A self-management psychoeducational eHealth program to support and empower people with advanced cancer and their family caregivers: Development using the scrum methodology

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ABSTRACT

Background: eHealth programs could be a flexible and scalable resource to support and empower people with advanced cancer and their family caregivers. A face-to-face intervention that has demonstrated effectiveness is the “FOCUS” program, developed and tested in the USA. Recently the FOCUS program was translated and adapted to the European context as part of an international study in six European countries, resulting in the “FOCUS+” program. FOCUS+ served as the basis for development of the web-based iFOCUS program.

Objective: We aim to (1) describe the development process of the iFOCUS program, (2) outline the challenges we encountered and how they were overcome, and (3) present findings regarding the acceptability and usability of iFOCUS.

Methods: We used the four phased agile Scrum methodology to develop iFOCUS and applied set timeframes of rapid program development and evaluation (sprints). Five teams were involved in the development i.e. a core development group, a web development team, an international consortium, audio-visual experts, and potential end-users.

Results: Development followed seven steps, integrated across the four phases of Scrum: (1) concept design, (2) development of mock-ups, (3) Feedback from the international consortium, (4) technical development of iFOCUS, (5) creating versions for the six participating countries, (6) preliminary testing of iFOCUS and (7) rapid program development and evaluation (sprints). Five teams were involved in the development i.e. a core development group, a web development team, an international consortium, audio-visual experts, and potential end-users.

Abbreviations: CEO, (chief executive officer); DIAdIC, (dyadic psychoeducational interventions for people with advanced cancer and their informal caregivers); eHealth, (electronic health); FOCUS, (family involvement, outlook, coping effectiveness, uncertainty reduction, symptom management); IT, (information technology); RCT, (randomized clinical trial).

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1. Introduction

Technological advancements, such as eHealth, are increasingly being recommended to address the challenges faced in healthcare (Hickey, 2020). eHealth refers to the use of technology, such as computers, to engage, inform, support, and empower users such as patients and family caregivers (Slev et al., 2016). By providing a cost-effective means of expanding the reach of clinical care and facilitating efficient patient communication and support, eHealth can improve quality of life in patients and family caregivers and reduce healthcare costs (Capurro et al., 2014), as well as reduce travel time and intrusive home visits for formal healthcare (Barbabella et al., 2017). Considering that most care for people living with serious illness is offered at home by family caregivers, eHealth could be considered as a potential way to provide psychoeducational support to patients with advanced cancer and their family caregiver (i.e. dyads) in how to cope with the impact of the disease on their lives (Saunders, 2006). However, a recent systematic review found that only nine psychosocial eHealth interventions have focused on dyads in which the care recipient had cancer (Shaffer et al., 2020). The review does not specify how many of these interventions have a specific emphasis on people with advanced cancer.

Emphasizing research into eHealth development for people with advanced cancer and their family caregivers is justifiable as people with advanced cancer and their family caregivers might have unique experiences related to the disease progression and treatment in comparison to patients and family caregivers involved in a non-advanced setting (Yong et al., 2023; Lee et al., 2021). Research shows that people with advanced cancer can experience reduced quality of life, which can worsen as the disease progresses (Sheykhangafshe et al., 2023; Zimmermann et al., 2014). Family caregivers of people with advanced diseases also experience higher levels of distress compared to other family caregivers (Van Goethem et al., 2022), and there is a positive correlation between distress levels in both cancer patients and their family caregivers (Hodges et al., 2005), affecting their overall quality of life (Northouse, 2012; Traa et al., 2015).

In order to cope with the unique experiences of patients with advanced cancer and their family caregivers the Transactional Model of Stress & Coping (Lazarus and Folkman, 1984) states that enhancing the dyad’s self-efficacy, problem-solving, and communication skills can lead to a more favorable response to stressors related to the illness. Research supports this theory, showing that increasing knowledge about the illness, self-efficacy, coping skills, decision-making involvement, improved communication, and mutual understanding can help the patient-caregiver dyad to better manage illness-related stressors (Slev et al., 2016; Penedo et al., 2020). Research also shows that adopting a salutogenic approach towards dyads, which focuses on improving health and social coherence rather than reducing illness can reduce distress and increase their quality of life (Gustavsson-Lilius, 2010).

