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Developing Internet Interventions to Improve Psychosocial Outcomes in Breast Cancer Survivors

Attitudes and practices in Portuguese cancer settings

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ABSTRACT

Background: Despite the psychosocial treatment gap in cancer settings and the significant body of evidence on the efficacy and cost-effectiveness of internet interventions, research targeting Breast Cancer Survivors (BCS) is scant, and implementation in clinical settings is limited. While the reasons for this research and implementation gaps are multifactorial, including funding, technical and organizational barriers, the attitudes of the distinct stakeholders in the internet interventions' ecosystem have been posited to play an important role in this regard. Yet, little is known about the attitudes and practices of key stakeholders such as BCS and Mental Health Professionals (MHP) toward these interventions or how they should be effectively designed to be widely accepted and easily implemented. Internet interventions' development is often viewed as a "black box". Important behaviour change processes and technological architecture design decisions are seldom reported, and development often neglects end-users' perspectives or the contexts in which internet interventions will be deployed. This lack of human-centeredness in the development process partly explains high attrition rates and poor engagement, as well as the failed implementation of internet interventions targeting cancer survivors. Hence, there is a need for methodologically sound internet interventions development research within psychosocial oncology, that is centred on the perspectives and practices of the several actors playing in the cancer setting.

Objectives: The current thesis attempts to answer this call and bring the perspectives of key stakeholders into the centre of survivorship internet interventions' development. Its overarching aim was to develop iNNOV Breast Cancer (iNNOVBC) – an internet intervention aiming at improving psychosocial outcomes in BCS - using a User-centred design approach, thereby anchoring development on the perspectives and practices of BCS and MHP. Its specific aims were i) to gather requirements for the development of iNNOVBC; ii) to prototype iNNOVBC; and iii) to evaluate iNNOVBC's usefulness, usability, and feasibility.

Methods: To this end quantitative (i.e., surveys and task analysis usability tests) and qualitative methods (i.e., in-depth and debriefing semi-structured interviews, think-

aloud lab-based usability tests and short-term field trials) were combined and four empirical studies were conducted. First, we assessed the attitudes of Portuguese Psychologists toward internet interventions and the potential barriers impacting its implementation (n= 1077; c.f., **Study I**). Second, we explored in-depth the perspectives and practices of MHP regarding Digital Mental Health (DMH), with a focus on internet interventions (n=13; c.f., **Study II**). Third, we characterized the attitudes of Portuguese BCS toward DMH and investigated the potential factors associated with such attitudes (n=336; c.f., **Study III**). Fourth, we documented the development of iNNOVBC and evaluated its usefulness, usability, and preliminary feasibility (n=24; c.f., **Study IV**).

Main findings: Despite Portuguese BCS' and MHP's limited knowledge, experience, and guarded stance toward internet interventions, iNNOVBC was considered highly useful by these end-users, configuring a promising point-of-need solution to bridge the psychosocial supportive care gap experienced by BCS across survivorship. However, to fulfil its full supportive role and reach high levels of usability and feasibility, iNNOVBC requires further refinement. Alterations are necessary regarding the aesthetics, information architecture, cognitive load, interaction design, and the technological media for intervention delivery (e.g., mobile app version). In addition, iNNOVBC might require further tailoring and a more flexible implementation approach, so that it better adapts to the needs and contexts of its target users. These aspects need to be assessed in future pilot and Randomized Controlled Trial studies.

Implications: The development of internet interventions targeting BCS should, whenever possible involve its target end-users so that interventions reflect their real needs and are more easily accepted and implemented. Furthermore, development teams should devise comprehensive plans for the translation of interventions to clinical practice, including appropriate training and communication plans, capable of overcoming potential knowledge, training, and attitudinal barriers to successful implementation.

Keywords: Acceptance and Commitment Therapy (ACT); Attitudes; Breast cancer Survivors; Cognitive Behavioural Therapy (CBT); Development Research; Digital Mental Health; E-mental health; User-centred design; Internet interventions; Usability.

ABSTRACT

Bakgrund: Trots att internetbaserade interventioner riktade mot bröstcanceröverlevande har forskningsstöd finns det ett gap mellan tillgång och efterfrågan. Attityder hos bröstcanceröverlevande och klinisk praxis inom vården kan påverka tillgången och bromsa utvecklingen.

Mål: Denna avhandling syftade till att utveckla iNOV bröstcancer (iNOVBC) - en internetbaserad intervention som syfter till att minska negativa psykosociala konsekvenser i samband med bröstcancer. Brukarcentrerad metod för design samt undersökning av attityder och praxis ingick. Mer specifikt var syftet att i) att samla in data av relevans för utvecklingen av iNOVBC; ii) utveckla en prototyp för iNOVBC; och iii) utvärdera användbarhet och genomförbarhet.

Metoder: I studierna kombinerades kvantitativa och kvalitativa metoder i fyra empiriska studier. De första studierna undersökte attityder gällande internetbehandling och digitl vård i en grupp portugisiska psykologer (**Studie I och II**). I en tredje studie undersöktes potentiella variabler som var associerade med attityder (**Studie III**). I den sista studien utvecklades iNOVBC och utvärderades gällande användbarhet och genomförbarhet (**Studie IV**).

Huvudsakliga fynd: Trots att portugisiska bröstcanceröverlevande och psykologer har en begränsad kunskap och avvaktande inställning till internetbaserad behandling sågs iNOVBC som en lovande sätt att förmedla psykosocialt stöd för bröstcanceröverlevande. Mer insatser behövs för att förbättra estetik, informationsarkitektur, kognitiv belastning, interaktionsdesign samt att kunna skräddarsy iNOVBC.

Konsekvenser: En övergripande plan för överföring av iNOVBC till klinisk praxis, inklusive utbildnings- och kommunikationsinitiativ, verkar nödvändig för ett framgångsrikt genomförande.

Nyckelord: Acceptance and Commitment Therapy (ACT); Attityder; Bröstcanceröverlevande; Kognitiv beteendeterapi (KBT); Digital psykisk hälsa; Internebehandling; Användbarhet; Användarcentrerad design.

Às minhas avós
To my grandmothers

PREFACE

The mornings were always vibrant in 2013 Luanda. The sun would have predictably risen before 6.00 am, and long before that, many Angolans would have kissed their children goodbye and answered the “São Paulo-Ilhaaaaa” call to embark on a two-hour *candongueiro* drive headed to the hospital. After crossing various unnamed dirty roads, at the sound of quite insightful *Kizomba* hits, the few existing doctors, nurses, psychologists, etc. would step down the white and blue vans and put on their white coats, while mentally preparing to endure both the 80% humidity rate and a long list of patients. In its turn, recently arrived patients, with surprisingly pristine shoes, would stoically wait for two... four... six hours to have an appointment, which many times wouldn’t occur because the specialist they wanted to see was retained at another hospital or perhaps because an administrative or a nurse had long forgotten their pain while dealing with someone else’s. This reality resulted not only in generalized low rates of patient satisfaction within the Angolan healthcare system but also in serious delays in patients’ diagnosis and treatment.

Whereas this reality was opposite to the aseptic and highly controlled environment of oncology clinical trials research where I had been working in Portugal for the past years, the Angolan reality looked strangely similar to the Portuguese one in certain aspects. Patients from remote areas didn’t have access to specialized care; accessing it required long and expensive commuting, and once arrived or departed from the hospital, they often felt lost and impotent. Communicating with healthcare teams was often perceived as a challenge and many of the pressing problems affecting patients in their living environments were under-recognized and under-treated. Clinical trial participants, in particular, seemed to dread being dropped out of clinical trials, not only because it often meant that their disease had progressed, but also because the close follow-up they had experienced in the past months and the exclusive communication channels they had been offered to reach their healthcare team, would possibly cease. In both contexts, access to mental healthcare was often necessary but limited.

Considering the position I had taken at the Communication, Marketing and Sustainability office at *Clinica Sagrada Esperança* healthcare network, and armed with the will to do something to improve healthcare in my birth country, or at least at that specific institution, I started to explore the Angolan problem. As a foreigner, it seemed important to better understand the country’s peculiar reality, so I decided to conduct mystery shopping, talked to the managers, doctors, nurses, and administrative staff working at the main hospital of the group, attended various staff meetings and came up with a potential diagnosis.

Despite the fact this was the largest healthcare network in Angola, the specialized clinical staff was very limited, highly mobile (not only within the hospital, but also between the other 26 clinics that the institution had built in the other provinces of the country), and burdened by the many problems affecting Angola, like those related with lack of training, funding, and basic infrastructure including housing, road, transportation, power and energy, water and waste management. In addition, healthcare provision

was significantly hindered by deficient communication both within healthcare teams, as well as between healthcare providers and patients.

While most diagnosed problems appeared to be unsolvable and out of my hand, the private investments that had been performed in the previous years in the telecommunications infrastructure seemed to provide an opportunity to improve communication within the group. The deployment of the national fibre backbone was progressing fast, mobile networks were already more extensive and reliable than landlines, and the cost of both feature and smartphones had plummeted significantly. Many Angolans had access to a personal or shared mobile device, and telecommunication companies were providing unlimited access to services like Wikipedia and Facebook to their clients. Being a clinical psychologist with an interest in healthcare management and clinical research, I had no idea if this could be used for the benefit of both patients and professionals, but it seemed too good a vehicle not to explore.

In the cancer centre I had worked in Portugal, the main internal communication network was based on feature mobile devices and it perfectly connected the healthcare force. Both the clinical and non-clinical staff used it continuously for very different tasks (e.g., clinical case discussion, ordering supplies, making appointments, etc.) and in clinical research, we used it to manage the projects, coordinate the services necessary to conduct the clinical trials (e.g., the radiology, the laboratories, the pharmacy, the day hospital, etc.) as well as to manage the participants' cases. Mobile technology could, therefore, facilitate communication between professionals, turn healthcare services more efficient and potentially be used for healthcare provision. In addition, social networks could provide an interesting direct communication channel to patients.

Having no prior experience in this line of work, I decided on screening the literature and exploring the services telecommunication companies had to offer, and the results were exciting. The main telecommunication company in the country had to deal with similar difficulties in the past and had developed a technical solution that could potentially be adapted to our reality. Moreover, reports on mobile health by the World Health Organization and various consultancy companies underlined the strategic role digital technology could play in harnessing healthcare services worldwide.

Encouraged by these reports and supported by the institutions' administration, a pilot provider-to-provider communication network based on mobile feature phones was created to link key human resources within the main hospital of *Clinical Sagrada Esperança* and successfully implemented. After a couple of months, communication was flowing and the requests from professionals to join the network had increased significantly and a positive appraisal of this initiative had been performed. The network was then extended to many other professionals and the remaining hospitals and clinics within the group, still being used today.

At the same time, we launched the group's social networks to create a direct and easily accessible communication channel between the institution and its patients, as well as to disseminate accurate information about the group and promote health education campaigns. I am not a very socially networked individual, but the number of self-care orientation requests we started receiving through this channel was striking. I knew a huge demand for healthcare existed, and that healthcare institutions were not capable

of fulfilling such demand, but at the time I had not reflected on the role social networks could have in healthcare provision or on how digital technology could be used for self-care. The way patients were appropriating our Facebook page also reminded me of the calls and SMS I had received from clinical trial participants while in Portugal. They used it to confirm appointments, report on adverse effects, request orientations on their management and pose questions on how to navigate the hospital and the clinical trial process. No digital platform was available at the time to support patients or clinical trial participants with both administrative and clinical concerns, but what if there was one? What if patients had access to a platform that provided them evidence-based information, a channel to report treatment's adverse effects, and that provided them with orientations to deal with such effects? What if healthcare professionals could diagnose, treat and follow-up on their patients at a distance? What impact could that have on their health outcomes, adjustment to cancer and quality of life? Could this be used to bridge the treatment gaps affecting both the Angolan and Portuguese healthcare systems?

The literature did not provide an answer to these questions and answering them would require funding, a multidisciplinary team and conducting research. Since the first two requirements were unavailable, writing a PhD research proposal that could allow the exploration of the above-mentioned questions with some sort of safety net seemed a good strategy. Unexpectedly, the research proposal, which at the time was very broad and ambitious as I believe early-stage PhD proposals usually are, got approved. Personal funding for three years was secured, but what about the rest?

The first challenge was assembling a multidisciplinary team to develop a project to which most people seemed to frown upon, with no funding. After knocking on several doors, it got clear that developing a platform from scratch was not feasible within that time frame or budget, but a few doctors and nurses I knew from the past were willing to support the project by recruiting patients and reviewing some content on their free time. Not having the expertise to follow up on patients' medical concerns, the project would have to be narrowed and focus solely on the psychological support I could provide. In addition, I would have to build upon a previous existing digital structure.

The second challenge consisted in finding an open-minded multidisciplinary orientation team. It is said that fortune favours the bold, and this process was surprisingly easy. I had the luck of being assigned Linköping University as my main university and there, there was a pioneer research group within Internet Interventions, a field I knew little about, headed by Gerhard Andersson. Over the years, this group had developed iTerapi, a platform to conduct clinical trials within internet interventions, that provided me with the opportunity of conducting a project close to what I had envisioned and meeting experienced researchers within the field. The lack of orientation within Psychology and Clinical Research, as well as the lack of technology problem, were solved, so I travelled next to Norway to pitch the project to Elisabete Weiderpass, an oncologist and epidemiologist I had met in Angola. In that meeting, Elisabete striped the project in 5 minutes, identifying all its risks, suggesting me more feasible 3-year PhD project alternatives, but still accepted to supervise me if I wanted to pursue my original idea. Knowing that such a project would never be implemented in a hospital without

an economical assessment, the following step was inviting to the supervision team, Rui Santana, a health management expert from my second university Escola Nacional de Saúde Pública at NOVA University of Lisbon.

The third challenge was building a research project that could be accepted by the ethical committees and administrations of the several hospitals we wanted to submit the project to, without having a track record of oncology internet interventions in Portugal. We aimed for testing the efficacy and cost-effectiveness of iNOV Breast Cancer (iNOVBC), an internet intervention to improve psychosocial outcomes in breast cancer survivors, using a randomized controlled design. However, during the literature review process, I became aware of the research-practice gap affecting the field of internet interventions. One of the barriers that had been singled out was attitudinal and this finding resonated with my previous experience both when suggesting more disruptive digital projects in Angola, as well as when pitching the PhD project across hospitals in Portugal. I knew this could kill the project at birth and that one of the reasons why the provider-to-provider communication network had worked out well was due to the in-depth understanding we had gathered on professionals' workflows, before its deployment. So, we cautiously planned for including in the project an assessment of the attitudes and practices of iNOVBC's main stakeholders: mental health professionals and breast cancer survivors.

The fourth challenge came with the results of the first attitudinal studies. Internet interventions were largely unknown in Portugal, both professionals and survivors held a guarded stance toward it, and limitations on the conceptual comprehension and implementation of self-help techniques by clients, as well as difficulties in the adaptation of treatment protocols to the digital format were identified as salient implementation barriers. These findings suggested that not only a deeper understanding of the perspectives and practices of iNOVBC's stakeholders was necessary, but also that the internet interventions development process in itself would have to be further explored. This required taking a step back in the research process and a set of skills I had only intuitively put to practice in Angola. Fortunately, the PhD program included an internship period, and we decided to use it to further develop these skills and better understand how to design iNOVBC to match our target users' attitudes, needs, skills, practices, and contexts of use, thus, improving its odds of successful implementation. This time, the answer was 2 km away from home at Fraunhofer Portugal AICOS and with the help of its Human-centred design team, and particularly Francisco Nunes, we steered the project to put both professionals and survivors at the heart of iNOVBC development. This decision added a new chapter to iNOVBC's development process, and repurposed this thesis, creating room to discuss the important process of internet interventions development and its potential impact on these programs' implementation. It also raised many new challenges related to iNOVBC's usability and feasibility, that otherwise would have been hidden, and could have potentially resulted in its failed implementation. By discussing them in this thesis, I hope to bring transparency to the internet interventions development process and to instigate other researchers to embrace human-centred development research, capable of contributing to bridging the treatment gaps affecting healthcare systems worldwide.

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The path for this dissertation has crossed various institutions, methodologies, and ingenious people. Completing it was only possible because, throughout, I stood on the shoulders of generous Giants.

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LIST OF SCIENTIFIC PAPERS

This thesis is based on the following publications:

I. **Mendes-Santos C**, Weiderpass E, Santana R, Andersson G. Portuguese Psychologists' Attitudes Toward Internet Interventions: Exploratory Cross-Sectional Study. *JMIR Ment Health* 2020;7(4):e16817. URL: <https://mental.jmir.org/2020/4/e16817>. DOI: 10.2196/16817

II. **Mendes-Santos C**, Nunes F, Weiderpass E, Santana R, Andersson G. Mapping mental health professionals' perspectives and practices regarding the implementation of Digital Mental Health: a qualitative study (submitted).

III. **Mendes-Santos C**, Campos T, Weiderpass E, Santana R, Andersson G. Breast cancer survivors' attitudes toward Digital Mental Health: an exploratory cross-sectional study (submitted).

IV. **Mendes-Santos C**, Nunes F, Weiderpass E, Santana R, Andersson G. Development and evaluation of the usefulness, usability, and feasibility of iNOV Breast Cancer: a mixed-methods study (submitted).

Other publications that are not part of the thesis, but may be considered related work are listed below:

V. **Mendes-Santos C**, Weiderpass E, Santana R, Andersson G. A guided internet-delivered individually-tailored ACT-influenced cognitive behavioural intervention to improve psychosocial outcomes in breast cancer survivors (iNOVBC): Study protocol. *Internet Interv.* 2019 Feb 10;17:100236. DOI: 10.1016/j.invent.2019.01.004. PMID: 30949435; PMCID: PMC6430035

VI. **Mendes-Santos C**, Andersson G, Weiderpass E, Santana R. Mitigating COVID-19 Impact on the Portuguese Population Mental Health: The Opportunity That Lies in Digital Mental Health. *Frontiers in Public Health.* 2020, 8,. DOI:10.3389/fpubh.2020.553345

GLOSSARY

Cancer survivorship: A process that begins at the moment of diagnosis and continues through the balance of life regardless of the ultimate cause of death (1).

Context of use: Users, tasks, equipment (hardware, software, and materials), and the physical and social environments in which a product is used (2).

Digital Mental Health (DMH): The use of digital technologies (e.g., mobile applications, videoconference and chat software, digital platforms, artificial intelligence, etc.) to provide mental healthcare (3,4). DMH encompasses a wide range of modalities that might be particularly suitable for supporting breast cancer survivors along the survivorship trajectory namely, screening and tracking tools (5,6), teleconsultation and videoconferencing counselling/psychotherapy (5,6), and internet interventions (5,7).

Feasibility: The extent to which an intervention is deemed for full-scale research, considering its acceptability, demand, implementation, practicality, adaptation, integration, expansion and/or limited-efficacy testing (8).

