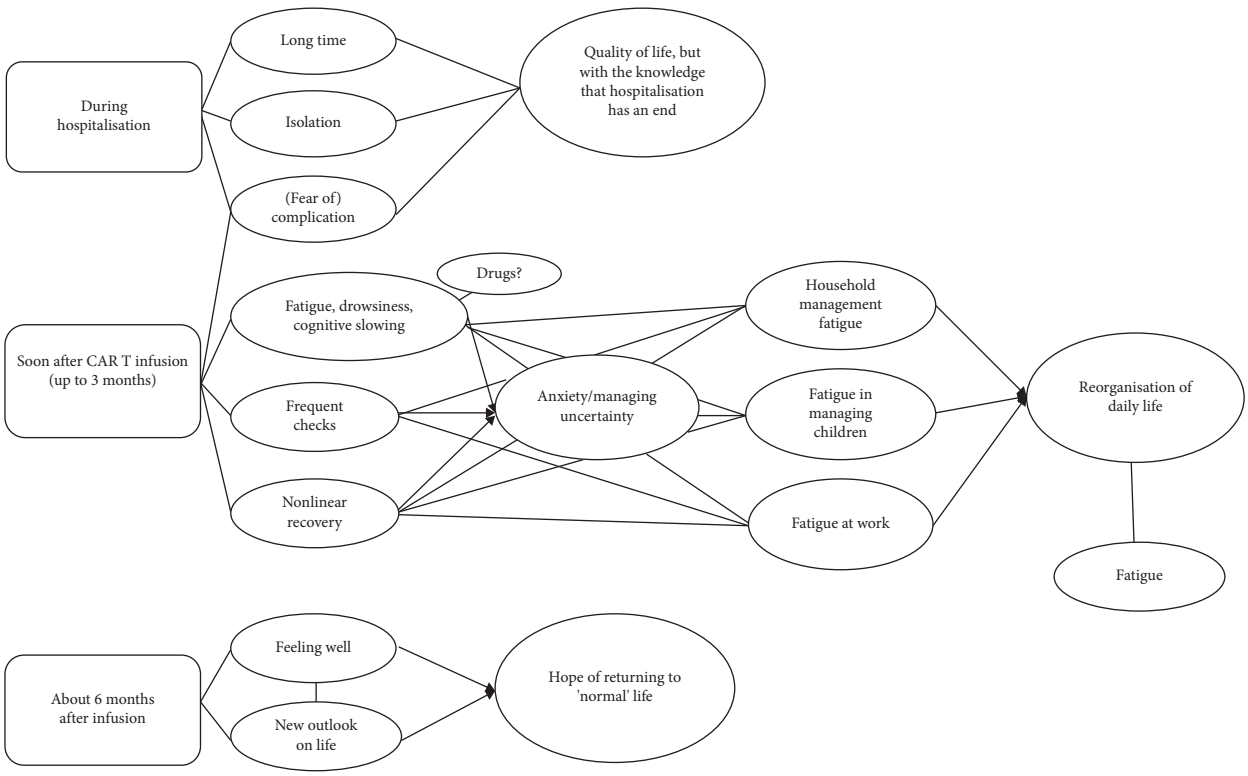

Figure 2: Summary of conceptual relationships between themes and subthemes in the three phases of CAR-T-cell therapy.

finally, although less frequently, those related to seeking closeness.

Proactive coping strategies were the most commonly used by patients, as they helped to occupy time and divert attention away from therapy and its potential outcomes, focusing instead on enjoyable activities.

'I am not used to staying at home. And so, I have to take the time my body may need, but my mind tells me the opposite. So I have to keep myself busy because the days when I am at home in immobility are hard days for me [. . .]. Because then I am always concentrating on the same subjects, on the same things, instead, the fact that I am working, that I am maintaining my habits of life, makes me a little lighter' (pt. 7).

These strategies could be distractions (i.e., personal hobbies or work), searching for information about the therapy on the internet, or expressing generativity by engaging in acts of reciprocity as a way of giving back the support one has received (i.e., doing volunteer work). Strategies that focused on restructuring one's ways of thinking and being were diverse, ranging from optimism about therapies and the future, as mentioned above, to faith in scientific research, as well as approaches such as irony and fatalism.

