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Development and Evaluation of a Portuguese Reproductive Health Educational and Decision Aid for Young Women with Breast Cancer

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Keywords:	Breast cancer, Young women, Fertility, Fertility preservation, Decision aid

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Development and Evaluation of a Portuguese Reproductive Health Educational and Decision Aid for Young Women with Breast Cancer

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Abstract

Introduction

Young breast cancer patients may face impaired fertility due to cancer treatments, which often leads to complex reproductive decisions. In order to aid decision-making about fertility, it is crucial women have access to high-quality information; however, in some clinical settings, their fertility information needs are often unmet. Decision Aids (DAs) are educational materials to assist with treatment decision-making, by addressing individual values and preferences. In oncofertility, DAs may constitute a valuable resource to help patients obtain more fertility-related information and make better informed decisions. The present paper reports on the protocol of the development and transcreation of a reproductive health-related DA booklet to support young Portuguese women with breast cancer, originally developed and validated for an Australian audience.

Methods and analysis

A process of forward translation, followed by an appraisal of the most recent literature and clinical guidelines on fertility for cancer patients, combined with a multidisciplinary panel of Portuguese experts will revise the scientific and cultural aspects of the DA content for a Portuguese context. After employing a process of back-translation, the adequacy of DA's content for a Portuguese audience, is assessed using Learning Verification (LV) in a qualitative cross sectional study. Two focus groups with 6 - 10 participants each within three main group categories of the intended audience: recently diagnosed young breast cancer patients, young breast cancer survivors and partners of young

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breast cancer patients will be employed. Results from the DA acceptability assessment will inform the final version of the DA. Data will be analyzed using content analysis and constant comparison method to identify key themes/textual units related to LV.

Ethics and dissemination

Ethical approval was granted by the Portuguese Institute of Oncology of Porto (IPO-Porto). Results will be disseminated through peer-reviewed journals and presented at relevant scientific meetings for academic and health professionals audiences.

Article Summary

Strengths and limitations of this study

- To our knowledge, this is the first study in Portugal to develop and validate an evidence-based DA specifically designed for young breast cancer patients to support and facilitate the complex fertility decision-making process that women face during their cancer trajectory.
- Results of this study will provide evidence of its acceptability to women at different stages of the cancer trajectory and their significant others/partners who may play a crucial role during the process of fertility decision-making.
- Results of this study will inform an emerging field of research in Portugal and highlight the importance of fertility discussions, by facilitating its implementation in clinical settings.

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- This study will be limited to Portuguese speaking women; however, since there are few validated DAs for young breast cancer patients worldwide, results of its acceptability and validation will inform a growing, but still scarce, field of research.

Key words: Breast cancer, Young women, Fertility, Fertility preservation, decision aid.

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Introduction

Oncofertility is currently a frontline research topic and a vital issue in clinical care for young breast cancer patients. As cancer survivors live longer, it is important to consider long-term effects of cancer treatment on fertility and offer optimal ways to improve quality of life (QoL)[1]. Often when young breast cancer patients are diagnosed, they have not initiated or completed their childbearing goals. Concomitantly, cancer treatment may impair fertility, permanently or temporarily[2]. In this context, consideration of a patients' fertility needs and the possibility to retain genetic reproductive potential should be included in the management of breast cancer as advocated by diverse professional bodies and clinical practice guidelines[3,4]. Such guidelines offer evidence for health care professionals and patients decision-making regarding appropriate, safe and cost-effective fertility care. Further, guidelines highlight health care professionals' duty to provide timely information on a cancer's treatments likelihood the threat to future fertility and to discuss fertility preservation options with women of childbearing age.

Strong evidence suggests fertility and other reproductive health issues are, in fact, important for these patients and a significant QoL concern[5-8], adding to the emotional burden of the cancer diagnosis for these young women[9]. Previous work on reproductive attitudes of young breast cancer survivors showed novel data for Portuguese women, corroborating the evidence that fertility is an important issue for these survivors, namely for those who are young and childless before the diagnosis[8]. Compared to a sample of US women, no significant differences were found among Portuguese women on the importance of fertility issues after a breast cancer diagnosis, demonstrating that women

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value these issues regardless of culture, background or the health system they belong to[8]. For some women, fertility concerns are important enough to influence or even change therapeutic decisions[8]. Currently, there are several available fertility preservation techniques to assist young breast cancer patients in preserving their fertility, most methods require use before the initiation of cancer treatment. In practice, this offers potential parenthood for patients who desire genetic children. Adoption and third party reproduction are other options for women who were not able to use fertility preservation techniques prior to the start of cancer treatment or for whom techniques were unsuccessful. However, all options, even simply waiting to see if fertility potential becomes impaired, typically entails a series of complex decisions for patients and health care professionals[10,11].

Fertility decisions are challenging in an oncology context. A variety of factors are at play such as consideration of the patients' values, goals, religious beliefs, partner status and medical factors and the need to make high quality informed decisions. Women need to thoroughly understand the potential of cancer treatment effects on fertility, available preservation options and potential risks associated with these options[12]. Research suggests women benefit from and have reduced remorse and regret when provided opportunities to learn about potential infertility, even if no options are available or elected[13]. Decisional conflict, which is the state of uncertainty about the course of action to be taken, tends to be associated with emotional distress, future regret or/and blame and delayed decision-making[11]. It is pivotal that women have access to high-quality information to aid decision-making. Several studies have shown that young

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cancer patients consider fertility information a priority; however, their fertility-related information needs are often unmet[5,7,14]. These findings are also corroborated by a study reporting some survivors did not recall any discussions about fertility with their health providers or were not satisfied with the explanations given about potential infertility[8].

Decision Aids (DAs) are educational materials designed to assist with treatment decision-making, by addressing individual values and preferences[5], and are particularly helpful in situations when there is limited time to make the decision[15]. DAs help make the decision explicit, describe options available and assist patients understanding of options as well as their possible benefits and harms. DAs assist patients in considering the options from a personal perspective, allowing them to participate with their health provider in shared decision-making[16]. Therefore, in an oncofertility context, DAs may constitute a valuable resource to help patients obtain more fertility-related information, make better- informed decisions, and reduce the amount of time the provider needs to spend explaining and discussing all options. The development of innovative tools to support patients, to deliver fertility related and other reproductive health care patient education, to meet patient's unmet needs and aid in the patient decision-making process is clinically valuable. Coupled with the knowledge of what the DA tools should contain is the desire of young women with breast cancer to receive written materials to inform their choices about fertility preservation[17]. Decision support tools may be also useful for healthcare professionals or researchers working with young cancer patients. However, validated tools to support patients in this process, including DAs, are scarce[18].

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One of the first fertility-related DAs for young breast cancer patients was developed and validated by Peate[5] in Australia. When compared with standard care, the fertility-related DA was shown to reduce decisional conflict about fertility options and reduce decisional regret about fertility treatments. In addition, women who received the DA reported more satisfaction with fertility information received and rated it more helpful than women who received standard information[5]. The DA also improved fertility related knowledge. Although, oncofertility in Portugal is still in the developmental stage[19], findings from a previous study suggest it is imperative to include fertility counselling in breast cancer management and also initiate efforts to address the unmet fertility-information needs of Portuguese cancer patients[8]. Based on the fertility-related DA validated by Peate[5], updated in 2016[20], we aim to transcreate and validate the fertility-related DA for young Portuguese breast cancer patients. Merely translating cancer educational materials, in this particular case from Australian English to Portuguese, has been shown to be insufficient to improve patients' knowledge[21]. Therefore, our study aims to transcreate the original DA to a Portuguese audience, which is a process that goes beyond direct translation of the text, and includes culturally relevant themes, images and context, ensuring that the text is reconstructed with cultural relevance to meet the young Portuguese breast cancer patients' informational needs[22]. It includes not only the translation but also the cultural adaptation. To our knowledge, our study is pioneer in Portugal, since there are no validated fertility related DA specifically designed for young breast cancer patients in Portuguese.