Human-centred design/User-centred design (UCD): Approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors/ergonomics and usability knowledge and techniques. The terms Human-centred design and User-centred design are often used synonymously (2).

Internet interventions: Self-help interventions that are implemented as a prescriptive online program operated via secure platforms (e.g., websites, web and mobile applications, etc.) to be used by consumers seeking health and mental-health related assistance (5,9,10).

Prototype: Representation of all or part of a product or system that, although limited in some way, can be used for evaluation. A prototype may be as simple as a sketch or static mock-up or as complicated as a fully functioning interactive system with more or less complete functionality (2).

Usability: Extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use (2).

Usefulness: The degree to which a person believes that using a particular system would enhance his or her performance (11).

LIST OF ABBREVIATIONS

ACT	Acceptance and Commitment Therapy
app	Mobile application
ATTIS-BCS	Attitudes Toward Internet Interventions Survey -Breast Cancer Survivors' version
ATTIS-MHP	Attitudes Toward Internet Interventions Survey – Mental Health professionals' version
BC	Breast Cancer
BCS	Breast Cancer Survivors
BIT model	Behavioural Intervention Technology Model
CBT	Cognitive Behavioural Therapy
DMH	Digital Mental Health
EMAS	Ecological Momentary Assessments
EORTC	European Organisation for Research and Treatment of Cancer quality of life questionnaire – Breast Cancer auxiliary module
QLQBR23	
EORTC	European Organisation for Research and Treatment of Cancer quality of life questionnaire – core questionnaire
QLQC30	
GAD-7	Generalized Anxiety Disorder Screener
GDPR	General Data Protection Regulation
HRQoL	Health-Related Quality of Life
IBL	Department of Behavioural Sciences and Learning at Linköping University
iCBT	Internet-delivered Cognitive Behavioural Therapy
iNOVBC	iNOV Breast Cancer
MHP	Mental Health Professionals
NHS	National Health Service
OPP	Ordem dos Psicólogos Portugueses (T.N: Portuguese Psychologists Association)
PHQ-9	Patient Health Questionnaire
PTSD	Posttraumatic stress disorder
RCT	Randomized Controlled Trial
SMS	Short Message Service
SPSS	Statistical Package for the Social Sciences
SUS	System Usability Scale
URL	Uniform Resource Locator
WLC	Waiting-list Control conditions

TABLE OF CONTENTS

ABSTRACT	I
PREFACE	VII
ACKNOWLEDGEMENTS	XI
LIST OF SCIENTIFIC PAPERS	XV
GLOSSARY	XVII
LIST OF ABBREVIATIONS	XVIII
1. INTRODUCTION	1
1.1. MOTIVATION	1
1.2. RESEARCH APPROACH	2
1.3. CONTRIBUTIONS	3
1.4. STRUCTURE OF THE THESIS	4
2. BACKGROUND	7
2.1. BREAST CANCER SURVIVORSHIP(S)	7
2.2. PSYCHOSOCIAL PROBLEMS AFFECTING BREAST CANCER SURVIVORS	9
2.3. PSYCHOSOCIAL INTERVENTIONS TO SUPPORT BREAST CANCER SURVIVORS	11
2.3.1. <i>Cognitive Behavioural Therapies</i>	12
2.3.2. <i>Acceptance and Commitment Therapy</i>	14
2.4. THE PSYCHOSOCIAL TREATMENT GAP WITHIN ONCOLOGY	15
2.5. INTERNET INTERVENTIONS IN CANCER SETTINGS	16
2.5.1. <i>Overview</i>	16
2.5.2. <i>Evidence</i>	19
2.5.3. <i>Implementation drivers and barriers</i>	21
2.5.4. <i>Development of Internet Interventions</i>	23
3. AIMS OF THE THESIS	29
4. EMPIRICAL DEVELOPMENT OF INNOV BREAST CANCER	31
4.1. PHASE 1: SPECIFICATION OF REQUIREMENTS	35
4.1.1. <i>State-of-the-art Review</i>	35
4.1.2. <i>Study I: Portuguese Psychologists' Attitudes Toward Internet Interventions: An Exploratory Cross-Sectional Study</i>	36
4.1.3. <i>Study II: Mapping Mental Health Professionals' Perspectives and Practices Regarding the Implementation of Digital Mental Health: a Qualitative Study...</i>	41

4.1.4. <i>Study III: Breast Cancer Survivors' Attitudes Toward Digital Mental Health: a Cross-sectional Study</i>	48
4.2. PHASE 2: PROTOTYPING iNNOV BREAST CANCER.....	52
4.2.1. <i>iTerapi translation, configuration, and adaptation</i>	53
4.2.2. <i>iNNOV Breast Cancer structure and content development</i>	54
4.2.3. <i>iNNOV Breast Cancer Prototype</i>	59
4.3. PHASE 3: EVALUATION OF THE USEFULNESS, USABILITY, AND FEASIBILITY OF iNNOV BREAST CANCER.....	61
4.3.1. <i>Study IV: Development and evaluation of the usefulness, usability, and feasibility of iNNOV Breast Cancer: a mixed-methods study</i>	61
5. DISCUSSION	67
5.1. MAIN FINDINGS.....	67
5.1.1. <i>Requirements for the development of iNNOV Breast Cancer</i>	67
5.1.2. <i>Prototyping iNNOV Breast Cancer</i>	72
5.1.3. <i>Evaluation of iNNOV Breast Cancer prototype</i>	75
5.2. STRENGTHS, LIMITATIONS AND FUTURE RESEARCH.....	78
5.3. IMPLICATIONS FOR THE DESIGN AND IMPLEMENTATION OF INTERNET INTERVENTIONS IN CANCER SETTINGS.....	81
6. CONCLUSIONS	83
7. REFERENCES	85
8. APPENDICES	121
APPENDIX 1: PAPER I.....	123
APPENDIX 2: PAPER II.....	145
APPENDIX 3: PAPER III.....	191
APPENDIX 4: PAPER IV.....	223
APPENDIX 5: OVERVIEW OF THE PUBLICATIONS REVIEWED ON THE DEVELOPMENT OF INTERNET INTERVENTIONS TARGETING BREAST CANCER SURVIVORS.....	301

"I am 32, I am a mother. I have two children. I do nothing. I am unemployed because I was diagnosed with breast cancer in 2018... and since then, I've been doing the treatments. I did 8 cycles of chemotherapy. I had surgery, radical mastectomy without reconstruction. Afterwards, I did 25 sessions of radiotherapy. I am on hormonal therapy... I am going to take it for 10 years. Currently, I am waiting on my doctor to discharge me... No, not to discharge me... I'll be on follow-up for several years, but to authorize me to get a job and start having a normal life. Leave the disease behind and move on. (...) Except that, it's hard for me to move on (...) because I still live in fear. (...) What if a metastasis suddenly appears? What if I die? What will become of my two children? (...) I pray every night for God to let me see them growing... Sometimes, I am asleep, and I wake up in the middle of the night with these thoughts... and I cry... I pray. (...) The word cancer seems to chase me, it's everywhere. On the radio, on the TV... It's there when I look at my children... when I hold my husband... when I look at myself in the mirror. I avoid looking into the mirror, it's difficult... Losing my breast shook my self-esteem, it shook everything (...) it's hard to live without it, I'm a woman. I... I'm incapable of being naked in front of my husband. I feel embarrassed... I'm not able to hug him anymore. I'm afraid he feels that it's not my breast, that it isn't real. I sleep... without the prosthesis, but I always try to sleep with my back to him and when I realize I'm facing him, I turn over right away (...) I'm afraid that if he sees me, he might lose his interest in me, that he stops desiring me. (...) We still have sex but it's not the same. I'm always afraid that he touches where he's not supposed to... I do not lean against him... I avoid his touch. It's difficult and... I know that there are women that deal with this well, but I... I do not (...) Maybe after I get the reconstruction things will get easier? Maybe then..."

(Participant BCS9)

1. INTRODUCTION

Despite Breast Cancer (BC) positive prognosis (12), the survivorship trajectory is often characterized by difficulties associated with sequelae of cancer and its treatment, and late physical and psychosocial effects that might hinder Breast Cancer Survivors' (BCS) Health-Related Quality of Life (HRQoL) (13,14). Conditions such as anxiety (15), depression (16), fear of cancer recurrence (17), fatigue (18), sleeping problems (19), and sexual dysfunction (20,21) affect a "significant minority" of BCS, manifesting up to several years after treatment completion (22,23).

In the past decades, several interventions have been developed to minimize psychosocial morbidity in BCS. Cognitive Behavioural Therapy (CBT) (24,25) and Acceptance and Commitment Therapy (ACT) (26–29) have been extensively studied, presenting attested efficacy in the improvement of most psychosocial problems affecting BCS. Nevertheless, intervention delivery is often limited in survivorship settings and various physical, attitudinal, and organizational barriers contribute to a psychosocial supportive care gap in this domain (30–32).

More recently, the implementation of virtual service models of care has been identified as a promising means of bridging this gap (33–35), and research on Digital Mental Health (DMH) interventions targeting BCS increased exponentially (36). Promising results have been published mostly on the effectiveness of internet-delivered CBT (iCBT) for the improvement of depression, distress, perceived stress, self-efficacy, and HRQoL in BCS (37). Nevertheless, internet interventions haven't seen significant uptake in clinical settings and most evidence-based internet interventions still lag translation (38). In Portugal, internet interventions targeting BCS are virtually non-existent.

1.1. Motivation

Across the globe, various studies (38–40) have been conducted to understand the research-practice gap affecting internet interventions in cancer settings and to identify potential implementation drivers and barriers to the approach. In these studies (38–40), the attitudes of the distinct stakeholders in the internet interventions' ecosystem

(e.g., survivors, Mental Health Professionals (MHP), oncologists, managers, etc.) were posited to play an important role in its adoption. Yet, little is known about internet interventions adoption predictors and their interrelationship (38–40), and guidelines to develop feasible and acceptable internet interventions in cancer settings are still lacking.

The development of internet interventions is often viewed as a “black box” (41–43). Important behaviour change processes and technological architecture design decisions are seldom reported or justified (42,43), and development often neglects end-users’ perspectives (e.g., individual’s attitudes, goals, needs, and skills) (44,45) or the contexts in which internet interventions will be deployed (38). This lack of human-centeredness in the development process partly explains high attrition rates and poor engagement often reported in Randomized-Controlled Trials (RCT) (46,47), as well as the failed implementation of internet interventions targeting cancer survivors (43,48). Hence, there is a need for methodologically sound internet interventions development research within psychosocial oncology, that is centred on the perspectives and practices of the several actors playing in the cancer setting.

1.2. Research approach

The current thesis attempts to answer this call and bring the perspectives of key stakeholders – BCS and MHP – into the centre of survivorship internet interventions’ development. Its overarching aim was to develop iNOV Breast Cancer (iNOVBC) - a guided, internet-delivered, individually tailored, ACT-influenced CBT program developed to treat mild to moderate anxiety and depression in BCS, as well as improving fatigue, insomnia, sexual dysfunction and HRQoL in this group - using a User-centred design (UCD) approach (45), thereby anchoring development on the perspectives and practices of both BCS and MHP. Its specific aims were i) to gather requirements for the development of iNOVBC (i.e., assessing its target users’ attitudes, needs, skills, practices, and contexts of use, and the drivers and barriers potentially impacting iNOVBC’s implementation); ii) to prototype iNOVBC, steering development on the pre-specified requirements; and iii) to evaluate iNOVBC’s usefulness, usability, and

feasibility so that the prototyped intervention could be further refined and gain better odds of successful implementation.

To attain these aims and inform the development process we combined quantitative (i.e., surveys and task analysis usability tests) and qualitative methods (i.e., in-depth and debriefing semi-structured interviews, think-aloud lab-based usability tests and short-term field trials), and conducted four empirical studies. First, we assessed the perspectives and practices (c.f., **Study I and II**) of Portuguese MHP regarding DMH, with a focus on internet interventions. The drivers and barriers impacting internet interventions' implementation in Portugal, were also explored (c.f., **Study I and II**). Second, we characterized the attitudes of Portuguese BCS toward DMH and investigated the potential variables associated with such attitudes (c.f., **Study III**). Finally, we evaluated the usefulness, usability, and preliminary feasibility of iNOVBC, listing important development requirements to fulfil while developing internet interventions for BCS (c.f., **Study IV**).

This research approach allowed us to make important contributions to the knowledge field of internet interventions.

1.3. Contributions

The main contributions from the thesis can be summed as follows:

- Characterization of Portuguese Psychologists' and BCS' knowledge and attitudes toward DMH and, specifically internet interventions.
- Characterization of the practices of Portuguese MHP regarding the implementation of DMH.
- Characterization of BCS' use of digital technology for healthcare purposes.
- Documentation of the main drivers and barriers impacting the implementation of DMH in Portuguese cancer settings.
- Translation and adaptation of iTerapi (49) – an information management system that allows the design of tailored internet interventions for research purposes – to the Portuguese context.

- Creation of a fully functioning prototype of an internet intervention to improve psychosocial outcomes in BCS.
- Identification of key requirements for the development of internet interventions targeting BCS.
- A preliminary insight on key aspects to address for the successful translation of internet interventions to Portuguese cancer settings.

Hopefully, this work will contribute as well to inform the future development of useful, usable, and feasible internet interventions capable of bridging the psychosocial supportive care gap within oncology.

1.4. Structure of the thesis

This thesis is structured into six sections that guide the reader from the inception of iNOVBC to the evaluation of its usefulness, usability, and feasibility. Following the current Introduction, **Section 2** provides an overview of the theoretical background supporting iNOVBC as well as the various research gaps it attempts to address. Topics such as the psychosocial problems experienced by BCS (c.f., **Section 2.2.**), the evidence-based psychosocial interventions developed to improve those problems (c.f., **Section 2.3.**), the psychosocial treatment gap in cancer settings (c.f., **Section 2.4.**) and the role internet interventions might play in bridging that treatment gap (c.f., **Section 2.5.**) are addressed. **Section 2** ends with a non-systematic analysis of internet interventions development research within psychosocial oncology and addresses the current limitations affecting the field that motivated this thesis (c.f., **Section 2.5.2.**).

Subsequently, **Section 3** outlines the aims of the thesis, linking them to the development process and the empirical work that was conducted. In **Section 4**, the thesis aims are operationalized into three development phases - *Phase 1 - Specification of requirements; Phase 2 - iNOVBC prototyping; Phase 3 - Evaluation of iNOVBC's usefulness, usability, and preliminary feasibility* – and documented. Furthermore, the studies that were performed (c.f., **Study I, II, III and IV**) in each of the development phases are

summarized in that section (c.f., **Section 4**). The main findings of these studies are presented and generally discussed in **Section 5**. The strengths and limitations of this research, its clinical implications and prospective research are also a target of debate (c.f., **Section 5**). Conclusions are provided at the end of this thesis (c.f., **Section 6**).

2. BACKGROUND

Breast Cancer (BC) is the most commonly diagnosed cancer worldwide and the leading cause of cancer mortality in women, with an estimated 2.3 million new cases (11.7% of all cancers) and 685,000 deaths in 2020 (12). Although the incidence of the disease has been rising, BC prognosis has significantly improved over the past decades. This improvement is a result of advances in early diagnosis, tumour molecular characterization, development of innovative systemic treatments and improvements in cancer management (50).

Presently, most women diagnosed with early BC (Stages I-III) are primarily treated with surgery (i.e., lumpectomy or mastectomy with sentinel lymph node dissection or axillary dissection). After surgery, they may undergo local or systemic adjuvant treatment with radiotherapy, chemotherapy, hormonal therapy and immunotherapy to reduce the risk of developing local and distant recurrent disease (51). As a result, overall survival has increased significantly in high-income countries (52–54), and 5-year survival rates reach approximately 90% (50). In Portugal, approximately 7,041 women were diagnosed with BC in 2020, and 27,051 were alive within 5-years post-diagnosis, making BCS the largest group of cancer survivors in the country (55).

2.1. Breast Cancer Survivorship(s)

There is not a unanimous definition of “survivorship”, and different criteria such as time frame, the outcome of treatment, stage and process of survival can be used to define the concept (56). Nevertheless, one of the most commonly used definitions, and the one adopted in this thesis, recognizes cancer survivorship as a process that begins at the moment of diagnosis and continues through the balance of life regardless of the ultimate cause of death (1). According to Miller et al. (57,58), survivorship tends to occur within a continuum, encompassing different stages and evolving from acute survivorship, through transitional and extended survivorship, to long-term or permanent survival.

The **acute survivorship stage** is dominated by diagnostic procedures, testing and treatment, and a confrontation with the risk of mortality (57). This stage is followed by a period of “watchful waiting” where survivors experience a changeover from active treatment to the follow-up phase. This **transitional stage** is marked by a decrease in the contact with the oncology team and physical, psychosocial, and financial readjustments that are introduced in the context of survivors’ family, work environment and community (57). As months go by, survivors enter a **stage of extended survivorship**. This stage is characterized by high heterogeneity as it includes three distinct groups of survivors: 1) survivors in complete remission and with a favourable prognosis; 2) survivors in complete remission but requiring ongoing treatment; and 3) survivors who are alive and “living with cancer” but necessitate ongoing treatment for active, recurrent, or advanced disease (57). Depending on the experienced trajectory, survivors in this group may be challenged with uncertainty about the future, treatments’ adverse effects and the challenges of leading a “regular life” that is affected by the “ups and downs” of living with cancer and its treatment. Finally, long-term, or **permanent survival** comprehends four diversified sub-groups of survivors: 1) survivors who are “cancer-free and free of cancer”; 2) survivors who are “cancer-free but not free of cancer” continuing to experience significant psychological, medical, financial, or legal consequences of cancer and its treatment and; 3) survivors who later develop a second primary cancer or treatment secondary cancers, re-entering the acute-phase of survivorship (57). These trajectories reflect the idiosyncrasy in survivorship and the variable outcomes that can impact its course and BCS’ HRQoL (59).

Most literature focusing on survivorship reports high levels of functioning and HRQoL in BCS (13,14), similar to those seen in healthy age-matched controls (60). However, the survivorship trajectory is frequently characterized by difficulties associated with sequelae of cancer and its treatment, and physical and psychosocial effects that can occur immediately to several years after primary treatment ends (22), creating a common health experience that is akin to living with a chronic condition (23).

Among the potential physical late and long-term effects BCS may experience are cardiovascular toxicity (61); musculoskeletal symptoms, accelerated bone loss and

fractures (62); pain (63); lymphedema (64); premature menopause, amenorrhea and infertility (65). In addition to physical late effects, psychosocial, emotional and cognitive effects may include anxiety (15); depression (16); fear of cancer recurrence (17); posttraumatic stress disorder (PTSD) (66); cancer-related fatigue (67); sleep problems (68); cognitive impairment (69); poor body image (70) and sexual dysfunction (71). Reports on the prevalence and degree to which these difficulties affect BCS vary in the literature, but previous research has consistently reported that a “significant minority” of 7-30% of BCS presents with clinically significant levels of distress (23,72,73) across the survivorship trajectory (74–77).

