

P6-05-40: Aqua polo: Preliminary feasibility and efficacy study of a programme of adapted, supervised water polo to reduce fatigue and improve women's psychological and social recovery after breast cancer treatment. A mixed-method design

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Aqua polo: Preliminary feasibility and efficacy study of a programme of adapted, supervised water polo to reduce fatigue and improve women's psychological and social recovery after breast cancer treatment: A mixed-methods design

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ABSTRACT

Physical activity has been shown to have many benefits, including reducing cancer-related fatigue (CRF) and improving psychological and physical recovery from breast cancer. Some authors have shown the benefits of aquatic practice, while others have detailed the benefits of group and supervised practice. We hypothesize that an innovative sports coaching proposal could allow a significant adherence of patients and contribute to their health improvement. The main objective is to study the feasibility of an adapted water polo programme (aqua polo) for women after breast cancer. Secondarily we will analyse the effect of such a practice on patients' recovery and study the relationship between coaches and participants. The use of mixed methods will allow us to question the underlying processes precisely. This is a prospective, non-randomized, monocentric study with a sample of 24 breast cancer patients after treatment. The intervention is a 20 week programme (1 session per week) of aqua polo in a swim club facility, supervised by professional water-polo coaches. The variables measured are patient participation, quality of life (QLQ BR23), CRF (R–PFS) and post-traumatic growth (PTG-I) as well as different variables to observe physical capacity (strength with dynamometer, step-test and arm amplitude). The quality of the coach-patient relationship will be evaluated (CART-Q) to explore its dynamics. Participatory observations and interviews will be carried out to report on the interactions between the coach and the participants during the sessions.

Registration number and name of trial registry: No. EudraCT or ID-RCB: 2019-A03003-54 and NCT: NCT04235946

1. Introduction

The GCO predicts that the worldwide incidence of breast cancer in women will increase by 1 million by 2040 [1]. The growing number of remissions [2] raises the question of quality of life also seriously affected by the chronicization of cancer-related fatigue (CRF) [3,4]. CRF directly impacts patients' vitality (exhaustion, lack of energy, weakness) and is multifactorial (reduced physical and mental capacities, effects of

treatments, anxiety, stress, pain, sleep disturbance) [5–7]. Between 56% and 95% of patients develop CRF after treatment [8]. 20% suffer from CRF several years after the end of the treatment [9,10]. In the course of the first year, most survivors say they lacked social support to manage the secondary effects and the long-term treatment complications, or to overcome uncertainties about recurrence [11,12]. Finally, some studies show that patients whose psychological distress or fatigue is greater have a higher risk of recurrence or mortality [13].

Abbreviations: GCO, Global Cancer Observatory; PA, Physical Activity; CRF, Cancer-Related Fatigue; PTG, Post-Traumatic Growth; DSM, Diagnostic and Statistical Manual of Mental Disorders; APA, Adapted Physical Activity; eCRF, Electronic Case Report Form.

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The literature shows that physical activity (PA) before and/or after breast cancer diagnosis may improve global and specific survival and reduce risk of recurrence [14]. Moreover, by limiting physical deconditioning, PA improves physical capacities such as strength, endurance and flexibility [15] and so brings functional benefits that maintain the general autonomy, essential for satisfactory quality of life [16,17].

Many recent studies have revealed that PA may reduce CRF [18,19]. Moreover, some authors have shown that PA programmes adapted to breast-cancer survivors' needs, wishes and characteristics help to counteract emotional distress [20]. Despite all the benefits mentioned above, in breast cancer survivors a 64% reduction in moderate physical activity was noted 12 months after diagnosis, resulting in a level of PA below the international recommendations [21,22]. Hence the characteristics of a specific PA and the conditions of practice should be considered [23] to encourage patients to be active in the long term and break the vicious circle of physical deconditioning.

Regarding aquatic activities, the literature shows that arm movements in water are less painful than similar movements on land [24]. A programme of aquatic activity improves physical capacities [25] and specifically the muscular and joint functions of the shoulder. It also reduces pain in women who have undergone a mastectomy [26] and hormone therapy-induced joint pains as well [27]. The feasibility and efficacy of activity in deep water for breast cancer survivors have been demonstrated [28]. Likewise, a recent randomized controlled trial showed that for breast cancer patients aquatic activity significantly improved endurance and body mass and reduced distress and fatigue levels [29]. However, the significant advantage of aquatic therapy over more conventional treatments still remains to be demonstrated [30].