'In life I am optimistic, I always have a smile on my face, [. . .]and I always try to deal with it in the best way possible. [. . .] It's happened and you try to resolve the situation, even though it's not easy and it's not going to be easy [. . .] I don't know what's going to happen to me. But I believe in research, then I think I'm lucky to live here in the north of Italy' (pt. 2).

'My wife would say [that I take the problem lightly], I joke about the situation. When I want to make my wife angry, I say: 'Let's worry about those who are sick, I'm fine, thank God. I'm cured, I'm fine,' and she gets angry at me [and says] 'you're not cured' (pt.6).

'I am not afraid of CAR-T-cell therapy, and I have an explanation for this [. . .]. When I was 18-19 years old, I got my first car, a Giulietta 2000. It was my pride and joy [. . .] and the first winter [. . .] on a Saturday night with ice, I drove straight ahead on a bend. The car broke in two around a plant. And the next morning the old ladies [. . .] who were going to church saw the car go by and made the sign of the cross. I came out of that situation with a stitch here and a stitch there, just because I was bleeding, not because I was ill. Since then I have been convinced that things are as they should be. What does that mean? That if this thing [the CAR-T therapy] goes wrong, it's not that I'm happy, I've got 1,000 things to do, I love my wife, I hope to stay here, but if it goes wrong next month, never mind! It may sound ridiculous, but it's related to that experience when I could have been killed [. . .]. That's why I'm frighteningly calm [about the outcome of the treatment]. My wife is terrified, but I try to cheer her up, to be funny. . .' (pt. 6).

Finally, seeking interpersonal closeness strategies included pursuing support from friends and work colleagues, as well as searching warmth and closeness from an animal friend.

3.2.7. The Needs. Patients verbalised numerous and varied needs, which could be grouped into 5 subthemes: (1) needs during hospitalisation; (2) existential needs; (3) needs to improve QoL; (4) needs for quality and quantity of information about CAR-T cells and (5) needs for care. With the exception of needs specific to re-hospitalisation, which is typical in this phase of therapy, most of the other needs spanned within three critical phases identified by patients: (1) during hospitalisation, (2) 3–6 months postinfusion and (3) beyond 6 months postinfusion. Many of these needs echo themes that have been previously discussed, so only a few new "needs" are presented here.

There were two types of needs during hospitalisation. The first was the need to speed up the perceived time spent in the hospital. This could be achieved by allowing patients to receive visitors, even if only behind glass, by providing access to activities such as television and the internet, and by ensuring that they were in comfortable, spacious rooms—amenities that were not always available in hospitals where patients have been admitted:

'These small rooms, so cramped for a person who is hospitalised from 2 to 29 days. . . I felt like a hamster because at the end I was always turning around. . . Perhaps the possibility of having a little more space can help from a psychological point of view, because it's obvious that direct contact is not possible, as it should be. . . So there is the glass through which you see your family. . .' (pt. 7).

The second need was related to the possibility of having staff capable of 'caring', hence, that was able to be empathetic and responsive to patients' needs that arose during admission (see also 'perceptions of the quality of care received').

'They [doctors and nurses] were always very kind and treated me properly, as you should treat a patient. I also had walking problems at the time and everyone was kind and straightforward as far as. . .. I have good memories' (pt. 4).

The needs defined as 'existential' were of three types. The first was related to the hope that CAR-T cell therapy will cure the disease and that the future will be positive and in continuity with the previous life (see also the theme 'CAR-T cell images):

I would need to hear some positive news, to be told: 'You're cured', that's what I would need. I don't lack for material things, but now of course I need a push to tell me: 'You're doing well', that the second check-up is going well [. . .], I really need some positive news' (pt.9).

The second need was related to the ability to decide whether or not to tell others about the illness and treatment itself (see also the subtheme "(Not) informing loved ones about the ongoing treatment").

'I did not say anything about my hospitalisation, I want everything to be normal and I want him [my 17-year-old son] to be calm. I've come here, doctor, to tell you that I've decided to show him normality. [. . .] To this day, I have tried to live with the illness, but mentally I have tried not to think of myself as ill' (pt. 7).