2.2. Psychosocial Problems affecting Breast Cancer Survivors

Cancer-related distress has been recognized as an important psychosocial sequela of cancer and its treatment (78). Formally, it is defined as “a multifactorial unpleasant emotional experience of a psychological (i.e., cognitive, behavioural, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment” (79). Cancer-related distress encompasses a broad spectrum of psychological problems, ranging from feelings of vulnerability, sadness, and fear to problems that can become disabling, such as anxiety and depression (79).

The prevalence of these affective disorders in BCS is high, ranging from 32.2% in **depression** (16) to 41.9% in **anxiety** (15). When compared to the general female population, the prevalence of depression was found to be higher and persistent over more than 5 years after diagnosis, while the prevalence of anxiety was considered equivalent to the general female population (80). Contrasting with these reports, a recent systematic review focusing solely on long-term cancer survivors (≥ 5 years after diagnosis) (73) found that the prevalence of symptoms of anxiety and depression among this group was lower (21.0%), and did not fundamentally differ from the general population. Another systematic review (78), aiming at identifying predictors of distress in BCS, reported that a more recent transition into survivorship was found to be a predictor of distress in BCS. Other BC-related predictors identified in that research were more

advanced cancer at diagnosis, treatment with chemotherapy, longer primary treatment duration and BC recurrence. Among the clinical-related predictors, suffering from comorbid conditions, pain, fatigue, sleep disturbance, history of mental health problems, and perceived functioning limitations were identified. In what regards sociodemographic characteristics, younger age, non-Caucasian ethnicity, being unmarried, having lower social support and lower socioeconomic status increased the risk of distress (78). Another potential underlying mechanism for increased distress in survivorship is fear of cancer recurrence (81).

Fear of cancer recurrence is highly prevalent in BCS (rates ranging from 52% to 86%) (17), being the dominant unmet supportive care need in this group (82). Fear of cancer recurrence seems to decline slightly over time but persists as a common mental health problem for long-term survivors even 10 years after the cancer diagnosis (83,84). Higher levels of fear of cancer recurrence have been associated with younger age, elevated anxiety, lower HRQoL, presence and severity of physical symptoms (81), higher health costs and lower surveillance rates, potentially compromising BCS health outcomes (85). Fear of cancer recurrence, mainly in the form of intrusive thoughts, has also been identified as a significant predictor of sleep disturbance in BCS (86,87).

Experienced over 5-10 years post-treatment, **sleep disturbance** is a long-term concern in BCS (68). Its prevalence is higher in BCS than in the general population and other cancer groups, ranging from 38% - 73% (19,88). Sleep disturbance has been associated with anxiety (68), lower HRQoL, greater severity of pain, and increased vasomotor symptoms (19). In addition, depressive symptoms, non-Caucasian race, menopausal status, and fatigue have been significantly associated with higher odds for developing sleep disturbances (88).

Cancer-related fatigue has been reported as one of the most frequent, persistent, and disruptive adverse effects experienced by BCS. Prevalence rates vary from 25% to 99% depending on the type of treatment received and method of assessment (67). Although its highest prevalence is during chemotherapy, around 30% of BCS experience enduring fatigue symptoms more than five years into survivorship (18). A recent meta-analysis (89) focusing on fatigue-related risk factors identified higher disease stages,

chemotherapy and receiving the combination of surgery, radiotherapy and chemotherapy with or without hormonal therapy as risk factors of severe fatigue in this population. Conversely, having a partner, performing surgery alone or surgery plus radiotherapy decreased the risk. Other studies have found an association between fatigue and younger age (90), pre-treatment fatigue (67), pain (91), dyspnea, depression, insomnia (90), physical inactivity, high body mass index (67), and poor HRQoL (92). Furthermore, mixed results have been reported in regards to the association between fatigue and BCS' sexual functioning (93,94).

Sexual dysfunction is a major but often neglected problem that BCS may experience during survivorship. BC treatments and associated side-effects may impair different areas of sexual function via a myriad of mechanisms, such as disrupting ovarian function, body image, intimacy, and relationships (95,96). Sexual dysfunction prevalence rates reach 73.4% in BCS (71), being higher than in the general female population. Sexual dysfunction may persist for several years after treatment completion (21) and compromise BCS' HRQoL (97). BCS of younger age and treated with a combination of radiotherapy, chemotherapy and hormonal therapy, aromatase inhibitors, and bilateral mastectomy, are at higher risk of developing sexual dysfunction (21,70,97,98). Likewise, BCS experiencing vasomotor symptoms, lymphedema, weight gain, pain, depression, and psychological distress are more prone to developing sexual dysfunction (21,70,97,98). Women that present with negative or body image disturbance, low perceived sexual attractiveness, poorer marital or relationship distress, also present greater odds of developing sexual dysfunction (21,70,97,98).

The psychosocial problems described above rarely occur in isolation, rather forming symptom clusters (99) that hinder BCS' wellbeing and HRQoL (13,14). Thus, comprehensively intervening in such conditions is highly relevant.

2.3. Psychosocial Interventions to Support Breast Cancer Survivors

In the past decades, several interventions have been developed to minimize the psychosocial problems affecting BCS and improve their HRQoL (100). Counselling, education, and specific forms of psychotherapy in their different formats (e.g., individual,

group, couples, and family therapy) and orientation (e.g., Cognitive Behavioural, Supportive-expressive, Existential and Psychodynamic) have been developed to intervene in the various conditions affecting BCS (101).

Overall, the literature focusing on the efficacy of the various forms of psychotherapeutic interventions in oncology suggests these interventions are efficacious in reducing psychiatric morbidity (24,102–105), and somatic symptoms (103,106) in BCS, as well as improving their HRQoL (100,102,104,107). The interventions with the most empirical support for treating the psychosocial problems affecting BCS include supportive-expressive group therapy (106,108), psychoeducational treatments (106–108), mindfulness-based interventions (104,109), and Cognitive-Behavioural Therapies (CBT) (24,25).

2.3.1. Cognitive Behavioural Therapies

CBT is often used as an umbrella term for designating interventions that are based on learning and/or cognitive theories (110). These interventions share the underlying assumption that psychological problems and mental disorders are caused and maintained by faulty patterns of thinking and behaviour (110–112). CBT includes empirically-supported approaches and integrates various concepts and methods (e.g., cognitive restructuring, behavioural activation, exposure, problem-solving, skills training, etc.), that have been developed along with the *first* (i.e., behaviour therapy) and *second* (i.e., cognitive therapy) historical waves of CBT (113). In general, CBT methods focus on changing patterns of unhelpful cognitions, reducing unwanted emotions, and modifying undesirable behaviours (110–112). This is mostly achieved through rational disputation techniques followed by the application of behavioural experiments that ought to test out the validity of clients' assumptions and predictions (114). Although CBT incorporates behavioural strategies, the primary theoretical mechanism of action tends to be cognitive change, which via cascading and reciprocal effects, leads to changes in both mood and behaviour (114) and, ultimately, symptom reduction and improved functioning and well-being (110).

The CBT approach has yielded large effect sizes in the treatment of various conditions, such as anxiety disorders, depression, and insomnia both in the general and distinct clinical populations (110). In what regards BC, CBT has been identified as the most effective intervention to treat anxiety and depression, often showing significant small to moderate between-group treatment effects in patients suffering from these conditions (24,108). Its effect in improving BCS' HRQoL has also been widely attested (100,102).

Despite gathered evidence for the efficacy of CBT, the model has not been exempted from criticism. First, CBT has been suggested to be relatively mechanistic, failing to address the concerns of the holistic individual (115). Second, CBT effect sizes in some conditions are modest, suggesting limitations in its application or weakness in the underlying model, leaving room for improvement (116,117). Third, component analysis research (118) has mostly failed to attest that cognitive interventions are differentially effective in reducing distress when compared to behavioural strategies. Finally, support for the hypothesized cognitive mediators of change in CBT is limited (115,119,120). While these findings might be explained by flaws in the design of dismantling studies, where the act of separating treatment components could have neutralized what makes them effective i.e., the interaction between cognitive and behavioural techniques (118), altogether the appointed limitations have cast doubt upon the importance of targeting direct cognitive change to obtain clinical improvement (121). In this context, a *third wave* of treatments including Acceptance and Commitment Therapy (ACT), Dialectical Behaviour Therapy, Mindfulness-based Cognitive Therapy, and Meta-cognitive Therapy, has been unfolding in the last two decades (122). These intervention frameworks place less emphasis on changing the form or content of psychological experiences (e.g., thoughts, sensations, emotions, etc.) and more emphasis on changing the relationship that human beings establish with these inner experiences, as well as their function (123). This is mainly accomplished by integrating the change-based methods of the *first two waves of CBT* with concepts such as mindfulness, acceptance, dialectics, and values (123). ACT, due to its model of healthy adaptation to difficult circumstances and transdiagnostic approach, has been appointed as

particularly useful in addressing the high levels of psychological and medical comorbidities that manifest in cancer populations (26,124,125).

2.3.2. Acceptance and Commitment Therapy

ACT is based on the Relational Frame Theory (126) and posits that psychological inflexibility – the rigid dominance of cognitive psychological patterns, over chosen values and contingencies, in guiding action (127) – is a root cause of human suffering and maladaptive functioning (128). In other words, psychopathology may result from a pattern in which behaviour is excessively controlled by inflexible verbal networks - one's thoughts, feelings and other internal experiences - or the avoidance of such internal experiences, at the expense of more effective and meaningful actions (129).

ACT's main goal is, therefore, to contradict the rigid relational pattern that individuals establish with their internal experiences and increase psychological flexibility (27). It does not specifically target symptom reduction (e.g., anxiety, negative thoughts) rather encouraging the engagement in values-based actions regardless of the presence or absence of symptoms (130).

In this context, psychological flexibility is perceived as the ability to be mindful of experiences in the present moment, in an accepting and non-judgmental manner, while behaving consistently with one's values, even when one's thoughts and feelings oppose taking valued action (129). Psychological flexibility is produced through processes of acceptance, mindfulness, commitment, and behaviour change (27). Specifically, the core therapeutic processes of ACT are (128,131): acceptance (i.e., active and aware embrace of both wanted and unwanted experiences such as difficult thoughts, memories, or emotions), contact with the present moment (i.e., consciously connecting with and engaging with one's experiences), self as context (i.e., maintaining perspective about oneself within one's experiences), cognitive defusion (i.e., being able to detach from unwanted experiences), committed action (i.e., engaging in actions that move toward important values of life), and values (i.e., staying connected to personal values or areas of life that are important to the individual). Each of these areas is

conceptualized as a positive psychological skill to be developed, and not merely as a method of avoiding psychopathology (128).

In the past years, various systematic reviews (26,131,132) have been conducted to assess ACT's effectiveness across a range of psychological and physiological conditions and populations. These reviews have provided support for small to medium positive effects of ACT in improving depression, anxiety, substance abuse, and chronic pain (26,131,132). ACT was also found to be generally superior to inactive control conditions (e.g., waitlist, placebo), treatment as usual, and most active conditions, except for CBT (132). Concerning cancer survivors, recent systematic reviews, and meta-analysis (26–29) found that ACT is effective in significantly reducing psychological distress, anxiety, and depression, and in improving psychological flexibility, HRQoL and sense of hope in this group, generally yielding immediate and long-term medium to large between-group effects (26–29). Equivalent findings have been reported in the literature focusing specifically on BCS (28). Nevertheless, further research is necessary to establish the effectiveness of ACT in improving physiological symptoms, fear of cancer recurrence and psychological flexibility in this cancer group (28).

Despite the attested efficacy of the abovementioned intervention frameworks in treating the various psychosocial problems affecting BCS, such conditions continue to be under-recognized and under-treated in most cancer settings, and a psychosocial treatment gap exists (30).

2.4. The Psychosocial Treatment Gap within Oncology

The **diagnosis and treatment gap** for mental health problems among cancer patients is frequent and universal (30,133,134), affecting survivors at transitional and extended stages to a greater extent (135). This gap has different causes, including related to the **attitudes** of patients and professionals (e.g., stigmatization, mental health illiteracy, etc.), **training** aspects (e.g., diagnosis and referrals depend often on cancer specialists who are not trained in mental health), and **the healthcare system** (e.g., out of pocket costs, distance from mental health services, shortage of health professionals,

lack of information about services, and survivorship models of supportive care provision not fulfilling survivors' needs, etc.) (30–32).

The dominant model of psychosocial support provision within oncology draws on in-person psychosocial interventions, where BCS are scheduled to meet a health care professional (HCP) face-to-face at pre-specified intervals. This model is highly susceptible to human resources limited capacity, competing priorities and constrained health and social care budgets; all of which may hinder the provision of patient-centred supportive care and the scaling-up and dissemination of treatment programs (30,31,33). These systemic problems suggest that current models of psychosocial supportive care provision are no longer adequate to address the chronic and complex survivorship needs of BCS and a redesign of such services is necessary to reach those in need while controlling the costs of healthcare provision without diminishing the quality of service (33,136). As such, **virtual and hybrid service models of care** have recently gained momentum and the exploitation of technological innovation to deliver integrated, tailored, and cost-effective survivorship care to BCS is increasingly being perceived as a plausible means of achieving such results (33–35).

In this regard, **Digital Mental Health (DMH)** - the use of digital technologies (e.g., mobile applications (app), videoconference and chat software, digital platforms, artificial intelligence, etc.) to provide mental healthcare (3,4) - and particularly internet interventions, may provide remarkable opportunities in overcoming the aforementioned constraints, as presenting an effective strategy (36,137–139) to fulfil the unmet support needs of BCS and help to bridge the mental healthcare gap within oncology (34).

2.5. Internet Interventions in Cancer Settings

2.5.1. Overview

Internet interventions - also known as a web-based treatment, computerized CBT, e-therapy, minimal contact interventions, internet-delivered interventions, iCBT, etc. (140) – consist of self-help interventions that are implemented as a prescriptive online program operated via digital platforms (e.g., web and mobile apps, etc.) to be used by

consumers seeking health and mental-health related assistance (5,9,10). These intervention programs usually aim at creating positive change and/or improving knowledge, awareness, and understanding via the provision of sound health-related materials (5,141). Internet interventions are often based on psychotherapy models adopting a schedule and length that is pre-determined and similar to face-to-face treatment protocols, ranging from five to 15 weeks (141).

During treatment, patients usually log in to a secure web or mobile app, where the online environment is similar to online banking or an e-learning platform (141). Once logged in, patients have access to text, audio and/or video content, and individualized instructions that may be read/streamed online or downloaded/printed. The online materials are organized into a series of treatment modules (9) – the equivalent of a face-to-face psychotherapy “session” (142).

Treatment typically starts with psychoeducation content, continues with modules that are based on treatment manuals for specific disorders (e.g., anxiety, depression, etc.) and ends with a relapse/prevention module (141). It can include fixed modules and follow a **linear structure** or comprise optional modules and be **individually tailored**. In the latter case, treatment is organized according to a case formulation, client preferences and/or characteristics and a transdiagnostic perspective is frequently adopted (141), particularly in the cancer setting (143). Tailored interventions are mostly relevant when addressing comorbidity or overlapping conditions since the patient has the power to determine which problems or symptoms are more urgent to deal with (142). On the course of treatment, homework assignments are prescribed (e.g., relaxation techniques, exposure exercises, etc.). Patients are expected to complete those assignments before the next treatment module is made available and the use of mobile technology enables real-time submission of homework assignments (141). Furthermore, during treatment, patients are asked to complete computer-administered questionnaires adequate to their condition and appropriate to monitor their progress, safety, and outcomes (141). The addition of other interactive features such as discussion forums, messaging services (e.g., chat), videoconference, quizzes, Ecological Momentary Assessments (EMAS) (144) and SMS reminders is also a possibility (9,141).

Regarding human support, these programs may include a **guided or unguided structure**, involving or not therapist/clinician contact, respectively. Guided interventions can be further divided into those including **synchronous interaction** (e.g., real-time contact via the telephone, video, or messaging services) or **asynchronous interaction** (e.g., encrypted e-mail communications) with patients, during which therapists answer to patients' questions, clarify how to implement treatment techniques, assess homework assignments and treatment outcomes, and encourage patients' continued work (145). More recently, programs adopting a **blended-care approach**, thereby combining in-person or videoconference therapist-led sessions with self-care online sessions, have emerged (146,147).

Internet interventions hold several advantages when compared to face-to-face therapies or when blended with traditional delivery of care, that are particularly interesting to the cancer survivorship setting (9,141,148,149). The most well-known advantages of internet interventions include their **low-threshold accessibility and convenience**. Internet interventions easily reach a wide range of patients, including those living in rural or remote areas and those whose symptoms, limited mobility or negative associations to the healthcare environment constrain their access to healthcare (9,141,148,149). In addition, internet interventions are characterized by high **flexibility and self-pace use** (141), allowing patients to access asynchronous care at their convenience, independently of the time, location, or availability of healthcare professionals. This aspect has also been associated with **patients' empowerment** (150), as it may promote their self-efficacy. Furthermore, these programs are generally standardized, adopting a scripted nature that certifies **treatment fidelity** (e.g., content and structure) (9) but are also **highly adaptable** to patients' needs, limitations, and preferences (142). Programs may be developed to comply with a high level of **anonymity and privacy**, to overcome the potential stigmatizing effects of accessing psychosocial support, especially for those suffering from mental health concerns (9). In addition, **treatment compliance and progress** can be easily and **accurately monitored** by integrating online questionnaires, adaptive testing, automatic scoring, and visualization tools into built programs (149). Finally, internet interventions may hold a **high dissemination**

potential (149). The cost of developing internet interventions has plummeted in the past decade and internet interventions can adopt a systemic organization, being developed and/or managed by specialist centres and deployed in several clinics and health centres within a community, preventing duplication of resources and facilitating training and supervision (e.g., (151)).

The many potential advantages of internet interventions have driven the interest of clinicians and researchers within the field and research on internet interventions has been growing exponentially (152).

2.5.2. Evidence

Over the last years, numerous RCTs, systematic reviews and meta-analyses have been conducted and **attested the efficacy and effectiveness** of internet interventions across different populations (e.g., children, adults, and older adults) (153), geographies (e.g., high-income, and middle-income countries) (137), care settings (e.g., clinical research and routine care settings) (154) and mental health conditions (139). Internet interventions, particularly iCBT, proved to be more effective than treatment as usual and as effective as face-to-face therapies for treating conditions such as panic disorder, social anxiety disorder, generalized anxiety disorder, PTSD and major depression, generally yielding moderate to large between-group effects (139).