The therapeutic alliance and group cohesion among the patients are factors that contribute to effective participation in the activity [31]. Studies on the use of the Dragon Boat (team sport using a dugout-type boat that can hold up to 22 participants) in breast cancer patients showed the efficacy of team sports in ensuring the continuity of participation in a PA [32] and in contributing to patients' post-traumatic growth (PTG) [33]. PTG is part of the patient's psychosocial recovery and is defined as an experience of significant psychological development leading the individual to make structuring changes (changed priorities, closer and warmer interpersonal relations, new life possibilities and perspectives, spiritual development) [34]. It is part of the patient's psychosocial recovery.

These latest findings in the literature lead us to think that regular, collective, aquatic physical activity makes it possible to achieve maximum efficacy and would favour the participants' commitment. Consequently, given that at the present time water polo is the only existing aquatic collective sport, devising this physical and recreational activity seems to be a relevant, innovative and ambitious choice. Indeed, since recent studies suggest that the social support resulting from the activity significantly benefits the patient's mental health and psychological well-being [35,36], we suggest that a collective sport of this type can create a supportive social environment. This raises the question of whether the links that are built up between the patients (considered here as athletes) and the coaches [37] play a significant role in the maintenance of physical activity and the patients' physical and psychological well-being. In addition, several studies have corelated the quality of the coach-athlete relationship with athletes' well-being [38-40]. These works are part of a current of reflection on psychosocial support inspired by sport for patients in remission [41,42]. The specificity of the population and the pathology in question lead us to take account of psychosocial variables characterizing psychological and social recuperation in this context.

Our aim is to establish the feasibility of a programme of adapted water polo (aqua polo) for women after breast cancer. The secondary objective is to explore the efficacy of such a programme on general physical capacities. We are also interested in the effect on quality of life, and on CRF and PTG, variables which are widely observed among breast cancer patients. Finally, our study aims to explore the potential

correlation between these result variables and the quality of the participants' relationship with the coaches.

2. Method

2.1. Study design

This is a prospective interventional, monocentric, non-randomized study aiming to measure the preliminary feasibility and efficacy of a programme of adapted water polo for breast cancer patients with a view to contributing to their physical, psychological and social recovery. The intervention proposed here consists of a programme of supervised physical activity lasting 20 weeks, with one 2h session per week. Each participant will be evaluated on inclusion once a month over the 10-month study. The evaluation conditions are specified in the assessment section.

2.2. Study setting

The study takes place in the regional cancer centre, the Institut Paoli Calmettes (Marseille, France), and in the water sports club Cercle des Nageurs de Marseille (France). Finally, the patients will be examined by a sports doctor at the Centre Provençal de Médecine du Sport (Marseille, France).

2.3. Recruitment and screening

The team of surgeons and radiotherapists in charge of breast cancers in the cancerology centre inform patients of this protocol in a face-to-face interview. An information brochure is distributed, explaining the outlines of the programme and the expected benefits and risks, and giving the contact details of the researchers in charge of the study, who are available to answer questions. After this consultation, patients agreeing to take part must sign an informed consent form. They are then invited to the sports medicine centre for all the physical examinations preceding inclusion.

2.4. Participants

The study aims to recruit a total of 24 patients having been treated in the cancerology centre. The patients' demographic and clinical characteristics will be summarized in descriptive statistics.

2.4.1. Inclusion criteria

- Women aged 18 to 65
- Breast cancer diagnosis (all types of cancer and treatment)
- Inclusion between three weeks and three months after end of chemotherapy and/or radiotherapy (patients who have had surgery may be included from six weeks after the operation).
- Live within 40 km of the cancer centre
- Have a basic swimming level
- Certificate of fitness for the activity from the Sports Medicine Centre¹
- For immunotherapy patients: no anomaly detected in most recent cardiac echography.

2.4.2. Non-inclusion criteria

- Undergoing chemotherapy
- Incomplete healing
- Metastatic cancer

 $^{^1}$ To obtain this certificate of fitness, patients are given a series of tests by specialist doctors (e.g., cardio-vascular examination, pulmonary examination, etc.). See Appendix 1.

- Asthma provoked by physical exercise
- Proved mental disorder (dsm-5)
- Pregnant or breast-feeding
- Inability to read and understand French.