Finally, the third aspect addressed the need for patients to feel recognised as individuals facing a challenging time in their lives, ensuring that their unique needs and struggles were fully recognised rather than minimised.

'I don't want to be belittled, I don't want to be pitied, often I don't say anything even when I feel bad. But always trying to see the glass as half full [. . .] is something that bothers me, because I need to be understood and I need someone to say to me: 'I know how much you are suffering' (pt.9).

The need for improvement in QoL presents three aspects: improvement in physical symptoms/side effects of CAR-T cells (more energy, less fatigue and better sleep at night), being able to do what you love, and finally being able to access CAR-T cell treatment without having to wait for other prior treatments.

'What we are going to work on, and are already working on, is the control of side effects and everything to reduce the side effects of CAR-T, both immediately and in the long run' (pt.9)

'It would be great if we could skip the step of autotransplantation and go directly to CAR-T after the first-line therapy in the day hospital, which is easily manageable. Because first of all, physically it was very, very hard and then because you pay the consequences anyway. At the level of the bone marrow, it is so weakened that it would be better to skip this step, because for some people it leads to a positive result, but for many people it is an intermediate step between the transplant and CAR-T and it is not a small step! The best thing would be [. . .] to go straight to CAR-T' (pt. 8).

The needs for improvement in the quality and quantity of information on CAR-T cells were related to the availability of more details on therapies, more precise links between professionals and between hospitals, and better knowledge of the services offered to patients with diseases such as myeloma, lymphoma, etc. In addition, patients would like to see greater cultural awareness of oncohaematological diseases.

The first aspect relates to the need for a clearer understanding of the purpose of CAR-T cell therapy—whether based on research or clinical use—both through better communication from physicians and more streamlined, understandable informed consent processes. In addition, patients would want a transparent understanding of the therapy's progress, including information about the possibility of treatment failure.

'I have to know how things are. . . there is no point in not knowing, even if they tell me there is nothing more to do. Then it's up to me to decide what to do with my life, how to

live. But it is right that a patient, at least as I see it, rightly knows what is there. That they really tell me things as they really are' (pt.9).

'In view of improvement, certainly more efficient communication… efficient… that makes people understand! That reassures the patient, not only from a bureaucratic point of view!' (pt.10)

The second aspect was represented by the need for voluntary organisations to raise awareness of the initiatives available, especially those offered free of charge, to support oncohematology patients. These included psychological support, assistance with transport to treatment and access to nearby accommodation during hospital care, etc.

'Even in the institute itself, perhaps at the entrance to the wards in the waiting rooms, this [opportunity for patients] should be sponsored a little more' (pt. 5).

Finally, care needs were diverse and could be divided into four aspects. Firstly, psychological support, which is available to both patients and carers who felt they needed it at a particular stage of the illness or therapy, and the promotion of any services that offer it free of charge:

'I asked if there was the possibility [of psychological support], but it was my request and in my opinion, you [psychologists] should propose it. I don't know how much availability you have […] but make it clear that the patient knows that if he/she needs help, there is a good help, which is you' (pt. 5).

'I dare say that [psychological support] should be… absolutely… standard! That is to say, all along the way! […] then you decide whether you need it or not' (pt. 10).

'Also for the carers. Because I see that my wife, for example…. Almost unconsciously, subconsciously… Her emotional state as a result of the controls… […] I notice changes in her attitude, in her behaviour, whenever I go to the hospital' (pt. 1).

The second aspect was related to the need for comparison with other patients on the same treatment; patients expressed, in fact, the need to share experiences, emotions and strategies to cope with the disease and the challenges of therapy with other people who were undergoing the same treatment:

'Sometimes I have this curiosity… even to compare myself with someone who is going through what I have been through' (pt.9).

The third aspect concerned the enhancement of the NHS, both in its 'structural' aspects (e.g., speeding up diagnosis, treatment, availability of free places to carry out analyses and examinations, etc.) and in aspects of empathy, caring and communication skills of healthcare personnel:

'I think we should prioritise, prioritise the neediest cases, those who cannot wait…. […] '(pt 1).