The impact of human support on internet interventions' effectiveness has also been studied. The **beneficial impact of guidance** in interventions delivery has been reported in several studies (155–158). These studies suggest guided interventions are superior to unguided interventions (155–158) and that mean effects estimates become increasingly higher with increased support (158). Guided interventions have also been associated with lower attrition rates and higher engagement (153). Nevertheless, there are some exceptions, and previous research focusing on interventions providing support as needed (159) has shown comparable improvement in symptoms (e.g., depression, anxiety, and psychological distress), satisfaction, and engagement between participants receiving optional weekly therapist support and participants receiving standard weekly therapist support. Furthermore, there is still a lack of research comparing the

outcomes of blended treatments with classic face-to-face or nonblended treatments (146).

In regards to cancer survivors, the report of internet interventions research has mostly increased from 2015 onwards (34). Since then, various systematic reviews including mixed cancer populations, with a preponderance to BC, have been published (160). In general, internet interventions have been considered efficacious in improving anxiety (37,160–162) and depressive symptoms (37,160–163), as well as distress (37,164,165) and HRQoL (37,166–168) in cancer populations, yielding small to moderate between-group effect sizes. Internet interventions have also been appointed as promising for improving psycho-sexual problems in cancer survivors (169) and symptom management (160,165,170), including fatigue (171). Nevertheless, the heterogeneity of reviewed studies is emphasised across reviews and meta-analyses, indicating that these findings should be interpreted with caution and further research, based on well-designed RCTs, is necessary.

Considering women previously diagnosed with BC, the impact of internet interventions on the improvement of psychosocial outcomes is still unclear (34). Previous reviews (34,37,167) suggest that internet interventions are feasible and acceptable to BCS with most studies reporting improvements in their intended outcomes. Internet interventions were found to be superior to usual care, being associated with **improved HRQoL, higher self-efficacy and less depression, distress and perceived stress in BCS** (37). Mixed results have been reported concerning the impact of internet interventions on BCS' anxiety symptoms (37,167). More recently, various RCT studies have been conducted, adding mostly to the evidence of iCBT in the improvement of depression (172), anxiety (173), distress (174), fear of cancer recurrence (175), sleep quality (176,177), sexual functioning (178) and HRQoL (179,180) in BCS. To the best of our knowledge, no study assessed yet the efficacy of ACT-based internet interventions in improving psychosocial outcomes in BCS.

Internet interventions have also been **considered potentially cost-effective** when compared to group treatment, attention control groups or Waiting-list Control conditions (WLC) (181–184). A recent report (185) suggests internet interventions may

contribute to sustainable cancer survivorship care in a cost-effective manner. However, additional economic evaluations are necessary to determine the cost-effectiveness of these interventions, when compared to the most cost-effective treatments currently available (182).

Despite the potential usefulness and cost-effectiveness of internet interventions in the cancer domain, research in this area is scant (37) and **implementation in clinical settings is limited** (38). In Portugal, at the moment of this thesis redaction, only three additional studies targeting cancer populations appeared to be ongoing since 2020/21 (186–188) and none had been translated yet into clinical practice. This fact may be justified by a predominance of internet interventions' implementation barriers over implementation drivers in clinical settings, including the attitudes of MHP and survivors discouraging adoption (i.e., acceptance, uptake, and use) of such an approach.

2.5.3. Implementation drivers and barriers

Various studies have been performed to identify the potential drivers and barriers impacting internet interventions' adoption, as well as understanding MHP's and cancer survivors' attitudes toward these interventions (38–40). In general, previous research suggests that MHP's and cancer survivors' **attitudes range from neutral to generally positive** (39,40,189,190) and that various factors impact adoption.

Concerning MHP, **factors often identified as expediting adoption** concern internet interventions' low-threshold accessibility and convenience (191), professionals' knowledge and training in the field (192,193), and the possibility of introducing new treatment techniques in interventions (e.g., virtual reality, biofeedback, etc.) (194). In addition, the prospect of promoting patients' self-management skills (195), and MHP's positive attitudes toward the approach (40), including higher perceptions of usefulness and ease of use (195), have also been identified as potentially facilitating internet interventions' adoption.

Contrariwise, **factors frequently appointed as preventing adoption** relate to the absence of ethical, legal, and regulatory frameworks for providing online mental healthcare (196–198), professionals' lack of knowledge and training in the field

(192,193), (e.g., inadequate skills to manage crises online (197), training needs in online communication skills (199), etc.), and potential confidentiality and security breaches associated to digital systems (200). Furthermore, difficulties associated with the development and translation of behaviour change interventions to the digital format (194,201), lack of tailoring (202), usability issues (194), and scepticism about the feasibility of implementing internet interventions within existing care services (203,204) appear to hinder adoption. MHP's negative attitudes toward internet interventions (40) have also been identified as a factor inhibiting adoption. A greater acceptance of blended-care approaches has been reported across studies (194,205).

Concerning cancer survivors, **aspects previously identified as positively influencing adoption** refer to individuals' motivational readiness to use and engage with internet interventions (206,207), a perception of having unmet care needs (190,208–210), and viewing internet interventions as a means of having increased access to supportive care or an alternative to traditional care. This has been observed particularly in survivors presenting with sensitive symptoms (209,211) and valuing anonymity (150). Interventions' ease of use (206,207,212), perceiving the content of interventions as relevant (209), and the possibility of self-pace use (206,207,212) were also reported as empowering (150) and facilitating adoption. Likewise, the timely, tailored (39), and flexible (150) delivery of interventions have been identified as important adoption drivers in previous research.

Opposingly, experiencing comorbid physical symptoms, and cancer recurrence (206,207,211) have been reported as **aspects hindering adoption in cancer survivors**. Similarly, internet interventions' limited usefulness (e.g., irrelevant content), perceptions that these interventions do not fit into daily routines (207,209,210), lack of internet skills (213), and usability issues (e.g., navigation difficulties) have been documented as barriers deterring implementation in survivorship settings (39). The intention to leave the period of being ill behind has also been appointed as a reason for not using internet interventions in previous research (213). Mixed findings have been reported regarding the use of in-person support (39).

Although these findings provide valuable insight on the possible factors influencing the adoption of internet interventions by both MHP and cancer survivors, **adoption predictors and their interrelationship are largely unknown** (38–40). In Portugal, only one additional study addressed the topic of MHP’s attitudes toward electronic psychological interventions (214), and none focused on BCS’ attitudes toward this treatment approach or the drivers and barriers impacting internet interventions’ implementation in the country. This reality underlines the importance of conducting additional research on internet interventions’ implementation, as perceived by important ecosystem stakeholders (e.g., MHP, BCS, Healthcare organizations). It also calls attention to the importance of understanding how internet interventions targeting BCS need to be developed to ensure they are not only effective but also widely accepted and easily implemented.

Nevertheless, internet interventions’ development has been the focus of few reports (42) and more often than not, **intervention development can be viewed as a “black box”** of complex intervention trial design (41–43). Published intervention descriptions often fail to provide detailed information about how its content was created, how design decisions were performed or how interventions are hypothesised to produce a change in its outcomes of interest. This absence of evidence-based reasoning behind development (43) adds to the research-practice gap in the cancer survivorship internet interventions domain, wherein evidenced-based treatments struggle to be adopted in routine care (45). Thus, additional research focusing on the internet interventions development process, the methods it may include, and its theoretical and empirical underpinning is warranted.

2.5.4. Development of Internet Interventions

Being at the intersection of medical, psychological, social, computer and design sciences, the development of internet interventions has been either entirely driven by developers intuition, ignoring important psychological, design or engineering principles (215,216), or by models that are predominant in each of these fields (e.g., the Theory of Planned Behaviour (217), the Social Cognitive Theory (218), etc.). Whereas

some of these models are useful to describe facets of developed internet interventions (e.g., the selected behavioural change strategies), they often fail to provide a comprehensive understanding of how behaviour change is better achieved via digital technology, not addressing the interdisciplinary challenges that developing internet interventions entail (219).

To address this problem, a few authors have proposed **design models to inform digital interventions development** namely, the Behaviour Change Model for Internet Interventions by Ritterband et al. (220), the Behavioural Model for Persuasive Design by Fogg (221), the Persuasive System Design model by Oinas-Kukkonen and Harjumaa (222), and the Behavioural Intervention Technology Model (BIT model) by Mohr et al. (219). Of these, Mohr et al.'s (219) contribution is of particular interest, since it provides a hybrid framework that combines behavioural principles with technological features, supporting the translation of treatment aims into an implementable treatment model that defines both the conceptual (i.e., clinical and usage aims and how these aims will be achieved via change behaviour strategies and interventions' interactive components) and the technological architecture (i.e., specific attributes of the system components with which users interacts with) of internet interventions. However, the BIT model fails to consider design processes that integrate information on the needs, desires, and limitations of users into developing interventions (219), which may be critical to ensure these interventions are feasible and widely adopted (223). This **lack of human-centeredness in the development process** partly explains high attrition rates and poor engagement often reported in RCTs (46,47), as well as the failed implementation of internet interventions targeting cancer survivors (43,48).

To fulfil this gap, development teams have increasingly developed or adopted frameworks that focus on understanding and accommodating the perspectives of the people who will ultimately use internet interventions into developing systems such as, the Person-based approach (224), User-centred design (UCD) (45), and Participatory Design (44). These approaches differ in what concerns the role that is ascribed to end-users during development. In the Person-based approach and UCD, end-users are mostly informants in the process. The design work is anchored on their elicited

perspectives (e.g., via interviews), but development is done on their behalf by development teams. In participatory design, end-users work alongside the development team (e.g., co-design workshop), integrating it, and often interventions' content, structure, and features are co-created (225). Despite underlying differences, these approaches share the understanding that incorporating end-users' perspectives into developed interventions is capital.

A previous review (42) focusing on the development of digital interventions in the cancer setting has identified a similar trend within the internet interventions' development community. The studies included in that review underlined the **importance of stakeholder engagement** (e.g., cancer patients, healthcare providers, etc.) during the development process. This involvement was considered key to ensure the unique needs of interventions' end-users were addressed, and developed interventions fulfilled their expectations. To this end, various studies conducted **formative research**, using both qualitative and quantitative methods along the development process (42). In addition, iterative **pre- and pilot-testing activities** were deemed important before RCTs' implementation, so that the development process could be streamlined, and developed interventions could be human-centred and, therefore adopted (42). **Grounding development on established theoretical and development frameworks** was also advised (42).

In what concerns BCS, and according to our best knowledge, no such review has been conducted. Nevertheless, the non-systematic analysis of the literature that we have performed on the development of internet interventions' targeting BCS (c.f. Appendix 5), builds on the findings of that previous review (42). A consensus in terms of the practices to be adopted during internet interventions' development seems to be unfolding.

Studies documenting the development of internet interventions for BCS (c.f. Appendix 5) have largely increased since 2017, although a few older reports can be found (226–230). These studies have mostly described interventions aimed at improving HRQoL and supporting self-care and symptoms' management (38,226,231–234), promoting coping and adjustment to BC (227,228), managing distress, anxiety, depression and

fear of cancer recurrence (175,235–238), and promoting empowerment in this population (229). In general, development was grounded in a combination between psychosocial theoretical frameworks (e.g., most often CBT (38,232,234–236,238,239)) and UCD (226,232,234,238,239), the person-based approach (224,235,237), or participatory design (233,236). Few interventions (175,237) anchored development on design models such as the ones proposed by Ritterband et al. (220) or Mohr et al. (219). Furthermore, the development process was typically **iterative and conducted by a multidisciplinary team** (227,231,233,235,236,238) or advised by experts with different backgrounds, including BCS (226,228,229,240).

The implemented methodology usually combined mixed methods, encompassing literature reviews, in-depth interviews (38,226,228,229,231,233,234,236–238,240), focus groups (38,226,227,237), surveys (228,231,233,240), co-design sessions (233,236), usability tests (175,226,227,229,232–235,237,238,240), heuristic assessments (226), and field (239) or feasibility trials (233). Moreover, study samples generally involved women with a history of BC, and healthcare professionals (38,227,231,233,234,238), and/or charity staff and volunteers (38). Participants were often involved in different activities along the development process and results of the various rounds of testing often translated into significant refinements in prototyped interventions (i.e., content, and technological features). Finally, most publications reported that the involvement of a multidisciplinary team and representative end-users in the development process was instrumental to obtain useful, usable, and acceptable internet interventions (227,232,234,236,237).

The methods described above provide direction on how to develop human-centred internet interventions for BCS. However, to date, only five out of the 15 reviewed studies appear to have been tested using an RCT design (172,175,179,241,242), and none seems to have been translated yet into clinical practice. Only two interventions (236,241), in which development started approximately 10 years ago, look like being on the verge of it.

While the reasons for this “Death Valley” within evidence-based internet interventions in oncology are certainly multifactorial and were already partially documented above,

internet interventions development studies within psychosocial oncology are scarce, and little is known about the development process, the difficulties research teams face during development, or how to overcome such difficulties to expedite the development process. The current thesis intends to contribute to bridging this knowledge gap by studying in-depth the development process of an internet intervention targeting BCS.

3. AIMS OF THE THESIS

The overarching aim of this thesis was to develop iNOV Breast Cancer (iNOVBC) – a guided, internet-delivered, individually tailored, ACT-influenced CBT program developed to treat mild to moderate anxiety and depression in BCS, as well as improving fatigue, insomnia, sexual dysfunction and HRQoL in this group – using a UCD approach (45), thereby anchoring development on the perspectives and practices of its primary and secondary end-users, i.e., BCS and MHP.

Within the scope of this, three specific aims were defined: i) To gather requirements for the development of iNOVBC; ii) To prototype iNOVBC; and iii) To evaluate iNOVBC's usefulness, usability, and preliminary feasibility. These specific aims structured iNOVBC development into three correspondent development phases, during which four empirical studies were conducted:

- **STUDY I** reported on Psychologists' knowledge, training, use and attitudes toward internet interventions, as well as on potential variables associated with previous use and attitudes toward these interventions. This study also identified the drivers and barriers impacting the implementation of internet interventions in Portugal, as perceived by Psychologists (243).
- **STUDY II** characterized in-depth the perspectives and practices of MHP regarding the implementation of DMH, including internet interventions, as well as the factors influencing such perspectives and practices (submitted).
- **STUDY III** explored BCS' attitudes toward DMH and investigated potential variables associated with such attitudes (submitted).
- **STUDY IV** reported on iNOVBC's development and the perceived usefulness, usability, and feasibility of a prototype version of this intervention among BCS and MHP (submitted).

4. EMPIRICAL DEVELOPMENT of iNOV Breast Cancer

The development of iNOVBC followed a UCD approach (45), combining quantitative and qualitative research methods. Our vision was to develop a generalisable but nuanced supportive care program, that could provide psychosocial support to BCS in various contexts of use but that reflected an in-depth understanding of BCS' experiences and MHP practices. We believed that if we could materialize this concept, iNOVBC would be highly accepted by its primary and secondary end-users and be successfully implemented, helping to bridge the mental healthcare gap within cancer settings.

To comply with this vision, we organized the development process into three interdependent phases that operationalized the specific aims of this thesis: Phase 1 - Specification of requirements; Phase 2 - iNOVBC prototyping; Phase 3 – Evaluation of iNOVBC's usefulness, usability, and preliminary feasibility.

- **Phase 1:** focused on specifying the requirements for the development of the program and included state-of-the-art reviews, survey studies (c.f., **Study I**, and **Study III**), and interview studies (c.f., **Study II**, and **Study IV**).
- **Phase 2:** was mainly dedicated to prototyping iNOVBC (i.e., Prototype version 1.0) and included activities related to iTerapi (49) translation, configuration and adaptation. iNOVBC's structure and content were also created during this phase. **Study I**, and **Study III** informed these activities.
- **Phase 3:** evaluated iNOVBC's usefulness, usability, and preliminary feasibility via in-depth semi-structured interviews, usability tests, short-term field trials, and surveys (c.f., **Study IV**). Insights gathered in **Study IV** were afterwards translated into new requirement specifications to be applied to a future refined prototype, i.e., Prototype Version 2.0.

An overview of iNOVBC's development process is depicted in Figure 1. To provide clarity, iNOVBC's development is portrayed as unfolding linearly. However, iNOVBC's development was necessarily recursive and iterative, with research and development activities pertaining to its different development phases often co-occurring and informing one another.

Figure 1. iNOVBC development process

Table 1 displays an overview of the performed studies and their respective aims, design, methods, and study samples.

Table 1: Overview of study aims, design and methods (Studies I-IV)

	Study I	Study II	Study III	Study IV
Aims	To explore Portuguese psychologists' knowledge, training, use and attitudes toward internet interventions and the factors associated with previous use and attitudes toward these interventions.	Characterizing in-depth the perspectives and practices of MHP regarding the implementation of DMH and exploring the factors influencing such perspectives and practices.	To explore BCS' attitudes toward DMH and to investigate variables associated with these attitudes.	Evaluate iNNO-VBC's usefulness, usability, and feasibility among its target users.
Study design	A quantitative, cross-sectional, descriptive, and correlational study	A qualitative in-depth interview study	A quantitative, cross-sectional, descriptive, and correlational study	Quantitative and qualitative methods, using in-depth interviews, surveys, lab-based usability tests and field trials
Method	Questionnaire	In-person semi-structured interviews	Questionnaires	In-person semi-structured interviews, usability tests, surveys, and in-loco field trials
Participants	1077 psychologists registered at OPP	13 mental health professionals (i.e., two psychiatrists and 11 clinical and health psychologists)	336 BCS attending the Day Hospitals or Breast Clinics of five hospitals in Porto (Portugal)	24 participants (i.e., 11 BCS and 13 MHP)
Setting	A professional sample recruited online via OPP	Purposeful professional sample	Clinical sample of BCS	Purposeful professional and

					clinical/commu- nity sample of BCS
Measures	ATTIS-MHP	Semi-structured interview script	GAD-7, PHQ-9, EORTC QLQC30, EORTC QLQBR23, ATTIS-BCS	Semi-structured interview scripts, usability tests, SUS, modules' usefulness assess- ment survey	
Cronbach's α co- efficient	ATTIS-MHP=.91	N/A	GAD-7=.93; PHQ- 9=.87; EORTC QLQC30=.90; EORTC QLQBR23=.82; ATTIS-BCS=.93	SUS MHP=.90; SUS BCS=.87	
Outcomes	DMH use, DMH self-reported knowledge and attitudes toward DMH	Participant's per- spectives and practices	Anxiety; depres- sion; HRQoL; DMH use, DMH self-re- ported knowledge; and attitudes to- ward DMH	Participants' per- spectives and practices; perfor- mance metrics and acceptance scores	
Data analysis	Descriptive statis- tics, χ^2 test	Analysis used Braun and Clarke's thematic analysis method (244).	Descriptive statis- tics, Spearman rank correlations, χ^2 test, multiple re- gression analyses (method: enter).	Descriptive statis- tics, qualitative analysis using Braun and Clarke's thematic analysis method (244).	