2.5. Intervention

This study consists in the organization of one session of aqua polo (adapted water polo) per week over a period of 20 weeks. To comply with the international recommendations on levels of physical activity [21], patients will be encouraged to undertake sessions of autonomous physical activity in addition to the supervised sessions. The adapted physical activity (APA) teacher and the coaches on the premises will guide the patients in this activity.

The aqua polo programme will be divided into three phases: the first is devoted to physical preparation, the second to practical learning (technique and tactics) and the third to preparing for a tournament. Each session will be organized as follows: 1 h training in water, followed by 30 min' collective or individual "debriefing" with the coach. The total length of the session will be 2 h inclusive of transport and changing.

An APA teacher will be involved and will be in charge of adapting the activity in collaboration with the water polo coaches. The senior coach and two other coaches will thus take part in this study and will coconstruct the sessions with the APA teacher. The participating coaches will be trained in applying the principles of a good relationship [43].

Adapted water polo (aqua polo) is an activity that has never been studied with women who have had breast cancer. The setting-up of such an activity, the proposed exercises and adaptations will therefore be subject to in-depth discussion between the water-polo coaches and the APA teacher specialized in oncology. To meet the recommendations and the participants' needs, the sessions will include exercises of endurance, muscle strengthening and stretching [44].

In the first sessions, particular attention will be paid to strengthening the shoulder muscles, especially for patients who have undergone a mastectomy with axillary dissection. To avoid the appearance of problems (e.g., capsulitis), exercises aimed at strengthening the stabilizing muscles will be a priority, followed by exercises for the rotatory muscles [45,46]. During the first phase, a comprehensive retraining in effort will be carried out. The participants must therefore adapt the intensity of the exercises according to their capacities. If difficulties are encountered in performing some aquatic exercises, the APA teacher may propose adjustments (flotation aids) or an on-land equivalent. The reasons for absences or dropping out of PA during training will be recorded in the intervention logbook by the social psychology researchers. The objective of this programme is to bring together the patients around a common

sports project. The rules of aqua polo are the same as those of water polo, the adaptation consists essentially in a reduction of the field size, provision of floating aids and simplification of water movements. These adaptations will be adjusted on a regular basis according to the patients' abilities. The whole programme is detailed in Fig. 1.

In addition, the proposed programme will be designed to allow the development of the constitutive dimensions of an effective coach-athlete relationship [37], from the point of view of both coach and athlete. To encourage autonomy, flotation aids and sport equipment will be provided so that the participants can adapt the activity or initiate a specific warm-up according to their needs. The training sessions will provide a safe environment favouring permanent dialogue between coaches and athletes, especially as regards the patients' aims and aspirations. To this end, a 30-min group debriefing will follow each session of training in water. In addition, two individual meetings between coach and athlete will take place in the middle and at the end of the study. The coaches will be asked to give regular individual and collective feedback to the participants during the session, and to invite them to express their feelings or difficulties. Pauses between each activity and the next are organized to encourage discussion and recuperation.

The factors conducive to joining an aquatic programme after breast cancer are facilitated by the logistical conditions in which the programme takes place and the interactions with the group [24]. For this reason, the logistics of this innovative physical activity programme have been carefully thought through and drawn up (e.g., access to changing rooms, participants' comfort). In this regard, with a view to limiting problems associated with body image, swimming costumes specially designed for women after a mastectomy will be offered to the patients at the start of the protocol. Finally, full personalized equipment will be distributed to all participants and the coaches so as to favour a collective identity and social bond among all the people involved.

2.6. Assessments

The main objective will be to determine the feasibility of a supervised water polo programme by evaluating the patients' participation in this programme. The secondary objectives are to observe change over time in the physical and psychological parameters and to explore the nature of the coach-patient relationship. The frequency of the measurements is summarized in Table 1.

Health research is nowadays tending to widen its research questions so as to examine not only the efficacy of a given intervention but also the modes of action of the processes at work [47,48]. To do this, it favours a mixed research methodology. This term refers to the systematic integration of quantitative and qualitative data within the same study [49].

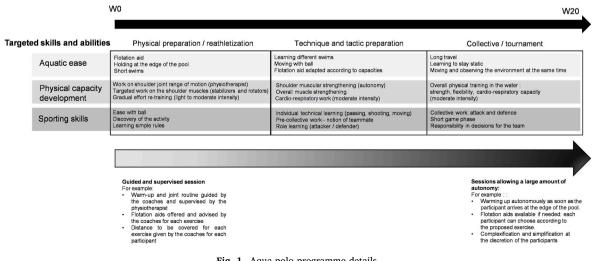


Fig. 1. Aqua-polo programme details.