'I'm here now, I'm keeping my fingers crossed, I'm still here and I'm doing well. But if I hadn't had certain connections…. […] I ask myself, where could I have been? Because there are some things that don't work, and I think they can all be solved, because they are important things, especially for those who are sick, because at the end of the day, someone who is told: 'I can't find a place to do some tests or an echocardiogram to continue the second therapy'… Eh, if you don't have the echocardiogram that the cardiologist gives you, you can't continue with the second therapy…' (pt. 1).

'[In another hospital] they gave me an appointment with one of their doctors, but this doctor, the first time I went there, without even providing me a diagnosis, says to me: 'Do you have private insurance? ', 'Uh, no, I don't have insurance'… I mean, a person who comes to you so full of fear, because this doctor didn't give me much hope anyway… […] I want to be treated first of all as a person and not as a number or as a source of money' (pt. 5).

The fourth aspect focused on the need for extensive support from voluntary organisations, particularly in relation to the availability of accessible accommodation near the hospital during treatment, as well as assistance with transport to visits and therapies.

'I am lucky because I live in Milan, very close to the Istituto dei Tumori. […] I see a lot of people arriving with suitcases because they are staying in hotels' (pt. 1).

'And then also knowing that there is this support network of [name of organisation] was very important for me. […]I benefited, I was lucky to have this flat and I benefited from the accompaniment to the therapies. But I also knew that they were there in case I needed something else, for that it was fundamental' (pt. 8).

'the accompaniment to therapies, which I used a lot' (pt. 8).

Finally, the fifth aspect concerned the need for practical help (e.g., with housework, childcare, etc.) during treatment, a time when patients felt particularly tired and lacked in energy:

'It's tiring! If you manage not to lose your temper… […] and then you need everyone… if you don't hold up well, you can need a lot of people' (pt. 1)

Starting from quotations, we identified 41 different needs. Table 3 provides a comprehensive list of all identified needs, organised by the five subthemes (checklist).

4. Discussions

The present study shows that patients undergoing CAR-T cell therapy experience novel and significant challenges in relation to prior therapy, which vary across three different phases of their care pathway. The hospitalisation period is perceived as excessively long and lacking of distractions,

Table 3: Needs checklist.

Macro areas	List of needs	Presence/absence of needs assessment for the patient
Needs for improving QoL	1. During hospitalisation, the possibility of receiving visitors with all the necessary precautions	Yes 0 No 0
	2. To have the opportunity to socialise with other patients while in hospital	Yes 0 No 0
	3. During hospitalisation, to have leisure activities to pass the time	Yes 0 No 0
	4. Being able to enjoy a pleasant and well-maintained environment while in hospital	Yes 0 No 0
	5. Having staff to look after my physical needs during my hospital stay (e.g. taking me to the toilet, etc.)	Yes 0 No 0
	6. During my stay in hospital, I feel that the staff are attentive to all my needs	Yes 0 No 0
Existential needs	7. Knowing that my life will get better	Yes 0 No 0
	8. Thinking that CAR-T cell therapy will be OK	Yes 0 No 0
	9. Knowing that CAR-T is not the last possible therapy, that there are other therapies available	Yes 0 No 0
	10. Telling myself that everything is going well	Yes 0 No 0
	11. Need for consistency/continuity with my previous life	Yes 0 No 0
	12. Faster healing time	Yes 0 No 0
	13. Being able to decide whether or not to tell others about my condition	Yes 0 No 0
	14. Others recognising the hardship of my illness and treatment/not belittling my situation as a sick person	Yes 0 No 0
Needs to improve quality of life	15. Slowing down the pace of daily life	Yes 0 No 0
	16. Dedicate my time to my passions and hobbies	Yes 0 No 0
	17. Have more energy	Yes 0 No 0
	18. Not feel physical pain	Yes 0 No 0
	19. Sleep well at night	Yes 0 No 0
	20. Receive CAR-T cell treatment immediately	Yes 0 No 0
	21. Reduce side effects of CAR-T cells	Yes 0 No 0
Need for quality and quantity of information	22. Better understanding of the purpose of CAR-T cells	Yes 0 No 0
	23. Know how long the beneficial effect of CAR-T cells lasts	Yes 0 No 0
	24. Have a clear idea of how the therapy is progressing	Yes 0 No 0
	25. Receive clearer and more concise informed consent for CAR-T cell treatment	Yes 0 No 0
	26. Cultural awareness of the disease and possible treatments	Yes 0 No 0
	27. More free initiatives for patients by care organisations	Yes 0 No 0

Table 3: Continued.