The FOCUS program, developed in the USA in the early 2000s, is a nurse-led psychoeducational dyadic intervention designed for people with cancer and their family caregivers (Northouse et al., 2002) based on the Transactional Model of Stress & Coping (Lazarus and Folkman, 1984). FOCUS consists of five modules: Family involvement, Optimistic outlook, Coping effectiveness, Uncertainty reduction, and Symptom management. The program is simultaneously delivered to the patient and family caregiver by a nurse and has been shown to improve quality of life and self-efficacy, and reduce emotional distress in dyads in an advanced cancer trajectory (Northouse et al., 2002; Northouse et al., 2007). A self-managed web-based format of the “Family involvement” component of the FOCUS program was developed in the USA (Northouse et al., 2014). Development of content and program design happened simultaneously for the original FOCUS program. A multidisciplinary team was involved in the process of development encompassing three stadia namely ideation and prototyping (1), iterative design and development (2), and internal testing and final development (3). For usability testing four focus groups and four patient-caregiver dyads per session reviewed the sessions and found the programs structure, design and content favorable (Zulman et al., 2012). Dyads with advanced cancer who completed this web-based format as part of a phase II feasibility trial reported a decrease in emotional distress, improved quality of life, and more benefits from illness and caregiving (Northouse et al., 2014).

As part of the international DIAdIC project which involves six European countries (Belgium, The Netherlands, Denmark, Italy, The United Kingdom, and Ireland) we developed two adaptations of the US-based FOCUS program, namely a face-to-face program named FOCUS+ and a web-based program iFOCUS and will determine whether these two adaptations could effectively improve the emotional well-being and self-efficacy of people with advanced cancer and their family caregivers (Matthys et al., 2021). In the present article we specifically report on the development process of the iFOCUS program. Development of the FOCUS+ program has been reported elsewhere (van der Wel et al., 2022).

The aim of this article is three-fold:

1. To describe the process of development of the eHealth iFOCUS program.
2. To outline the challenges encountered during the development of the eHealth iFOCUS program and how they were overcome.
3. To present the results of the acceptability and usability of the eHealth iFOCUS program through user testing.

2. Methods

2.1. Study design

Predating the actual development of iFOCUS the FOCUS program has been reported elsewhere (van der Wel et al., 2022).

To describe the process of development of the eHealth iFOCUS program.

To outline the challenges encountered during the development of the eHealth iFOCUS program and how they were overcome.

To present the results of the acceptability and usability of the eHealth iFOCUS program through user testing.
modifications and additional features for translation to the European context. In a next phase FOCUS was adapted and translated to a face-to-face program for people with advanced cancer and their family caregivers namely FOCUS+. This process is extensively described elsewhere (van der Wel et al., 2022). FOCUS+ served as the foundation for the development of the iFOCUS program.

We developed the iFOCUS program using the four phases of the Scrum methodology, which are: design, development, go-live, and maintenance & support (Hema et al., 2020) (Fig. A). To support agile software development, we utilized “sprints”, which are periods of rapid program development and evaluation (Hema et al., 2020; Forsman and Sisak, 2020). During each sprint, the team responsible for the technical development decides on the deliverables and related tasks and meets on a daily base to synchronize their work, to discuss the progress and plan the next days. Each sprint is ended by a retrospective evaluation of that sprint (Morales Garzón, 2017). We applied sprints of two weeks throughout the process of design, development, and maintenance & support. During the go-live period, we had weekly sprints. Using the agile Scrum methodology allowed us to instantly and efficiently resolve emerging problems (Morales Garzón, 2017).

The core development group designed a seven-step development process (Fig. B). These steps can be integrated into the four phases outlined in the Scrum model. The seven steps are followed in a sequential, yet flexible manner, allowing for revisiting previous steps for continuous refinement and correction (Lawal and Chukwu Ogbu, 2021). During the Scrum phases of design and development (step one to six) an iterative process was used within each step. The iterative process of development involved cycles of brainstorming, development and evaluation within each phase. Multiple feedback rounds were conducted before concluding a particular phase. Each feedback round provided insights which shaped subsequent iterations of development. This approach allowed for continuous refinement and improvement based on user feedback and evaluation.

2.2. Study procedure

2.2.1. Groups involved in the development

Five groups participated in the development process (Fig. C). The core development group (1) consisted of academics, clinicians, and healthcare professionals who were actively involved in the daily development of program content and flow. The web development team (2) was made up of software developers, a user expert/cancer survivor, and the CEO of the IT firm who acted as the technical project manager and handled all technical and administrative tasks. The international consortium (3) involved in the DIAdIC project comprising researchers and experts in palliative and supportive care provided oversight, input, and feedback on the program development. Experts on videos and visualization (4) were consulted as needed. Finally, potential end-users (5) from each participating country provided input and feedback during the feasibility and usability evaluation.

2.3. Step 1: concept design

Two earlier studies that modified one module of the original FOCUS program to a web-based format were analyzed to gain insight into the procedures and tailoring (Northouse et al., 2014; Ellis et al., 2017). Based on these findings, the core development group created a visual representation of the proposed web program using MS PowerPoint, with each slide corresponding to a screen of the intended program. They also identified the technical requirements. Justifications for the choices regarding program flow, slide design, and technical requirements were documented and added to the slides, referencing the philosophy of the FOCUS+ program. During the phase of concept design we continued to be aware of the intended end-users, being patients with advanced cancer and their family caregivers. In light of this, we conscientiously considered functionalities which could mediate program difficulties due to side effects resulting from the disease or treatment trajectory of patients with advanced cancer and their family caregivers. Feedback was sought from the international DIAdIC consortium.