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Our project entails the development, transcreation, and validation of a DA to support young Portuguese breast cancer patients who are at the potential stage of making fertility preservation decisions before the initiation of their cancer treatment. The project consists of a longitudinal prospective study, to be conducted in a two-phases process: Phase I) development and transcreation of a reproductive health-related DA booklet to support young Portuguese women diagnosed with breast cancer, originally developed, validated and updated for an Australian audience[5, 20]. Phase II) validation of the fertility-related DA for a Portuguese audience and to establish efficacy of the tool. The present paper reports on the protocol of the project's Phase I, the fertility-related DA development and transcreation to a Portuguese audience.

Methods and Analysis

Based on an updated version of the fertility-related DA validated by Peate[5,20], we aim to develop and transcreate the fertility-related DA for young Portuguese breast cancer patients. Figure 1 illustrate study Phase I process.

DA content development to a Portuguese audience

The development of the original DA has used a framework guided by the International Patient Decision Aid Standards (IPDAS) collaboration[23]. The DA consists of a booklet, whose content focuses on breast cancer, female fertility and fertility preservation options for young breast cancer patients. Specifically, it includes background information about breast cancer, its treatments and impact on fertility, a summary of female fertility and a description of current fertility preservation options, including relevant scientific information, costs and risks.

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In addition to its informational content, the DA also has an interactive part, constituted by a set of value clarification exercises, which present the advantages and disadvantages of each treatment option. Women are asked to rate each option in light of their values and life situation, using a 5-point scale ranging from "I am leaning towards (fertility option) to "I am not leaning towards (fertility option)". Collectively, the DA produces a personalized summary of each fertility option, enabling and facilitating decision-making about fertility preservation[5, 20] .

First, we will employ a process of forward translation, in which the content of the original fertility-related DA for early breast cancer patients will be translated to European Portuguese language by two independent professional translators. Second, a literature review and appraisal of the most recent clinical guidelines on fertility for cancer patients, combined with a multidisciplinary panel of Portuguese experts in the field (oncologists, fertility specialists, gynaecologists, psycho-oncologists, nurses, social security officer), will revise the scientific and cultural aspects of the DA content for a Portuguese context. Third, we will employ a process of back-translation, in which the final version will be back-translated from Portuguese to Australian-English to assess content equivalence between the original and the final adapted version. Afterwards, the adequacy of the DA's content will be assessed for a Portuguese audience, accounting for possible country differences in treatment options, medical management and health system between Australia and Portugal. Lastly, the results from the DA acceptability assessment will inform and lead to the final version of the DA.

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DA acceptability assessment

To assess acceptability of the DA, regarding attractiveness, comprehension, cultural acceptability, self-efficacy and persuasion, we will use a process called Learner Verification (LV)[24]. This consists of a quality control process and a technique that helps to ensure the educational materials are suitable for the intended audience and adequate for patients' learning needs[24]. LV is rooted in information processing theory, focusing on the persuasiveness of a health message, providing a systematic process for assessing the intended message of a DA[25]. In our study, specific components of LV will be assessed with a sample of young Portuguese who were diagnosed with breast cancer patients, survivors and partners, such as message attraction ("Does the DA appeal to young Portuguese breast cancer survivors?"), comprehension ("Do young Portuguese breast cancer survivors understand the information in the DA?"), self-efficacy ("Are young Portuguese breast cancer survivors capable of making a decision?"), cultural acceptability ("Do young Portuguese breast cancer survivors perceive the message to be relevant and acceptable?") and persuasion ("Does the DA convince young Portuguese breast cancer survivors that need for a decision is relevant ?")[25].

Design and sample

A qualitative cross sectional study will be used. The acceptability of the DA will be assessed with focus groups from a Breast Unit in a national oncology hospital in Portugal. For LV, only small samples of the intended audience are needed (6 to 10 participants in a group)[25]. Therefore, we will cover three main group categories of the intended audience: recently diagnosed breast cancer

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patients, young breast cancer survivors and partners of young breast cancer patients. For each category, two focus groups will be conducted with 6-10 participants each. Patients will be grouped by age in the focus groups. The decision to have a group only with partners of young breast cancer patients during the development of the DA was based on findings from a previous study that indicated partners may play an important role in shaping women's fertility attitudes and decisions[8], as prior research has shown the inclusion of women's significant others, particularly their partners, is important for fertility decisions [26]. Eligible participants for the sample of recently diagnosed breast cancer patients will include women diagnosed between 6 months to 2 years before the study; aged 18-45 years at recruitment; who are undergoing or have undergone breast cancer treatment; able to read and write Portuguese language and willing to provide written consent. The lower limit of 6 months was chosen to avoid increased burden of women surrounding the diagnosis period. Eligible participants for the sample of young breast cancer survivors will include: women diagnosed more than 2 years ago; aged 18 to 45 years at the time of diagnosis; not on active cancer treatment (except endocrine therapy); able to read and write in the Portuguese language and willing to provide written consent. Lastly, eligible participants who take part in the partners group will include partners of young women diagnosed with breast cancer; who will be able to read and write Portuguese language and willing to provide written consent. Partners will include males or females in a relationship with the patient. Furthermore, instead of a partner, the patient may indicate a significant other who is caring for her or cared for her during the course of their treatment.

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Analysis

Data will be analyzed using content analysis and the constant comparison method to identify key themes/textual units related to LV. We will aim for thematic saturation (where data collection does not generate substantially new information and the range of perspectives appear to be completely covered) from the focus groups[27]. All focus groups will be audiotaped and verbatim transcripts coded for key themes with the goal of at least 85% inter-coder reliability between at least two coders.

Patient and public involvement

Neither patients nor public were involved in the development of this study design.

Discussion

Oncofertility is widely accepted and supported by the scientific community as a key component of young women's oncological care and quality of life. However, in clinical settings its implementation is still sub-optimal. A recent study conducted in Portugal and USA, showed similar priorities and concerns regarding fertility and childbearing for young breast cancer patients. Lack of fertility discussions and dissatisfaction with fertility information provided by health care professionals were reported[8]. DAs are educational tools that may have the potential to facilitate the delivery of fertility information and aid in the complex decisional pathway that the patient and health professionals have to go through. A recent systematic review of decision tools for fertility supports the view that the use of these tools in clinical settings should be encouraged, since

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DAs were found to be highly useful, leading to discussions about fertility preservation and less decisional regret[28]. The number of available written materials about fertility preservation for young cancer patients is growing. However, there are few validated DAs for young breast cancer patients worldwide; to our knowledge, they are nonexistent in Portugal.

Our project represents the first study in Portugal to develop and validate a DA for young breast cancer patients to support and facilitate the fertility decision-making process during a very difficult and stressful period of women's cancer trajectory, the diagnostic phase. Providing the clinical cancer care team with an evidence based tool to administer to all women during this period will encourage health care providers to have more fertility discussions with their patients, helping them to make appropriate and timely referrals for fertility specialists, and ultimately, raising awareness for the inclusion of fertility and childbearing within their clinical practice.

Future research integrated in this project includes a Randomized Control Trial (RCT) developed to validate and assess DA's efficacy in a sample of young women with breast cancer (Phase 2). Based in findings using its original version in Australia[5] and from the literature in general[28], we anticipate that the DA will be an acceptable and useful tool for these group of patients during the fertility decision-making process, contributing to increase their fertility preservation knowledge and satisfaction with the information provided, as well as, to contribute to decrease the emotional burden of this impactful disease in the lives of these young women. The innovative nature of this study addresses

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gaps in the scientific and clinical practice cited above, targeting an emerging field of research in Portugal, with the expectation of improving clinical practice, patient provider communication and knowledge in Oncofertility.