Macro areas	List of needs	Presence/absence of needs assessment for the patient
Needs for care	28. Having someone to support me psychologically	Yes 0 No 0
	29. Having someone to provide psychological support for my loved ones	Yes 0 No 0
	30. Comparing myself with other patients undergoing CAR-T cell therapy	Yes 0 No 0
	31. Having someone to help me manage my daily life	Yes 0 No 0
	32. Having someone close to me during treatment	Yes 0 No 0
	33. Having a telephone number where a competent person can answer in case of need	Yes 0 No 0
	34. Having the support of organisations	Yes 0 No 0
	35. Having accommodation close to the hospital during CAR-T cell therapy	Yes 0 No 0
	36. Rapid access to visits and tests	Yes 0 No 0
	37. Being able to easily find places for visits and tests	Yes 0 No 0
	38. Free access to visits and tests	Yes 0 No 0
	39. Receiving timely treatment after diagnosis	Yes 0 No 0
	40. Having compassionate healthcare personnel	Yes 0 No 0
	41. Having available healthcare personnel adequately trained in the pathology (competence)	Yes 0 No 0

defining the experience as highly dull. Three to six months after infusion, as demonstrated by prior research [13], physical symptoms emerged including fatigue, drowsiness, and cognitive slowing or dysfunction, resulting in patients experiencing difficulty in self-recognition. These symptoms frequently appear/disappear abruptly, leaving patients feeling unprepared and insecure. Moreover, the regular checkups at the referral hospital significantly impact patients' QoL, particularly for those residing at a distance from the treatment centre, as previously indicated in the study conducted by Stenson et al. [15] Despite these three moments, certain challenges encountered by patients are transversal: the physical and psychological adaptation to the new (and recurring) therapy; the multitude of emotions, often concurrently, that require management; the decision of whether to disclose yet another line of treatment to loved ones; and the worry regarding economic circumstances related to unstable employment or costs associated with healthcare migration.

The creation of subthemes did not bring to light the spiritual dimension that some authors consider to be an important part of QoL [23, 24], but they do reveal a strong fatalism and a 'magical' belief in the positive outcome of CAR-T cell therapy, already highlighted by previous studies [13, 15]. Mao et al. [13] call this belief 'new hope' (p. 303) and explain it by the fact that for many patients, it is the last possible treatment option. Indeed, as shown in other studies and confirmed in this study, surveyed patients received CAR-T cell therapies after numerous other unsuccessful treatment attempts [9, 15].

Engaging in a process of reflexivity, we acknowledge that our analysis (and, in particular, the two themes "Emerging issues to address" and "Three challenging moments") is informed by our previous knowledge of the concept of "quality of life" in oncology. Researchers linked specific elements identified throughout the analysis to QoL dimensions already known in the existing literature (e.g., economic impact).

The results of the present study are consistent with those of existing research [9, 15], which identify deterioration in several domains, including social, emotional, physical, and cognitive functioning and fatigue when evaluating QoL. However, this study did not address the coping strategies that are essential for patients to manage the demanding and exhausting nature of CAR-T cell therapies.

This study also reveals numerous and diverse coping strategies, in particular those defined as 'active coping' (e.g., seeking information, trying to 'hold on' and fight the illness, seeking psychological support, surrounding oneself with affection, trying to live life as best one can, etc.), those defined as 'distraction/self-affirmation' (e.g., trying to distract oneself), those defined as 'minimising importance' (e.g., minimising the importance of the seriousness of the situation, etc.), and those defined as 'religiousness', the latter as acknowledging only the gravity of the situation. Less present are 'depressive' strategies (e.g., avoidance of others) [25].

It is important to study the coping strategies used to manage the challenges of therapy, as they may influence the psychosocial adjustment with which one copes. The adopted coping strategies are also among the factors that most influence QoL and the adherence to medical treatments [26]. The theme 'Perception of the quality of care received' highlights how the doctor-patient relationship could be improved, particularly in the care pathway of patients in centres that are not referral centres for CAR-T cell therapy: specific attention must be paid to the presentation of informed consent.