2.4. Step 2: development of mock-ups

The web development team created digital mock-ups based on the MS PowerPoint presentation as a first draft representation of iFOCUS. As part of the functional and technical analysis, there were several meetings between the web development team and the core development group to discuss the main functionalities required and the technical specifications. At the same time, the core development group, in collaboration with the video and visualization experts, prepared various materials, such as videos, written text, external resources, and references, to be included in iFOCUS.

2.5. Step 3: feedback from the international consortium

A workshop was held to gain more perspectives on the form and content of the program. During this meeting, the consortium members...
Fig. B. iFOCUS Development flow.

Fig. C. Teams involved during development.
discussed the proposed content, concepts, functionalities, and materials. The core development group presented the initial MS PowerPoint concept and the first digital mock-ups. Throughout the subsequent development steps, the international DIADIC consortium was consulted to provide feedback on language, cultural significance, and additional materials.

2.6. Step 4: technical development of the iFOCUS program

The web development team calculated the time and cost required for the technical development of iFOCUS. A digital platform was created which allowed the core development group to input videos, images, and certain functionalities, such as exercises and tailored feedback. This resulted in the first web-based version (V1.0) of iFOCUS in English.

2.7. Step 5: creating an iFOCUS version for the six participating countries

To implement iFOCUS in each of the six participating countries, country-specific versions were created. The core development group asked the international consortium for translations of all written text, spoken text, and references to external local resources into their respective languages. This process involved both translators and professionals with experience in palliative and supportive care. The core development group then systematically added all translated information and materials to the digital platform, resulting in a viable version (V2.0) of iFOCUS in six languages: Dutch (Belgium), Dutch (The Netherlands), English (The United Kingdom), English (Ireland), Italian, and Danish.

2.8. Step 6: preliminary testing of iFOCUS

To validate the functionality and user experience of iFOCUS, both professionals and end-users were consulted through functional and user testing. The results were used to identify and fix any bugs or errors and to further optimize the program to meet current technological standards and user requirements.

2.8.1. Functional testing

Version 2.0 of the iFOCUS program underwent functional testing from August to October 2020. Functional testing evaluates the performance of a device across its various modes of operation and verifies that the application’s features and operational behavior match its specifications (Shala et al., 2017). Initially, seven members of the core development group acted as dyads going through iFOCUS. Next, five teams from the international consortium (UK, Ireland, The Netherlands, Denmark, and Italy) accessed the web sessions in their respective language and performed functional testing in the same manner as the core development group. The procedure for analyzing the data can be found in Appendix A. Based on the feedback obtained from this functional testing, the core development group resolved all identified bugs and errors, resulting in Version 2.1.

2.8.2. User testing

User testing of Version 2.1 of iFOCUS took place between October 2020 and March 2021. User testing involves evaluating a program by its potential end-users (Cabanas and Rainosa-Madrunio, 2020). As part of the user testing, we wanted to assess the preliminary acceptability and usability of the iFOCUS program as well as control the program for bugs and look for potential improvements to the program as defined by potential end users. We considered a program acceptable when the content and the program structure were agreeable (Adrian et al., 2020) and satisfactory to the dyads after having engaged with the program (retrospective acceptability) (Nadal et al., 2020). We aimed to conduct online semi-structured interviews with people with advanced cancer and their family caregivers to assess their evaluations of the user-friendliness, content, and layout of iFOCUS. Interviews were conducted using an interview guide with questions and probes (Appendix B).

Questions such as “What was your experience logging in”, “What are your experiences going through this chapter X” and “What did you think going through chapter X” were asked and participants were encouraged to think aloud and express their thoughts as they went through the program (Ghenai et al., 2020). The core development team analyzed the data and made necessary adaptations to the program.

Based on a diminishing return analysis model, a participant population of five to fifteen is considered sufficient to detect defects (Esteve et al., 2021). Considering that the technical functionalities are the same across countries we aimed to recruit five dyads (10 participants) per country participating in the international RCT, resulting in 30 dyads (60 participants) across six countries, through purposive sampling. Participants were dyads similar to those planned for inclusion within the international RCT. Patients were over 18 years old and had been diagnosed with advanced cancer, i.e. were no longer receiving curative treatment. Patients with brain cancer or non-solid cancer, a prognosis of fewer than three months, or without a family caregiver were excluded. Family caregivers were over 18 years old, were appointed by the patient as the main family caregiver, and did not receive a cancer diagnosis 12 months prior to study participation. We aimed to include a diverse range of participants in terms of sociodemographic characteristics such as age, sex, and patient-family caregiver relationship.