Footnotes

Contributors: VG conceived the idea, contributed to the design of the study and protocol, coordinated the decision aid development, secured funding, and drafted this manuscript. LT participated in the decision aid development and in the decision aid revision. PF provided intellectual and scientific insight during the decision aid development and participated in the decision aid revision. GQ contributed to the design of the study, provided intellectual and scientific input during the development of the study protocol, grant application process and during the development of the decision aid. All authors reviewed and approved the final version of the protocol.

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Competing interests: None declared

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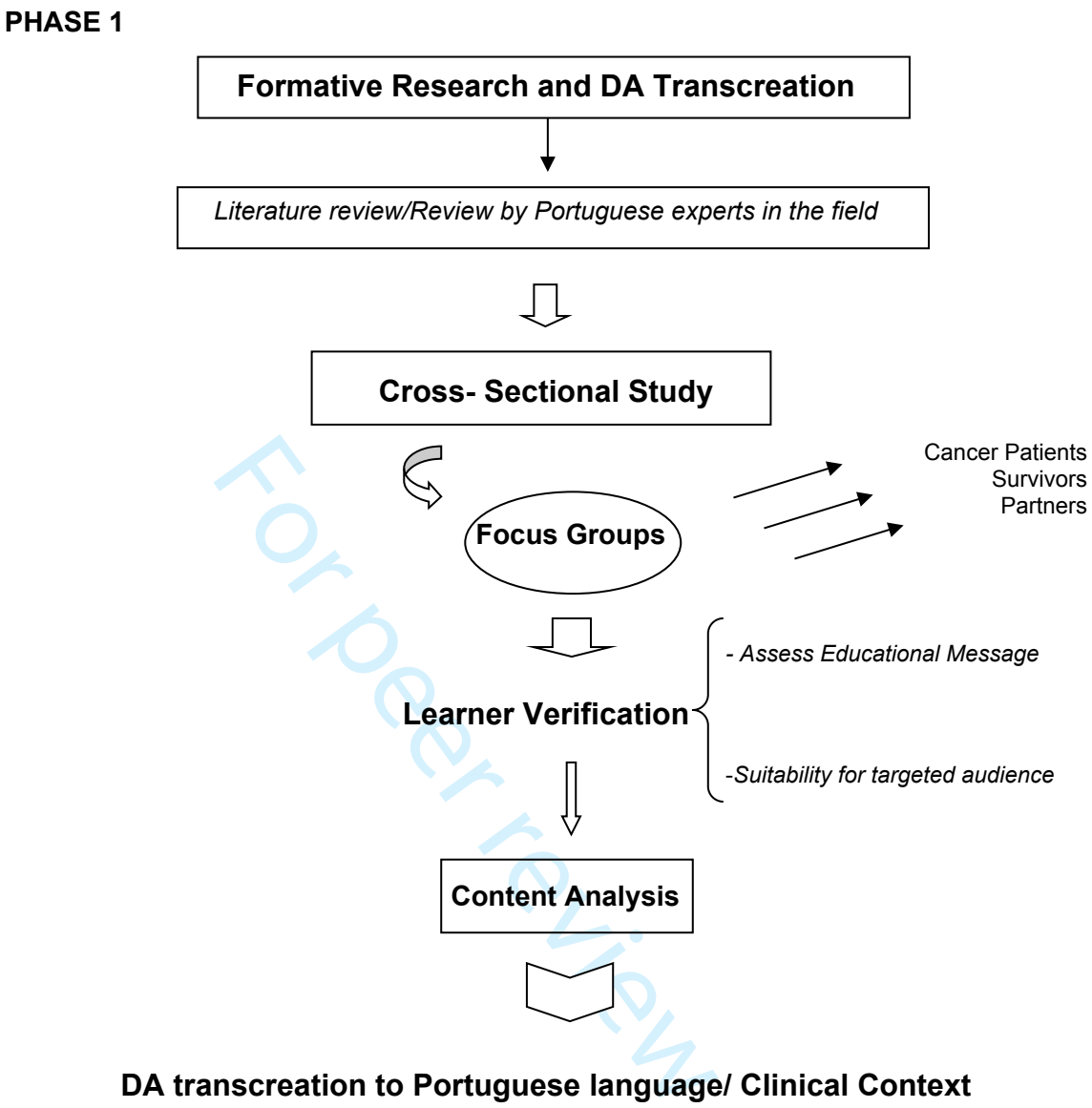

Fig 1: Study phase 1 process

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A Protocol for the Development and Acceptability of a Fertility-related Decision Aid for Young Women with Breast Cancer in Portugal.

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Keywords:	Breast cancer, Young women, Fertility, Fertility preservation, Decision aid

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A Protocol for the Development and Acceptability of a Fertility-related Decision Aid for Young Women with Breast Cancer in Portugal

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Abstract

Introduction

Young breast cancer patients may face impaired fertility due to cancer treatments, which often leads to complex fertility decisions. To aid fertility decision-making, it is crucial women have access to high-quality information; however, their fertility information needs are often unmet. Decision Aids (DAs) are educational materials to assist with decision-making, by addressing individual values and preferences. In oncofertility, DAs may constitute a valuable resource to help patients obtain information and make better informed decisions. This paper reports on the protocol of the development and transcreation of a fertility-related DA booklet to support young Portuguese breast cancer patients, originally developed and validated for an Australian audience.

Methods and analysis

Recent literature on clinical guidelines will be reviewed. A summary of these guidelines will be created and will inform the first round of DAs revisions. A forward translation process will translate the DA from Australian English to Portuguese. A multidisciplinary Portuguese experts panel will revise and give feedback on the scientific and cultural aspects of the DA content for Portuguese audience. Next, a backward translation process will assess content equivalence between the original and the final adapted version. Finally, Learning Verification (LV) will be used in a in a qualitative study of young breast cancer patients and their partners. Two focus groups with 6 - 10 participants each will be conducted with: 1) recently diagnosed young breast cancer patients; 2)

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breast cancer survivors and 3) their partners. Results from the DA acceptability assessment will inform its final version. Data will be analyzed using content analysis and constant comparison method to identify key themes/textual units related to LV.

Ethics and dissemination

Ethical approval was granted by the Portuguese Institute of Oncology Porto. Results will be disseminated through peer-reviewed journals and presented at scientific meetings for academic and health professionals audiences.

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Strengths and limitations of this study

- To our knowledge, this is the first study in Portugal to develop and validate an evidence-based DA specifically designed for young breast cancer patients to support and facilitate the complex fertility decision-making process that women face during their cancer trajectory.
- Results of this study will provide evidence of its acceptability to women at different stages of the cancer trajectory and their significant others/partners who may play a crucial role during the process of fertility decision-making.
- Results of this study will inform an emerging field of research in Portugal and highlight the importance of fertility for young breast cancer patients, by facilitating the implementation of fertility discussions in clinical settings.

- This study will be limited to Portuguese speaking women; however, since there are few validated DAs for young breast cancer patients worldwide, results of its acceptability and validation will inform a growing, but still scarce, field of research.
- The use of qualitative methods in the focus groups and learner verification reduces generalizability. The exclusive focus on breast cancer patients also limits application to other cancer sites.

Key words: Breast cancer, Young women, Fertility, Fertility preservation, decision aid.

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Introduction

Oncofertility is currently a frontline research topic and a vital issue in clinical care for young breast cancer patients. As cancer survivors live longer, it is important to consider long-term effects of cancer treatment on fertility and offer optimal ways to improve quality of life (QoL)[1]. Often when young breast cancer patients are diagnosed, they have not initiated or completed their childbearing goals[2]. Concomitantly, cancer treatment may impair fertility, permanently or temporarily[3]. In this context, consideration of patients' fertility needs and the possibility to retain genetic reproductive potential should be included in the management of breast cancer as advocated by diverse professional bodies and clinical practice guidelines[4,5]. Such guidelines offer evidence for health care professionals and patients decision-making regarding appropriate, safe and cost-effective fertility care. Further, guidelines highlight health care professionals' duty to provide timely information on a cancer treatments likely threat to future fertility and to discuss fertility preservation options with women of childbearing age. Those options offer strategies to preserve women's fertility and the ability to have genetic children[3].