Abbreviations: OPP - Ordem dos Psicólogos Portugueses (T.N: Portuguese Psychologists Association); DMH - Digital Mental Health; ATTIS-MHP - Attitudes Toward Internet Interventions Survey – Mental Health professionals' version; HRQoL – Health-Related Quality of Life; GAD-7 - Generalized Anxiety Disorder Screener; PHQ-9 - Patient Health Questionnaire; EORTC QLQC30 - EORTC quality of life questionnaire – core questionnaire; QLQBR23 - EORTC quality of life questionnaire – Breast Cancer auxiliary module; ATTIS-BCS - Attitudes Toward Internet Interventions Survey -Breast Cancer patients' version.

The conducted research activities were approved by the ethics review boards of Instituto Português de Oncologia do Porto Francisco Gentil, EPE, Unidade Local de Saúde de Matosinhos, EPE., Centro Hospitalar Universitário do Porto, Centro Hospitalar S. João, Hospital CUF Porto, and Ordem dos Psicólogos Portugueses (OPP; T.N: Portuguese Psychologists Association), as well as the Portuguese Data Protection

Committee (approval number: 10727/2017). Written Informed Consent was obtained from all participants before the onset of study procedures.

iNOOVBC's development and the empirical findings supporting the development process are further described below.

4.1. Phase 1: Specification of Requirements

The first phase of iNOOVBC's development aimed at explicitly identifying iNOOVBC's target users and acquiring a nuanced understanding of their attitudes, goals, needs, skills, and contexts, so that key development requirements could be categorized and steer development. To accomplish this, a state-of-the-art review, two survey studies (c.f., **Study I**, and **Study III**), and two interview studies (c.f., **Study II** and **Study IV**) were performed.

4.1.1. State-of-the-art Review

An initial state-of-the-art review was conducted to attain a comprehensive understanding of the BC survivorship trajectory; the most common psychosocial problematics affecting BCS; and the type and reach of supportive care provided to address such problematics. This initial contact with the literature allowed us to identify iNOOVBC's potential primary (e.g., BCS, partners and family of BCS, and informal caregivers, etc.), secondary (e.g., MHP, oncologists, nurses, other healthcare professionals, etc.), and tertiary end-users (e.g., healthcare organizations, insurance companies, software development companies, etc.). Considering the time and budget limitations of the project, BCS and MHP were defined as priority end-users to be involved in the development process.

The primary and secondary outcomes to be addressed by iNOOVBC, namely anxiety and depression, and fatigue, sleeping problems and sexual dysfunction, respectively were also defined at this stage, based on its high prevalence (16,18–20,80). Findings from **Study III** confirmed this decision. Subsequently, the psychosocial intervention frameworks applied to BCS' psychosocial problematics; DMH, with an emphasis on

internet interventions targeting BCS; the drivers and barriers impacting the implementation of these interventions; and the attitudes and practices of both BCS and MHP regarding internet interventions were further reviewed. An analysis of internet interventions development studies within oncology was also conducted to identify good-practice guidelines on how to develop human-centred internet interventions for BCS. The main findings of this review were narratively summarized, discussed within the research team, and categorized to inform iNNOVBC's development.

During this process, CBT and ACT were elected as basilarly theoretical behaviour change models to frame iNNOVBC. CBT due to its attested effectiveness in treating prevalent psychosocial problems affecting BCS (24,108), and ACT due to its transdiagnostic approach of healthy adaptation to difficult circumstances and limited research within the internet interventions cancer domain (124,125).

The DMH modality to be used in iNNOVBC was also defined at this stage and validated during **Study I, II** and **III**. We opted for developing a guided internet intervention, due to its self-care approach and superiority over unguided interventions and treatment as usual (156,245). Furthermore, the research gaps identified during this process that could significantly impact iNNOVBC's development and implementation (e.g., the attitudes and practices of both BCS and MHP; internet interventions implementation barriers in Portugal; the components and attributes to be included in the intervention, etc.) were listed as research priorities within the project and explored in subsequent empirical studies (c.f., **Study I, Study II, Study III**, and **Study IV**). The main findings of these studies are summarized below.

4.1.2. Study I: Portuguese Psychologists' Attitudes Toward Internet Interventions: An Exploratory Cross-Sectional Study

4.1.2.1. Aims

This study aimed to explore Portuguese psychologists' knowledge, training, use and attitudes toward internet interventions and study potential factors associated with

previous use and attitudes toward these interventions. A further aim was to investigate the perceived advantages and limitations of internet interventions among this group and to identify potential drivers and barriers impacting its implementation.

4.1.2.2. Methods

4.1.2.2.1. Procedures

A cross-sectional study design was used. Due to the scarcity of adequate instruments designed to evaluate the attitudes of MHP toward internet interventions, the Attitudes Toward Internet Interventions Survey – Mental Health Professionals version (ATIIS-MHP) (243) was developed for this study. The questionnaire was lodged at LimeSurvey (246) from November 2018 to February 2019, and disseminated by OPP, via e-mail, to its registered members. No follow-up reminders were sent to recipients of the questionnaire. The collected data was exported from LimeSurvey (246) to IBM Statistical Package for the Social Sciences (SPSS) v. 24.0 (247) to be statistically analysed.

4.1.2.2.2. Measures

ATTIS-MHP (243) is a 38-items, self-report questionnaire, assessing four main categories: 1) the use of digital technology in practice; 2) knowledge and training in the DMH/internet interventions field; 3) perceived advantages, limitations, drivers and barriers impacting the implementation of DMH/internet interventions; and 4) attitudes toward internet interventions. Items are answered using dichotomous, multiple-choice questions, and five-point Likert scales (0=“*Completely disagree*” to 5=“*Completely agree*”). The attitudes section is composed of 21 items clustering in two dimensions labelled as “*positive attitudes*” and “*negative attitudes*”. Higher summated/transformed scores reflect more positive attitudes toward internet interventions. ATTIS-MHP was preliminarily validated to the Portuguese Psychologists’ population in the context of this study ($\alpha=.91$) (243).

4.1.2.3. Analysis

Descriptive statistics (i.e., frequency distributions, measures of variability, measures of central tendency and percentiles) were used to characterize the study sample and participants responses to ATTIS-MHP. Subsequently, χ^2 analysis and posthoc tests were used to determine if demographic and background factors, knowledge, training, previous experience of use, recommendation, future use, and attitudes toward internet interventions would be associated and differed between participants holding extreme attitudes toward internet interventions (i.e., scoring <Q1 or >Q3 in ATTIS-MHP attitudes section).

4.1.2.4. Results

A total of 1077 psychologists registered at OPP responded to the survey (Response rate = 5.08%). 91.6% (N=987) of respondents were female and participants' mean age was 38.21 (Range:20-77years; SD=9.49). Most participants held a license and/or master's degree (67.0%; N=722) and were active (91.6%; N=986), working primarily in private practice (25.1%; N=270), educational/research institutions (23.4%; N=252) and charities/non-profit organizations (19.3%; N=208). Only 12.3% (n=132) of psychologists worked at the National Health Service (NHS). In what concerns professional experience, the sample was evenly distributed (Range: 0-21 years). CBT was the most common theoretical orientation (56.0%; N=603), followed by Psychodynamic (14.8%; N=159) and eclectic (13.5%; N=145) orientations.

The results of this study showed that most psychologists were unfamiliar with the concept of providing psychological support via the internet or digital technology (62.9%; n=615), having no prior experience using digital technology for this purpose (n=758; 70.4%). In addition, only a minority reported having the necessary training to work within this domain (19.2%; n=188). Regarding participants with prior experience of use (29.6%; N=319), the majority were clinical and health psychologists (84.3%; N=269) and used the telephone (23.8%; N=256), e-mail (16.2%; N=175) and SMS services (16.1%; N=173) as a complement to face-to-face interventions (90.3%; N=288), rather than as

stand-alone interventions (9.7%; N=31). Videoconference (8.7%, n=94), chat-services (6.1%; N=66), and guided (1.3%; N=14) and unguided (1.5%; N=16) internet interventions were seldom used.

Considering the perceived advantages of internet interventions, accessibility (79.9%; N=860), convenience (45.7%; N=492) and cost-effectiveness (45.5%; N=490) were identified as the most important in this research. Likewise, the possibility of facilitating access to information and psychological care was reported as the main driver for using digital technology in practice (54.5%; N=174). Contrariwise, clients' ICT illiteracy (43.2%; N=465), ethical concerns (40.7%; N=438), clients' attitudes toward internet interventions (37%; N=398) and information systems' potential lack of security (35.8%; N=386) were identified as key limitations of internet interventions, which could hinder implementation. Additional implementation barriers identified in this research concerned: limitations on the conceptual comprehension and implementation of self-help techniques by clients (62.8%; N=676); insufficient scientific evidence on the efficacy and cost-effectiveness of internet interventions (62.2%; N=670); difficulties in the adaptation of treatment protocols to the digital format (61.7%; N=665); and low adherence both from patients (43.3%; N=466) and psychologists (40.6%; N=437) toward such programs. Negative attitudes held both by clients (38.7; N=417) and therapists (38.6; N=416) were also considered important obstacles to overcome in the implementation of internet interventions.

An evaluation of participant Psychologists' attitudes toward internet interventions revealed a slightly negative/neutral stance (Median=46.21; IQR=17.46). Significant associations were found between attitudes of respondents and self-reported knowledge ($\chi^2(12)=109.74$, ($P<.001$)); self-reported training ($\chi^2(12)=64.70$, ($P<.001$)); previous experience of use ($\chi^2(3)=38.42$, ($P<.001$)); recommendation ($\chi^2(3)=42.12$, ($P<.001$)); and future use ($\chi^2(3)=123.14$, ($P<.001$)) of internet interventions. No significant associations were found between the attitudes of respondents and demographic or background factors. In addition, significant associations were found between previous

experience of use and age ($\chi^2(4)=42.44, P<.001$); theoretical orientation ($\chi^2(6)=27.66, P<.001$); work context ($\chi^2(7)=50.87, P<.001$); years of professional experience ($\chi^2(7)=49.02, P<.001$); knowledge ($\chi^2(4)=90.38, P<.001$); training ($\chi^2(4)=94.63, P<.001$); recommendation ($\chi^2(4)=37.28, P<.001$) and attitudes ($\chi^2(3)=38.42, (P<.001)$ toward internet interventions.

These findings suggest that psychologists reporting moderate to high knowledge of internet interventions and adequate training on this modality were more likely to present favourable attitudes toward internet interventions and to have prior experience on its implementation. Psychologists with prior experience of use were also more likely to hold more positive attitudes toward internet interventions. Furthermore, Psychologists with more than 16 years of experience, holding a psychodynamic theoretical orientation, and working at the NHS or private practice were more likely to have prior experience using digital technology in practice. Finally, participants with prior experience of use and holding more positive attitudes toward internet interventions had a higher probability of recommending it to their clients. Those with a more positive stance toward internet interventions were also more likely to consider using it in the future.

4.1.2.5. Conclusions

Results from Study I indicate that, at the time of the study, most Portuguese psychologists were not familiar with and had no training or prior experience using digital technology for mental healthcare provision. A slightly negative/neutral attitude toward internet interventions was identified, suggesting that Portuguese psychologists were cautious toward the use of these interventions. Moreover, psychologists reporting moderate to high knowledge of internet interventions, as well as adequate training on this approach were more likely to present favourable attitudes toward internet interventions than psychologists reporting the absence of knowledge and training. The former group was also more likely to have prior experience of use than the latter group. These findings suggest that lack of knowledge and training might be important internet

interventions acceptance and implementation barriers. In this context, awareness and training initiatives focusing on internet interventions could promote acceptance of such an approach within psychologists and expedite the adoption of internet interventions in clinical settings.

Considering that the findings of Study I provided some insight on psychologists' acceptance and use of internet interventions but failed to provide an in-depth understanding of their perspectives and practices regarding its implementation, further investigation was necessary to identify the requirements INNOVBC would have to fulfil to be widely accepted by Psychologists, as well as other MHP potentially providing support to BCS. Study II aimed at bridging this knowledge gap by adopting a qualitative approach and involving both psychologists and psychiatrists in conducted research activities. Considering the limited experience participants of Study I had on internet interventions, a broader approach to the topic was adopted in this second study and the perspectives and experiences of MHP regarding different modalities within DMH (e.g., teleconsultation and videoconferencing counselling/psychotherapy, internet interventions, etc.) were explored.

4.1.3. Study II: Mapping Mental Health Professionals' Perspectives and Practices Regarding the Implementation of Digital Mental Health: a Qualitative Study

4.1.3.1. Aims

Study II aimed at characterizing in-depth the perspectives and practices of MHP regarding the implementation of DMH and exploring the factors influencing such perspectives and practices.

4.1.3.2. Methods

4.1.3.2.1. *Procedures*

This qualitative study used in-depth semi-structured interviews. A nonprobabilistic, stratified purposeful sample of Portuguese MHP – psychologists and psychiatrists –

was planned to capture variation. Possible participants were identified following referrals from the researchers and contacts in the health community. A total of 28 MHP were invited to participate via e-mail or telephone. Of the invited professionals, 15 replied and/or agreed to participate. Meaning saturation was established as a stopping criterion.

Interviews were conducted between November and December 2019, face-to-face, at Fraunhofer Portugal AICOS, in Portuguese. The thesis author acted as the main interviewer in all interviews. Overall, 13 MHP were involved, resulting in around 10 hours of audio recordings. The average duration of an interview was 49 minutes (range: 00:26 – 01:21). Interviews were audio-recorded, transcribed verbatim (CMS, AA), and stored in a pseudo-anonymized format in a secure password-protected location. Transcripts were coded and analysed in parallel to data collection to enable the data collection to be driven by analysis.

4.1.3.2.2. Measures

A semi-structured interview guide was developed based on a literature review and analysis of data resulting from Study I. The interview guide included 33 questions and explored five main domains: a) Professional background and digital technology proficiency; b) Knowledge and use of DMH; c) Attitudes toward DMH; d) Advantages and limitations of DMH; e) Drivers and barriers toward adoption and implementation of DMH; and f) Therapeutic process and alliance in DMH interventions. In addition, follow-up questions were used to clarify participants' perspectives and practices.

4.1.3.3. Analysis

The analysis used Braun and Clarke's (244) thematic analysis method. Coding was performed in parallel by two researchers (CMS, AA). After an initial familiarization with data through interviews transcription and repeated transcripts reading, initial codes capturing salient content were independently generated. Scrivener software (248) was used to support the coding of interview transcripts and the writing of memos.

Regular discussions between researchers were promoted to discuss results and coding trees (CMS, AA, EO, FN). Data patterns were then identified and iteratively organized into themes by clustering and collapsing codes based on similarities and differences. Thematic maps were then assembled and refined as they were applied to the data. Patterns within and across themes were systematically explored and examined until consensus between researchers was achieved and no additional insights were resulting from the analysis of the data. Preliminary and final reports were submitted for participants' validation.

4.1.3.4. Results

Thirteen MHP, including two psychiatrists and 11 clinical psychologists, participated in the study. Most interviewees were female (11/13; 85%) and the median age of our participants was 35 years (IQR=11; Min: 25; Max: 56). Participants had a median of 11 years of professional experience (IQR=11), and 39% held a master's degree (5/13). Ninety-two per cent of participants were active (12/13), working at different universities/research institutions (5/13; 39%), distinct hospitals of the National Health Service (4/13; 30%) and various private practices or charities (3/13; 23%). Most participants (9/13; 69%) developed some sort of clinical practice at the time of the interviews. Thirty per cent (4/13) worked in Psycho-oncology services. Four participants (31%) worked exclusively as Clinical and Health Psychology researchers in the field of DMH. Around half of our sample held a CBT orientation (7/13; 54%). Considering participants' knowledge and experience using DMH, the sample was evenly distributed including non-users (6/13; 46%), as well as occasional (4/13; 31%) and regular users (3/13; 23%). In what concerned the type of technology used by participants in clinical practice, videoconference (4/13; 31%) and web platforms (e.g., Moodbuster, Google classroom, Be a mom, etc.) (4/13; 31%) were the most used, followed by e-mail (3/13; 23%), messaging apps (2/15; 23%) and social networks (2/15; 23%).

Five main themes and 16 sub-themes became salient in the analysis and characterized the perspectives and practices deemed important or undertaken by professionals during the implementation of DMH. These perspectives and practices are listed below (c.f. Table 2).

Table 2: Themes and sub-themes describing participants’ perspectives and practices	
Themes	Sub-themes
Indication evaluation	Assessment of Digital Mental Health uptake drivers Appraisal of Digital Mental Health uptake barriers Casuistic assessment of Digital Mental Health’s applications and indications
Therapeutic contract negotiation	Clinicians’ credentials presentation Therapeutic setting definition Therapeutic boundaries framing Contingency plan construction Privacy, confidentiality, and data protection procedures disclosure Legal, jurisdictional, and billing considerations discussion
Digital psychological assessment	Dealing with the absence of validated technology Perceived lack of control over the psychological assessment process
Technology setup and management	Adapting non-clinical software to clinical purposes Developing Digital Mental Health technology
Intervention delivery and follow-up	Appraising the impact of the absence of evidence-based usable interventions in practice Therapeutic alliance bolstering Perceived lack of control over the therapeutic process

Indication Evaluation

Professionals considered DMH could be useful for prevention, screening, (self-care) intervention, and rehabilitation purposes. However, DMH’s indication should be casuistically and continuously assessed to comply with equity and beneficence requirements. While assessing the indication of DMH to a given client, MHP’s perceived duty to provide support, and DMH’s low-threshold accessibility, and ubiquity incentivized professionals’ uptake of DMH. Contrariwise, a lack of practice guidelines and structured intervention frameworks inhibited their uptake of DMH.

Therapeutic Contract Negotiation

To compensate for this lack of structure, various professionals searched for or formulated procedural and relational rules to organize their online practice. These aspects were debated and negotiated with their clients at the onset of the therapeutic process. Key points that were addressed at this stage were: professionals' credentials; the digital setting rules (e.g., the intervention's structure, format, and frequency, and the technical orientations to be followed while using digital technology); the therapeutic boundaries (e.g., the exclusive use of institutional accounts for communication purposes); and contingency plans to be activated in case of technology failure or crisis (e.g., collecting emergency contacts and mapping local institutions to be activated under crises circumstances). The data collection and protection procedures to be adopted (e.g., storage of personal, health and psychological data); and the legal and jurisdictional frameworks to be applied to the intervention, were also discussed at this stage.

Digital Psychological Assessment

After framing the unfolding therapeutic relationship, professionals usually conducted a psychological evaluation. This practice was significantly impacted by the scarcity of validated online platforms and instruments or their high subscriptions costs. Professionals were often forced to either narrow the scope of evaluation or autonomously adapt non-clinical software and paper and pencil instruments to the online environment. Nevertheless, various participants were uncomfortable with these alternatives, as they could negatively impact the psychological assessment process or be non-compliant with the General Data Protection Regulation (GDPR) and intellectual property rights. The therapists' confidence in using online mediums for assessment purposes was also demised by difficulties in assessing non-verbal communications cues or environmental factors potentially affecting clients' behaviours, and lack of training. However, a few participants acknowledged that digital technology could facilitate the

observation of their clients' living environments, bringing an ethnographic dimension to the psychological assessment process.