Table 1Protocol flow chart.

	Inclusion	W4	W8	W10	W12	W16	W20
INCLUSION							
Criteria for inclusion and non-inclusion	X						
Signature of informed consent	X						
Pregnancy test (if applicable)	X						
Visit to sports doctor to validate aptitude for aqua-polo INTERVENTION	X						
		**					
Sessions of adapted water polo (1/ week)		X	X	X	X	X	X
PHYSICAL MEASURMI	NTS						
Height	X						
Weight	X	X	X		x	X	x
Fat/lean mass	X	X	X		X	X	X
Amplitude of arm on side of treated breast	X			X			X
Step test 3 min	X			X			X
Handgrip strength	X			X			X
Quadriceps strength (dynamometer)	X			X			X
SCALES AND QUESTIC	NNAIRES						
QLQ-BR23	X			X			X
R-PFS	X	X	X		X	X	X
CART-Q				X			X
PTGI	X						X
INTERVIEWS							
Semi-directive	X			X			X
interviews							
Participant		X	X	X	X	X	X
observations							

It enables methodological triangulation and thus strengthens the results obtained.

2.6.1. Feasibility measurements (primary endpoint)

As a prospective study the feasibility of this proposal for supervised sport will be evaluated by the percentage of patients completing the programme (>60% of sessions completed).

2.6.2. Physical measurements (secondary endpoints)

These measurements will be made by the APA teacher and a physiotherapist.

Fat/lean mass ratio:

The fat/lean mass ratio will be evaluated with the measuring device Biody XPERT II (eBIODY, La Ciotat, France).

• Amplitude of arm movement on side of treated breast:

This measurement will be calculated in degrees, based on the projection of an angle on a wall from which the mobility of the treated arm will be evaluated. This measurement will be made by a physiotherapist.

• 3-min. Step test:

The 3-min step test is a sub-maximal test to measure aerobic capacity. It consists in stepping up and down on a step at a rate given by a metronome for 3 min. To make it easier to apply, the test will be adapted. Participants' heart rate is recorded before the test (initial), at the end (final), after a minute's recovery (+1 min) and after 3 min' recovery (+3 min). This test, which is easy to administer, is used on many populations [50].

• Grip strength:

To measure the grip strength of both hands, we use a hand dynamometer. Several authors have demonstrated the predictive potential of grip strength for the general state of health [51]. Each patient can perform two tests for each hand; the better test of the two will be kept for analysis. The stronger hand of each patient will be noted.

• Strength of quadriceps (dynamometer):

To measure the strength of the quadriceps, we shall use a test in seated posture with a conventional dynamometer [52]. The recent study by Morishita et al. [53], on a similar population, showed the pertinence of this test. Each patient can perform two tests for each leg; the better test of the two will be kept for analysis.

2.6.3. Psychosocial measurements (secondary endpoints)

All the questionnaires, validated in French, will be administered face to face before the sessions by a member of the social psychology research team.

- Post-Traumatic Growth Inventory (PTGI) [34,54]. This questionnaire
 has 21 items and the response scale is a 6-point Likert scale. It consists of 5 sub-scales: new possibilities (5 items), relating to others (7
 items), personal strength (4 items), appreciation of life (3 items) and
 spiritual change (2 items).
- Quality of Life Questionnaire Breast-Core QLQ-BR23 [55]. This
 questionnaire is self-administered and specific to breast cancer. It has
 23 questions to evaluate body image, sexual functioning, sexual
 pleasure, future perspectives, secondary effects of systemic treatment, mammary symptoms, symptoms of the arm and problems
 caused by hair loss. All the questions evaluate quality of life in the
 previous week and month.
- Revised Piper Fatigue Scale (R-PFS) [56,57] for breast cancer survivors. This tool has 22 items which the patient answers using a Likert-type scale of feelings. There are four sub-scales: sensory, affective meaning, cognitive/mood, behavioural/severity.
- Coach-Athlete Relationship Questionnaire (CART-Q) [58,59]. This tool examines the relational dynamic between coach and athlete. It is an 11-point self-questionnaire measuring the three dimensions presented previously: commitment, proximity and complementarity. All these elements are measured on a Likert scale from 1 to 7. There are two versions (direct and meta perspective) to evaluate co-orientation within the relationship.