Strong evidence suggests fertility and other reproductive health issues are important for women of reproductive age and a significant QoL concern[2,6-8], adding to the emotional burden of the cancer diagnosis for these young women[9]. Previous work on reproductive attitudes of young breast cancer survivors showed novel data on Portuguese women, corroborating the evidence from other countries that fertility is an important issue for these

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survivors, namely for those who are young and childless before the diagnosis[8]. Compared to a sample of women from the United States of America (USA), no significant differences were found among Portuguese women on the importance of fertility issues after a breast cancer diagnosis. These results are corroborated by other studies[10,11], demonstrating that women value these issues regardless of culture, background or the health system they belong to[8]. For some women, fertility concerns are important enough to influence or even change therapeutic decisions[8].

Currently, there are several available fertility preservation techniques to assist young breast cancer patients in preserving their fertility. These options include embryo and oocyte freezing and the experimental option of ovarian tissue cryopreservation. National guidelines typically suggest these methods be used prior to the initiation of gonadotoxic treatment, such as chemotherapy, although some providers and patients attempt preservation methods during a break in or immediately following treatment[12]. Adoption and third party reproduction are other options for women who were not able to use fertility preservation techniques prior to the start of cancer treatment or for whom techniques were unsuccessful. However, all options, even simply waiting to see if fertility potential becomes impaired, typically entails a series of complex decisions for patients and health care professionals[13,14]. These decisions are intricate for a variety of reasons including the uncertainty about one's health and lifespan, the interest in raising a child with a partner, the disposition of stored gametes, one's religious and moral values associated with the use of assisted reproductive technologies, financial issues (however, in Portugal, the National

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Health System covers fertility preservation procedures for cancer patients, in public health institutions[15]), medical issues and the need to make high quality informed decisions [2,13,16,17].The demand to consider a fertility decision usually occurs within a chaotic context for the patient: the emotional turmoil of receiving a cancer diagnosis and the vital need of starting a cancer treatment. Furthermore, guidelines suggest established and experimental fertility preservation options be utilized prior to commencement of gonadotoxic cancer treatment[18]. Despite the complexity of decision making, It is imperative that women have access to high-quality information to aid decision-making. Several studies have shown that young cancer patients consider fertility information a priority; however, their fertility-related information needs are often unmet[6,7,19]. Particularly in Portugal, findings also reported that some survivors did not recall any discussions about fertility with their health providers or were not satisfied with the explanations given about potential infertility[8]. However, young women with breast cancer wish to receive written materials to inform their choices about fertility preservation[20]. Moreover, women desire to thoroughly understand the potential of cancer treatment effects on fertility, available preservation options and potential risks associated with these options[21]. Research suggests women benefit from and have reduced remorse and regret when provided opportunities to learn about potential infertility, even if no options are available or elected[22]. Decisional conflict, which is the state of uncertainty about the course of action to be taken, tends to be associated with emotional distress, future regret or/and blame and delayed decision-making[14].

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Decision Aids (DAs) are educational materials designed to assist with treatment decision-making, by addressing individual values and preferences[6], and are particularly helpful in situations when there is limited time to make the decision[23]. DAs help make the decision explicit, describe options available and assist patients understanding of options as well as their possible benefits and harms. DAs assist patients in considering the options from a personal perspective, allowing them to participate with their health provider in shared decision-making[24]. Particularly for an oncofertility context, DAs may constitute a valuable resource to help patients obtain more fertility-related information such as documented by a recent systematic review, which concluded that fertility related DAs for cancer patients can be effective complements to current fertility care by increasing fertility information satisfaction and help patents to make better- informed decisions[25]. However, validated tools to support patients in this process, including DAs, are scarce[26]. One of the first fertility-related DAs for young breast cancer patients was developed and validated by Peate[6] in Australia. Compared with standard care, the fertility-related DA was shown to reduce decisional conflict about fertility options and reduce decisional regret about fertility treatments. In addition, women who received the DA reported more satisfaction with fertility information and rated it more helpful than women who received standard information[6]. The DA also improved fertility related knowledge. Other evaluated DAs, include one for young women with breast cancer in Dutch[27] and another DA in German for young female cancer patients[28]. Two DAs for young female cancer patients in English are currently under evaluation[29,30]. Although, oncofertility in Portugal is still in the

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developmental stage[31], findings from a previous study suggest it is imperative to include fertility counselling in breast cancer management and initiate efforts to address the unmet fertility-information needs of Portuguese cancer patients[8]. Based on the Peate fertility-related DA[6], updated in 2016[32], we aim to transcreate and validate the fertility-related DA for young Portuguese breast cancer patients. Merely translating cancer educational materials, in this particular case from Australian English to Portuguese, has been shown to be insufficient to improve patients' knowledge[33]. Therefore, our study aims to transcreate the original DA to a Portuguese audience, which is a process that goes beyond direct translation of the text, and includes culturally relevant themes, images and context, ensuring that the text is reconstructed with cultural relevance to meet the young Portuguese breast cancer patients' informational needs[34]. It includes not only the translation but also a cultural adaptation. To our knowledge, our study is a pioneer in Portugal, since there are no validated fertility related DAs specifically designed for young breast cancer patients in Portuguese.

Our project entails the development, transcreation, and validation of a DA to support young Portuguese breast cancer patients who are at the potential stage of making fertility preservation decisions before the initiation of their cancer treatment. The project consists of a longitudinal prospective study, to be conducted in a two-phases process: Phase I) development and transcreation of a fertility-related DA booklet to support young Portuguese women diagnosed with breast cancer, originally developed, validated and updated for an Australian audience[6, 32], Phase II) validation of the fertility-related DA for a

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Portuguese audience and to establish efficacy of the tool. The present paper reports on the protocol of the project's Phase I, the fertility-related DA development and transcreation to a Portuguese audience.

Methods and Analysis

DA content development to a Portuguese audience

The development of the Peate DA used a framework guided by the International Patient Decision Aid Standards (IPDAS) collaboration[35], and was validated in a sample of women aged between 18 and 40 years (inclusive).[21] The DA is a booklet that includes background information about breast cancer; its treatments and impact on fertility; a summary of female fertility; and a description of current fertility preservation options, including relevant scientific information, financial costs and associated risks with each fertility preservation method. In addition to its informational content, the DA also has an interactive portion, consisting of a set of value clarification exercises, which present the advantages and disadvantages of each treatment option. Women are asked to rate each option in light of their values and life situation, using a 5-point scale ranging from "I am leaning towards (fertility option) to "I am not leaning towards (fertility option)". Collectively, the DA provides the patient with a personalized summary of each fertility option, enabling and facilitating decision-making about fertility preservation[6, 32] .

The transcreation process will be informed by 3 phases: 1) our previous work in the field of fertility preservation[2,8,18]; 2) the completion of a narrative review of

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current guidelines for fertility preservation; 3) a narrative review of DAs for young women with cancer. A summary of our previous findings and the narrative reviews will be created and guide the first round of revisions to the DA. Next, a process of forward translation, in which the content of the original fertility-related DA for early breast cancer patients will be translated to European Portuguese language by two independent professional translators, will be employed. Finally, a multidisciplinary panel of Portuguese experts in the field (oncologists, fertility specialists, gynaecologists, psycho-oncologists, nurses), will revise the scientific and cultural aspects of the DA content for a Portuguese context. The summary from the experts' feedback will be analyzed by the research team and any incongruences will be clarified with the experts, if necessary. The research team will discuss all feedback until consensus is reached. Then, we will employ a process of back-translation, in which the final version will be back-translated from Portuguese to Australian-English to assess content equivalence between the original and the final adapted version. The adequacy of the DA's content will be assessed for a Portuguese audience, accounting for possible country differences in treatment options, medical management and health system between Australia and Portugal. Lastly, the results from the DA acceptability assessment will inform and lead to the final version of the DA, which will be validated using a randomized control trial (RCT) in Phase 2. This project began in January 2017 and it will end in December 2021. Figure 1 illustrates the process of study Phase I.