As the COVID-19 pandemic affected participant recruitment, we allowed some flexibility by 1) recruiting four dyads instead of five; 2) using alternative recruitment methods such as Patient and Public Involvement, self-referral, contacting dyads involved in the testing of FOCUS+, existing groups or networks of patients and family caregivers, 3) recruiting dyads where the patient was not in an advanced stage of cancer, and 4) recruiting bereaved family caregivers.

2.9. Step 7: implementing the final version in an RCT

Feedback gathered from the functional and user testing resulted in the final version of the iFOCUS program (V3.0).

2.10. Ethical considerations

This study is performed following the Declaration of Helsinki. The Ethics Committee of the Ghent University Hospital (UZ Gent), Ethics Committee of the North Emilia Wide Area (AVEN), Italy; St. Vincent's University Hospital Research Ethics Committee, Ireland; Medical Ethics Review Committee Erasmus Medical Centre Rotterdam, the Netherlands; and NHS/HSC Research Ethics Committee, United Kingdom, approved the study procedure and materials. The Denmark Scientific Ethical Committee system determined that the protocol did not require formal approval.

All personal data were processed in accordance with the General Data protection Regulation (GDPR) (EU, 2016/679), in effect since May 25th 2018. All information is gathered confidentially. All data gathered was pseudonymized and accessible to researchers or physicians involved in the study only.

Informed consent was obtained from all participants. Participants did not receive any financial compensation for participating in the study.

3. Results

3.1. Step 1: concept design (May 2019 – September 2019)

We identified seven key characteristics as part of the iFOCUS concept design (Table A). iFOCUS is a psychoeducational intervention (1) that addresses the five core components of the FOCUS+ program (2) in four sessions as opposed to three sessions in FOCUS+. The challenge of redistribution of the session content into four sessions was handled by the core development group by iteratively reviewing different renditions of the program structure. The increased number of sessions allows for
Table A

Key characteristics of the iFOCUS program and their operationalization.

<table>
<thead>
<tr>
<th>Key characteristics</th>
<th>Operationalization of key characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. iFOCUS should be a psycho-educational program</td>
<td>Modus operandi of providing information: To provide information, a logic flow was implemented based on the Stress Coping model from Lazarus and Folkman along with the evidence-based FOCUS program. We aimed to introduce a topic, and assess the needs, priorities, or situation of dyads, followed by providing tailored feedback. For example, as part of the iFOCUS program, in the part ‘Symptom Management’ both patient and caregiver individually get the chance to grade different symptoms. Based on the grading of the symptoms they are referred to provide information or resources on the symptoms they graded higher. Most exercises and topics end with guiding questions, facilitating reflection or discussion. Long-term learning effect: To allow dyads to reflect in the long term on the information they received and entered into the web program, a reference work in the form of a personal workbook was implemented. This is generated as dyads complete their sessions. The personal workbook functions as a logbook in which the dyads receive standard information based on the content of the sessions and personalized information based on the answers they gave to the exercises and their choices on what additional references (existing information or brochures) they would like to add. The personal workbook can be downloaded in pdf format upon completion of at least one session and can be viewed at any time.</td>
</tr>
<tr>
<td>2. iFOCUS should address the five core components of the FOCUS+ program</td>
<td>The different FOCUS+ components are: “Mutuality and engagement in dyad communication” (F), “Resilience and meaning-making” (O), “Coping and Self-efficacy” (C), “Uncertainty reduction” (U), and “Symptom management” (S). These components provide the basis for both FOCUS+ and iFOCUS. Since iFOCUS is based on the face-to-face FOCUS+ program, they are similar both in content and order of presented topics. As part of the ‘F’ component, dyads are encouraged to establish an alliance, assess their roles, analyze their communication patterns, and reflect on how they support one another. In the ‘O’ component, dyads’ emotions are normalized and dyads are encouraged to keep a positive outlook while acknowledging difficulties and setting goals. As part of the ‘O’ component, visual imagery and advance care planning are also discussed. The ‘C’ component concerns their coping styles and how they manage their stress levels, body image, and lifestyle. As part of the ‘U’ component, the dyad is stimulated to discuss and map their uncertainties and identify who can assist them with handling these. The ‘S’ component of symptom management covers the side effects of the treatments as well as the effect on intimacy. Dyads are referred to additional resources for all topics covered. All five FOCUS and FOCUS+ core components are addressed across four web-based sessions. Compared to the FOCUS+ program, iFOCUS has four sessions spread over twelve weeks instead of 2 sessions and 1 follow-up call as for the FOCUS+ intervention. In the FOCUS+ intervention duration of the face-to-face sessions was estimated at 1.5h per session, which we reduced to 1h for the iFOCUS intervention. Extra attention was paid to obtaining a good program flow both within and between the different sessions by linking topics to one another and building on previous information.</td>
</tr>
<tr>
<td>3. iFOCUS should have a varied pedagogic approach</td>
<td>Didactically varying materials: Various materials such as written text, voice-overs, exercises, tailoring, animated PowerPoints and videos, testimonials, referrals to external sources such as peer support groups and a personal workbook are needed to increase engagement with the program content and to reduce fatigue in patient-caregiver dyads. Relatable content: For the content of the FOCUS program, the international consortium was instructed to obtain culturally appropriate and contemporary information or resources. To find this information national scientific and grey literature used in healthcare related settings were used. Visually recognizable: Visually, we aimed to increase relatability for different types of dyads by providing diverse images regarding age, sex, ethnicity, and dyad relationship. Furthermore, we included testimonials to increase recognizability for dyads. Testimonial videos are played at the beginning of the session and depict a dyad that completed the session, reflecting on what they learned from it. Number of sessions and session duration: Increasing the number of sessions and the period in which the program is to be completed allowed us to reduce the length of each session. This decision was based on the preliminary assumption that reduced session length would increase the information retention of dyads as it is less exhausting than longer sessions. Program flow within and between sessions: To ensure a positive experience for dyads when going through the iFOCUS program, it was necessary to obtain a good program flow within and between the sessions. All materials gathered for the FOCUS+ intervention on the five FOCUS components were analyzed. Firstly, an overarching structure per individual component was created to provide an overview of which topics per component were discussed in which sessions. The overarching content is divided in such a way that each session/topic builds on previous information related to that session or topic. Having a good program flow across sessions meant that information was built upon, but not repeated. Once the topics and components were spread over the four sessions, we examined each session separately, identifying ways to link different topics together. This was achieved by changing the order of topics within a session in such a way that it allowed a coherent story. Tailoring: Tailoring allows programs to process the information they receive from users into an individualized reply. This means that tailored programs are likely to fit better to the individual context and needs of their end-users, in contrast to default programs in which content remains the same for all users. Although tailoring was well received in the original web-based FOCUS program, development of tailoring proved to be very time consuming resulting in only the F-component being translated to a web-component (Northouse et al., 2014). Because of basic tailoring in the iFOCUS intervention, all components have been translated to a web-based format.</td>
</tr>
<tr>
<td>4. the content of iFOCUS (information and exercises) should be tailored to identified needs, priorities and situation of the patient-caregiver dyads</td>
<td>Guiding questions: During the sessions, dyads are asked to reflect on themselves, one another, or the dyad. In doing so, they are encouraged to think about their strengths, problems and needs (continued on next page)</td>
</tr>
</tbody>
</table>
towards in-depth personalization through tailoring. Given the time and effort required to develop a fully tailored program, we focused on basic exercises, and tailoring. Additionally, a personal workbook is created for monials, referrals to external resources or contact information, exercises, and tailoring. The functionalities included: information icons, written text, voice-overs to read large sections of text aloud, animated text presentations with imagery of the desired program pages and its related functionalities.