2.6.4. Semi-directive interviews (secondary endpoints)

Semi-directive interviews will be planned and conducted by social psychology research team and an interview guide will be drawn up. These semi-directive interviews will be conducted face to face with each participant. They are devised so as to study specifically the pertinence of the relational approach and to discover the impact of the APA programme on the psychological variables of interest and the processes of establishment of the relationship. The participants will be questioned in particular on the psychological state they experienced during the programme and the nature and quality of their relationship with the coach, in emotional, cognitive and behavioural terms.

2.6.5. Participant observations (secondary endpoints)

These observations will be made by two members of the social psychology research team. They are called "participant" observations because the researchers will be immersed in the field for exploratory purposes but will be involved in a measured way in the life of the group, in accordance with the methodology of peripheral participant observation [60,61]. An observation grid will be drawn up in advance and will be adjusted in the course of the study based on the processing of the first qualitative results. The choice of two researchers is justified by a

concern for reliability and cross-checking of the data thus collected.

2.7. Data collection and flow chart

The physiological tests, the questionnaires and the interviews following inclusion will be carried out in the cancer centre; they will then take place before training sessions in the water sports centre as set out in the flow chart (Table 1). The semi-directive interviews will be recorded on Dictaphone, after the patient has given written agreement. The observations will take place during each session in the programme.

The patient's whole pathway is summarized in Fig. 2.

Several undesirable events will be considered as related to the research: cardiac accident, traumatic injury requiring hospitalization, risks related to aquatic activity. Adverse events will be reported by the coaches during training and collected in the eCRF dedicated to the project. In the event of a serious adverse event, the investigator will inform the promotor centre, which will write a report and inform the competent authorities, in this case the national drug safety agency.

2.8. Patients and public involvement

Participants are not involved in the development of the research and

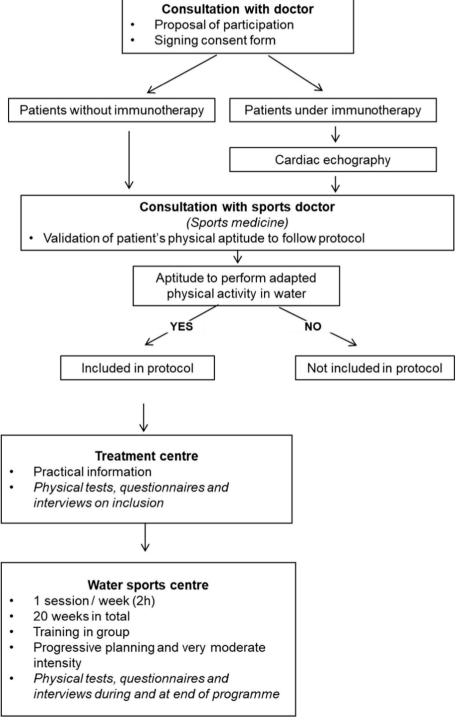


Fig. 2. Patient's pathway.

the design of the study. However, we plan to conduct semi-structured interviews and group debriefing sessions to allow readjustment of the intervention during the programme. Patients will be kept informed of the results of the study if they request it.

3. Data analysis

3.1. Sample size (and power estimate)

It is expected that 70% of the patients will complete 60% of the scheduled sessions. We plan to enrol a total of 24 patients to reach a power of 95% so as to demonstrate with the aid of a unilateral Fisher's exact test for binary proportion with a 2.5% error risk that the real proportion of patients who complete at least 60% of the scheduled sessions is higher than the unacceptable proportion (p0) of 40% [62].

3.2. Analysis of main criterion

The main criterion of the study is the percentage of patients who complete 60% of the scheduled sessions. It will be estimated with a 90% confidence interval for binomial proportions. The null hypothesis (H0: p \leq 40%) will be rejected if the lower bound of the estimated confidence interval remains higher than the pre-set 40% threshold.

3.3. Analysis of secondary criteria

Patients with an inclusion value and at least one post-inclusion value will be regarded as evaluable for each questionnaire. It is not planned to impute missing evaluation criteria. In view of the planned number of patients, no correction of significance thresholds of the various tests is planned.