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DA acceptability assessment

To assess acceptability of the DA, we will use a process called Learner Verification (LV) that assesses elements such as attractiveness, comprehension, cultural acceptability, self-efficacy and persuasion[36]. LV is also a quality control technique that helps to ensure the educational materials are suitable for the intended audience and meet patients' learning needs[36]. LV is rooted in information processing theory, focusing on the persuasiveness of a health message, providing a systematic process for assessing the intended message of a DA[37]. In our study, specific components of LV will be assessed with young Portuguese who were diagnosed with breast cancer, including current patients, survivors, and partners. The LV components include message attraction (such as "Does the DA appeal to young Portuguese breast cancer survivors/patients/partners?"), comprehension (such as "Do young Portuguese breast cancer survivors/patients/partners understand the information in the DA?"), self-efficacy (such as "Are young Portuguese breast cancer survivors/patients/partners capable of making a decision?"), cultural acceptability (such as "Do young Portuguese breast cancer survivors/patients/partners perceive the message to be relevant and acceptable?") and persuasion (such as "Does the DA convince young Portuguese breast cancer survivors/patients/partners that need for a decision is relevant ?")[37].

Design and sample

A qualitative study will be used. The acceptability of the DA will be assessed with focus groups from a Breast Unit in a national oncology hospital in Portugal.

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We will enroll three populations of the intended audience: a) recently diagnosed breast cancer patients aged 18-45 at diagnosis and between 2-6 months since the initial diagnosis; b) breast cancer survivors diagnosed at age 18-45 and not receiving active cancer treatment other than aromatase inhibitors; and c) partners (of any age) of patients or survivors aged 18 to 45 years at the time of diagnosis. Furthermore, instead of a romantic partner, the patient may indicate a significant other who is caring for her or cared for her during treatment. The decision to have a group of patients' partners during the development of the DA was based on findings from a previous study that indicated partners often play an important role in shaping women's fertility attitudes and decisions.[8]

For each population of the intended audience, two focus groups will be conducted with 6-10 participants each, since for LV only small samples of the intended audience are needed (6 to 10 participants in a group)[37]. The goal of the qualitative LV endevour is to achieve saturation and thus if saturation is not reached (no new information) we will recruit additional participants as needed. Inclusion criteria for all focus groups, will be the requirement to read and write in the Portuguese language and willing to provide written consent. .

Analysis

Data will be analyzed using content analysis[38] and the constant comparison method to identify key themes/textual units related to LV. We will aim for thematic saturation (where data collection does not generate substantially new information and the range of perspectives appear to be completely covered)

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between the population specific focus groups[39]. All focus groups will be audiotaped and verbatim transcripts coded for key themes with the goal of at least 85% inter-coder reliability between at least two coders.

Patient and public involvement

Neither patients nor public were involved in the development of this study design but they will be involved in the development and validation of the DA.

Ethics and dissemination

Ethics approval was granted by the Portuguese Institute of Oncology of Porto (IPO-Porto; CES IPO: 34/2018). Results will be disseminated through peer-reviewed journals and presented at relevant scientific meetings for academic and health professionals audiences.

Discussion

Oncofertility is widely accepted and supported by the scientific community as a key component of young women's oncological care and QoL. However, in clinical settings its implementation is still sub-optimal. A recent study conducted in Portugal and USA, showed similar priorities and concerns regarding fertility and childbearing for young breast cancer patients. Lack of fertility discussions and dissatisfaction with fertility information provided by health care professionals were reported[8]. DAs are educational tools that may have the potential to facilitate the delivery of fertility information and aid in the complex decisional pathway that the patient and health professionals have to go through. A recent systematic review of decision tools for fertility supports the view that

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the use of these tools in clinical settings should be encouraged, since DAs were found to be highly useful, leading to discussions about fertility preservation and less decisional regret[25,40]. The number of available written materials about fertility preservation for young cancer patients is growing[27,28] as online fertility-related information from different organizations[41]. However, there are few validated DAs for young breast cancer patients worldwide; to our knowledge, they are nonexistent in Portugal.

Our project represents the first study in Portugal to develop and validate a DA for young breast cancer patients who speak Portuguese to support and facilitate the fertility decision-making process during a very difficult and stressful period of women's cancer trajectory, the diagnostic phase. Providing the clinical cancer care team with an evidence based tool to administer to all women during this period will encourage health care providers to have more fertility discussions with their patients, helping them to make appropriate and timely referrals for fertility specialists, and ultimately, raising awareness for the inclusion of fertility and childbearing within their clinical practice.

Future research integrated in this project includes a Randomized Control Trial (RCT) developed to validate and assess DA's efficacy in a sample of young women with breast cancer (Phase 2). Based on findings using its original version in Australia[6] and from the literature in general[25], we anticipate that the DA will be an acceptable and useful tool for these group of patients during the fertility decision-making process, such as contributing to an increase in their fertility preservation knowledge and satisfaction with the information, as well as,

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helping to decrease the emotional burden of cancer. The innovative nature of this study addresses gaps in the scientific and clinical practice cited above, targeting an emerging field of research in Portugal, with the expectation of improving clinical practice, patient provider communication and knowledge in oncofertility.

Footnotes

Contributors: VG conceived the idea, contributed to the design of the study and protocol, coordinates the decision aid development, secured funding, and drafted this manuscript. LT participates in the decision aid development and in the decision aid revision. PF provides intellectual and scientific insight during the decision aid development and participates in the decision aid revision. GQ contributed to the design of the study, provided intellectual and scientific input during the development of the study protocol and grant application process. In addition, GQ provides intellectual and scientific input during the development of the decision aid. All authors reviewed and approved the final version of the protocol.

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Figure 1: Study phase 1 process

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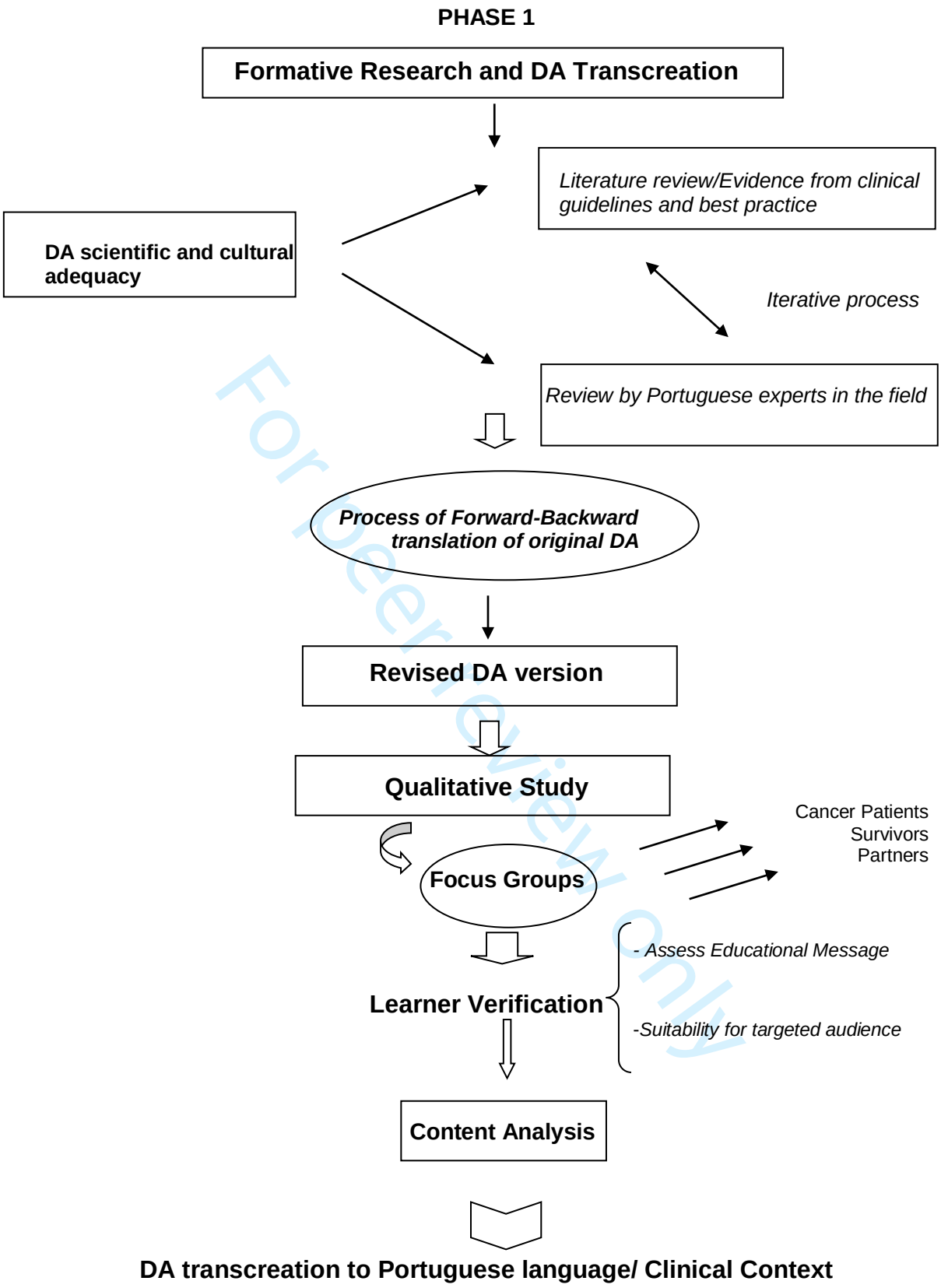