### 3.2. Step 2: development of mock-ups (September 2019 – October 2019)

The digital mock-ups had limited visuals and were based on the initial PowerPoint and the required technical functionalities (Table B). The functionalities included: information icons, written text, voice-overs to read large sections of text aloud, animated text presentations with guidelines, animated explainer videos for more complex topics, testimonials, referrals to external resources or contact information, exercises, and tailoring. Additionally, a personal workbook is created for each dyad as a reference tool for long-term information retention. The workbook can be downloaded and printed for convenience.

We experienced considerable limitations in available time and effort towards in-depth personalization through tailoring. Given the time and effort required to develop a fully tailored program, we focused on basic tailoring such as customizing the dyad names, patient-caregiver roles, and exercises. The personal workbook logs both general information as well as personalized information, including answers to exercises.

### 3.3. Step 3: feedback from the international consortium (November 2019)

The international consortium agreed on redistributing information across program sessions but had concerns with the proposed log-in procedure using two-factor authentication and the impact on program accessibility. To ensure data protection and program accessibility, it was agreed to use a log-in procedure linked to email addresses instead of two-factor authentication, as this could decrease accessibility for participants and reduce retention during the trial. No major issues with the proposed functionalities were identified. This feedback was relayed to the web development team for implementation.

### 3.4. Step 4: technical development of the iFOCUS program (November 2019 – January 2020)

We developed the iFOCUS program into an entirely new platform. The first fully functional English version of iFOCUS (V1.0) was developed featuring all required technical functionalities. The web development team uploaded a limited amount of information to the platform to present a front-end visualization to the international consortium. Table C shows which topics are presented in each session. We have added a few images from the program as Figs. D, E, F and G.

### 3.5. Step 5: creating an iFOCUS version for each of the six participating countries (January 2020 – August 2020)

iFOCUS is available in six languages. As it was developed based on FOCUS+, many materials to be used for iFOCUS had already undergone translation (van der Wel et al., 2022). New materials and information were translated by professional translators with input from palliative care experts who spoke the respective native language. All partners provided their translations, which were integrated into the program by the core development team. Since the information was added by non-native speakers, some language errors were expected and were addressed by presenting the program in their respective language to each international partner for feedback. Any linguistic mistakes were reported to the core development team with a clear description, location, and suggested correction. These were addressed by the core development team.