Technology Setup and Management

The absence of dedicated and GDPR compliant technology forced most professionals not only to adapt non-specific software to clinical purposes but also to conciliate the use of various non-clinical tools to develop their online practice. This posed a high technological burden on professionals, compromising their efficiency and satisfaction. Thus, most professionals underlined the importance of developing dedicated, tailorable, comprehensive, and usable platforms to implement DMH interventions efficiently and cost-effectively. Nevertheless, the development process was perceived as long, expensive, and challenging by various participants. It required the support of a multi-disciplinary team and conducting comprehensive literature reviews and user research so that the medium for treatment delivery and the content and features to be included in the program under development could be defined. Moreover, the integration of strategies to prevent, monitor, and address possible adverse effects was deemed necessary, to comply with safety and beneficence requirements.

Intervention Delivery and Follow-up

Most participants considered that the intervention process, and particularly, the therapeutic alliance could be affected by poor technology design, adaptation, or failure. Thus, close monitoring of both relational and technological dimensions of the therapeutic process was considered necessary. Furthermore, the fact that most professionals did not have access to guidelines or training in DMH, heightened their perception of lack of control over the therapeutic process. This perception of lack of control seemed to be influenced by the intervention format and type and frequency of communication established between therapist and client. It ranged from residual in unguided interventions, to augmented in blended-care interventions. The management

of crises in online settings was another major concern for professionals. Most considered specific training on how to build contingency plans and how to early detect risk situations online to be necessary.

4.1.3.5. Conclusions

Results from Study II suggest that, at the time of the study, most MHP considered important or engaged in the following practices to implement DMH: 1) Indication evaluation; 2) Therapeutic contract negotiation; 3) Digital psychological assessment; 4) Technology setup and management, and 5) Intervention delivery and follow-up. These practices tended to unfold subsequently, but could also co-occur, overlap, be omitted, or assume a recursive nature, depending on the purpose of the intervention, the selected treatment modality and drivers and barriers encountered along the process. DMH's low threshold accessibility, ubiquity, and professionals' perceived duty to provide support to their clients were identified as key DMH adoption drivers. Conversely, the lack of guidelines and structured intervention frameworks; the unavailability of usable, validated, and affordable technology; and the absence of structured DMH training programmes, negatively impacted therapists' perception of control over the therapeutic process and, consequently, professionals' uptake or sustained adoption of DMH.

To overcome the abovementioned barriers and expedite professionals' adoption of DMH, the publication of legal, regulatory and practice frameworks, that can be easily transferred to practice seems necessary. In addition, providing training in the development and implementation of DMH interventions could provide MHP with the necessary knowledge and confidence to work online.

Insights gathered during Study II complemented the findings of Study I, providing a characterization of MHP' attitudes, goals, needs, skills and contexts of DMH use and allowed us to compile a comprehensive list of the MHP's requirements for the development of iNOVBC. The main drivers and barriers potentially impacting the future

implementation of the program by MHP were also identified via these studies. To acquire an equivalent understanding of BCS' perspectives and practices concerning DMH, **Study III** was conducted. Given the residual knowledge in Portugal regarding internet interventions, this study also focused on the more general concept of DMH. The exploratory interviews conducted during **Study IV** also provided valuable information on BCS' perspectives and practices (c.f. **Section 4.3.1**).

4.1.4. Study III: Breast Cancer Survivors' Attitudes Toward Digital Mental Health: a Cross-sectional Study

4.1.4.1. Aims

This study aimed to explore BCS' attitudes toward DMH and to investigate variables associated with these attitudes.

4.1.4.2. Methods

4.1.4.2.1. *Procedures*

The study adopted an exploratory cross-sectional design. Participants were conveniently recruited by the research team from the Day Hospitals or Breast Clinics of five hospitals in Porto (Portugal), during 2019. Eligibility criteria included being female, aged ≥ 18 years, with a confirmed history of BC, and the ability to read/write in Portuguese. Patients willing to participate were invited to fill in either a paper-and-pencil or an online questionnaire lodged at iTerapi (49).

4.1.4.2.2. *Measures*

Clinical, Socio-demographic and internet-related use characteristics; anxiety; depression; HRQoL; and attitudes toward DMH were assessed. A background questionnaire tailored to the target population, the Generalized Anxiety Disorder Screener (GAD-7) (249), the Patient Health Questionnaire (PHQ-9) (250), and EORTC QLQ-C30 (v.3.0) and QLQ-BR23 (251,252) were used for this purpose. In addition, due to the scarcity of adequate instruments designed to evaluate the attitudes of BCS toward DMH, ATTIS-MHP (243) was adapted to the Portuguese BCS population. ATTIS-BCS resulted in a 34-items,

self-report questionnaire, that assessed: 1) the use of digital technology for healthcare purposes; 2) DMH self-reported knowledge; and 3) attitudes toward DMH. The attitudes section included 16 items clustering in two dimensions labelled as “positive” and “negative” attitudes. Items were scored using a 5-point Likert scale (0=“*Completely disagree*” to 5=“*Completely agree*”). Higher scores indicated more positive attitudes toward DMH. ATTIS-BCS attitudes section was preliminarily validated to the Portuguese BCS’ population in the context of this study ($\alpha=.93$).

4.1.4.3. Analysis

First, descriptive statistics (i.e., counts/percentages, medians, interquartile ranges, and percentiles) were used to characterize the study sample, explore participants’ DMH use and self-reported knowledge, and examine self-reported measures’ scores. Second, associations between attitudes and socio-demographic, clinical, internet-related characteristics, anxiety, depression and HRQoL were evaluated. Spearman rank correlations were used to assess continuous variables. χ^2 analyses and posthoc tests were calculated to evaluate if categorical variables would be associated and differed between participants holding extreme attitudes (i.e., scoring <Q1 or >Q3 in ATTIS-BCS attitudes section). Third, multiple regression analyses (method: enter) were conducted to investigate the relationship between associations previously identified as statistically significant, while controlling for age and education, as these could be potential confounders. The preliminary assumptions of regression analysis were tested before the analysis. All hypothesis tests were conducted at a confidence level of 95% with a P-value of .05. IBM SPSS Statistics v.27.0. was used to conduct the analysis.

4.1.4.4. Results

336 BCS participated in the study (Response rate = 67%). The median age of participants was 53 years (IQR=15; Min: 26; Max: 82). Most respondents were married/in de facto relationships (67%; n=225) and one third (32%; n=107) was professionally active. The majority was diagnosed with an invasive ductal carcinoma NST (73%; n=231), Luminal B Her2- (33%; n=88) or Luminal B Her2+ (31%; n=82), 2 years before the study

(Range: 0-24). Most participants had performed lumpectomy (n=156; 49%) with sentinel lymph node biopsy (73%; n=230) and received adjuvant treatment (67%; n=215) with chemotherapy and radiotherapy (n=120; 38%), and hormone therapy (n=172; 54%). Forty per cent (n=128) of the women had a psychiatric history before cancer. The prevalence of symptoms of anxiety and depression was 63% (n=211) and 65% (n=217), respectively. Considering HRQoL, the sample median global health status was 50 (IQR=33).

In what concerned the use of digital technology, most participants had access to the internet (78%; n=263), using it daily (85%; n=217) on their mobile devices (52%; n=174) or personal computers (21%; n=70). A majority used the internet to search for health-related and cancer-related information (65%; n=219) autonomously (55%; n=184). Around 18% (n=60) of the participants had prior experience accessing remote healthcare. Most used modalities were teleconsultations with physicians (13%; n=42) and nursing staff (8%; n=28), and SMS (4%; n=12), e-mail (2%; n=8) and chat (1%; n=4) communications with physicians.

Results showed that most BCS were unfamiliar with DMH (n=248; 74%) and none had prior experience using videoconference counselling/psychotherapy or internet interventions. However, 44% (n=146) believed to be skilled to use DMH and 54% (n=181) reported willingness to use it if provided by their cancer centre.

An analysis of BCS attitudes toward DMH revealed a neutral attitude toward DMH (Median=50.0; IQR=23). Significant positive weak associations were found between DMH self-reported knowledge ($\beta=.332$ $P<.001$); online health information ($\beta=.240$ $P<.001$) and mental healthcare ($\beta=.180$ $P<.001$) seeking; social networks use ($\beta=.212$ $P<.001$); remote healthcare use ($\beta=.107$ $P<.047$); PHQ-9 ($\beta=.109$, $P<.041$) and ATTIS-BCS continuous scores. Furthermore, significant negative weak associations were observed between emotional ($\beta=-.129$, $P<.017$), cognitive ($\beta=-.136$, $P<.013$) and body image ($\beta=-.168$, $P<.002$) functioning and ATTIS-BCS continuous scores. No significant associations were found between ATTIS-BCS and socio-demographic or clinical variables.

These results indicate that higher DMH self-reported knowledge; online health information and mental health care-seeking; social networks use; and prior experience using remote healthcare were significantly associated with a more positive attitude toward DMH. Likewise, higher depression scores and lower levels of emotional, cognitive, and body image functioning were significantly associated with a better stance toward DMH.

4.1.4.5. Conclusions

Considering the high prevalence of psychological distress symptoms in participant BCS, their neutral stance toward DMH, and readiness to use digital technologies for self-care, results from Study III suggest that DMH might be a promising strategy to bridge the mental healthcare gap within oncology. However, most BCS were not familiar with DMH and their lack of knowledge was significantly associated with a more negative stance toward DMH. Thus, creating DMH awareness among this population could potentially increase BCS acceptance and use of DMH. Furthermore, additional research is necessary to explore how BCS' unmet care needs, and particularly psychological distress severity, may impact BCS' acceptance and use of DMH.

The findings from the literature review and **Studies I, II and III** were preliminarily analysed and translated into general requirements that steered iNNOVBC's prototyping (c.f., Table 3).

Table 3: iNOVBC's prototyping requirements

iNOVBC	Prototyping requirements
Aims	Target primarily anxiety and depression. Fatigue, sleeping problems and sexual dysfunction should be secondary outcomes.
Components: behaviour change strategies	Incorporate CBT and ACT behaviour change strategies adequate to address iNOVBC's aims.
Components: treatment approach	To privilege a self-care approach capable of empowering BCS.
Components: treatment modules	Include information related to BC, healthy lifestyle habits, and main psychosocial problems affecting BCS. Create an introductory module to operationalize the therapeutic contract negotiation.
Components: public website	Include information regarding iNOVBC's promoters, as well as the research team behind its development, to attest the credibility of the intervention. Document compliance with GDPR.
Features: a multifeatured integrated platform	Develop a comprehensive platform including psycho-educational content, communication features, and validated data collection measures to be automatically administered, scored, and visualized.
Features: Human support	Include guidance by MHP, namely synchronous (i.e., videoconference) and asynchronous (i.e., e-mail and SMS) communication channels.
Attributes: format	Adopt a responsive design to be widely accessible
Attributes: structure	Be tailorable, to better respond to BCS unmet care needs and comply with the identified flexibility requirement.
Attributes: security infrastructure	Comply with data protection and security regulations.

4.2. Phase 2: Prototyping iNOV Breast Cancer

The second phase of iNOVBC's development (c.f. **Figure 1**) was dedicated to transferring the insights gathered during Phase 1 into a tangible internet intervention for BCS. To this end, iTerapi (49) – an evidence-based web treatment platform developed at Linköping University – was selected to build and lodge the intervention because it already fulfilled many of the requirements specified above. iTerapi was translated from English to Portuguese (Portugal), and configured to iNOVBC, during this phase.

iNOVBC's structure and content were also adapted and created during this period. These activities are summarized below.

4.2.1. iTerapi translation, configuration, and adaptation

iTerapi (49) is a responsive and comprehensive information management system that allows the design of tailored internet interventions. Its structure encompasses:

- i) A **Start page**, that shows the entry points to all sections available in the platform and a notification centre, that alerts users to essential information or actions they must reply to.
- ii) A **Treatment section**, that includes a self-help directed treatment area displaying treatment modules (that can include text, images, PDF files/hyperlinks, video, audio materials, information collection forms/worksheets, and EMAS), a communication system (enabling synchronous and asynchronous communication exchanges between participants and clinicians via internal e-mail, chat, or videoconference), and a discussion forum.
- iii) A **Questionnaires section**, that comprises a data collection built-in system where therapists can create new questionnaires or adapt previously validated instruments to the online setting.
- iv) An **Administrative section**, where therapists can access a listing of all participants and information related to them such as answers to questionnaires and forms, progress within treatment modules, activity logs, and the patient journal.
- v) And a **Help section**, providing support information about the platform.

iTerapi is compliant with the GDPR (253). For further information on iTerapi's affordances and characteristics please see (49).

To guarantee iTerapi's cultural appropriateness, the platform was translated from English to Portuguese (Portugal) using the following procedures: iterative forward translation from English to Portuguese (Portugal) using an exportable Excel file (CMS, GV); a back-translation from Portuguese to English of the commands that raised doubts in its

interpretation; a second forward translation from English to Portuguese (Portugal); a critical review of the translated commands, in a web environment, using iNOVBC's prototype version 1.0 (CMS); and further assessment, validation and refinement during the usability tests performed in **Study IV** (CMS, AA, EO).

Considering iTerapi's configuration, a child platform with its URL address, data space, and design was developed for iNOVBC (GV, CMS). The program included all iTerapi's original sections, features, and elements except the EMAS and the discussion forum. These elements were excluded from iNOVBC's initial development because they would increase the complexity of the program, while it still needed to be assessed in terms of usability and efficacy (254). Moreover, developing and appraising the data resulting from these elements would require additional human and financial resources that were not available at the time of development. Nevertheless, the acceptability of MHP and BCS toward such features was assessed during the semi-structured interviews conducted in **Study IV** and iNOVBC's prototype may be further refined, to include such functionalities.

Once a digital framework was available to lodge iNOVBC, we started working on its structure and content.

4.2.2. iNOV Breast Cancer structure and content development

iNOVBC is a guided, internet-delivered, individually tailored, ACT-influenced CBT program that was developed to address prevalent psychosocial needs of BCS (i.e., mild to moderate anxiety and depression, fatigue, insomnia, and sexual dysfunction) and improve their HRQoL. iNOVBC's structure and content build on prior research interventions developed by the Department of Behavioural Sciences and Learning (IBL) at Linköping University that have been considered effective for the treatment of anxiety and depression in the general population or other clinical populations (142,255–258). After an analysis of these interventions, the content that was considered applicable to BCS was translated from Swedish and English to Portuguese

(Portugal). Subsequently, additional content was created based on peer-reviewed sources (259–263), to address the specific needs of BCS that had been identified via literature review and previous empirical studies. The intervention’s content was then reviewed by external advisors (i.e., an oncologist, a nurse, a psychologist, a BCS and a layperson) and iteratively modified to incorporate the provided feedback.

iNOVBC resulted in a transdiagnostic intervention program that encompasses 10 treatment modules (c.f., **Table 4**), namely five mandatory modules – Living with breast cancer and beyond; Depression; Anxiety; Relaxation; and Planning for the future – and five optional modules – Behavioural activation Parts I and II; Sleep; Fatigue; and Interpersonal relationships, sex, and intimacy. An introductory module provides general information about the platform and the intervention, framing it.

The key behaviour change strategies used in iNOVBC are psychoeducation, acceptance, cognitive defusion, connecting with values, committed action and relaxation. By cultivating the abovementioned processes through experiential exercises, metaphors and homework assignments considered appropriate to BCS, the intervention aims at increasing psychological flexibility and therefore, improve its target outcomes. For participants selecting the optional modules, the mentioned core processes may be adjuvated by one or more of the following strategies and techniques: behavioural activation, exposure, sleep management, energy conservation techniques, problem-solving and sensate focusing. An overview of the iNOVBC structure and content is presented in the adjacent table (c.f. **Table 4**).

Table 4: INNOVBC's structure and content

Core Processes and Intervention Techniques		Content
Module		
About this treatment (Week 0)		<ul style="list-style-type: none"> General introduction to INNOVBC aims, theoretical framework, structure, and format. Introduction to iTerapi's functionalities.
Living with breast cancer and beyond (Week 1)	<ul style="list-style-type: none"> Psychoeducation Contextual Functional Analysis Values 	<ul style="list-style-type: none"> Information about breast cancer; the survivorship trajectory; and the common late side effects and psychological comorbidities associated with breast cancer. Introduction to Cognitive Behaviour Therapy (CBT) and Acceptance and Commitment Therapy (ACT) rationale: the relationship between cognition, emotion, and behaviour; the ABC model; values as chosen life directions; and how to set treatment goals. <i>Activities:</i> Identifying and hierarchizing values; setting treatment goals; Telling my story.
Depression (Week 2)	<ul style="list-style-type: none"> Psychoeducation Acceptance Cognitive Defusion 	<ul style="list-style-type: none"> Information about Unhappiness and depression; depression aetiology, signs, and symptoms; feelings, behaviours, and thoughts in depression; and feeling depressed after breast cancer. Introduction to experiential avoidance and acceptance concepts. <i>Activities:</i> Identifying sources of discomfort and the actions taken to ease the discomfort; Naming and observing inner experiences.
Behavioural Activation: Part I (Week 3; Optional)	<ul style="list-style-type: none"> Psychoeducation Behavioural activation Committed Action 	<ul style="list-style-type: none"> Introduction to behavioural activation rationale. <i>Activities:</i> Activity Scheduling/ Activity Plan; My positive activities; My negative activities; Increasing the probability of executing positive activities; Evaluating and redesigning your Activity Plan.
Behavioural Activation – Part II (Week 4; Optional)	<ul style="list-style-type: none"> Psychoeducation Behavioural activation Committed Action 	<ul style="list-style-type: none"> Introduction to negative activities and strategies to manage negative activities. <i>Activities:</i> Dividing negative activities into smaller activities; Examining previous week Activity Plan; Designing a reward list; Evaluating and redesigning your Activity Plan to integrate previously identified rewards.