Fig 1: Study phase 1 process

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A Protocol for the Development and Acceptability of a Fertility-related Decision Aid for Young Women with Breast Cancer in Portugal

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Abstract

Introduction

Young breast cancer patients may face impaired fertility due to cancer treatments, which often leads to complex fertility decisions. To aid fertility decision-making, it is crucial women have access to high-quality information; however, their fertility information needs are often unmet. Decision Aids (DAs) are educational materials to assist with decision-making, by addressing individual values and preferences. In oncofertility, DAs may constitute a valuable resource to help patients obtain information and make better informed decisions. This paper reports on the protocol of the development and transcreation of a fertility-related DA booklet to support young Portuguese breast cancer patients, originally developed and validated for an Australian audience.

Methods and analysis

Recent literature on clinical guidelines will be reviewed. A summary of these guidelines will be created and will inform the first round of DAs revisions. A forward translation process will translate the DA from Australian English to Portuguese. A multidisciplinary Portuguese experts panel will revise and give feedback on the scientific and cultural aspects of the DA content for Portuguese audience. Next, a backward translation process will assess content equivalence between the original and the final adapted version. Finally, Learning Verification (LV) will be used in a in a qualitative study of young breast cancer patients and their partners. Two focus groups with 6 - 10 participants each will be conducted with: 1) recently diagnosed young breast cancer patients; 2)

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breast cancer survivors and 3) their partners. Results from the DA acceptability assessment will inform its final version. Data will be analyzed using content analysis and constant comparison method to identify key themes/textual units related to LV.

Ethics and dissemination

Ethical approval was granted by the Portuguese Institute of Oncology Porto. Results will be disseminated through peer-reviewed journals and presented at scientific meetings for academic and health professionals audiences.

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Article Summary

Strengths and limitations of this study

- To our knowledge, this is the first study in Portugal to develop and validate an evidence-based DA specifically designed for young breast cancer patients to support and facilitate the complex fertility decision-making process that women face during their cancer trajectory.
- Results of this study will provide evidence of its acceptability to women at different stages of the cancer trajectory and their significant others/partners who may play a crucial role during the process of fertility decision-making.
- Results of this study will inform an emerging field of research in Portugal and highlight the importance of fertility for young breast cancer patients, by facilitating the implementation of fertility discussions in clinical settings.

- This study will be limited to Portuguese speaking women; however, since there are few validated DAs for young breast cancer patients worldwide, results of its acceptability and validation will inform a growing, but still scarce, field of research.
- The use of qualitative methods in the focus groups and learner verification reduces generalizability. The exclusive focus on breast cancer patients also limits application to other cancer sites.

Key words: Breast cancer, Young women, Fertility, Fertility preservation, decision aid.

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Introduction

Oncofertility is currently a frontline research topic and a vital issue in clinical care for young breast cancer patients. As cancer survivors live longer, it is important to consider long-term effects of cancer treatment on fertility and offer optimal ways to improve quality of life (QoL)[1]. Often when young breast cancer patients are diagnosed, they have not initiated or completed their childbearing goals[2]. Concomitantly, cancer treatment may impair fertility, permanently or temporarily[3]. In this context, consideration of patients' fertility needs and the possibility to retain genetic reproductive potential should be included in the management of breast cancer as advocated by diverse professional bodies and clinical practice guidelines[4,5]. Such guidelines offer evidence for health care professionals and patients decision-making regarding appropriate, safe and cost-effective fertility care. Further, guidelines highlight health care professionals' duty to provide timely information on a cancer treatments likely threat to future fertility and to discuss fertility preservation options with women of childbearing age. Those options offer strategies to preserve women's fertility and the ability to have genetic children[3].

Strong evidence suggests fertility and other reproductive health issues are important for women of reproductive age and a significant QoL concern[2,6-8], adding to the emotional burden of the cancer diagnosis for these young women[9]. Previous work on reproductive attitudes of young breast cancer survivors showed novel data on Portuguese women, corroborating the evidence from other countries that fertility is an important issue for these

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survivors, namely for those who are young and childless before the diagnosis[8]. Compared to a sample of women from the United States of America (USA), no significant differences were found among Portuguese women on the importance of fertility issues after a breast cancer diagnosis. These results are corroborated by other studies[10,11], demonstrating that women value these issues regardless of culture, background or the health system they belong to[8]. For some women, fertility concerns are important enough to influence or even change therapeutic decisions[8].

Currently, there are several available fertility preservation techniques to assist young breast cancer patients in preserving their fertility. These options include embryo and oocyte freezing and the experimental option of ovarian tissue cryopreservation. National guidelines typically suggest these methods be used prior to the initiation of gonadotoxic treatment, such as chemotherapy, although some providers and patients attempt preservation methods during a break in or immediately following treatment[12]. Adoption and third party reproduction are other options for women who were not able to use fertility preservation techniques prior to the start of cancer treatment or for whom techniques were unsuccessful. However, all options, even simply waiting to see if fertility potential becomes impaired, typically entails a series of complex decisions for patients and health care professionals[13,14]. These decisions are intricate for a variety of reasons including the uncertainty about one's health and lifespan, the interest in raising a child with a partner, the disposition of stored gametes, one's religious and moral values associated with the use of assisted reproductive technologies, financial issues (however, in Portugal, the National

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Health System covers fertility preservation procedures for cancer patients, in public health institutions[15]), medical issues and the need to make high quality informed decisions [2,13,16,17].The demand to consider a fertility decision usually occurs within a chaotic context for the patient: the emotional turmoil of receiving a cancer diagnosis and the vital need of starting a cancer treatment. Furthermore, guidelines suggest established and experimental fertility preservation options be utilized prior to commencement of gonadotoxic cancer treatment[18]. Despite the complexity of decision making, It is imperative that women have access to high-quality information to aid decision-making. Several studies have shown that young cancer patients consider fertility information a priority; however, their fertility-related information needs are often unmet[6,7,19]. Particularly in Portugal, findings also reported that some survivors did not recall any discussions about fertility with their health providers or were not satisfied with the explanations given about potential infertility[8]. However, young women with breast cancer wish to receive written materials to inform their choices about fertility preservation[20]. Moreover, women desire to thoroughly understand the potential of cancer treatment effects on fertility, available preservation options and potential risks associated with these options[21]. Research suggests women benefit from and have reduced remorse and regret when provided opportunities to learn about potential infertility, even if no options are available or elected[22]. Decisional conflict, which is the state of uncertainty about the course of action to be taken, tends to be associated with emotional distress, future regret or/and blame and delayed decision-making[14].