### 3.6. Step 6: preliminary testing of iFOCUS

A ticketing system was established using an online platform for collaborative project development to manage and track bugs during and after the functional and user testing. Bugs were reported to the core development team with a description and location of the issue. Potential solutions were discussed in weekly meetings with the web development team.
led users to irrelevant information. Fixing certain bugs was difficult across all sessions and languages. In some exercises, the program logic failed, impacting the user experience. All major bugs were fixed, while minor bugs negatively hindered the program's functionality, while minor bugs negatively impacted the user experience. All major bugs were fixed, while minor bugs were evaluated based on their impact versus the effort required to resolve them.

Spelling and grammatical errors, primarily minor, were identified in all sessions and languages. In some exercises, the program logic failed, leading users to irrelevant information. Fixing certain bugs was difficult due to the interconnected nature of the program. Inconsistencies in layout, such as the use of different fonts or colors, were corrected by standardizing the text. Some national teams reported issues with images, such as the depiction of age, gender, or ethnicity, which were replaced. Issues with audio volumes, such as being too loud or soft, were not considered substantial enough to make changes due to the impact on time and budget.

3.6.1. Functional testing

Bugs were classified as either major or minor. Major bugs completely hindered the program's functionality, while minor bugs negatively impacted the user experience. All major bugs were fixed, while minor bugs were evaluated based on their impact versus the effort required to resolve them.

Spelling and grammatical errors, primarily minor, were identified in all sessions and languages. In some exercises, the program logic failed, leading users to irrelevant information. Fixing certain bugs was difficult due to the interconnected nature of the program. Inconsistencies in layout, such as the use of different fonts or colors, were corrected by standardizing the text. Some national teams reported issues with images, such as the depiction of age, gender, or ethnicity, which were replaced. Issues with audio volumes, such as being too loud or soft, were not considered substantial enough to make changes due to the impact on time and budget.

Modifications were made by the responsible partner, research team, or web development team, depending on the situation.

3.6.2. Functional testing

Table B

<table>
<thead>
<tr>
<th>Session</th>
<th>Mutuality and engagement in dyad communication</th>
<th>Outlook, Resilience and meaning making</th>
<th>Coping and Self-efficacy</th>
<th>Uncertainty reduction</th>
<th>Symptom management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Establish alliance</td>
<td>Normalizing emotions</td>
<td>Different coping styles</td>
<td>Different treatments</td>
<td>Side-effects of treatments</td>
</tr>
<tr>
<td></td>
<td>Assess roles and teamwork</td>
<td>Maintaining a positive outlook</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identify additional needs for support</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Communication patterns</td>
<td>Acknowledging difficulties</td>
<td>Communication towards others</td>
<td>Mapping uncertainties</td>
<td>Side-effect assessment</td>
</tr>
<tr>
<td></td>
<td>Reflection on previous session</td>
<td>Setting goals</td>
<td></td>
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<td>Impact on family and friends</td>
<td>Impact on body image</td>
<td>Managing body changes</td>
<td>Talking about uncertainties to a healthcare provider</td>
<td>Information on side-effects</td>
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<td>Tips to cope with stress</td>
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<td>Intimacy and sexuality</td>
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<td>3</td>
<td>Reflection on mutual support</td>
<td>Evaluate change in attitude</td>
<td>Encouraging a healthy lifestyle</td>
<td>Evaluate capability for managing uncertainty</td>
<td>Evaluate symptom development</td>
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<td>4</td>
<td>Reflection on previous sessions</td>
<td>Advance care planning</td>
<td>Coping with stress and energy management</td>
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<td>Refer to extra sources</td>
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Table C

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3.6.2. User testing, preliminary acceptability and usability and points of improvement

Twenty dyads and two bereaved family caregivers reviewed the sessions. Patients and family caregivers use the program simultaneously and together behind the same medium (computer or tablet).

Participants were mostly female (57.1%) and 55 to 74 years old (72.4%), with most being spouses (81.1%). Breast cancer (25%) and prostate cancer (20%) were the most diagnosed types of cancer among participants. The majority of participants (60%) was in an advanced metastatic stage of cancer (Table D). After participation to the user testing, participants stated that the program structure and content was agreeable and no major issues with program acceptability were mentioned. The program was found to be useful and clear, but some participants felt that some information may not be relevant to them. The session duration was considered appropriate, and participants were satisfied with the variety of videos, text, and exercises. Most comments related to text size and font, spelling errors, and bugs. Videos were well received, although some minor remarks were made about the testimonial videos and their ability to increase the sense of recognition among dyads. Patients with cancer had similar feedback as patients with advanced cancer. No difficulties pertaining to an advanced cancer disease trajectory or its treatment were identified.