- <u>Physiological measurements</u>: The raw values and changes in the parameters height, weight, fat mass, lean mass, amplitude of treated arm, 3-min step test, grip test, quadriceps strength, will be presented in descriptive statistics. Global change in each parameter will be measured by the global slope estimated by a random slope linear regression model with a 95% bilateral confidence level.
- <u>Scales and questionnaires</u>: Changes in scores after inclusion will be modelled by a linear regression model, the random slope model, taking into account the number of weeks from inclusion and the random effects linked to the subject (random intercept) and the random slope. The global change will be evaluated by the global slope estimated by the model and framed by a 95% bilateral confidence level.
- Interviews and observations:

The semi-directive interviews will be transcribed and subjected to inductive qualitative analysis using the NVivo software on the methodological basis of coding by category [63,64].

The observations will be subject to a specific coding within a grid. The frequency of the selected behaviours can be compared with the qualitative data and processed using the NVivo software.

4. Discussion

This protocol is conceived as an exploratory study aiming first to measure cancer survivors' participation in an original scheme for APA in a context of real practice. Collecting these data will make it possible to establish the feasibility of the protocol as conceived here, to be envisaged, in a second stage, in a larger-scale study. Analysis of the interviews and observations will provide valuable indications especially for increasing the efficacy of the intervention, using a triangulation of data made possible by a mixed-methods approach. However, the lack of a comparison group and of monitoring of long-term effects are the two main limits of this study.

It is now well established that regular PA after diagnosis and post-treatment is associated with reduced risk of mortality [14]. Beyond survival, meta-analyses have shown that women who regularly practice an APA after treatment enjoy improved quality of life [65]. This protocol aims to describe physical, psychological and social recovery through collective, supervised aquatic physical activity. Moreover, collective aquatic activities have a positive impact on psychological state [66,67] and lead to reduced CRF in women treated for breast cancer [27]. Enblom et al. [24] have shown that relationships established between peers favoured long-term commitment to the activity. The concept of commitment is particularly interesting, because it is a lever of maintenance in the activity, which can lead the patient toward psychological well-being.

Our protocol is part of a post-cancer support approach, in particular involving professionals from the world of sport (here, the coaches), capable of providing the continuous support needed for the patients' recovery [68]. Moreover, the collaboration with the patients' referring doctors may lead them to undertake the activity confidently and favour their commitment [69]. Questions of commitment are indeed central to optimizing the effects of the activity in the medium and long term. To our knowledge very few studies have examined the role of interpersonal relations in joining and participating in such sport programmes [70]. This protocol is conceived as a first stage study of the coach-athlete relationship in the context of APA. This relationship is essentially the means by which the patients keep coming back; the hypothesis put forward is that a good relationship with the coach makes it harder for patients to abandon their APA programme. The important thing here is how this relationship develops and is maintained throughout the intervention.

More generally, this study is in line with the logic of the holistic biopsychosocial model [71] which proposes a multidisciplinary approach integrating the patient and his/her needs into the therapeutic decisions that concern him/her.

Ethics and dissemination

Confidentiality

In accordance with the regulations, the information collected on the participants and the voice recordings of the semi-directive interviews contain only a non-identifiable study identifier (ID). A separate document linking the study IDs with the participants' identifiers is stored in a locked file

Premature termination of the study will be done either by decision of the competent authorities or by the promoter. Access to interim data will be open to all investigators.

Data safety monitoring plan

All data collected will be stored on a digital platform (eCRF) belonging to the Department of Clinical Research and Innovation of the cancerology centre running the project, which is responsible for keeping them secure.

Contributors

Sarah Cuvelier, Charlène Villaron and Sarah Calvin contributed to all phases of the protocol writing (initial idea, research question, design and assessments). Monique Cohen, Agnès Tallet and Patrice Viens are involved in the elaboration of the research question and the definition of the patient pathway. Marguerite Berline completed the final version of the protocol and submitted it to the Ethics Committee. Jean-Marie Boher is involved in the calculation of the sample and the statistical analysis of the data collected. Sophia Jowett provided extensive comments and feedback for improving the manuscript. Pierre Dantin and Sébastien Justafré are involved in the grant proposal preparation.

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Ethics approval

Ethics approval was obtained from the Institutional Review Board of Paoli Calmettes Institute (IPC 2019–028) and the National Ethics Committee (SI:20.01.20.54741). Any substantial modification of the protocol must be the subject of an amendment to the ethical authorities and the National Drugs Safety Agency.

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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101120.

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