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Decision Aids (DAs) are educational materials designed to assist with treatment decision-making, by addressing individual values and preferences[6], and are particularly helpful in situations when there is limited time to make the decision[23]. DAs help make the decision explicit, describe options available and assist patients understanding of options as well as their possible benefits and harms. DAs assist patients in considering the options from a personal perspective, allowing them to participate with their health provider in shared decision-making[24]. Particularly for an oncofertility context, DAs may constitute a valuable resource to help patients obtain more fertility-related information such as documented by a recent systematic review, which concluded that fertility related DAs for cancer patients can be effective complements to current fertility care by increasing fertility information satisfaction and help patents to make better- informed decisions[25]. However, validated tools to support patients in this process, including DAs, are scarce[26]. One of the first fertility-related DAs for young breast cancer patients was developed and validated by Peate[6] in Australia. Compared with standard care, the fertility-related DA was shown to reduce decisional conflict about fertility options and reduce decisional regret about fertility treatments. In addition, women who received the DA reported more satisfaction with fertility information and rated it more helpful than women who received standard information[6]. The DA also improved fertility related knowledge. Other evaluated DAs, include one for young women with breast cancer in Dutch[27] and another DA in German for young female cancer patients[28]. Two DAs for young female cancer patients in English are currently under evaluation[29,30]. Although, oncofertility in Portugal is still in the developmental stage[31], findings from a previous study suggest it is imperative to

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include fertility counselling in breast cancer management and initiate efforts to address the unmet fertility-information needs of Portuguese cancer patients[8]. Based on the Peate fertility-related DA[6], updated in 2016[32], we aim to transcreate and validate the fertility-related DA for young Portuguese breast cancer patients. Merely translating cancer educational materials, in this particular case from Australian English to Portuguese, has been shown to be insufficient to improve patients' knowledge[33]. Therefore, our study aims to transcreate the original DA to a Portuguese audience, which is a process that goes beyond direct translation of the text, and includes culturally relevant themes, images and context, ensuring that the text is reconstructed with cultural relevance to meet the young Portuguese breast cancer patients' informational needs[34]. It includes not only the translation but also a cultural adaptation. The decision to use a developed and validated fertility related DA specifically designed for young breast cancer patients to guide our work was based in its efficacy, previously documented in this population. Furthermore, one of the advantages of this tool is that its' original language is English, a language in which the majority of the research team is fluent. To our knowledge, our study is a pioneer in Portugal, since there are no validated fertility related DAs specifically designed for young breast cancer patients in Portuguese.

Our project entails the development, transcreation, and validation of a DA to support young Portuguese breast cancer patients who are at the potential stage of making fertility preservation decisions before the initiation of their cancer treatment. The project consists of a longitudinal prospective study, to be conducted in a two-phases process: Phase I) development and transcreation of

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a fertility-related DA booklet to support young Portuguese women diagnosed with breast cancer, originally developed, validated and updated for an Australian audience[6, 32], Phase II) validation of the fertility-related DA for a Portuguese audience and to establish efficacy of the tool. The present paper reports on the protocol of the project's Phase I, the fertility-related DA development and transcreation to a Portuguese audience.

Methods and Analysis

DA content development to a Portuguese audience

The development of the Peate DA used a framework guided by the International Patient Decision Aid Standards (IPDAS) collaboration[35], and was validated in a sample of women aged between 18 and 40 years (inclusive).[21] The DA is a booklet that includes background information about breast cancer; its treatments and impact on fertility; a summary of female fertility; and a description of current fertility preservation options, including relevant scientific information, financial costs and associated risks with each fertility preservation method. In addition to its informational content, the DA also has an interactive portion, consisting of a set of value clarification exercises, which present the advantages and disadvantages of each treatment option. Women are asked to rate each option in light of their values and life situation, using a 5-point scale ranging from "I am leaning towards (fertility option) to "I am not leaning towards (fertility option)". Collectively, the DA provides the patient with a personalized summary of each fertility option, enabling and facilitating decision-making about fertility preservation[6, 32] .

For peer review only

The transcreation process will be informed by 3 phases: 1) our previous work in the field of fertility preservation[2,8,18]; 2) the completion of a narrative review of current guidelines for fertility preservation; 3) a narrative review of DAs for young women with cancer. The narrative reviews will follow standard PRISMA methods using Boolean search operators and will include quantitate, qualitative and mixed methods peer-reviewed publications by searching the databases: Medline, EMBASE, ISI Web of Knowledge, PubMed and PsychLit[36]. A summary of our previous findings and the narrative reviews will be created and guide the first round of revisions to the DA. Next, a process of forward translation, in which the content of the original fertility-related DA for early breast cancer patients will be translated to European Portuguese language by two independent professional translators, will be employed. Finally, a multidisciplinary panel of Portuguese experts in the field (oncologists, fertility specialists, gynaecologists, psycho-oncologists, nurses), will revise the scientific and cultural aspects of the DA content for a Portuguese context. The summary from the experts' feedback will be analyzed by the research team and any incongruences will be clarified with the experts, if necessary. The research team will discuss all feedback until consensus is reached. Then, we will employ a process of back-translation, in which the final version will be back-translated from Portuguese to Australian-English to assess content equivalence between the original and the final adapted version. The adequacy of the DA's content will be assessed for a Portuguese audience, accounting for possible country differences in treatment options, medical management and health system between Australia and Portugal. Lastly, the results from the DA

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acceptability assessment will inform and lead to the final version of the DA, which will be validated using a randomized control trial (RCT) in Phase 2. This project began in January 2017 and it will end in December 2021. Figure 1 illustrates the process of study Phase I.

DA acceptability assessment

To assess acceptability of the DA, we will use a process called Learner Verification (LV) that assesses elements such as attractiveness, comprehension, cultural acceptability, self-efficacy and persuasion[37]. LV is also a quality control technique that helps to ensure the educational materials are suitable for the intended audience and meet patients' learning needs[37]. LV is rooted in information processing theory, focusing on the persuasiveness of a health message, providing a systematic process for assessing the intended message of a DA[38]. In our study, specific components of LV will be assessed with young Portuguese who were diagnosed with breast cancer, including current patients, survivors, and partners. The LV components include message attraction (such as "Does the DA appeal to young Portuguese breast cancer survivors/patients/partners?"), comprehension (such as "Do young Portuguese breast cancer survivors/patients/partners understand the information in the DA?"), self-efficacy (such as "Are young Portuguese breast cancer survivors/patients/partners capable of making a decision?"), cultural acceptability (such as "Do young Portuguese breast cancer survivors/patients/partners perceive the message to be relevant and

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acceptable?") and persuasion (such as "Does the DA convince young Portuguese breast cancer survivors/patients/partners that need for a decision is relevant ?")[38].

Design and sample

A qualitative study will be used. The acceptability of the DA will be assessed with focus groups from a Breast Unit in a national oncology hospital in Portugal. We will enroll three populations of the intended audience: a) recently diagnosed breast cancer patients aged 18-45 at diagnosis and between 2-6 months since the initial diagnosis; b) breast cancer survivors diagnosed at age 18-45 and not receiving active cancer treatment other than aromatase inhibitors; and c) partners (of any age) of patients or survivors aged 18 to 45 years at the time of diagnosis. Furthermore, instead of a romantic partner, the patient may indicate a significant other who is caring for her or cared for her during treatment. The decision to have a group of patients' partners during the development of the DA was based on findings from a previous study that indicated partners often play an important role in shaping women's fertility attitudes and decisions.[8]

For each population of the intended audience, two focus groups will be conducted with 6-10 participants each, since for LV only small samples of the intended audience are needed (6 to 10 participants in a group)[38]. The goal of the qualitative LV endevour is to achieve saturation and thus if saturation is not reached (no new information) we will recruit additional participants as needed. Inclusion criteria for all focus groups, will be the requirement to read and write in the Portuguese language and willing to provide written consent. .