“The fact that the videos are supported by text increases the clarity of the information and makes it so that you will remember it longer.”

(S, female, Patient, fourth session)

Two major bugs were reported by users: 1) The text was being automatically translated into English and back into their own language...
while trying to log in, causing the program language to be less than acceptable; 2) Some users were unable to log in due to using outdated software such as Internet Explorer. Most users found the login process to be clear, however, some participants had difficulty navigating the webtool, particularly in starting the videos. Some exercises were also reported to be unclear.
3.7. Step 7: implementing the final version in an RCT (February 2021)

The final iFOCUS program consists of four sessions that patients and their family caregivers access together and simultaneously using the same device over a 12-weeks period, with a three-week break between sessions. Each session lasts approximately 60 min. The program has been implemented in six different languages for six European countries participating in an RCT to evaluate its effectiveness. To implement iFOCUS in the RCT, an onboarding procedure was deemed necessary to introduce participants to the program’s timeline and goals and to gather the necessary information for enrolment. This information, including the participants’ names and their relationship, will be entered into the system and used to tailor the program. The onboarding procedure was developed by the core development group in collaboration with data collectors and was approved by the international consortium. The process was written down in a guide to be used by data collectors during recruitment. After setting up a profile, both the patient and family caregiver will receive an email inviting them to complete the first session together on the same screen. The program automatically sends emails to participants at a set time for future sessions. Currently, iFOCUS is being evaluated as part of an international RCT to determine its effectiveness on the quality of life, emotional functioning, self-efficacy, healthcare resource use, and cost-effectiveness among patients with advanced cancer and their family caregivers (ClinicalTrials.gov Identifier: NCT04626349) (Matthys et al., 2021). The study will also gather information on participant satisfaction with iFOCUS and aim to uncover its underlying mechanisms.

4. Discussion

4.1. Main findings

The iFOCUS program consists of four sessions over a 12-week period, with a three-week gap between each session. During its development, seven steps were taken: (1) concept design, (2) development of mock-ups, (3) obtaining feedback from the international consortium, (4) technical development of the program, (5) creating country-specific versions for each of the six participating countries, (6) preliminary testing through user and functional testing and (7) implementing the final version for the RCT. Using the Scrum methodology allowed for flexibility and adaptability in the development process, as it included alternating periods of program development and evaluation. Collaboration between different teams and integration of different perspectives helped resolve issues related to program flow, content, language, layout, and bugs, but some pragmatic choices were necessary considering project limitations. User and functional testing showed that the program was acceptable and functional. By building on the philosophy of the FOCUS and FOCUS+ program for patients with advanced cancer and their family caregivers, and by keeping the emphasis on this population during development, no specific remarks pertaining to advanced cancer were identified, indicating the program's successful adaptation to address patients with advanced cancer and their family caregiver. The development process resulted in a self-management psychoeducational eHealth program for people with advanced cancer and their family caregivers that can be used autonomously by the patient-caregiver dyad. Currently, the effectiveness of iFOCUS is being tested in an international RCT. Various challenges were encountered across different steps of development (Table E). The challenges we encountered were related to transferring ideas into working functionalities, spreading of the content, tailoring, determining the log-in procedure, input of translated materials and determining an onboarding procedure.
Additionally, although eHealth interventions might be more cost-effective than face-to-face interventions, designing and developing technology (Zulman et al., 2012). Since advanced cancer is more common in older adults (Estape, 2018) who often have lower digital competence (Antonio and Tuffley, 2015) it is also critical to be aware of challenges associated with age and the uptake of technological innovations which can be reflected in difficulties with onboarding, logging-in or working with the program in general.

iFOCUS is designed to be used outside of clinical settings, but still requires personal interaction as part of the registration process due to barriers to digital program participation such as limited access to the internet or data, low computer use, and low digital literacy (Czaja et al., 2013). Interpersonal contact is crucial in overcoming these barriers (Hernandez-Ramos et al., 2021) and enhancing the user experience and program adherence by improving verbal and non-verbal communication, and building trust between clinicians and participants (Borgerink, 2016; Christie et al., 2018). Nevertheless, it is essential to be aware of the potential impact of personal interaction as part of the iFOCUS onboarding procedure (Banbury et al., 2021) without compromising the intended self-sufficient nature of the program.

### 4.2. Interpretation and implications of the findings

We encountered challenges common to eHealth development in general as well as specific challenges related to the requirements of the iFOCUS webtool. A general challenge was that despite being functional and usable, there is always room for improvement in eHealth web programs, as they are continually evolving (Pieterse et al., 2018). Estimating the effort and resources required to develop an eHealth program is challenging, as previous research has shown that eHealth development costs depend on specific program requirements (Wu et al., 2014).