Moreover, patients' needs were numerous, diverse and often unmet. While some needs, such as ensuring treatment success, could not be met, many others could. These included improving doctor-patient communication and establishing a psychological support pathway as a standard (though not mandatory) option for patients undergoing CAR-T cell therapies. In addition, better management of treatment side effects and increased awareness of free services available within the hospital represent important areas for improvement. Patients included in this study shared some common needs with the general oncology population, as already identified in other studies also conducted within INT (e.g., some psychological, care and QoL improvement needs, comparison with other patients undergoing the same treatment, etc.) [27–30]. However, other needs appeared to be specific to this treatment and were not reported in the existing literature (e.g., improving the time and space of long-term hospitalisation, greater dissemination of initiatives within the hospital, the importance of support from voluntary organisations, etc.). Reflecting the lack of QoL dimensions related to spiritual well-being, patients did not spontaneously verbalise needs in this area.

Knowing these patients' needs is a starting point, not only to increase the scarce knowledge about these patients' experience, but also to think about how to respond to some of their needs. For this reason, a first draft, which may or may not be confirmed by future studies, of a needs assessment checklist has been prepared. At present, it has been proposed as a list of items with yes/no answers, but it might be useful to rate it as a multistage Likert response (e.g., from 1 = 'not at all' to 5 = 'very much'). Once finalised, it may be useful to administer the checklist together with a QoL instrument during and after CAR-T cell infusion to continuously monitor these aspects during the three crucial phases of therapy and subsequently develop intervention strategies. In addition, future studies could highlight the intensity of these needs in each specific phase of treatment.

4.1. Limitations. The present study has several limitations that should be taken into account. First, most of the participants interviewed after CAR-T infusion reported a positive experience. We did not have any respondents who expressed dissatisfaction with their choice of treatment, which could influence the results presented here. However, it is important to note that some dissatisfied patients may have died, and their views and experiences could not be recorded. Secondly, as the study is monocentric and in line with its research objectives, the experiences reported by patients may not be generalisable to other contexts. Finally, due to the

research methodology, it is not possible to quantify or prioritise the needs identified; we can only list them. Future studies could better address these limitations.

5. Conclusions and Future Research

The present study serves as an initial survey of aspects that are underexplored in the existing literature but are essential to lay the foundation for a quantitative phase. This quantitative phase could quantify and prioritise the needs identified in the first phase. In addition, the quantitative findings could be used to inform intervention projects, such as addressing the priority needs of this population, developing a specially structured diagnostic and therapeutic care pathway, and implementing advocacy interventions.

From a research perspective, future developments could include the use of Patient Reported Outcome Measures (PROMs) to systematically investigate the QoL and needs of these patients [31–34].

HCPs could use this information to better support patients before, during and after treatment. Taking QoL into account is essential when making treatment decisions, particularly as there are multiple treatment regimens for cancer. This is particularly important for patients, like those who have been interviewed, who received CAR-T cell therapy after a long and arduous course of treatment. In addition, the present study provides initial insights into the development of multidisciplinary diagnostic-therapeutic-support pathways that are aligned with community services. Furthermore, the importance of training HCPs on CAR-T cell treatment should not be underestimated, as it is still poorly covered in university courses for general practitioners, nurses and mental health professionals (i.e., psychologists and psychiatrists). In order to provide full support to patients undergoing this treatment, specific and quality training is necessary.

Voluntary organisations could also implement some of the proposed solutions. Psychological support, the availability of companions for patients during treatment and accessible accommodation close to the hospital were particularly valued by this study's patients. However, the latter suggest that such services should be more widespread and accessible. The continuation and expansion of these services are essential for patients undergoing CAR-T cell therapy.

Data Availability Statement

Data are available on request from the authors.

Conflicts of Interest

A. Chiappella: Advisory boards and/or honoraria for lectures/educational events: Abbvie, Gilead Sciences, Eli Lilly, Incyte, Ideogen, Hoffmann La-Roche, Janssen-Cilag, Novartis, SecuraBIO, Takeda. The remaining authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. *(Supporting Information)*

Appendix 1: Semistructured interview outline.

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