Anxiety (Week 3 or 5)	<ul style="list-style-type: none"> • Psychoeducation • Cognitive Defusion • Exposure 	<ul style="list-style-type: none"> • Information about anxiety, worries and fear of recurrence and strategies to manage anxiety. • Activities: Anxiety Ladder; Planning a time to worry and feel anxious (includes worries diary); Exposure to an object, situation, or thought.
Relaxation (Week 4 or 6)	<ul style="list-style-type: none"> • Psychoeducation • Relaxation techniques 	<ul style="list-style-type: none"> • Introduction to relaxation rationale and techniques. • Activities: Progressive muscle relaxation; Applied relaxation - diaphragmatic breathing, using a relaxation word, faster relaxation, relaxing in anxious situations.
Sleep problems (Week 5 to 9; Optional)	<ul style="list-style-type: none"> • Psychoeducation • Sleep management techniques 	<ul style="list-style-type: none"> • Information about sleep, sleeping problems and sleep management techniques. • Activities: Mapping your altering sleep factors; choosing and implementing your sleep management techniques: a) Sleep hygiene, b) Relaxation; c) Stimulus control; d) Sleep restriction.
Fatigue (Week 5-9; Optional)	<ul style="list-style-type: none"> • Psychoeducation • Energy conservation techniques 	<ul style="list-style-type: none"> • Information about fatigue and strategies to cope with it. • Activities: Fatigue diary; 6P energy conservation techniques; Identifying fatigue-promoting occupations and identifying energy conservation strategies to adapt and deal with these occupations; prioritizing my activities and planning my day.
Interpersonal relationships, Sex, and Intimacy (Week 5-9; Optional)	<ul style="list-style-type: none"> • Psychoeducation • Problem-solving • Sensate focus 	<ul style="list-style-type: none"> • Interpersonal relationships, sex, and intimacy difficulties in survivorship. • Activities: Practical problem solving; sensate focusing.
Conclusion: Planning for the future (Week 5 or 10)	<ul style="list-style-type: none"> • Psychoeducation • Relapse prevention 	<ul style="list-style-type: none"> • Summary of the treatment program; Therapy goals reassessment; Overview and assessment of the learned techniques; Preparing for the unexpected; Setbacks and relapse.; Situations where setbacks can occur; Planning for maintenance and relapse prevention.

To promote engagement with the program, the study intervention was developed according to the following persuasive system principles (222): responsiveness, tunnelling, tailoring, personalization, reminders, and professional support.

At the onset of the intervention, participants should tailor their treatment with the support of their assigned therapist and select the treatment modules to complete according to their baseline assessment and preferences. The program is to be completed for up to 10 weeks. BCS are prompted to complete the modules in one week. Each module takes approximately 60 minutes to complete and comprises text, images, videos, audio files; quizzes; ACT and CBT based exercises, homework assignments and respective worksheets. Professional feedback and guidance are to be provided once a week, within 24h of module completion, by certified psychologists and/or psychology trainees under supervision. Therapists feedback should be based on the following guidelines (145): validation of participants' work and reported difficulties; problem-solving and clarification on the implementation of treatment techniques; therapeutic alliance bolstering; task prompting; progress reinforcement and; encouragement of continued work. Integrated two-way communication features such as e-mail, chat, SMS, and videoconference may support this process.

4.2.3. iNOV Breast Cancer Prototype

As soon as a representative set of mandatory and optional modules was completed (i.e., Living with breast cancer and beyond; Anxiety; Relaxation; Sleep, and Fatigue), iNOVBC's prototype v.1.0 (c.f., **Figure 2-3**) was assembled with the purpose of early testing iNOVBC's concept and the interactions that were considered crucial for iNOVBC's use.

Figure 2. INNOVBC's landing page. From this page, BCS can go to self-care treatment modules, tasks, agenda, or the chat functionality to talk with their clinicians.

Figure 3. INNOVBC's introductory and 10 treatment modules.

While this was still an archetype of what iNNOVBC intended to be, this prototype was already highly functional. The prototype was developed so that we could early test the assumptions of the program and rapidly iterate on its structure and content and build the rest of the program based on iNNOVBC's target users' feedback. The prototype's usefulness, usability and feasibility were assessed at the third phase of the development process, via **Study IV**.

4.3. Phase 3: Evaluation of the usefulness, usability, and feasibility of iNNOV Breast Cancer

The last phase of development was dedicated to assessing the usefulness, usability, and preliminary feasibility of iNNOVBC and specifying refinement requirements to the improvement of iNNOVBC's prototype v.1.0. This was achieved by conducting **Study IV**.

4.3.1. Study IV: Development and evaluation of the usefulness, usability, and feasibility of iNNOV Breast Cancer: a mixed-methods study

4.3.1.1. Aims

Evaluate iNNOVBC's usefulness, usability, and feasibility among its target users.

4.3.1.2. Methods

4.3.1.2.1. *Procedures*

Mixed methods, namely in-depth semi-structured interviews, lab-based usability tests, short-term field trials, and surveys, were combined to assess iNNOVBC's usefulness, usability, and feasibility among MHP and BCS. The eligibility criteria included being a registered psychologist or psychiatrist; or a woman aged ≥ 18 years, with a history of histologically confirmed BC, who had completed primary adjuvant treatment (except for hormone therapy) and was capable of reading/writing in Portuguese. A non-

probabilistic sample of BCS and MHP was recruited following referrals from the researchers, professionals working at treatment centres in Porto (Portugal) and via snow-ball sampling. Participants were purposively sampled for diversity in age, academic degree, and digital technology proficiency. A total of 28 MHP and 16 BCS were invited to participate in the study in person, via e-mail or by telephone. Of the invited participants, 15 MHP and 14 BCS agreed to participate. Meaning saturation was used as a stopping criterion (264).

Data collection took place between November 2019 and February 2020. The research protocol included an exploratory semi-structured interview; a think-aloud lab-based usability test followed by the completion of a self-reported usability survey; a debriefing post usability test interview; and a two-week field trial. These activities occurred in-person at Fraunhofer Portugal AICOS meeting rooms. Field trials were conducted in participants' living settings. In total, 24 participants (n=11BCS and n=13MHP) were involved, resulting in around 36 hours of audio recordings and 9 hours of video recordings. The average duration of pre-test interviews was 49 minutes (range: 00:26 – 01:21) for MHP and 74 minutes for BCS (range: 00:39 – 01:46). Usability tests were completed on average in 20 minutes and followed by 28 minutes (range: 00:10 – 00:46) post usability test interviews. Interview recordings were transcribed verbatim (CMS and AA) in parallel to data collection, using oTranscribe (265). Usability tests were assessed using pre-developed observation grids and by registering participants' voiced remarks. Data were stored in a pseudo-anonymized format in a secure password-protected location.

4.3.1.2.2. Measures

Clinical, socio-demographic and internet-related use characteristics were assessed with background questionnaires tailored to each target group. iNOVBC's usefulness was evaluated using semi-structured interview guides that were developed based on a literature review and findings of **Studies I**, and **III**. A questionnaire developed to assess the quality of iNOVBC's treatment modules assessed the usefulness of the

program's modules. The usability of the program was examined via usability tests and by analysing the performance and acceptance of the system. Performance was assessed through task analysis using observation grids developed for this purpose. Acceptance was measured using the Portuguese version of the System Usability Scale (SUS) (266). A post-test debriefing semi-structured interview was used to identify content and design changes to be performed to improve user experience and satisfaction with iNNOVBC. Finally, the feasibility of the program was assessed via post usability test semi-structured interviews, iNNOVBC's treatment modules assessment questionnaire and written comments by field trial participants.

4.3.1.3. Analysis

A combination of quantitative and qualitative methods was applied to assess iNNOVBC's usefulness, usability, and perceived feasibility. Descriptive statistics (i.e., counts, percentages, medians, and interquartile ranges) were computed to characterize the study sample, measure performance data and, assess preference data collected via SUS and the treatment modules' assessment questionnaire. No efficiency metrics were calculated since the think-aloud method was applied. Microsoft Excel was used to compute quantitative variables. Qualitative data resulting from the interviews and BCS written comments were transcribed verbatim and analysed with Braun and Clarke's thematic analysis method (244). First, a deductive approach was adopted, based on three pre-determined high-level themes: usefulness, usability, and feasibility. Subsequently, inductive analysis was performed on the data collected within those themes, and salient sub-themes were coded. Initial coding was performed by the thesis author (CMS). Regular discussions were promoted between researchers (CMS and FN) to discuss results and coding trees. Data patterns were then identified and iteratively organized until consensus between researchers was achieved. Scrivener software (248) was used to support the coding process.

4.3.1.4. Results

24 participants, i.e., 11 BCS and 13 MHP were included in the study. The median age of BCS was 48 (IQR=14; Min: 32; Max: 68). Most survivors were married (7/11), college-educated (7/11), and professionally active (6/11). A majority had been treated with surgery (11/11), chemotherapy (9/11), radiotherapy (8/11) and hormonal therapy (9/11). The sample was heterogeneous in terms of survivorship status (58) including participants at acute (2/11), extended (3/11) and permanent (6/11) survivorship stages. None of BCS had prior experience using DMH. However, the majority reported medium (4/11) to strong (5/11) skills in using digital technology.

The sub-sample of MHP included two psychiatrists and 11 clinical psychologists. Most professionals were female (11/13; 85%) and their median age was 35 years (IQR=11; Min: 25; Max: 56). Ninety-two per cent of professionals were active (12/13) and had a median of 11 years (IQR: 11) of professional experience. Thirty per cent (4/13) worked in Psycho-oncology services. Fifty-four percent held a CBT orientation (7/13; 54%). Considering participants' proficiency using digital technology, most professionals reported medium skills (11/13) and around half of the professionals (7/13; 54%) had prior experience using DMH programs.

Overall, participants considered iNOVBC highly useful, with most interviewees reporting on the pertinence of its scope, digital format, content, and features/elements. Participants valued that iNOVBC integrated evidence-based psycho-educational content; synchronous and asynchronous communication tools; a questionnaire assessment and documentation system; and automatized scheduling and notification features, considering that it could allow a more efficient and comprehensive assessment and follow-up of BCS. Furthermore, iNOVBC was viewed as a useful point-of-need solution that could help to bridge the psychosocial supportive care gap experienced by BCS across the survivorship trajectory.

Nevertheless, various usability issues were identified, and users considered the program should be refined by simplifying navigation paths; using a more dynamic colour

scheme; including more icons and images; grouping information in single thematic modules to be displayed in various formats and versions; and developing smartphone and tablet versions. In addition, participants suggested the conversion of data entry tables into plain text boxes and the inclusion of data visualization dashboards to facilitate the tracking of progress. The importance of using iNOVBC flexibly was reiterated by various participants. BCS considered iNOVBC should be tailorable to their changing needs along the cancer continuum.

4.3.1.5. Conclusions

Results from Study IV suggest that iNOVBC was considered useful by both BCS and MHP, configuring a promising point-of-need solution to bridge the psychosocial supportive care gap experienced by BCS across the survivorship trajectory. However, to fulfil its full potential, the program's aesthetics, information architecture, cognitive load, and interaction design should be refined. The importance of dynamically tailoring iNOVBC was underlined by various participants.

5. DISCUSSION

5.1. Main Findings

The current thesis aimed at developing iNOVBC using a UCD approach, thereby anchoring development on the elicited perspectives and practices of BCS and MHP. Its specific aims were to i) gather requirements for the development of iNOVBC, ii) to prototype iNOVBC; and iii) to evaluate iNOVBC's usefulness, usability, and preliminary feasibility. To fulfil these aims, four empirical studies, using a combination of quantitative and qualitative methods (c.f., **Study I, II, III and IV**), were conducted. The main findings of these studies are comprehensively summarized and discussed below.

5.1.1. Requirements for the development of iNOV Breast Cancer

5.1.1.1. Internet interventions are poorly known, and their use is residual

The first important finding in this research was that surveyed BCS presented with significant levels of anxiety and depression, which were generally higher than what has been reported in other geographies (15,16) (**Study III**). Considering that BCS had access to the internet, using it daily and autonomously, on their devices (**Study III**) iNOVBC could, therefore, configure a viable approach to address their psychosocial unmet care needs. However, both BCS and MHP self-reported knowledge and prior experience using internet interventions, were residual (**Study I and III**).

MHP's experience consisted mainly of sporadic use of the telephone, e-mail, SMS services, and videoconference as a complement to in-person interventions, rather than as stand-alone interventions. Their use of chat services, and internet interventions for clinical purposes, was negligible (**Study I**). Concerning BCS, the experience of using remote healthcare was scarce and limited to episodic teleconsultations, SMS and e-mail exchanges with physicians and nursing staff. None of the participants had prior experience using videoconference counselling/psychotherapy or internet interventions (**Study III**). Nevertheless, the majority used the internet to search for health-related

information, including information about psychological problems. Moreover, around half of surveyed BCS perceived themselves as skilled to use DMH interventions (**Study III**). Hence, other aspects than access to technology or digital literacy seem to be delaying the adoption of internet interventions targeting BCS in Portuguese cancer settings.

5.1.1.2. Cautious attitudes toward internet interventions prevent their adoption

An analysis of the factors potentially associated with Portuguese psychologists' previous use of digital technology in practice, revealed a significant association between prior experience of use, and their attitudes toward internet interventions. Psychologists holding a more negative stance toward internet interventions were less likely to have used it in the past (**Study I**). Similar findings have been reported in prior work (40,189,192,193). Considering BCS, and aligning with the literature (267,268), significant associations were also found between prior experience using remote healthcare and a more positive stance toward DMH (**Study III**). These results suggest that the attitudes of both BCS and MHP toward DMH play an important role in its adoption.

An assessment of the attitudes of both Psychologists and BCS toward internet interventions revealed slightly negative and neutral stances, respectively (**Study I** and **III**). Psychologists appeared to present a more guarded stance toward this approach, than BCS. When compared with the literature, these results align with Neves et al. (214) report on the attitudes of Portuguese psychologists towards electronic psychological interventions, but contrast with reports from abroad documenting that MHP's attitudes toward internet interventions or DMH range from neutral to generally positive (40,189). In what concerns BCS, reports assessing specifically the attitudes of BCS toward internet interventions are scarce (269), but BCS have generally endorsed e-health (270–276) and DMH in particular (269). Overall, these findings suggest that both Portuguese Psychologists and BCS have a cautious attitude toward internet interventions and that this aspect may partly explain the low uptake of internet interventions in the country.

5.1.1.3. Higher knowledge and training, prior experience of use, and unmet care needs positively influence attitudes toward internet interventions, potentially expediting their adoption

Considering the factors impacting Psychologists' attitudes toward internet interventions, significant associations were found between psychologists' positive attitudes and higher self-reported knowledge and training. Psychologists reporting prior experience of use were also more prone to endorsing internet interventions (**Study I**), which corroborates previous research (40,189,192,193). Likewise, significant associations were found between a higher self-reported knowledge of DMH and a better stance toward DMH in BCS participating in **Study III**. In addition, significant associations were found between prior use of remote healthcare, online health information and mental healthcare-seeking and positive attitudes toward DMH (**Study III**). Similar findings have been previously reported in the literature (267,268). Considering clinical factors influencing BCS attitudes toward DMH, higher levels of depressive symptoms were significantly associated with a more positive attitude toward DMH. Likewise, lower levels of emotional, cognitive, and body image functioning were significantly associated with a better stance toward DMH (**Study III**). Taken together, these results suggest that higher knowledge and training, prior experience of use and unmet care needs positive influence these stakeholders' attitudes toward internet interventions, potentially expediting their uptake.

5.1.1.4. Accessibility, convenience, and professionals' perceived responsibility to provide support are important drivers to adoption

Other important potential adoption drivers identified in this research by MHP relate to internet interventions low-threshold accessibility, convenience, and potential cost-effectiveness (**Study I and II**). This was also a finding in previous studies (40,191,277). In **Study II**, professionals' perceived duty to provide support to their clients was identified as another important driver to adoption. Such responsibility, often superimposed MHP's preferences, concerns, and DMH's perceived limitations, being the triggering point for various participants to start delivering online interventions. Among BCS, accessibility, flexibility, and the possibility of communicating with therapists online were

the most endorsed advantages of internet interventions. Aspects such as interventions' anonymity and empowerment were also viewed positively, echoing previous research (150,278). A greater willingness to use DMH if provided by reference centres was also reported, suggesting that interventions credibility is another important aspect to attest (**Study III**).

5.1.1.5. Lack of intervention frameworks, dedicated technology, and training demise professionals' perception of control over internet interventions, preventing adoption

Contrariwise, concerns about the security, accuracy, and efficacy of DMH have been reported by both participant BCS (**Study III**) and MHP (**Study I and II**) and in previous research (194,196,197,272,279–281). Simultaneously, participants viewed face-to-face treatment strategies as more efficacious and easier to acquire in-person than via DMH. They also perceived in-person approaches as better for handling crises than DMH, corroborating previous research (150,278).

An in-depth analysis of MHP's perspectives and practices over DMH added some nuance to the abovementioned findings. In **Study II**, and corroborating prior studies (196–198,280), the absence of structured intervention frameworks presenting clear guidelines on how to implement DMH in an ethical, legal, and secure way, was identified as a salient implementation barrier. To overcome this gap, MHP independently formulated rules and procedures to organize their online practice, placing great emphasis on the negotiation of the online therapeutic contract (**Study II**). Nevertheless, most interviewed MHP questioned their self-efficacy to assess and intervene online and a marked perception of lack of control over the implementation of DMH prevented them from fully adopting such an approach (**Study II**). This perception of lack of control has been documented before concerning technology (282), the therapeutic setting (283), the therapeutic process (284) and the management of crises situations online (285). However, no study deeply explored this barrier.

Adding to these findings, insights from **Study II** showed that adoption was hindered by perceptions of lack of control over case formulation; the assessment of treatment outcomes; and the detection, management, and monitoring of treatments' adverse

events. **Study I** corroborated these findings. In that study, most participants perceived remote psychological assessment processes as inaccurate, increasing the possibility of misdiagnosis, and unsuitable for crises management. This was also a finding in previous research (198,279,280,286). Nevertheless, other studies have validated telephone-based behavioural assessments (287) and the equivalence between paper-and-pencil and online testing has been consistently documented (141,288). More importantly, a previous study by Godleski and colleagues (289) reported that suicide risk assessment can be effectively completed via telemedicine and is as effective as suicide risk assessment completed in person. This discrepancy between participants' stance toward DMH and evidence has been previously identified in other studies (290) and confirms the important knowledge and training gap in this domain, shedding some light on how it may hinder professionals' perception of control over the online therapeutic process, ultimately deterring internet interventions adoption.

Another major obstacle to DMH's implementation identified in **Study II** referred to the absence of usable, validated, and affordable DMH technology capable of framing and safeguarding MHP's online practice. This gap often forced MHP to either narrow the scope of their online clinical work or to devise alternative ways of pursuing their practice (**Study II**). Mirroring other professionals' procedures (291,292), the adaptation of non-clinical software (e.g., Gmail, zoom, etc.) to psychological evaluation and intervention purposes was a strategy frequently adopted by MHP in this regard. However, such practice often posed a high technological burden over both MHP and their clients and risked non-compliance with GDPR, intellectual property rights and good clinical practice. Concerns over the negative impact that non-usable, validated, or defective technology could have on treatment adherence, outcome, and rapport were also patent (**Study II**). Consequently, most professionals underlined the importance of expediting the development of secure, evidence-based and comprehensive DMH technology capable of framing therapists' online practice (**Study II**). This potential for technology to structure the clinical process was also a finding in previous studies (293).