Program-specific challenges during the development of iFOCUS included deciding on the level of tailoring to be implemented. Tailoring can ensure that the program is applicable to the dyad by increasing the perceived program relevance (Jüstria et al., 2013). Moreover, it increases program engagement and improves outcomes (Penedo et al., 2020), but also adds complexity to the coding and can result in errors (Ryan et al., 2019; Cruz-Martínez et al., 2021; Islam et al., 2019). Additionally, although eHealth interventions might be more cost-effective than face-to-face interventions, designing and developing tailored programs is a very resource-consuming endeavor (Abdelrakb et al., 2018) which explains why we limited the level of tailoring in iFOCUS. Another difficulty encountered during the development of iFOCUS and reported in similar studies is the rapid advancements in technology (Zulman et al., 2012). Since advanced cancer is more common in older adults (Estape, 2018) who often have lower digital competence (Antonio and Tuffley, 2015) it is also critical to be aware of challenges associated with age and the uptake of technological innovations which can be reflected in difficulties with onboarding, logging-in or working with the program in general.

4.3. Strengths and limitations

Other than the FOCUS program that iFOCUS was based on, there are to our understanding no other dyadic, self-managed, tailored eHealth programs for people with advanced cancer and their family caregivers. The iFOCUS program benefits from being built on the evidence-based face-to-face FOCUS program and its underlying conceptual framework, Lazarus and Folkman’s Model of Stress & Coping, and a salutogenic approach. The development of iFOCUS was carried out through an iterative process that involved various teams with different areas of expertise, leading to a wider range of perspectives and access to a broad spectrum of skills. Using the Scrum methodology allowed for multiple feedback loops during development, both within and between teams, which allowed efficient contributions towards improving the quality of the program and its content.

This study also has some limitations. Due to limited time and resources, it was only possible to receive feedback from end-users in one of the later stages during the development process, i.e. during user testing. Ideally, we would have liked to involve end-users in all stages of the program development as end-users’ experiences, insights, and interests are often better incorporated in a co-design process (Fuchs et al., 2010), which can contribute to long-term program availability and implementation (Higgins et al., 2018). Due to limitations in both time and resources, the development team was forced to make pragmatic choices. Furthermore, the COVID-19 pandemic made recruitment for the functional testing challenging. As such we also included bereaved caregivers and people with non-advanced cancer who might have different experiences than those in an advanced stage of the disease (Yong et al., 2023; Lee et al., 2021).
4.4. Conclusions

Developing a tailored, self-managed eHealth program for dyads is a complex process and involves making pragmatic choices, particularly regarding the level of tailoring. By its nature, an eHealth program requires constant revision and updates. Communication between program developers and end-users is recommended during and after the development of the program, to improve program quality.

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Declaration of competing interest

None.

Data availability

The data sets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Acknowledgements

VVG, SD, OM, LN, LD, LL, PH, ADV and JC contributed to conception and design of the study. VVG and OM acquired and analyzed the data. All authors contributed to the interpretation of the data. VVG, SD, ADV, and JC drafted the manuscript. All authors revised the manuscript critically for important intellectual content and approved of the version of the manuscript to be published.

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Appendix A. Procedure for analyzing data of functional testing

We identified four categories (“language and translations”, “logic”, “layout” and “video and audio”) that were subsequently divided into 1) applicable for all countries or 2) applicable for a specific country. To determine if, or in what order we would implement adaptations, the items within these categories were divided into two groups; “Simple solution identified” or “No simple solution identified”. To grade whether a solution was simple or not, questions were asked on: 1) the monetary burden on the national or international teams and 2) time consumption and its effect on planning and time management. All items where a simple solution was identified were adapted accordingly. For items with no simple solution on an international scale, pragmatic choices were made on what adaptations we could make. For all items with no simple solution on a national scale, the country reporting the issue was contacted to request if they would make these adaptations themselves.

Appendix B. Interview guide for user testing without probes

<table>
<thead>
<tr>
<th><strong>IFOCUS user testing: SESSION ONE</strong></th>
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<tbody>
<tr>
<td>Starting your session</td>
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<tr>
<td>Mutual support &amp; family involvement</td>
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<tr>
<td>Communication</td>
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<tr>
<td>Emotions</td>
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<td>Coping</td>
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<td>Treatments</td>
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<td>RECAP</td>
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<tr>
<td>General remarks</td>
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1. Did you experience any bugs?
2. How do you evaluate the read aloud option?
3. How was the use of pictures? What effect did this have on you?
4. How do you evaluate the use of different exercises?
5. How do you evaluate the length of the tool?

<table>
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<tr>
<th><strong>IFOCUS user testing: SESSION TWO</strong></th>
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<tbody>
<tr>
<td>Starting your session</td>
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<td>Impact of the illness</td>
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<td>Talking with children</td>
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<tr>
<td>Uncertainty</td>
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<td>Goal</td>
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<td>Symptom management</td>
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<td>RECAP</td>
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