For peer review only

Analysis

Data will be analyzed using content analysis[39] and the constant comparison method to identify key themes/textual units related to LV. We will aim for thematic saturation (where data collection does not generate substantially new information and the range of perspectives appear to be completely covered) between the population specific focus groups[40]. All focus groups will be audiotaped and verbatim transcripts coded for key themes with the goal of at least 85% inter-coder reliability between at least two coders.

Patient and public involvement

Neither patients nor public were involved in the development of this study design but they will be involved in the development and validation of the DA.

Ethics and dissemination

Ethics approval was granted by the Portuguese Institute of Oncology of Porto (IPO-Porto; CES IPO: 34/2018). Results will be disseminated through peer-reviewed journals and presented at relevant scientific meetings for academic and health professionals audiences.

Discussion

Oncofertility is widely accepted and supported by the scientific community as a key component of young women's oncological care and QoL. However, in clinical settings its implementation is still sub-optimal. A recent study conducted

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in Portugal and USA, showed similar priorities and concerns regarding fertility and childbearing for young breast cancer patients. Lack of fertility discussions and dissatisfaction with fertility information provided by health care professionals were reported[8]. DAs are educational tools that may have the potential to facilitate the delivery of fertility information and aid in the complex decisional pathway that the patient and health professionals have to go through. A recent systematic review of decision tools for fertility supports the view that the use of these tools in clinical settings should be encouraged, since DAs were found to be highly useful, leading to discussions about fertility preservation and less decisional regret[25,41]. The number of available written materials about fertility preservation for young cancer patients is growing[27,28] as online fertility-related information from different organizations[42]. However, there are few validated DAs for young breast cancer patients worldwide; to our knowledge, they are nonexistent in Portugal.

Our project represents the first study in Portugal to develop and validate a DA for young breast cancer patients who speak Portuguese to support and facilitate the fertility decision-making process during a very difficult and stressful period of women's cancer trajectory, the diagnostic phase. Providing the clinical cancer care team with an evidence based tool to administer to all women during this period will encourage health care providers to have more fertility discussions with their patients, helping them to make appropriate and timely referrals for fertility specialists, and ultimately, raising awareness for the inclusion of fertility and childbearing within their clinical practice.

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Future research integrated in this project includes a Randomized Control Trial (RCT) developed to validate and assess DA's efficacy in a sample of young women with breast cancer (Phase 2). Based on findings using its original version in Australia[6] and from the literature in general[25], we anticipate that the DA will be an acceptable and useful tool for these group of patients during the fertility decision-making process, such as contributing to an increase in their fertility preservation knowledge and satisfaction with the information, as well as, helping to decrease the emotional burden of cancer. The innovative nature of this study addresses gaps in the scientific and clinical practice cited above, targeting an emerging field of research in Portugal, with the expectation of improving clinical practice, patient provider communication and knowledge in oncofertility.

Footnotes

Contributors: VG conceived the idea, contributed to the design of the study and protocol, coordinates the decision aid development, secured funding, and drafted this manuscript. LT participates in the decision aid development and in the decision aid revision. PF provides intellectual and scientific insight during the decision aid development and participates in the decision aid revision. GQ contributed to the design of the study, provided intellectual and scientific input during the development of the study protocol and grant application process. In addition, GQ provides intellectual and scientific input during the development of the decision aid. All authors reviewed and approved the final version of the protocol.

For peer review only

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Competing interests: None declared

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Figure 1: Study phase 1 process

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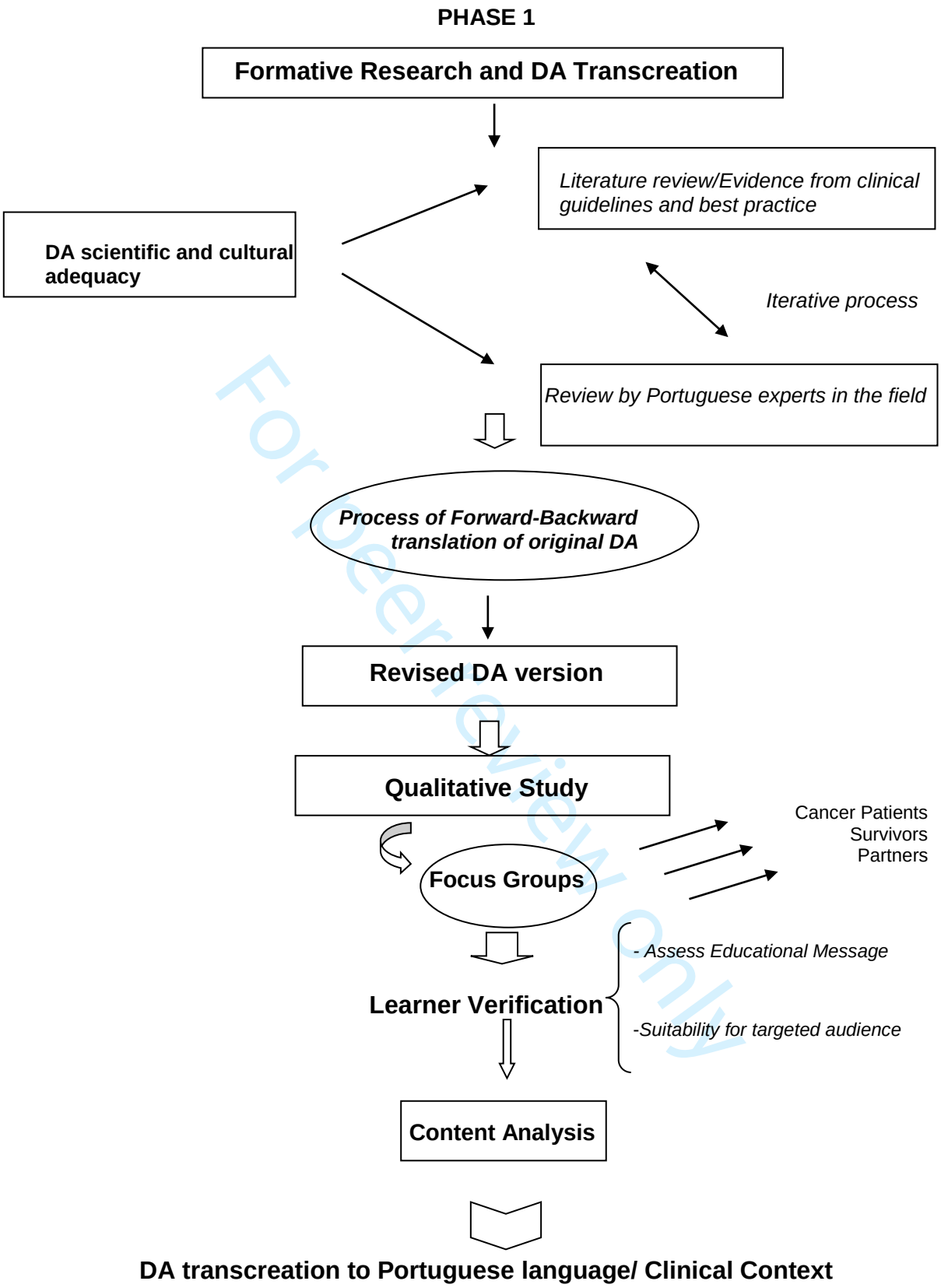

Fig 1: Study phase 1 process

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