A comprehensive analysis of the abovementioned results suggested that iNOVBC would have to be designed to fulfil both BCS and MHP unmet needs in what concerned psychosocial support and the online practice, respectively. In addition, it would have to be able to overcome many of the knowledge, training, attitudinal and security barriers impacting the implementation of internet interventions in Portugal.

iNOVBC would have to be compliant with evidence-based internet interventions but also be culturally sensitive and relevant to BCS, approaching their most pressing needs in a positive, yet informed tone. Trust and transparency needed to be embedded in the structure of the program and empathy had to be conveyed through the developed materials. iNOVBC would have to be able to portray emotional and relational nuance to fit different BCS, being tailorable. Simultaneously it would have to be concise and possible to scale up and adapt to different formats, being responsive. Furthermore, it would have to be able to frame MHP's online practice, integrating multiple features, such as psycho-education material, communication, and notification tools, as well as validated data collection measures suitable to conduct a comprehensive psychological assessment. Information about the therapeutic contract would have also to be conveyed, to clarify the nature of the online intervention process. Moreover, iNOVBC would have to be guided by MHP, including synchronous (i.e., videoconference) and asynchronous (i.e., e-mail and SMS) communication channels, capable of matching MHP and BCS prior experiences of use, and represent an alternative to BCS valuing anonymity. Finally, a comprehensive strategy for the translation of iNOVBC to clinical settings, including training and communication plans, would have to be outlined, so that knowledge, training, and attitudinal barriers did not compromise its assessment and implementation in clinical settings.

5.1.2. Prototyping iNOV Breast Cancer

Despite the important insights gathered during the first phase of the development process, prototyping iNOVBC was demanding mostly due to time, human resources, and budget constraints. Corroborating the findings of **Study II**, iNOVBC's prototyping

process was long, complex, and only possible to accomplish within the available time and budget frames because iTerapi (49) was made available.

Being developed incrementally over the years by Clinical Psychology researchers and developers, iTerapi fulfils many of the development requirements identified in this thesis, providing a secure, state-of-the-art, comprehensive framework for internet interventions' development. iTerapi also allows for the development of fully functioning prototypes, therefore, expediting the development process. Still, adapting it to the Portuguese context required many iterations. The translation of simple commands from English to Portuguese in many cases couldn't be literal and conveying the same ideas in Portuguese often required longer sentences, difficult to insert in a responsive system. Such difficulties extended to the translation and adaptation of the treatment materials and incorporating the pre-specified development requirements into an inclusive, usable, and relevant prototype was not always easy, requiring a balance between technological constraints and the requirements abstracted from the literature, the empirical studies, and our own clinical experience. It required understanding how the characteristics of iTerapi could be better used to promote the intended behaviour change. The text length, type of audio-visual content, exercises and features possible to be included in each module had to be experimented with and assessed, and the impact that the choices made could have on treatment efficacy had to be considered. Similarly to what has been reported in **Study II**, an attempt to fulfil these requirements led to numerous internal conversations with hypothetical BCS. However, steering development on fictitious BCS often challenged our perception of control over the development process, demanding a thorough revision of the developed materials and many iterations so that iNOVBC could potentially contain the many possible outcomes of its use. Possible adverse effects had to be anticipated and strategies to ensure they were prevented, monitored, and addressed had to be incorporated into iNOVBC to comply with safety and beneficence requirements. This process was time-consuming and difficult to complete without the active and continuous involvement of iNOVBC's representative end-users (i.e., psychologists, physicians, nurses, managers, and BCS) and in loco understanding of the cancer settings' workflows in which iNOVBC could

ultimately be deployed. iNOVBC's development was indeed backed up by the implementation of a UCD approach and in-depth insight of its target users' perspectives and practices, as well as the support of external experts (i.e., an oncologist, a nurse, a psychologist, a BCS and a layperson). Nevertheless, the prototyping phase would most likely have benefited from involving these distinct stakeholders in closer collaboration. While misalignments, conflicts of interest (**Study II**), and power imbalance (294) may constrain participatory development, previous studies (227,233,236) have mostly documented the positive impact of actively involving different stakeholders in the development process and, in retrospect, bringing together the several iNOVBC stakeholders to co-design it from the outset, could have been fruitful. It would have possibly allowed a richer debate of the treatment materials, making them more robust. It could have provided the development team with a greater sense of control over the development process, expediting it. It could have also allowed the anticipation of many of the design caveats that were identified during iNOVBC's prototype evaluation.

However, mobilizing these stakeholders from the outside (even as a former insider in some cases) to actively participate in a non-funded project to which they held a guarded stance, was difficult. In the case of oncologists and nursing staff, surveying their attitudes toward internet interventions proved already to be a challenge. Even after partnering with hospitals administrations and national oncology associations, we could not get sufficient data on their perspectives and practices to inform iNOVBC's development. This suggests that attitudinal barriers may impact the implementation process right from the start, in the user research and development phases, possibly hindering it and repercussing into future implementation difficulties due to lack of insight into clinical settings. Resonating the perspectives of some of the participants of **Study IV**, the implementation of programs like iNOVBC in cancer settings is necessarily dependent on referral workflows and, therefore, designing early on for sustainability (295) seems key. As such, embedding the development process into clinical settings, to prototype iNOVBC from the inside and as a complement to a previously existent service, could have possibly resulted in a greater mobilization of its various stakeholders, ultimately benefiting the program.

This perception aligns with a current discussion around internet interventions development and implementation processes. Previous publications have discussed the need for turning such processes more agile (296), solution-focused (295) and integrated into clinical practice (152,297). Moreover, a paradigm shift toward the design of DMH Services seems to be unfolding (3,298) and end-to-end frameworks such as the Accelerated Creation-to-Sustainment Model (295), that combine methods from UCD, service design, and implementation science are being proposed as an alternative to inform and expedite classical development processes. In the light of this, iNOVBC should next be taken inside cancer settings, to be further refined in loco, into co-designed pilot services. Results from the assessment of iNOVBC's usefulness, usability, and feasibility obtained in **Study IV** should steer this refinement process.

5.1.3. Evaluation of iNOV Breast Cancer prototype

During **Study IV**, most participants reported on the pertinence of iNOVBC's scope, digital format, content, and features, considering it highly useful. iNOVBC was perceived as a valuable contribution to bridge the supportive care gap experienced by BCS across the survivorship trajectory. Similarly to previous research (234,237,240), survivors valued having access to ubiquitous evidence-based self-care information that was organized in accordance with the cancer continuum, considering that it could help them better manage and cope with their condition and difficulties. Another important aspect contributing to participants' perception of the usefulness of iNOVBC, concerned the multi-featured and integrated nature of the program. Participants appreciated the fact that iNOVBC combined psycho-education, communication, documentation, and automatized scheduling and notification features, allowing a more efficient and comprehensive assessment and follow-up of BCS. Furthermore, the possibility of communicating both synchronously and asynchronously (e.g., via chat, e-mail, and videoconference) through the platform, as well as in accordance with different degrees of personal exposure was valued by various participants, as it could facilitate self-disclosure in BCS and promote the timely discussion of sensitive topics. Previous research

(299,300) has documented the potential for internet interventions to decrease stigma toward seeking mental healthcare.

Nevertheless, various usability issues were identified, and participants considered the program should be refined to achieve better effectiveness, efficiency, and satisfaction among its target users. According to participants, iNNOVBC's aesthetics and user interface could be improved by using a minimalist and recognizable design. Adding a more dynamic colour scheme, as well as icons, images, and shortcuts were suggested to improve iNNOVBC's usability and facilitate the recognition of the program's affordances. According to participants, interaction design was another aspect to be improved. Navigation within the program should be made more consistent and constrained. In this regard, participants suggested that a simplification of navigation paths and the use of an opening dashboard could facilitate the handling of iNNOVBC. Adding labels and preview options to the most used functionalities was also considered important to increase the discoverability of the program. Previous research has yielded comparable results (232,237,240,301,302), suggesting that single-page websites or apps that enable properly labelled interactions and that make use of different colour depths, familiar icons, and images, are more usable and acceptable to cancer survivors.

Moreover, participants underlined the importance of reducing iNNOVBC's cognitive load. Information should be grouped more concisely (e.g., short modules addressing a single thematic); delivered using various media (e.g., web, smartphone, and tablet), and be displayed in different formats (e.g., text, audio, and video) and versions (e.g., include female and male audio clips). In addition, data entry should be performed using plain text boxes instead of tables, to make the program more inclusive and easier to use. Complementarily, the integration of data visualization dashboards providing digested information on completed or to be completed tasks and questionnaires, its scores and cut-off points being exceeded or achieved, was appointed by interviewees as relevant. Participants anticipated that such a strategy could facilitate the handling of the program and the assessment of BCS treatment progress, promoting their engagement to iNNOVBC. These findings echo many of the limitations and development

requirements gathered in previous research aiming at developing digital programs for supporting cancer survivors (232,237,238,240,301–304).

Another salient finding in **Study IV** was the importance of further tailoring iNNOVBC. Being conceived as an individually tailored program, iNNOVBC permits some degree of tailoring, namely in what concerns the treatment modules. However, participants considered further layout and content customization should be allowed so that the program could adapt to the idiosyncrasies of each of the survivorship trajectory stages. Participants considered comprehensive support should be provided along this continuum, not compartmentalizing survivors' needs, but shaping and transforming the program according to its evolution. Like a rhapsody, iNNOVBC should adopt "an episodic yet integrated, free-flowing structure, featuring a range of highly contrasted moods, colour, and tonality" (305), to be used freely and flexibly as needed. This finding aligns with previous research (234,304,306,307) and emphasises the importance of building flexibility into digital programs targeting cancer survivors, not only in terms of tailoring but also in terms of frequency and timing of use, to ensure its uptake by target users. However, such an understanding of iNNOVBC contrasts with its original concept and theoretical grounding. While participant survivors mentioned the intention to use the program as an *à la cart* platform or self-care toolbox, where different content and strategies could be prescribed simultaneously and/or used as needed, and not in a prescriptive manner, evidence suggests the implementation of structured approaches, that are theoretically grounded and validated to specific contexts of use best serve survivors (24,108). This discrepancy adds to the technical, usability, funding, attitudinal, and training limitations identified in this thesis and the literature (243) as potentially hindering iNNOVBC successful implementation and underlines the importance of simplifying and optimizing interventions. In this regard, dismantling research is key to determine what behaviour change techniques need absolutely to be inserted in programs like iNNOVBC, so that they are feasible, but still effective. Furthermore, the role of just-in-the-moment adaptive approaches (JITAI) (308) (i.e., interventions using EMAS, sensors and artificial intelligence to assess individuals needs and provide the type/amount of support needed, at the right time, and only when needed – in fulfilling

the dynamically tailoring requirement introduced by BCS seems promising and should be further explored.

Thus, iNNOVBC will be soon pilot tested in cancer settings (254) not only to assess its preliminary efficacy, but also to further assess its feasibility and gather requirements for the design of a human-centred service that fits into BCS lives, professionals' evidence-based practices, and cancer centres' workflows. After piloting and further refining iNNOVBC, the program will be tested for its efficacy and cost-effectiveness using a multicentre, randomized, waiting-list, controlled design (254). Results from this parent study will determine if iNNOVBC should be transferred to routine care.

5.2. Strengths, Limitations and Future Research

Strengths of this thesis include the adoption of a UCD approach combining mixed methods (e.g., surveys, in-depth interviews, usability tests and short-term field trials) that were used to specify the requirements for the development of iNNOVBC, as well as to evaluate its usefulness, usability, and preliminary feasibility in a comprehensive manner. Furthermore, the studies included in this thesis were conducted by an interdisciplinary team and involved iNNOVBC's primary and secondary end-users, i.e., BCS and MHP, benefiting from complementary input by these stakeholders.

In **Study I** and **II**, the size of the surveyed samples was large, and its demographic and background characteristics were similar to those published in previous census (309) and national reports (310), suggesting that study samples were probably representative of the populations under study and that our findings present good odds of being generalizable to those populations. In addition, in **Study II** and **IV** participants have been purposefully sampled for diversity in age, academic degree, digital technology proficiency, and DMH use allowing us to capture variance and aim for a more inclusive approach to iNNOVBC. Furthermore, in **Study II** and **IV** data collection was theory-informed and co-occurred with data transcription, helping to reveal areas of the data that required more exploration in subsequent interviews, enriching the data set. Continuous reflection and a consensus approach were also adopted during data collection and analysis. This practice raised awareness of potential research biases impacting

these studies. Finally, respondent validation and investigator triangulation have also been used to increase the validity of the results of **Study II**.

Concerning limitations, in **Study I**, ATIIS-MHP online dissemination and the study sample self-selection might have introduced selection bias, limiting the generalizability of the obtained results. Digital illiterate psychologists as well as those presenting more negative attitudes towards internet interventions might not have participated in this study, lowering the response rate, and biasing its results. In **Study III**, our results reflect the attitudes of a convenient sample, that may not be representative of BCS. Furthermore, despite ATIIS-MHP and ATTIS-BCS good psychometric properties, the two selected factors in **Study I** and **III** only accounted for 44% and 61% of the variance explained, respectively. Although in the social sciences it is not uncommon to consider solutions that account for 40-60% of the variance explained as satisfactory (311), this suggests additional research is necessary to identify other factors to which MHP's and BCS' attitudes might be attributable to. Future studies should build upon established frameworks, warranting comprehensive prediction models to be tested. Longitudinal studies assessing how attitude predictors translate into DMH uptake and treatment outcome would also provide valuable insight.

In **Study II** and **IV**, although a stratified purposeful sample was selected to capture variation, as in many qualitative studies, the representativeness of the sample cannot be established. Results are based on the in-depth analysis of interviews provided by a small sample of Portuguese MHP and BCS and therefore, may not be transferable to other contexts. The fact that DMH is still at an embryonic stage in Portugal, might have influenced participants' attitudes and opportunities to explore DMH and therefore it is unclear if the same issues would be identified among professionals and BCS living, for example, in DMH frontrunner countries (203). Another aspect to consider is that, in **Study II**, the main interviewer was previously known to most participants from her roles of DMH researcher or clinical psychologist. This fact may have introduced a social desirability bias, possibly leading interviewees to be less critical of DMH. Simultaneously, it may have made participants more comfortable, facilitating data collection. In

addition, in **Study II** other forms of triangulation, such as method, theory, and data source triangulation were not conducted, which would have been advisable to test the validity of obtained results and gain a more comprehensive understanding of the implementation of DMH. In **Study IV**, participant BCS were younger than the general Portuguese BC population (310) and participant survivors were not screened for mild to moderate anxiety or depression. These aspects may have prevented the identification of usability issues associated with older age or psychological morbidity, thereby limiting the overall generalizability of the usability tests results. Nevertheless, there is some consensus that usability tests may include a minimum of 5 participants per iteration and that around 80% of usability issues are discovered with as few as 4-6 participants (312). The fact that results obtained in that study align with previous research supports its ecological validity. Furthermore, this thesis did not assess the perspectives and practices of other important iNOVBC stakeholders such as oncologists, nurses, managers, social workers, and informal caregivers. Involving these stakeholders in the subsequent phases of iNOVBC development could be useful to facilitate its future implementation and uptake. Considering the pervasive impact of cancer in the various spheres of BCS lives, the perspectives and practices of the partners and family members of BCS could also be explored in future research.

Finally, the fact that data collection occurred before the COVID-19 pandemic may compromise the generalizability of the findings of the studies included in this thesis. Nevertheless, considering that the COVID-19 pandemic underlined the strategic role DMH might play in closing the mental healthcare gap worldwide, we believe our research may provide an important point of comparison to future studies addressing DMH acceptability and adoption determinants among BCS and MHP. Comparative research is necessary to understand the pandemic's impact on MHP's and BCS' attitudes toward DMH.

5.3. Implications for the design and implementation of internet interventions in cancer settings

The results of this thesis hold important implications for the further development and implementation of programs like iNOVBC. First, DMH programs targeting cancer survivors could benefit from the early and active involvement of its primary, secondary, and tertiary end-users in the development process. By involving survivors, healthcare professionals, and managers in co-development activities (e.g., surveys, in-depth interviews or focus groups, usability tests, co-design workshops and field trials), interventions could be designed to address stakeholders' real needs and development could better align with their practices and contexts, increasing the odds of successful implementation. Second, involving interdisciplinary teams in the development process is key, to ensure comprehensive solutions are developed and design caveats are timely anticipated, identified, and refined, not compromising the usefulness, usability, and feasibility of such programs. Third, internet interventions targeting BCS must be designed to comprehensively accommodate the following: evidence-based content that is organized into single thematics, displayed in various formats and versions; synchronous and asynchronous communication features, compliant with different degrees of personal exposure; and built-in data collection systems, that are easy to use and capable of accurately monitoring BCS' treatment progress. Information abstracted through these systems should be automatically analysed and portrayed into data visualization dashboards, providing tailored feedback to its different users. Fourth, DMH interventions must be conceived as supportive point-of-need services capable of adjuvating and extending cancer care delivery. Programs must portray emotional and relational nuance and adopt a flexible yet integrated structure capable of being continuously tailored to end-users changing needs, evolving along the cancer continuum. In this context, the optimization and simplification of interventions are advised and the role of JITAI interventions should be further explored. Adopting a transdiagnostic therapeutic approach also seems important. Finally, DMH interventions need to plan early on for sustainment and translation to clinical practice, aligning development and research

protocols with these aims. Implementation research must be conducted to determine the effectiveness of developed programs and identify requirements for the delivery of DMH services. Delivery bottlenecks (e.g., lack of training) need to be timely diagnosed and fast-track solutions (e.g., training programs, digital navigators, awareness campaigns, etc.) must be devised, tested, and implemented.

6. CONCLUSIONS

iINNOVBC was considered highly useful by both BCS and MHP, configuring a promising point-of-need solution to bridge the psychosocial supportive care gap experienced by BCS across the survivorship trajectory. To fulfil its full supportive role and reach high levels of usability and feasibility, iINNOVBC requires further refinement. Alterations are necessary for the aesthetics, information architecture, cognitive load, interaction design, and the technological media for intervention delivery (e.g., mobile app version). In addition, iINNOVBC might require further tailoring and a more flexible implementation approach, so that it better adapts to the needs and contexts of its target users. These aspects need to be assessed in future pilot and RCT studies. Furthermore, a comprehensive strategy for the translation of iINNOVBC to clinical settings needs to be outlined. Appropriate training and communication plans need to be operationalized in parallel to iINNOVBC's implementation so that MHP's lack of knowledge, training, and experience in DMH delivery do not compromise the access of BCS in need to iINNOVBC. Hopefully, this strategy will also prove successful in improving the documented cautious attitudes of MHP and BCS toward internet interventions, expediting the adoption of internet interventions in Portuguese cancer settings.

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8. APPENDICES

Papers

The papers associated with this thesis have been removed for copyright reasons. For more details about these see:

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